PSI
THE PHARMACEUTICAL SOCIETY OF IRELAND
Cumann Cógaiseoirí na hÉireann
THE PHARMACY REGULATOR

Comments received during public consultation on NON-PRESCRIPTION MEDICINAL PRODUCTS CONTAINING CODEINE: Draft Guidance for Pharmacists on Safe Supply

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NON-PRESCRIPTION MEDICINAL PRODUCTS CONTAINING CODEINE:
Draft Guidance for Pharmacists on Safe Supply

	Comments Received	PSI Response
1. **Boots**		
	Boots is a leading provider of pharmacy services in Ireland, employing over 120 pharmacists in 49 registered retail pharmacy businesses across the country. We are committed to the provision of professional services to the highest standards and welcome the opportunity to contribute to the development of practice guidelines.	Noted
	Boots has been proactive in raising concerns regarding the sales of codeine containing medicines and has supported our pharmacists in the development of procedures and policies to ensure the safe, effective and appropriate sale and supply of medicines. Recently a practice project was conducted in our Grafton Street pharmacy, the purpose of which was to ensure the appropriate sale of codeine containing medicines using a documented intervention advising on side effects and concerns re dependence. A copy of the published paper is included with this submission for your information (Appendix 1).	Noted
	Draft Guideline (Background section)	
	The draft guidance document refers in the background section to recent publications by UK societies and authorities. It would also be useful to reference the situation in other countries, for instance Australia where scheduling changes will be implemented in May 2010 which will introduce restrictions on combination analgesics containing codeine. Part of this initiative will include government agencies taking a lead role in community engagement, awareness campaigns and mass audience strategies to ensure that those who wish to self manage their medicines have all the necessary information. References should also be included for the initial statement that concerns are well established, to ensure the guidance document is grounded in evidence.	This information is helpful. In addition to Australia, reviews have taken place in other countries all of which are leading in the direction of more strict controls on the supply of codeine containing products. The potential pharmacist only and pharmacist supervised supply exists under the Pharmacy Act 2007 and it is on that understanding that the draft guidance for pharmacists has been prepared.
	With regard to the guidance that patients need to be fully advised of the correct use of these products, does the Patient Information Leaflet (PIL) fulfill this requirement?	While patient leaflets (PLs) are helpful, they cannot replace the verbal guidance provided by pharmacist in counselling the patient. It is essential that counselling should support the information given in PLs and that the pharmacist should fully discharge his or her professional role in the supply of medicines.

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	It would also be useful if the guidance document addressed the issue of management of misuse, what steps the pharmacist can take to help manage misuse, and when referral is necessary and to whom. The guidance to facilitate patients in obtaining medical assistance for health problems relating to misuse will be compromised by the lack of public services available to deal with codeine abuse. As observed by an All Party Parliamentary Group in England, if the pharmacist or doctor has no expertise in the area of codeine misuse and if there is nowhere to refer the patient for support, all schemes to reduce availability will have little effect on the problem. [1] The development of a step wise algorithm for reduction of inappropriate use may facilitate pharmacists in ensuring the safe supply of these medicines.	Agreed. It is envisaged that the competent pharmacist should be in a position to address all of these issues and that the health services and others involved in this area including those involved in continuing education of health care professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed.
	Page 2 Draft Guideline Codeine. Combination analgesics containing codeine and ibuprofen or paracetamol are not recommended because i) there is no evidence that with this dose of codeine there will be any benefits over ibuprofen alone and ii) the combination increases the likelihood of adverse effects[2]. Given that codeine is most often used as a combination product for pain relief, there is no evidence to support a recommendation that the combination product be used as a step up when paracetamol, aspirin or ibuprofen have not proven sufficient to relieve symptoms. To include this is in the guidance document will reinforce the incorrect assumption that combination products with sub-therapeutic does of codeine are in some way stronger or better when in fact there is no evidence to support any implication that they are more efficacious. Any proposed second line analgesic should be evidence based and part of a pain "ladder".	Noted. The current draft guidance is based on the IMB 2004 guidance (reference 1) and the NMIC 2005 guidance (reference 4), which also refers to the WHO analgesic ladder.

1 All-Party Parliamentary Drugs Misuse Group: An Inquiry into Physical Dependence and Addiction to Prescription and Over-the-Counter Medication (2007 – 2008 Parliamentary Session). Available at http://www.seroxatusergroup.org.uk/parliamentary-drugs-misuse-OTC.pdf

2 Andrew Dickman Choosing over-the-counter analgesics. The Pharmaceutical Journal 2008;281: 631

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	The guidance document should specifically state when it is appropriate to use the combination products at the recommended doses currently authorized for the Irish Market.	It is not the intention of this document to provide such detail which should be more than adequately covered by the SPC and PL as approved by the IMB for each of these products.
	To ensure pharmacist can fully discharge their responsibilities it is important that the array of medicines available to them to recommend to customers be appropriate and evidence based.	Agreed.
	Restricting medicinal products not proven to be efficacious to "second" line will not facilitate best practice in pain management by pharmacists, and give the general public the wrong impression, reinforcing the perception that these products are better.	Since products should not be on the market if their efficacy has not been proven the issue should not arise. A better understanding of the rational use of these products including the WHO analgesic ladder would be helpful here.
	It is note worthy that in Australia there is an OTC combination product containing Paracetamol 500mg and codeine 15mg. At the maximum dosage of 2 tablets four times a day, there is proven benefits and therapeutic doses of both ingredients, and this allows for appropriate management of short term pain by the pharmacist. It appears that part of the problem in Ireland is the lack of a fully effective combination product for short term use.	This is a matter for the product manufacturers and the Irish Medicines Board.
	Draft Guidelines: Code of conduct.	
	The reference to suitable controls and accountability mechanisms is ambiguous and does not give sufficient guidance regarding what controls and mechanisms are required. Clear guidelines in this regard will facilitate the transparent implementation of the final guidance document. Specific reference should be made to the issue of documentation. What level of documentation will be required to demonstrate the effectiveness of the controls and mechanisms in place? It is important that this is clearly outlined to create a consistent approach across the pharmacy profession as a whole. The issue of recording of OTC sales of codeine containing products should also be addressed, with clear guidance to the profession in this regard.	Such codes can only deal with matters at a high level. It would not be possible or practical to include all the detail that would be necessary to meet this objective in the draft guidance document proposed. Pharmacists, whatever their roles are, should sufficiently acquaint themselves with whatever resources are available. Pharmacists should remember that minimum compliance with the strict legal requirements may not always be acceptable in the discharge of their professional responsibilities.

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	Section 2: Storage The issue of self selection will need to be defined and determined further, to ensure consistency of implementation across the profession. Is the back wall-behind the pharmacy counter considered to be self selection? Many pharmacies are now designed with a more "open" plan, to facilitate greater communication between pharmacists and patients. As a result medicines which are stored in the dispensary may still be seen by the public. Will this constitute a breach of the guidance? Is a request for a product by name considered self selection (regardless of whether the product is visible or not)?	While the Pharmacy Act 2007 and the Regulation of Retail Pharmacy Business (RPB) Regulations 2008 require that all medicines be supplied by or under the personal supervision of a pharmacist and that in addition all non-prescription medicines be the subject of appropriate counselling (regulation 10), it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restrictions are imposed which require that those products would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the controlled drug (CD) products concerned may only be stored in a pharmacy under the direct control of the pharmacist in a manner that would require his or her direct involvement in the supply and may only be supplied in a manner where the advice of the pharmacist is obtained and which provides the potential of his or her professional intervention.
	Section 3: Supply It is of note that in Australia non soluble presentation of combination codeine containing analgesics products are currently licensed for OTC sale. (d) and (h) The clear implication is that after 3 days treatment, referral to a medical practitioner is necessary. Will GPs be advised of, and in a position to accommodate, the increased rate of referral. What will their approach be? And perhaps development of a fuller role for pharmacist in pain management would be a better solution. (e) And (i) Re counselling, the guidance document should clearly indicate if verbal counselling is sufficient and how compliance will be documented.	These comments pertain to the marketing authorisation requirements for these products which are already in place. The potential exists for a fuller role for pharmacists in pain management. Verbal counselling is all that can be required for the time being.

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	Section 4 Suspected abuse and misuse. Concerns about the availability of appropriate addiction management services should be discussed and clarity is also required regarding audit requirement. Is it the intention that a numeric or volume based audit will be conducted or an audit of compliance with counselling? What documentation of such audits will be necessary or is personal supervision by the pharmacists sufficient to meet this requirement?	Ideally self-auditing arrangements should be in place with a view to giving some indication of the counselling that is being delivered. The number of whole-time pharmacists who are available in pharmacies will also be an indicator of the degree of compliance with these and other requirements.
	Considerations for the introduction of a new guidance With regard to the introduction of any new guidance relating to codeine containing medications, adequate notification of the implementation date will need to be provided to retail pharmacy businesses, to allow for formulation of a policy, dissemination to all supervising pharmacists and training of staff. From an operational perspective, it must be recognised that significant adjustments need to be made to stock holding and merchandising to facilitate full compliance. Immediate implementation would cause operational difficulties to all in the sector and would be likely to negatively impact on ability to comply fully with the guidelines. In contrast, adequate notification should result in fuller compliance.	Noted.
	Appendix 1; Published Irish Pharmacist; Issue 8; Volume 11 (September 2009) p30 ***The development of a protocol for the sale of codeine-containing medicines in community pharmacy: A practice report*** *David Carroll, Supervising pharmacist, Boots Grafton Street* **<u>Introduction</u>** In 2008, combination analgesics contributed more new sales than any other sub-sector in the Irish OTC market.[i] In particular, sales of analgesics containing codeine grew strongly and this has been raised as a concern within the Irish healthcare community.[i] This concern is not a new one, with the potential for misuse or abuse of "over-the-counter" codeine products being repeatedly	Publication noted with thanks.

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	highlighted as an issue which needs to be considered in countries where codeine is available without prescription[ii,iii,iv,v]. The advantages of using compound analgesic preparations containing paracetamol or aspirin with a low dose of an opioid analgesic (e.g. 8mg of codeine phosphate per tablet) have not been substantiated and their use can lead to increased side effects.[vi] In my pharmacy, I had become increasingly concerned that a high proportion of our analgesic sales were made up of products containing codeine. As a result, I decided to revise our protocols for the sale of codeine containing medicines (CCMs), with the aims of educating customers on their appropriate use and reducing the level of codeine usage. Because actual use could not be measured (i.e. we could not follow patients home to see how much codeine containing medicines they used), the sales figures for CCMs were used as a proxy measure for codeine usage. This paper describes the steps that we took and shares some insights into the issues that arose from our actions. **Development of a new protocol** Although we already had protocols in place for the appropriate sale of prescription-exempt medications in our pharmacy, we decided to introduce additional safeguards for the sale of CCMs in October 2008. This involved limiting the sale to a maximum of 24 tablets per transaction and telling all customers that the product should not be used for more than 3 days continuously. In addition there was more proactive monitoring of repeat customers, with pharmacists intervening in sales where customers were found to be making regular purchases. Whilst these measures went some way to increase patient awareness, it was felt that they were not sufficient to alert customers to the specific concerns relating to codeine. The warning about the 3 day limit often appeared to get lost in the haze of conversation and questioning which arose during customer transactions. Moreover, the intervention did not result in any reduction of CCM sales, which we took to indicate no change in usage. Following a review of this initial intervention I felt it was necessary to provide more specific information to customers on the concerns relating to CCMs. It was also decided that a register should be established, with a requirement for each customer to sign for each purchase. This would ensure that customers understood the possible side-effects and problems which could arise from	

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	misuse of CCMs and would be a valuable aid in identifying regular users. At the end of March 2009 we revised the protocol to include these measures. Every time a CCM was requested, the healthcare assistant informed the customer that we had a new protocol and provided some information to the customer about CCMs (as per the Patient Information Summary) after which the customer was requested to sign the register to confirm that they had received this information. The Patient Information Summary consisted of direct extracts from the patient information leaflets of Solpadeine® and Nurofen Plus®, including warnings about side-effects and the effects of prolonged, regular use. If a customer refused to listen to the information, or to sign the register, the sale would not proceed and the pharmacist would be asked to intervene. This process was used for every sale of CCM, no matter how long the queue was, how rushed the customer was or what time of day it was. A few days into the trial we made a couple of amendments to the process. Firstly, we recognised that the term "codeine register" caused difficulties with some customers. It was suggested, for example, that we were keeping a register of codeine addicts. As a result we changed the heading on the register to "Sale of medicines register" [Figure 1] and there were no subsequent objections. Secondly, we felt that the protocol as it stood still did not provide enough information to the customer about the lack of evidence for an additional analgesic effect from codeine. As stated in the BNF, "*combining a non-opioid with an opioid analgesic can provide greater pain relief than a non-opioid analgesic given alone. However, this applies only when an appropriate dose combination is used. Most combination analgesic preparations have not been shown to provide greater pain relief than an adequate dose of the non-opioid component given alone. Moreover, combination preparations have the disadvantage of an increased number of side-effects*." A single sentence summary of this information was included in the Patient Information Summary, and was followed with a warning about the possible side-effects and withdrawal symptoms [Figure 2]. After these amendments, it was felt that the information was more practical, possibly more stark, and at least gave an opportunity for the sale to be redirected to an alternative non-codeine painkiller rather than making the transaction simply an information-giving exercise.	

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	Outcomes After 2 weeks of the trial, the weekly sales of CCMs had reduced by 12.35% with significant increases in the sales of paracetamol and ibuprofen. As a proportion of overall analgesic sales, CCMs had decreased by 11%, which we took to be indicative of reduced codeine usage, while sales of paracetamol had increased by 4% and ibuprofen had increased by 7%. Two months into the trial, the downward trend of codeine sales was still continuing, with paracetamol sales 19% above levels before the start of the trial and ibuprofen up by 32%. While we had expected to suffer a significant reduction in analgesic sales, we were surprised to find that the trial had no effect on overall sales. Most importantly, we had ensured that absolutely 100% of our customers who purchased CCMs were made fully aware of both the potential side-effects and the problems associated with taking it on a continuous basis. All of these people were informed of alternative analgesics that would give them an equivalent degree of pain relief without any of the problems associated with codeine. Therefore we felt that we had taken very firm steps to ensure the safe and appropriate use of medicines in our pharmacy, and had demonstrated that we placed the health and well-being of our customers above any interest in maintaining sales figures. The vast majority of people who purchased CCMs had no problem with the new protocol. By the time 2,000 customers had signed our register, we had recorded just 19 complaints from customers – fewer than 1% of the total. The majority of these arose in the second week when people returned to buy a CCM and complained to us that they had signed the register previously. This provided an opportunity for the pharmacist to intervene to ascertain why they needed another pack so soon. Every one of these customers admitted to taking codeine regularly though only a couple acknowledged that they may have a problem with it. Excuses ranged from "allergy to paracetamol" to dislike of the taste of other analgesics and inability to swallow them because of their shape. A small number of healthcare professionals refused to sign as they said that they "know all about it and buy it regularly" while one man claimed his doctor told him to take it to help with his depression since he neither drank nor smoked. Two customers reacted very aggressively, shouting at staff. Notably,	

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	all of the customers who reacted negatively to the protocol admitted in one way or another that they are regular users of CCMs and so, even though the sale was ultimately refused and they may not decide to come to our pharmacy again, at least we can be sure that we gave them sound advice and we can hope that our intervention may encourage them to reconsider what they are doing and possibly seek professional help. On the other hand, we have received a number of instances of positive feedback including six people who admitted that they knew they had a problem but that since nobody had confronted them about it they were reluctant to deal with it. All of these people had consultations with the pharmacist who advised them on how to deal with codeine withdrawal and 4 of the 6 returned to us some weeks later to tell us that they were now off codeine completely and to thank us for our help. Two customers who happened to observe us reading out the protocol to other people made a point of speaking to the pharmacist about their situations: one of them had undergone a four month withdrawal programme from codeine under their doctor's supervision, while the other person had been prescribed methadone for a period to help them withdraw. Interestingly, one American lady commended us on our protocol and told us that in her state, even though CCMs are restricted to prescription-only, they have a similar protocol to ours which the pharmacist must go through each time he dispenses the prescription. She felt that in the absence of prescription regulations here, we were taking all the necessary steps to ensure the safe and appropriate use of CCMs. There was some initial resistance amongst the healthcare staff to the idea of maintaining the register. They had concerns over the amount of time this would take and how it would be perceived by customers. Following implementation however, they have recognised the benefit to customers, and were particularly heartened by the fact that CCM sales were being reduced as a result of their interaction. The protocol is running very smoothly now, and has just become part of our routine. The information takes approximately 25 seconds to read to the customer and therefore has not had a significant impact on workload.	

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	Conclusions I feel this initiative has helped contribute to patient safety in my pharmacy while emphasising the positive role of the pharmacists in guaranteeing the safe and appropriate use of medicines. As a result, we have decided to implement it on a permanent basis. Clearly we cannot influence what happens to the people who are regular users of CCMs who are refused a sale in our store and who simply go to the next pharmacy up the road. However, we can ensure that the message is conveyed to them clearly and professionally, and we can hope that they will reconsider what they are doing and seek professional help. Although I feel that this initiative has been effective, it only goes a small way to addressing the wider issue of codeine misuse. A more effective measure would be to introduce a national protocol for the sale of codeine, and I would welcome such an initiative. Given the concerns that have been raised regarding the levels of CCM use in Ireland it would be useful to have consistent standards across pharmacies to ensure that the general public received a clear, unambiguous message about codeine use. However, if this were to happen, greater support mechanisms would be needed for the rehabilitation of individuals who have developed codeine dependency and referral pathways would need to be established from pharmacies. Such issues need to be considered at a national level. In the meantime, I hope that the insights provided in this article prove useful to other pharmacists who may be considering revising their protocols for the sale of codeine containing medicines. (i) Euromonitor International. *OTC Healthcare in Ireland*. 2009 [cited May 2009]; Available from: http://www.euromonitor.com/OTC_Healthcare_in_Ireland?print=true. (ii) Hughes, G., McElnay, J., Hughes, C. and McKenna, P., *Abuse/misuse of non-prescription drugs.* Pharmacy World & Science, 1999. **21** (6): 251. (iii) Ford, C. and Good, B., *Over the counter drugs can be highly addictive.* BMJ, 2007. **334**: 917. (iv) Ó Cionnaith, F., *Call to end over-the-counter sales of codeine*. Irish Examiner, Thursday, April 23, 2009 (v) Matheson, C., Bond, C. and Pitcairn, J., *Misuse of over-the-counter medicines from community pharmacies: a population survey of Scottish pharmacies.* The Pharmaceutical Journal, 2002. **269** (66-68) (vi) Section 4.7: Analgesics, from the British National Formulary. March 2009. BMJ group and RPS Publishing.	

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2. PSNI		
	The draft guidance is well expressed and covers all the main matters pertinent to public safety in relation to the sale of codeine containing products. We support all the key points expressed in page 1 of the guidance. We are open to conversations with the PSI on joint endeavours to communicate to pharmacists legal and professional obligations an good practice in dispensing products containing codeine and communicating at large relevant safety information	These comments are welcomed
	The pharmaceutical society has issued guidance regarding codeine sales and this is available on our website see http://www.psni.org.uk/documents/376/PSNI+Advice+on+Codeine.pdf which may be of value to you. A Specific issue id the requirement that Pharmacists should be mindful that they are uniquely positioned to intervene where codeine addiction is suspected and they should seek to refer any such patient to appropriate help or support services. This also requires that the pharmacist has knowledge of support services available.	Noted with thanks.
3. Brian Walsh MPSI, Galway		
	I have a few points regarding the *draft guidance* that you are to introduce in relation to the sale of codeine containing products.	
	I must start off by stating that I am fully aware of the need to curb the usage of codeine products by the public, and support the initiative that is being pursued with these guidelines.	Noted.
	The biggest issue that I have in relation to the guidelines is the reference to non-display of codeine containing products. I don't think this will deter anybody from attempting to purchase, or, for that matter, anybody engaged in selling the products. As pharmacists we should be adhering to the first principle in the code of conduct and, therefore, we should not make a sale of a codeine product where they are not appropriate. If the PSI has a vision on pharmacists prescribing into the future, then I think a much better idea would be, that we must record the name and address of the patient requesting the codeine	Noted. It is not clear that the recording of sales would have the intended purpose or that they could be readily collated and used in the manner suggested. Furthermore these products (including alli®) have already been authorised and placed on the market and regulated in a manner which would allow the pharmacist the necessary degree of control.

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	product. We can then track usage and identify any patterns. Without recording of sales, you will not have any means track sales, either from a quantitative or from an appropriateness aspect. You will be relying on sale figures from the pharmaceutical companies. This recording of patient information could be a type of *pharmacist prescribing* where the item is then dispensed and labelled according to protocols. This category could then be expanded to include *alli* and other products that may be presently open to abuse and in the future any products that drop out of the POM category. This would be more of a 'carrot' approach then a 'stick' approach.	
	We would see, as pharmacists, that there will be more benefits down the road whereas, if the guidelines are just as is, then there is nothing in it for individual pharmacists other than an increased work load and possibly an increase in dispensing mistakes, due to be called out to intervene in every sale from *feminax* to *syndol*. It could also increase the traffic in a dispensary, if that is where you are storing the products, because once you have OK'd the sale, one of the assistants is going to go and get the box from the dispensary to complete the transaction.	This is an important point which calls into question the pharmacist manpower that should be available on a whole-time basis in each pharmacy to fulfil these and other requirements under the Pharmacy Act 2007.
	I know the PSI is not concerned with monetary issues, when they concern the individual pharmacists but a 'prescription' based approach would allow members to charge a *professional* fee for the time involved in either making, or not making, a sale. This would then cause the price to jump significantly, which I think will reduce sales dramatically as more and more people are price conscious.	Noted.
	Might it not be worthwhile querying the use of codeine at 8mg in these products and to whether it offers any real pain killing quality over their not codeine containing counterparts.	This is a function of the IMB in granting the relevant marketing authorisations.
	I don't think the visual selection restrictions of tobacco products have drastically cut smoking rates in the state, so that would also concern me, if we are only engaged in an act to appear to be doing something because it looks and sounds good but doesn't achieve its stated aim. I would also wonder where this approach would end, do we have to consider taking laxatives off our shelves as their abuse can be a significant factor in anorexia. Enforcement of	Argument noted. While the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that in addition all non-prescription medicines be the subject of appropriate counselling (regulation 10), it must be noted that because of the particular characteristics of those medicines containing controlled drugs

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	our universal responsibilities rather than micro-managing individual scenarios might reduce your work-load and encourage individuals to take ownership of their career rather than sitting back and waiting for their duties to be spoon-fed to them.	(i.e. codeine) furthers restriction are imposed which requires that those products would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be stored in a pharmacy under the direct control of the pharmacist in a manner that would require his or her direct involvement in the supply and may only be supplied in a manner where the advice of the pharmacist is obtained and which provides the potential of his or her professional intervention.
	Finally, as I stated at the start of this e-mail, I applaud the idea but am worried as to how this will impact on individual pharmacists and the rest of their work. I agree the professionalism of our industry needs to me kept at a very high level, to maintain the confidence of our patients and our pay-masters. I understand Boots did some work in relation to switching solpadeine sales to that of plain paracetamol, during the summer, and I would ask that these guidelines are trialled in independent pharmacies to see how they impact on us, as Boots and other major chains have the resources to dedicate pharmacists to the sale or non-sale of these products, whereas the majority of us don't have the wherewithal to do likewise.	Noted. See comments above
4. **Christine Bender-Pototzki MPSI, Forristal's Pharmacy, Co Cork.**		
	I am a German Pharmacist and was practising 15 years in Germany, 4 years of which I had my own pharmacy business, before I came to Ireland in June 2008.	
	In Germany, <u>all</u> products containing codeine whatsoever dosage are <u>prescription only</u>. I have been always very much concerned about the fact that these products are sold over the counter here, as well as products containing diphenhydramine for children. I appreciate the effort by the PSI to control the OTC sale of codeine-containing products, but I firmly believe this will not resolve the problem in total. Codeine-addicted people will find some ways to buy Solpadeine or Nurofen plus in small quantities in different pharmacies. Of course, pharmacists can contribute to the safe use of these products, but I	Noted. It is possible that if the draft guidelines are not adhered to and the control exercised by pharmacists does not effectively result in the safe use of these non-prescription medicinal products containing codeine that, like in Germany, those products will also become prescription-only in this country. However, this decision lies with the IMB as the licensing authority.

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	honestly think they should only be available on prescription. A patient with headaches or backpain or menstrual pain who gets no relief from ibuprofen, aspirin or paracetamol alone needs to consult his doctor to get a proper diagnosis instead of practicing "trial and error" with codeine medicines.	Agreed. Unresolved pain should always be referred to a medical practitioner for investigation.
5.	**David Jordan MPSI, Jordan's Pharmacy, Kimmage, Dublin**	
	I wish to raise the following points in relation to these draft guidelines. Just before this I would like to address the PR handling of the announcement of this draft. The perception given out was that anybody who takes a codeine containing product is an addict. I know that this was not the intention but I have already had one patient refuse to take a codeine containing product that was prescribed for her because in her words "I don't want to become an addict". While the PSI cannot control how various media outlets present the subject I feel that some PR advice should be taken and spokespersons prepared before these announcements are made. Getting back to the draft guidelines, the first key point is that these products should be stored out of sight in the pharmacy. This might have some effect if the general public did not know about these products. But while these products themselves may not be advertised directly to the public a large number of their namesakes are. These products have a level of brand recognition that most PR people would give their right arm for. Reading the rationale for this one thing bothered me. The current regulations state that they must not be available for self selection by the public. It would now seem that the PSI has interpreted this to mean that as well as physically inaccessible they must also be visually inaccessible. This is a big legal leap by yourselves. You have taken an interpretation which to my mind is legally dubious, seek to put it into guide lines which will be enforced by the Code of Practice which in turn can be used to discipline pharmacists. I could see our legal colleagues having a field day with this one if you decide to haul somebody over the coals on this basis. Storing them in the pharmacy gives these products an added mystique. There is a perception that because they are in the pharmacy that they are somehow better and more attractive.	Noted. Noted. The point here is to have the products into the dispensary would bring these products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is

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		that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.
	The second key point is that they should only be recommended as second line products. This would seem to imply that most pharmacists reach for these first when recommending an analgesic to a patient. I find this assumption patronising. One of the reasons that these products are popular is not that they are addictive but that they are effective analgesics. Saying that we should not recommend these unless other simple analgesics have been shown to be ineffective is like saying that a car sales man should not sell a BMW to a client until they have driven a Skoda for a few days. I recommend an analgesic on the basis of the patients symptoms and my experience. Patients will very quickly learn the "correct" way to ask for a packet of these products. "I've tried paracetamol for a few days now but it has not fully effective. I would like a pack of (insert preferred product) and yes I am aware of the potential risks associated with misuse." This makes the entire process a form ticking exercise and would very quickly become a laughing stock.	A better understanding of the rational use of these products including the WHO analgesic ladder would be helpful here. Furthermore pharmacists have a statutory code of conduct with which they must comply, and in the discharge of their professional obligations they must strive to ensure that all use of medicinal products is rational and evidence-based, including use by reference to the analgesic ladder, in their interactions with patients.
	The next key point shouldn't even need to have been put into the document. The maximum pack size of 24 means that anything other than short term use necessitates repeat visits to the pharmacy. Even without these draft guidelines this is something which would precipitate a response within the pharmacy.	This is a matter which may have to be responded to by the manufacturers and the IMB as the licensing authority.
	The fourth key point is patronising to patients. Yes some patients need to be advised on the correct use of these products but many more if not most, are fully aware of how they should be taken. By insisting that we counsel everybody on risks associated with misuse we will lose our credibility with the public if we start treating everybody as a potential addict. All this presumes that patients are ignorant about their own condition and their own response to various medicines. If they know the risks then they can make their own decisions. We as a society already accept this for alcohol and tobacco. Combine this with hiding them away in the pharmacy and we end up treating patients like children.	This point presumably relates to paragraph 3(e) of the guidance document. Apart from the regulatory requirements previously outlined, it is good practice to remind patients/users of the implication of their use or continued use of these products. The latter may require the referral for appropriate investigation to a medical practitioner and the intervention by the pharmacist may be sufficient to trigger such an outcome.

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	And now some positive suggestions. The first thing I would like to see is the current regulations being enforced. And this means for all pharmacies regardless of whether they are an independent or part of a chain. I'm sure you are aware of pharmacies that offer cut price medicines including codeine containing ones, have in-store and window advertising, hand out leaflets and have codeine containing products available for self selection. These products should be BEHIND a counter and not just behind a plastic leaf. No pharmacy should be allowed to advertise (including in store) price reductions on medicines but for these products in particular. If these pharmacies treated these products with a bit more responsibility then the need for these guidelines would undoubtedly be diminished.	Noted. The comments here underline the clarity that is necessary in relation to the regulatory controls that apply to these products. It must also be borne in mind that all of the products concerned are under the strict control of pharmacists who, if the activities referred to are discovered, could be severely dealt with under the Pharmacy Act 2007.
	The next is outside the PSI's remit but I'm sure you could bring their influence to bear. While these products are not advertised as I wrote above their namesakes are. So the PSI should push for a ban on advertising to the public of all the namesake products. To go one step further when the product licences come up for review the manufacturers should not be allowed to use similar names for dissimilar products. Also phrases such as "Analgesic from the makers of...." should be banned. This might not go down too well with the drug companies but the PSI (and the IMB for that matter) have to decide who they serve, the public or the multi-nationals.	Noted. This is a long-standing issue where line-extensions are concerned.
6. **Irish Medicines Board**		
	1 GENERAL COMMENTS 1.1 The IMB welcomes the review conducted by the PSI which aims to ensure the safe supply of these products and supports the proposed guidelines for enhanced control of the provision of codeine-containing products. The storage of these medicines out-of--sight of the public and the prohibition of in-pharmacy adverts and display material are a positive development.	Noted.
	1.2 The IMB has taken action in relation to the sale of codeine-containing medicines in the interest of public health following concerns about the potential misuse/abuse of codeine containing analgesic products. The sale of these medicines is subject to a number of restrictions including low dosage,	Noted.

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	sale under expert pharmaceutical guidance only, restrictions in pack size or bottle volume, and the inclusion in the product information of a statement on the possibility of physical and psychological dependence associated with prolonged use of these products. The IMB has also written to holders of marketing authorisations for non-prescription products containing codeine to highlight the prohibition on any advertising to the public of these products.	
	1.3 In the early part of 2010, the IMB intends to conduct a formal regulatory review of codeine-containing medicines and their product information based on available evidence from a range of data sources, an evaluation of the adequacy of existing risk minimisation measures, and stakeholder consultation. Recommendations in this guidance document for pharmacists will be taken into account as part of our review. At the conclusion of the review, an implementation plan for updated product information will be agreed to ensure consistency of the guidance for pharmacists with the regulatory position.	Noted. The PSI would be happy to support such a review and at this stage suggest that some of the comments made in the course of this consultation would be considered as part of such a review.
	2 SPECIFIC COMMENTS **2.1 Page 2: Codeine** In the first line after the word 'moderate' we propose that 'opioid (narcotic)' should be inserted. The second paragraph in this section goes on to discuss the use of non-opioid analgesics in preference to codeine. It is not clear up to that point that codeine is an opioid.	Agreed.
	In the third paragraph in this section the reference to the scheduling of codeine is incorrect. Codeine and its higher strength products are controlled under schedule 2 to the Misuse of Drugs Regulations. It is only the low dose preparations that are in schedule 5. We therefore suggest inclusion of the following text within this section to clarify this: 'Codeine, due to its potential for misuse, is a drug controlled under the Misuse of Drugs Acts 1977 and 1984. Low dosage preparations containing codeine (less than 100mg) are regulated as schedule 5 controlled drugs'.	Agreed.
	2.2 Pages 4 and 5: Medicinal Products (Control of Advertising) Regulations, 2007 In the third paragraph after the words 'controlled drug' it might be worth adding the following clarification 'irrespective of the schedule into which the	Agreed.

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	drug is classified under the Misuse of Drugs Regulations'. Very often, wholesalers and pharmacists are not aware that the provisions of the Advertising Regulations relating to controlled drugs are applicable to all controlled drugs, irrespective of their scheduling.	
	Given the importance of the prohibition on advertising in this initiative, we think that the document should provide a definition (or maybe an abridged version of it) for the word 'advertising'. This is available in the Medicinal Products (Control of Advertising) Regulations 2007. This would help support and explain the prohibition of any form of advertising to the public.	Agreed. Will attempt insertion as a footnote.
	In addition, we recommend rephrasing the relevant sentence on page 5 to read: 'This would include any form of window displays, in-pharmacy promotions and promotional displays, promotional leaflets and shelf stickers.' This wording would completely prohibit codeine-containing medicines from being included in '3 for 2' or other kinds of special offers where pricing is a factor. The same change would also be required on page 8.	Agreed.
	3 OTHER COMMENTS **3.1 Page 5: Storage of codeine medicines in retail pharmacy businesses** Storage out of sight of purchasers is sensible as codeine products should not be visible for self selection. Storage in the dispensary might cause problems of a practical nature as many dispensaries would not have room for storage of such products given the range and quantities of products which needed to be stored there. It would be useful for pharmacists if acceptable alternative storage areas were mentioned, e.g., behind/under the counter in a position accessible to staff but not accessible or visible to patients.	Noted. Will be reconsidered when all comments have been taken into account.
	3.2.1 Page 7: Suspected abuse and/or misuse We suggest that the concept of monitoring sales is clarified for the benefit of pharmacists, as monitoring could mean that the pharmacist 'keeps an eye' on sales or that some record-keeping is required. The former may not give a reliable indicator of the pattern of sales to individual patients and allow the pharmacist to make an intervention.	Noted. This is a difficult area where the experienced pharmacist in managing his or her pharmacy is concerned and in the course of which he or she should be on the alert for incidents of such abuse and/or misuse.

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7.	**Dr. Martin Ruttledge Consultant Neurologist** ***Headache / Migraine Clinic*** ***Beaumont Hospital*** **Esther Tomkins** ***CNS Headache / Migraine*** ***Beaumont Hospital*** **Patrick Little** ***CEO Migraine Association of Ireland***	
	Medication Overuse Headache (MOH) & Chronic Daily Headache (CDH) Chronic daily headache or CDH (defined as headache on more than fifteen days per month) is the most frequently encountered problem at specialist headache centres worldwide, affecting 3% - 4% of the general population. Figures from the US estimate that up to 80% of patients attending specialist headache clinics have CDH. A significant proportion of such headaches are attributed to the overuse of analgesics, termed medication overuse headache (MOH). This is usually in the context of a patient with migraine. MOH occurs after the regular intake of any kind of analgesic, non-steroidal agent (NSAID) or triptan (anti-migraine drug) over a period of months or years. Over the counter analgesics (such as paracetamol or ibuprofen) and combination analgesics (for example, paracetamol with codeine or aspirin combined with caffeine) are often helpful in treating an acute attack of migraine. However, their use must be restricted to no more than five or six days per month. It is ironic that regular use of these agents can make the problem worse. The diagnosis of MOH is extremely important in clinical practice because patients rarely respond to migraine preventative medications if they continue to overuse analgesics.	Noted. This supports the need for greater vigilance by pharmacists and others where the use of analgesics is concerned, including the need for an appropriate and timely referral for medical investigation. Noted. See above

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	The 2004 guidelines from the International Headache Society (somewhat outdated) regarding analgesics and NSAID's are as follows: Opioids such as codeine and combination analgesics should not be taken more frequently than ten days per month. Most specialists are now advocating less regular use (no more than five or six days per month). The same is true for paracetamol and regular over the counter pain killers. It is important to remember that while analgesics may be extremely effective for treating episodes of migraine, using them too often (more than once or twice a week over several months or even weeks) can actually cause medication overuse headache. It appears that the number of days of dosing per month is the important fact, and not the number of individual doses of each medication taken each day. Regarding treatment, stopping analgesics completely is usually the fastest way to improve the condition. A gradual withdrawal programme may be recommended in some circumstances, depending on the type of drug overused. Specialist (doctor or nurse) guidance is recommended. The headache pattern may revert back to its original pattern within a number of months of discontinuation of the offending agent, just by stopping the analgesic/NSAID. In some situations, further medical treatment may be necessary.	Noted. This contribution underlines the potential for pharmacists to make an important contribution to the management of pain and the referral for appropriate and timely investigation and medical treatment as may be necessary.
8.	**Fiona Conlan**	
	Can i just point out that these new guidelines do not do anything to stop codeine addicts gaining access to the products. These measures do not go far enough at all. Why can't the product become prescription-only like in the USA? Another solution I propose is as follows: Codeine products remain OTC but are regulated by a **pharmaceutical card**. Each person in the country be issued with a national pharmaceutical card with a **unique chip that records all of their pharmaceutical purchases**, OTC and prescription. When a person goes to purchase tablets /products(A parent must provide card for child where necessary) the card should be swiped like a credit card reader and the info will appear on computer screen. The card could hold **1 years history of purchases**. This would **highlight** many issues such as **codeine**	This may be the outcome if the current controls and guidelines prove not to be sufficient or to gain sufficient support from pharmacists in regard to their implementation; however, this decision lies with the IMB as the licensing authority. Noted. However, this would require a regulatory intervention which would exceed the remit of the PSI.

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	addiction, prescription based addictions(Where customer goes to many Doctors with same complaint) and will also ensure that a crossover in medications with negative side effects will become less commonplace. Though is might prove expensive in the short term, the long term effects would surely make it worth it?	
9.	**Gary Smyth MPSI, Kiltimagh, Co Mayo**	
	Regarding section 4a I'm mailing to request that all addiction clinic details with a point of contact details for each part of the country be issued to each Pharmacy. I over the past ten years have referred 3 patients (2 eventually went on programmes) to our local treatment centre in Swinford. Its very easy to use the excuse that its someone else's issue to deal with ,but I feel we generally have a longstanding relationship with these at risk patients and can approach the matter in an understanding unconfrontational way and point the patient in the right direction . I found this information took a lot of searching for when I first went looking.	This is would seem to be a suggestion which would be worth pursuing with the appropriate authorities.
10.	**Gerard Garvey MPSI, Garvey's Pharmacy, Co. Galway**	
	The sale of codeine and codeine containing products is a constant source of worry to me as a pharmacist. Customers may have an addiction to codeine and be getting their supplies from numerous outlets. In spite of giving the usual warnings to patients about codeine I find certain customers continue to want to buy these products. It would be far better if all codeine containing products were made prescription only as pharmacy cannot police and control this problem.	Noted. This may be the outcome if the current controls and guidelines prove not to be sufficient or to gain sufficient support from pharmacists in regard to their implementation however this decision lies with the IMB as the licensing authority.
11.	**Tom Concannon MPSI and Paddy Hickey MPSI, Hickey's Pharmacy**	
	Given the nature of the proposed changes I would like to start by expressing my disappointment at the very tight time scale allowed for key professionals and the public to review these guidelines. A similar review in the UK allowed 2 years for submissions.	Noted. This is the MHRA review which is a different type of review. No legislative change is envisaged arising out of this initiative.

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	As pharmacists we are very aware of our responsibilities regarding the sale of OTC items subject to abuse. We have implemented strict sales protocols to assist us in this regard. All of our sales team are highly trained in OTC sales and in proper referral protocols. Codeine-containing products are not-accessible to the public for self-selection, so a consultation with a trained member of staff under the direct supervision of a pharmacist is required for any sale to proceed.	Noted.
	The key issue which I disagree with is the proposal that codeine containing products should be stored "out of view of the public to facilitate the legislative requirement that these products must not be accessible to the public for self-selection". Interpreting this regulation to include "visual" self-selection is in my opinion misinterpreting the original intention of section 5(e).	Noted. See comments below. Noted. The regulator can only act on an evidence base.
	Firstly may I express the opinion that is a poor indictment for any profession to have to hide products or services which need expert advice for their proper use. It regrettably, and perhaps inadvertently, sends a signal that the Regulator, in some way, "mistrusts" the profession in the appropriate management of the sale of these products.	Noted. This is unfortunately a reality on the global stage.
	The fact that Irish consumers are exposed to a high level of advertising of some of these products on TV (through UK based channels) ensures that these brands are continually reinforced for our patients. Therefore an "out-of-sight, out-of-mind" strategy will never work. (The voice-over on the UK TV advertisement of Solpadeine is that of an Irish actor which serves to further confuse consumers.) I also believe that attempting to hide codeine products will have absolutely no effect on their levels of misuse. Misusers are very familiar with these products and will continue to request them by name and will if anything become more devious if necessary. The fact that they the pharmacist will take the product from the dispensary, or somewhere else that is otherwise out of view, instead of the open shelf will be largely unnoticed.	Transferring the products into the dispensary would bring these products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to intervene professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed by the regulations which requires that those products (CD medicines) would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is

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		that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved. The current draft guidance is based on the IMB 2004 guidance (reference 1) and the NMIC 2005 guidance (reference 4), which also refers to the WHO analgesic ladder. A better understanding of the rational use of these products including the WHO analgesic ladder would be helpful here.
	Combination codeine painkillers do provide excellent pain relief with relatively few side-effects. In some cases, they may be more appropriate than single-ingredient products, and to delay their use until single-ingredient product has been tried (as the draft guidelines appear to suggest) unnecessarily prolongs the pain and discomfort of the patient, whose needs must always be our foremost consideration. The majority of users of these products use them correctly and as indicated. Hiding these products will stigmatise the products and could result in patients who need these products being afraid to ask for them. This could cause a delay in patients receiving an appropriate medicine (or no medicine) and ultimately result in unnecessary pain, as well as hospital and doctor visits and in many cases a discharge prescription for a much stronger product. Like all pharmacists I am aware of the potential for abuse with codeine containing products. Instead of introducing measures such as hiding products much more attention needs to be given to education. I think the RPSGP have taken a good approach in this regard. The addition of a warning on packaging "Can cause addiction. For three days use only" will help to educate patients. Increasing the prominence of such a pack warning would caution patients against accidental dependence. Also, as the end-user is often not the person presenting in the pharmacy it is a way of ensuring this important message gets to the person in question. There are currently insufficient sources of help for people experiencing a	Noted. Initiatives here are for the IMB, as the licensing authority, to consider. This is a matter which might be pursued with the appropriate authorities. Noted. The guidelines produced by the PSI will have a 'statutory effect' which makes them compulsory where pharmacists are

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	problem with the misuse of OTC medicines and hence limited options for pharmacists who wish to refer misusers for further support. I believe the HSE needs to address this urgently and I would like all stakeholders pushing for these services. I agree with the need for pharmacies to produce a protocol for the sale of codeine containing products and I think the IPHA/IPU protocol is excellent in this regard and should be the standard upon which any draft guidance is made.	concerned. Sales protocols are an important part of the procedures that will need to be put in place in a pharmacy to ensure adequate control of the supply of these products and adherence to the finalised guidance. However, all and any such protocols currently in place will need to be updated in light of the finalised guidance
12. **Irish Pharmaceutical Healthcare Association(IPHA)**		
	The Irish Pharmaceutical Healthcare Association (IPHA) welcomes the publication of guidance on the safe supply of non-prescription medicinal products containing codeine (hereafter codeine medicines). The IPHA recognises the need for action to prevent the misuse and abuse of codeine medicines. However, IPHA does not agree with the Pharmaceutical Society of Ireland's (PSI"s) interpretation of the legislation that these medicines should be placed out of sight. In particular, IPHA is of the opinion that placing these medicines out of sight would not in any way prevent misuse or abuse. IPHA agrees with the recommendations contained in sections 1, 3, 4 and 5 of the guidance and welcomes their introduction. However, we believe that we can add further to some aspects of these sections and will elaborate on this within the document. One of the principle objectives of the Consumer Healthcare industry is to ensure that patients use all medicines *"appropriately and safely"* and for many years the IPHA and individual member companies have provided training, guidance and protocols to ensure that codeine medicines are both supplied and used appropriately (Annex 2). The IPHA agrees that codeine medicines should not be available for self selection. However, we do not agree that they should be out of sight. Keeping these medicines behind the pharmacy counter ensures that they are not available for self selection but also enables patient choice, with appropriate professional intervention.	Noted. What is envisaged here is that there would be a more direct pharmacist involvement in the supply of codeine medicines with a view to assuring their rational use. Removal from self-selection is one of the steps that is intended to achieve that. Noted. Noted. The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise a direct involvement in the supply and enable him or her to exercise their professional judgement as to the appropriateness of the supply and to intervene professionally in

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		the supply as may be necessary. The Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed which requires that those products would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.
	Placing the product out of sight may lead to a reduction in the sale of these products, but crucially this will not equate to a reduction in misuse or abuse. In fact it may increase the level of harm to the public as it will result in increased, but ill informed, sales from the internet or from other jurisdictions. Additionally, a vital opportunity for the pharmacist to intervene to actively prevent misuse and abuse is likely to be lost. Any likely decrease in sales will relate to the thousands of people who correctly use the products who no longer consider them to be available. People who misuse or abuse products are unlikely to be affected by placing them out of sight.	It is not suggested that the products would cease to be available and even today the potential for securing products via the internet exists. In any event it is our understanding that in all EU/EEA countries, codeine containing products are only available via pharmacies and in a majority of these countries that these products are subject to prescription-only control.
	International best practice and international research suggests that it is the appropriate supply of the product that is the key control mechanism that needs to be tightened, not the labelling, location or quantity of product sold.	Noted. The intention is that these guidelines will achieve such supply, including rational use.
	In 2007 the UK Medicines and Healthcare products Regulatory Agency (MHRA) prepared an assessment report on codeine medicines, and although a number of other recommendations were made, placing it out of sight was not considered useful. Similarly, the Royal Pharmaceutical Society of Great Britain (RPSGB) examined the self selection of pharmacy medicines and concluded that they should remain on open display but not for self selection *(so they were to*	Noted. The different regime in this country which governs the practice of pharmacy and the advertising to the public of codeine containing products must be taken into account.

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	remain behind the counter etc).	
	Additionally, the UK All-Party Parliamentary Drug Misuse Group (APPDMG) had concerns about making access to codeine medicines in pharmacy too difficult because of the risk of displacing the problem onto the internet.	Noted. See above.
	Enforcing the existing legislative requirements that pharmacists *„inform the patient on correct use of the product* "together with frequent, random audits by the PSI would be the most effective step in ensuring that the potential misuse and abuse of codeine medicines is addressed. Such audits should be carried out in a collaborative manner, following initial information and education on the revised guidelines.	Noted. This will be a consequence of the adoption of the guidance.
	INTRODUCTION The IPHA represents the interests of the consumer healthcare industry in Ireland[1]. One of the principle objectives for the industry is to ensure that patients use all medicines *"appropriately and safely"* and it is in this context that the Association sets out its submission. 1 McNeil Healthcare Ltd, Bayer Plc Consumer Care, GlaxoSmithKline Consumer Healthcare, Novartis Consumer Healthcare, Procter & Gamble (H&BC) Ltd, SSL Healthcare Ireland Ltd, Reckitt Benckiser (Ireland) Limited and Wyeth Consumer Healthcare	Noted.
	The IPHA also acknowledges and welcomes the Society"s comments at the launch of the consultation at which it stated that codeine medicines were *"useful medicines when used appropriately and safely"*[2]. 2 Ms Kate O"Flaherty MPSI, PSI Director of Public Affairs, presentation at the launch of the consultation on draft guidance for pharmacists on the safe supply of non prescription medicinal products containing codeine (21.12.09)	Noted.
	The IPHA recognises the need for education on codeine medicines and welcomes the proposed PSI draft guidance, while noting some areas that require amendment.	Noted
	In autumn 2009 the IPHA, in collaboration with the IPU, produced and distributed a protocol (Annex 1) for the supply of codeine medicines to all IPU	Noted. Sales protocols are an important part of the procedures that will need to be put in place in a pharmacy to ensure

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	pharmacy members providing a comprehensive framework to ensure that these medicines are both supplied and used appropriately. The protocol is also accessible on the members' section of the IPU website and individual IPHA members have undertaken specific training of pharmacists and pharmacy staff on codeine medicines (Annex 2).	adequate control of the supply of these products and adherence to the finalised guidance. However, all and any such protocols currently in place will need to be updated in light of the finalised guidance.
	In 2008 the IPHA ran a Chronic Daily Headache Campaign in association with the IPU and the Migraine Association of Ireland (MAI) in which leaflets were distributed to pharmacies throughout Ireland highlighting strategies to address medication overuse headache. This highly successful campaign empowered and informed pharmacists and was well received.	Noted
	The IPHA has successfully developed and implemented a number of consumer focused campaigns such as Ask About Your Medicines (April 2005), Ask About Pain Relief (August 2007) and Master Your Medicines (2009) to highlight the importance of understanding medicines and following the instructions provided on the pack and in the package leaflet.	Noted
	The IPHA believes that continuing to inform and educate the public, together with effective pharmacist "gate keeping" will be more effective and will have better and wider reaching consequences than hiding products from a public that is well aware of their existence.	Patient information and education is a critical component of the safe use of any medicine however these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists to exert control over their supply and ensure the rational use of these products. The Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed which requires that those products would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.

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		The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise a direct involvement in the supply and enable him or her to intervene professionally in the supply as may be necessary.
	EVIDENCE The draft PSI guidance states that *„the safety concerns around the misuse of non prescription medicinal products containing codeine are well established ".* However, the IPHA is unaware of any Irish specific data regarding this other than the statistics provided by the Irish Medicines Board (IMB) that only 103 codeine related adverse events were reported between 1985 and 2005 and that according to the Health Research Board the numbers seeking treatment for codeine as a main problem drug was 844 in 2008. 3. According to the IMB statement on 16th August 05, *„reports of codeine abuse in Ireland appear to have mainly arisen in the context of multi substance drug abuse, with a very small number of isolated cases of codeine abuse reported compared to the volume of sales for these products. Since 1980, the IMB has received a total of 10 reports of dependence in association with codeine containing products, all of which arose with prolonged use, which is not recommended, or use of a higher than recommended dose"* 4. Statistics from the Health Research Board It is therefore disappointing that an extrapolation of problems occurring in another jurisdiction where the legal and regulatory framework for the supply of these products differs has been proffered to support the aforementioned statement. If there was evidence of a significant problem then the IPHA would be most interested in receiving the data. As was highlighted by the IMB"s Director of Human Medicines during a Prime Time Programme on 07th June 2005, the extrapolation of UK or European figures, while interesting, may not reflect the situation in Ireland. This is especially true since the regulations surrounding OTC medicines are different in Ireland to those in the UK and other countries - for example, codeine medicines cannot be advertised to the public in Ireland.	*"the safety concerns around the misuse of non prescription medicinal products containing codeine"* stem from the fact that this substance is an opiate and therefore the potential for psychological and physical dependence exists. Bearing this in mind many countries have adopted measures and introduced controls to address these concerns and minimise, and where possible to prevent, the misuse of this substance including restriction to prescription control.
	It is important to highlight that the IPHA continues to encourage healthcare professionals to report adverse events and has worked with the IMB on this matter. The IPHA medicines information website, www.medicines.ie includes a link to enable the on-line reporting of quality defects, suspected adverse	Noted

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	reactions or any incidents associated with medicines, to the IMB. Healthcare professionals have been reminded in correspondence from the IPHA that their reporting of adverse events that occur after a product is licensed, is very important in the correct assessment of the evolving benefit/risk of a medicine over its lifetime and it is expected that the link will facilitate that process. ROLE OF THE PHARMACIST & PATIENT EDUCATION Placing codeine medicines out of sight would not address the issue of misuse or abuse but it would inconvenience both pharmacy staff and the vast majority of pharmacy customers who use codeine medicines appropriately. The proposal to place codeine medicines out of sight undermines the pharmacist's role as a healthcare professional. It implies that the pharmacist is not capable of dealing with the issue of misuse without having the product taken out of sight of the customer. The proposal is disempowering towards pharmacists and their professional role – in fact it is the pharmacist who is ideally placed to stem and prevent misuse and abuse.	The Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed which requires that those products would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved. The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise a direct involvement in the supply and enable him or her to intervene professionally in the supply as may be necessary.
	The IPHA believes that one of the keys to prevention of misuse or abuse of codeine medicines is the role played by the pharmacist. The pharmacist is perfectly placed to advise patients on which medicine is appropriate for them and so avoid inappropriate use. The pharmacist's professional role as the effective gatekeeper is an essential function. While confronting potential misuse may be difficult or awkward, it is a situation that must be dealt with. In this regard the IPHA believes that it is important to empower pharmacists with the appropriate tools and strategies to better carry out their vital medicines management role rather than impede it.	Agreed. These products are placed directly under the control of pharmacists. See above comments.

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	Abuse of prescription medicines, which are always out of sight, is well documented. This is a further reason why keeping codeine medicines out of sight will do little to address abuse. What is required is 1) appropriate accredited training and 2) appropriate gate keeping by the pharmacist. Once those who misuse or abuse have been identified, pharmacists and pharmacy staff can be trained on soft skills and tools to deal effectively with them, advise on appropriate medication usage and direct to appropriate services where this is warranted. IPHA has for many years actively undertaken pharmacist education initiatives and details of these are provided later in the document and in Annex 2.	
	The IPHA welcomes the recent legislative requirement that pharmacists must[5] inform the patient on correct use of the product and *„that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and / or misuse "*. It is imperative however that pharmacists are given the appropriate tools and protocols to better enable them to carry out their role as gatekeeper. 5. Regulation 10 of SI 488 of 2008	Noted
	Much work has been done by the IPHA member companies to train pharmacy staff on the appropriate supply of codeine medicines (Annex 2). Indeed in late 2009 a detailed, comprehensive protocol for the sale and supply of codeine medicines was developed by the IPHA & the IPU and was distributed to pharmacists. It enables pharmacy staff to ensure the appropriate supply of these products. In section 4(a) page 7 of the draft PSI guidance it states that if the pharmacist becomes aware of a suspected *„abuse/misuse/addiction issue...they should make all reasonable attempts to ensure that the patient is facilitated in accessing services which will assist in the management of the addiction "*. The IPHA is of the opinion that this statement does not go far enough - formal training of pharmacists in brief interventions to deal with abuse/addiction are crucial if misuse and abuse are to be tackled effectively. Strategies are required by pharmacists to guide those in need towards appropriate services and there are many peer reviewed, statistically robust studies in the literature that outline how best to intervene and the common pitfalls encountered by	Noted. It is envisaged that the competent pharmacist should be in a position to address all of these issues and that the health services and others involved in this area including those involved in continuing education of health care professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed.

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	untrained individuals „trying to help". There are two types of use that need particular attention - misuse and abuse: • Misusers need to be identified, educated and advised. There are already clear warnings and instructions for use on these medicines. However, in addition to this pharmacists can ensure that the correct individuals receive the correct medicine and take it appropriately – thus preventing both misuse, and further along the line, abuse. • Abusers will not be deterred by having codeine medicines out of sight. Valuable time that could be spent assessing, advising and if necessary referring the patient to appropriate services will instead be spent retrieving the medicine and inconveniencing the majority of individuals who use the product correctly. The steps to prevent misuse and abuse are: • Intervention of healthcare professionals or trained staff working to agreed protocols using proper systems; • Effective IT/ePOS systems (cf those in place to ensure compliance with the paracetamol regulations); • Appropriate accredited training on how to deal with addiction and how to interact with those who may be misusing or abusing medication • An active, collaborative inspection approach and follow up policy by the PSI to ensure that pharmacists are engaging with customers on the supply of these medicines. The key finding from the UK APPDMG *(a group of members of parliament who meet to discuss issues and concerns on drug misuse)* was that *„for a proposal to be successful in reality, there must be support available for the addict when they present with this problem. If the pharmacist or doctor has no expertise in this area and nowhere to refer the patient for support, all these schemes to reduce availability will have little effect on the problem ".* ENFORCEMENT Enforcing the existing legislation, training pharmacists and introducing the draft PSI guidance *(excluding the requirement that codeine medicines be placed out of sight)* would effectively ensure the safe supply of codeine medicines.	The existing legislation i.e. the Pharmacy Act 2007 and the RPB regulations (in force since 29th November 2008) currently require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription

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	Importantly it would still allow those who correctly use it to do so while not restricting patient choice. One of the principles of the Governments „Better Regulation" is that existing requirements be enforced fully before new burdensome requirements are introduced. Enforcing the requirement that the supply of codeine medicines may only be made *„by or under the personal supervision "*of a pharmacist is critical before new requirements are considered. It is important that enforcement is accompanied by advice and education and that a collaborative approach is taken.	medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restrictions are imposed which require that those products would not be accessible to the public for self-selection (regulation 5(e)).
	CONTROL OF SUPPLY The requirement to place codeine medicines out of sight would inconvenience a large majority of people who use these products legitimately and correctly but it would not stop misuse or abuse. A likely drop in the number of people purchasing these products could be misconstrued as a corresponding reduction in the number of people abusing or misusing codeine medicines. This would not be the case. In reality the small minority who misuse or abuse codeine medicines, knowing that it is in the pharmacy but that it is simply out of sight, will not be inconvenienced by its new proposed location. They would still be aware of it's place in the pharmacy and likely to be resourceful enough to ask for it. Rather than asking the pharmacist to spend their time getting the product from the dispensary, it would be more appropriate to spend that time assessing the appropriateness of that medicine for the patient. Having the product in sight or out of sight will not affect the situation, but intervention will.	The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise their professional judgement as to the safety or appropriateness of the supply and enable him or her to intervene professionally as may be necessary. See above comments also.
	In March 2007 the placing of the product out of sight was also considered[6] by the Royal Pharmaceutical Society of Great Britain (RPSGB) in the UK. Following detailed analysis, examination and feedback they agreed that open display of pharmacy medicines should remain as should the prohibition of self selection and therefore the product remains behind the counter, within display cabinets, etc. 6 In March 2007 the RPSGB undertook a 6 week consultation to seek views on whether or not there should be restrictions on the way in which Pharmacy medicines were displayed to and accessed by the public. Specifically the RPSGB *"does not preclude methods of display which enable*	Noted. However because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restrictions are imposed under the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in force in this jurisdiction which requires that those products would not be accessible to the public for self-selection (regulation 5(e)).

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	patients to better view Pharmacy medicines, such as perspex shelf screens and display cabinets, or the display of empty boxes. The Society believes that this professional requirement addresses concerns raised during the consultation process about the importance of ensuring safe, appropriate selection of Pharmacy medicines and enabling pharmacy staff to advise and intervene where necessary. At the same time, it allows display methods which enable patients to more readily see the range of Pharmacy medicines available to them and have greater involvement and choice in the purchase of Pharmacy medicines". The IPHA strongly agrees with the RPSGB that certain medicines should not be self selected but should remain in open display. To really tackle misuse we must not restrict the patient"s knowledge, nor disadvantage the pharmacist. Instead we must educate the patient and enable the pharmacist. The IPHA believes that placing codeine medicines behind the counter in the pharmacy, so that they cannot be physically reached, is sufficient to avoid self-selection. It would be unhelpful to place codeine medicines in the dispensary as this would not assure the pharmacist"s intervention. Its physical removal out of sight is unlikely to deter a person who is abusing a product, but it would inconvenience the pharmacist. It is intervention at the point of sale that is the most appropriate, effective and practical action to reduce misuse or abuse. Here the qualified professional can quickly, appropriately and effectively determine the most appropriate product for the patient. Dr Garrett McGovern, a Dublin-based addiction specialist noted the following in relation to codeine7: 7 Evening Herald, 21st July 2008, page 22 8 http://www.who.int/mediacentre/factsheets/fs275/en/ *"The vast majority of people use these drugs safely and as directed. It would be unfair to penalise the majority because the minority are misusing them, however greater awareness and better treatment options are needed than currently exists."*	See comments made above in relation to this point.

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	RISKS ASSOCIATED WITH PLACING NON PRESCRIPTION MEDICINES OUT OF SIGHT The IPHA is concerned that placing the product out of sight will put patients at risk of using the internet instead where, according to the World Health Organisation, up to 50% of medicines purchases from illegal sites that conceal their physical address are counterfeit8. If codeine medicines are displayed but not available for self section, then the patient knows a legitimate safe source for the product, where they can also get information on its correct use and where the pharmacist can intervene to suggest an alternative product, if appropriate. In January 2009, the APPDMG published a report[9] on physical dependence and addiction to prescription and OTC medicines. Similarly to the IPHA it had concerns[10] about making access to codeine medicines in pharmacies too difficult *„because of the risk of displacing the problem onto the Internet. There are thousands of Internet sites selling medicines and, in evidence the inquiry received, some people did admit to buying both prescription and over the-counter medication online. "* 9 All-Party Parliamentary drugs Misuse Group Inquiry into physical dependence and addiction to prescription and over-the-counter medication. http://www.codeinefree.me.uk/img/APPDMGPOMOTCRptFinal.pdf 10 page 49 of the APPDMG report The conclusion of the APPDMG was that it is extremely important for pharmacists to monitor sales of certain products, and to challenge and act where necessary and stated that *„The front line in tackling this potential misuse lies with the pharmacist ".* INTERNATIONAL PERSPECTIVE In 2007 the RPSGB made a submission to the APPDMG inquiry that outlined how they address the issue of misuse of prescription only and OTC medicines through both their regulatory and professional roles. RPSGB inspectors help to monitor local trends in drug misuse and advise pharmacists on appropriate action when misuse is suspected. The RPSGB highlighted a study[11] that showed that pharmacists are confident in their ability to identify customers whom they suspect to be misusing OTC medicines and that they employ various strategies to limit access to medicines that might be misused.	It is not suggested that the products would cease to be available and even today the potential for securing products via the internet exists. In any event it is our understanding that in all EU/EEA countries, codeine containing products are only available via pharmacies and in a majority of these countries that these products are subject to prescription-only control. Agreed. Noted. The different regime in this country which governs the practice of pharmacy and the advertising to the public of codeine containing products must be taken into account. In addition to reviews have taken place in other countries e.g. Australia. all of which are leading in the direction of more strict controls on the supply of codeine containing products.

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	11 Mackridge A. Abuse of over the counter medicines: the pharmacists" perspective. *IJPP* 2007;**15** (Suppl. 2): B70 In September 2009 the MHRA *(the government agency responsible for regulating the effectiveness and safety of medicines and medical devices in the UK)* prepared a public assessment report titled „*Codeine and dihydrocodeine medicines: minimising the risk of Addiction*[12] ". Analysis of patient safety issues for these medicines led them to require changes to the information on the pack, advertising, indications etc. However, it did not, having made evidence based assessments, suggest or require placing such medicines out of sight. 12 http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON057115 PATIENT"S PERSPECTIVE There are clear warnings on packs and in the package leaflet of codeine medicines that these are for short-term use only, that they can cause dependence etc. These warnings have been stipulated by, and agreed with, the regulatory authorities. Additionally, the Industry"s focus is that patients get the best from their medicines and hence the IPHA has consistently promoted the message of responsible self-medication through its industry patient education initiatives including: - "Managing Your Minor Ailments Effectively" booklet (2000) - The IPHA"s schools pack "Medicines & You" (2001) - The IPHA/IPU joint leaflet on paracetamol (2002) - "Tips for Taking Medicines" (2004) - "Ask About Your Medicines" Campaign (2005) - Ask About Pain Relief Campaign (2007) - Chronic Daily Headache Campaign (2008) - Switch on to self care (2009) - Codeine Protocol (Autumn 2009) For example, the principal aim of the guide developed by the IPHA, Migraine Association of Ireland (MAI) and the IPU, entitled *"Chronic Daily Headache – a guide for pharmacy"*, was to provide pharmacists and pharmacy staff with information about chronic daily headache (CDH) and its relationship to overuse	Noted.

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	of headache medication because many people, including many healthcare professionals, were simply unaware of CDH associated with medication overuse as a „medical" condition. The IPHA believes that by understanding more about CDH and MOH, pharmacists and pharmacy staff are able to play a significant role in the initial recognition and treatment of the condition and if necessary in the appropriate referral of sufferers for further advice and medical management. The campaign involved the distribution of information to over 1,300 community pharmacies nationwide. The IPHA believes that Section 3 page 6 of the PSI guide should include a requirement to pharmacists to inform patients of the risks of CDH and MOH. CONTROL OF ADVERTISING REGULATIONS The Medicinal Products (Control of Advertising) Regulations, 2007 state that any codeine medicines cannot be advertised to the public. This includes window displays, in pharmacy promotional displays, promotional leaflets or shelf stickers. However, the legislation clearly indicates that product labelling falls outside the scope of the advertising regulations. Therefore, the IPHA does not agree with point 6 of the draft PSI guidance, that the display of codeine medicines is also prohibited under the Advertising Regulations. CONCLUSION The role of responsible self-medication in healthcare has been acknowledged by policy makers and professional organisations at the highest level including the European Commission, the European Parliament, WHO and the G10 Group as well as many international medical and pharmacy organisations. The IPHA has long supported responsible self-medication and aims to ensure that patients get the best from their medicines. The Association wishes to emphasise the crucial role that pharmacists play in the supply of these medicines and stress the value of the pro-active exercise of the pharmacist"s supervisory function in the supply of such medicines. It is through ensuring professional intervention, not *changing the location* of these well known medicines that issues will be addressed.	Agreed. This can be included in the guidance document. See above comments.

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	It is the IPHA's opinion that greater pharmacist intervention in the supply of codeine medicines and provision of appropriate pharmacist training to deal with misuse or abuse is the most effective action to address patients taking these medicines inappropriately. Placing the product out of sight such as in the dispensary would be a regressive step and would not address the potential for misuse or abuse. It would inconvenience the majority of consumers who use these products correctly and would not stop the small number of consumers who may be misusing or abusing from obtaining the product. IPHA would be happy to work with the PSI on alternative solutions to putting codeine medicines out of sight that we believe will be more effective to deliver the objectives of the PSI draft guideline. If the Society has any comments, queries or suggestions about working together please do not hesitate to contact Dr Rebecca Cramp, Scientific and Regulatory Affairs Manager, at the IPHA Offices. Page 9 of 11 **ANNEX 1 PROTOCOL FOR THE SALE OF CODEINE-CONTAINING MEDICINES** This protocol is in line with the requirements of the Pharmacy Act 2007 (20 of 2007), Section 2 of the Misuse of Drugs Act 1977 (12 of 1977), Medicinal Products (Control of Advertising) Regulations 2007 (541 of 2007). **Sale and Supply** THE SALE OF CODEINE-CONTAINING PRODUCTS MUST BE UNDER THE SUPERVISION OF THE PHARMACIST The customer should be interviewed to ascertain if a codeine-containing product is suitable for the condition they are seeking treatment **Precautions & Warnings** OTC codeine-containing analgesics are for short term use only and should not be taken for longer than 3 days, unless advised by a doctor Prolonged regular use, except under medical supervision, may lead to physical	

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	and psychological dependence (addiction) Pharmacists should advise the customer that it is important to follow the dosage instructions on pack and not to exceed the stated dose Codeine-containing products should not be taken while breast-feeding unless under the supervision of a doctor **Undesirable effects** Frequent use of pain-relievers for persistent headaches may make them worse. If you believe that a customer may be suffering from Medicine Overuse Headache, offer advice and information leaflets. If it persists, recommend they see a doctor. Codeine can cause constipation, nausea, dizziness and drowsiness according to dosage and individual susceptibility **Identifying potential for misuse or abuse** Frequent request for the same product by the same person Unusual requests from new customers in times of short supply Customer‟s behaviour and/or state Customer refusal to purchase an alternative product Irritation by customer about pharmacy staff intervention Customer wants to purchase large quantities of a product Customer gives the excuse that they are buying the product for someone else Product asked for by name or customer has a detailed knowledge of the product Headache present for more than 15 days per month **What to do if Abuse / Misuse is Suspected** Politely but firmly inform the patient that you cannot recommend any codeine-containing medicine for them and suggest they talk to their doctor. If you suspect that the customer is abusing codeine containing products, alert other pharmacies in the area, explaining your observations including a description of the person. Be prepared to offer advice to customers and have useful numbers and information leaflets to hand Offer alternative products, treatments or advice to people seeking codeine-	

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	containing products, where you believe a codeine-containing product to be inappropriate **ANNEX 2 COMPANY INITIATIVES** ▪ GSK Consumer Healthcare Limited Initiatives on Codeine and General Pain Management ▪ 2007: Pain Management Training – Pharmacists and Pharmacy Assistants ▪ 2008: Codeine Detailing for Pharmacy staff, highlighting appropriate use and conditions applying to codeine medicines. ▪ 2009: Pain Management training, guidelines for the use of codeine products such as Solpadeine to Pharmacists ▪ SSL Healthcare Ireland Limited initiatives on pain management ▪ Sales people use a Pharmacy Interactive Trainer module to educate pharmacists and assistants about adult pain and how to treat it. Additionally, pharmacies get information leaflets that are more product specific to give them knowledge for what types of pain the product should be used for and how it works. ▪ Reckitt Benckiser Ireland Limited initiatives on Analgesics ▪ Spotlight on pain training evenings - March 2008 - Analgesic training focussing on two key areas. 1. Category and product training. 2. Communication expert giving advice on how to ask the appropriate questions to advise the appropriate medicine along with advice and tips on how to say no to customers and how to deal with them in a difficult situation. ▪ Nurofen training manual for pharmacies to leave at the till along with Nurofen product specific information. ▪ Pharmacy sales team have brand specific training presentations on their lap top which they regularly give in store and are mandated.	

	Comments Received	PSI Response
13. **Irish Pharmacy Union (IPU)**		
	1. Introduction The Irish Pharmacy Union (IPU) is the representative and professional body for community pharmacists. Its mission is to promote the professional and economic interests of its members. Members of the Union aim to provide the best possible professional pharmacy service to all members of the public. They are committed to delivering a quality, accessible, personal and professional service that puts the patient first and has as its primary goal the optimisation of the health and well-being of society. Pharmacists are accountable for their professional conduct and strive to maintain the confidence and respect of their patients, customers, the State and other professionals in the healthcare field. The Union welcomes the opportunity to make a submission to the Pharmaceutical Society of Ireland (PSI) on its draft guidance for pharmacists on the safe supply of non-prescription medicinal products containing codeine. **2. Pharmacy Policy on Codeine Supply** The Union agrees that a pharmacy policy addressing the supply of medicines containing codeine should be in place. Over the past few years, the IPU has produced a number of Medicines Sales Protocols, designed to assist pharmacists and their staff in the appropriate sales of non-prescription medicines to the public. Indeed, in early December 2009, the IPU and the Irish Pharmaceutical Healthcare Association (IPHA) jointly produced a protocol to assist pharmacists in the sale of medicines containing codeine. This protocol was sent to all members of the Union and can be downloaded from the IPU website. A copy of the protocol is attached to this submission and the PSI is welcome to send it to all pharmacists on the PSI register. **3. Storage of Codeine Medicines** The Union agrees with the draft guidance that any medicinal product containing codeine must not be accessible to the public for self selection and that codeine medicines must be stored in an area of the retail pharmacy business where patients cannot self-select the product. The Union believes that this area would be behind the counter. This would ensure that all sales of	Noted. Noted Noted. Sales protocols are an important part of the procedures that will need to be put in place in a pharmacy to ensure adequate control of the supply of these products and adherence to the regulations and guidance. However, all and any such protocols currently in place will need to be updated in light of the finalised guidance. Noted. The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise their professional judgement as to the safety or appropriateness of the supply and enable him or her to intervene professionally as may be necessary. See above comments also.

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	codeine medicines would be under the supervision of the pharmacist, as recommended by the IPU/IPHA Codeine Sales Protocol. This is also in line with the guidelines from the Royal Pharmaceutical Society of Great Britain (RPSGB), following their consultation in March 2007, in which they highlighted that '*restrictions should not preclude methods of display which allow patients to better view pharmacy medicines'*. It is not practical to store codeine medicines in the dispensary. It is equally important that they should be placed in the patient environment, i.e. behind the counter, to facilitate patient choice, supported by the advice and supervision of the pharmacist, according to the Codeine Sales Protocol. **4. Supply of Codeine Medicines** The Union agrees with the draft guidance that the appropriateness for the supply of codeine medicines should be determined before each sale and that the duration of treatment should be no longer than 3 days. The IPU spearheaded a public awareness initiative, in conjunction with other organisations, in August 2007 highlighting the safe use of pain relievers and the problems associated with their overuse or abuse. In particular, people were advised to speak to their pharmacist on the appropriate use of codeine. The campaign recommended that people always follow the instructions which accompany the medicines and not use them for longer than stated on the pack, unless advised to do so by their doctor. The campaign highlighted that taking medicines which contain codeine for longer than instructed or misusing them can lead to physical and psychological dependence. The leaflets distributed during the campaign gave information on how and when to use products containing paracetamol, aspirin, ibuprofen and codeine. Posters in the pharmacy encouraged people to ask their pharmacist about pain relief. Pharmacists were provided with a Medicines Sales Protocol to use for all OTC sales. Local pharmacists around the country gave local media interviews. The Union would welcome the opportunity to run such a campaign again in association with the PSI. **5. Suspected abuse and/or misuse** The Union supports the proposal that patients should be facilitated in accessing services which will assist in the management of codeine addiction.	The Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed which requires that those products would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved. Noted.

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	Indeed, in September 2005, the IPU, in partnership with the Health Promotion Unit of the Department of Health and Children, ran a Drugs Awareness Campaign. Posters in pharmacies encouraged patients to ask their pharmacist about drugs misuse and abuse and leaflets gave details of how to access services. The Union would welcome the opportunity to run such a campaign again in association with the PSI. The Union does not believe that an audit or monitor of the sale and supply of codeine medicines is necessary as, if pharmacists comply with the Codeine Sales Protocol, any issues of abuse/misuse will be addressed. **6. Pharmacovigilance** The Union regularly reminds members to ensure that any suspected adverse reactions should be reported to the Irish Medicines Board via their online reporting system and will continue to do so. **7. Advertising of Codeine Medicines** The Union agrees that advertising of codeine medicines should be prohibited. **8. Conclusion** In conclusion, the Union welcomes the intent of the draft guidance from the PSI on the safe supply of non-prescription medicinal products containing codeine. The Union accepts that it is desirable that medicines containing codeine should not be available for self selection by the public. However, it is not necessary to locate the medicines in the dispensary in order to achieve the objectives of the guidance nor is it practical from a pharmacist's perspective in relation to the efficient workflow in a pharmacy or from the patient's perspective in relation to choice of medicines. The Union looks forward to working with the PSI on the production of final guidance to incorporate the issues addressed in this submission. The Union is available to meet with the PSI to discuss the issues raised above or indeed any other relevant issues.	

	Comments Received	PSI Response
	PROTOCOL FOR THE SALE OF CODEINE-CONTAINING MEDICINES This protocol is in line with the requirements of the Pharmacy Act 2007 (20 of 2007), Section 2 of the Misuse of Drugs Act 1977 (12 of 1977), Medicinal Products (Control of Advertising) Regulations 2007 (541 of 2007). **Sale and Supply** THE SALE OF CODEINE-CONTAINING PRODUCTS MUST BE UNDER THE SUPERVISION OF THE PHARMACIST The customer should be interviewed to ascertain if a codeine-containing product is suitable for the condition they are seeking treatment **Precautions & Warnings** OTC codeine-containing analgesics are for short term use only and should not be taken for longer than 3 days, unless advised by a doctor Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) Pharmacists should advise the customer that it is important to follow the dosage instructions on pack and not to exceed the stated dose Codeine-containing products should not be taken while breast-feeding unless under the supervision of a doctor **Undesirable effects** Frequent use of pain-relievers for persistent headaches may make them worse. If you believe that a customer may be suffering from Medicine Overuse Headache, offer advice and information leaflets. If it persists, recommend they see a doctor. Codeine can cause constipation, nausea, dizziness and drowsiness according to dosage and individual susceptibility **Identifying potential for misuse or abuse** Frequent request for the same product by the same person Unusual requests from new customers in times of short supply Customer's behaviour and/or state	Noted. The competent pharmacist should be in a position to address all of these issues and that the health services and others involved in this area including those involved in continuing education of healthcare professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed. As part of the ongoing quality assurance and governance framework in place in a pharmacy, superintendent and supervising pharmacists should ensure continuous review and evaluation of procedures and processes in place in their pharmacy. A self-audit or monitoring of the supply and associated counselling of all medicines is an integral part of this framework. Noted.

	Comments Received	PSI Response
	Customer refusal to purchase an alternative product Irritation by customer about pharmacy staff intervention Customer wants to purchase large quantities of a product Customer gives the excuse that they are buying the product for someone else Product asked for by name or customer has a detailed knowledge of the product Headache present for more than 15 days per month **What to do if Abuse/Misuse is Suspected** Politely but firmly inform the patient that you cannot recommend any codeine-containing medicine for them and suggest they talk to their doctor. If you suspect that the customer is abusing codeine containing products, alert other pharmacies in the area, explaining your observations including a description of the person. Be prepared to offer advice to customers and have useful numbers and information leaflets to hand Offer alternative products, treatments or advice to people seeking codeine-containing products, where you believe a codeine-containing product to be inappropriate.	Noted. This is a regulatory requirement. Noted. See comments above.
14. **Irish Cancer Society**		
	I would suggest some discussion around the packaging and supply of codeine based products. Thoughts I had were around highlighting more prominently on the packaging the dangers of over use and perhaps limiting the supply to 18 per individual packet which would be in line with the 3day rule. I would also suggest a discussion around over the counter codeine medications prescribed by GP's for those patients on medical cards. Again having a limit on the maximum to be prescribed at any one time.	Noted. However this matter is more relevant to the IMB.

	Comments Received	PSI Response
15.	**James Cassidy MPSI – Healthwise Pharmacies**	
	Firstly I would like to commend the society in addressing this issue and to express my support for the main thrust of the proposals issued. I would however like to ensure the professional role of the pharmacist remains intact, and that any guidelines / regulations issued do not remove the opportunity to exercise discretion in individual cases. E.G. a private patient with a prescription for higher strength codeine products that could manage on lower dose co-codamol product should not be forced to return to the Doctor and pay another consultation fee to facilitate a few weeks supply of medicine containing a lower dose of codeine than originally prescribed. I have frequently made such an intervention and hope new guidelines / regulations would not preclude such interventions in future - I always ensure such patients re-visit the Doctor for review if requesting supplies for longer than the original prescription duration.	Noted.
	I also have reservations on the assertion that visibility = products are available for self selection. In reality all pharmacists acting professionally should ensure all such products are not available for self selection , but this should be enforced by physical separation of product & patient (by counter / glass screen etc) and appropriate SOPs. The notion that all cold & flu treatments , painkillers & cough suppressants etc should be kept in the dispensary to prevent self selection ignores the fact that the pharmacist has a duty to prevent such self selection and should be capable of reinforcing relevant policies . A guideline recommending that they not be displayed prominently would be a good idea , but storage on the bottom shelves behind a counter would be a much more practical solution than enforced storage behind dispensary(even if the products were technically visible in a restricted fashion). Strict enforcement of such a guideline would also raise another practical problem :- what happens in modern dispensaries where the public can see inside (as a natural consequence of design allowing the pharmacist to see out and interact with patients and/or supervise otc counter).This would mean that technically POM medicines that were visible to public would be subject to visibility = self selection interpretation which would make no practical sense.	Noted. The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise their professional judgement as to the safety or appropriateness of the supply and enable him or her to intervene professionally as may be necessary. The Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed which requires that those products would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.

	Comments Received	PSI Response
	In summary, comprehensive guidelines as proposed are welcomed and should be supported by the profession without exception. To allow practical implementation the pharmacist should have ultimate responsibility for all sales and in limited individual cases , should retain the discretion to make an exceptional supply outside the terms of the guidelines . In any such case the pharmacist should be required to justify any such sale , and if no valid reason was provided could then be subject to sanction , thus retaining the professional discretion vital to best practice in certain rare cases.	Noted.
	Also the physical restrictions of some pharmacies, added to the preference for limiting traffic into dispensaries, e.g. during a flu epidemic, should be considered when addressing the issue of visibility of such products. A guideline to restrict visibility where possible and an acceptance of storage of codeine containing products on lower shelves behind the counter would be a more practical solution. I believe pharmacists should be trusted to police the sales of such medicines. Mystery shoppers etc added to the implementation of relevant sanctions ,could be used to ensure adherence to such guidelines. I would have no support for any failure to follow best practice but would hope that practical considerations will temper the framing of new guidelines or regulations.	Noted.
16.	**John MacNamara MPSI, MacNamara Pharmacy, Co. Dublin**	
	In general, the overall thrust of these guidelines is to be welcomed. There has been a small but growing problem of codeine dependency evident to most pharmacists of the last few years. Pharmacists(and pharmacy staff) frequently intervene to refuse the sale of these products to members of the public. The problem was that these refused patients just went elsewhere and the concerns regarding addiction were left unresolved. I feel that to have any real impact there needs to be much more uniformity between all pharmacies in how they approach this problem and I hope that these new regulations will achieve this.	Noted. The guidance document attempts to include all relevant points for the supply of these products to ensure consistent practice.

	Comments Received	PSI Response
	I would like to make the following observations on the proposed new codeine guidelines: **There should be a much stronger warning about potential dependency on all product boxes**. At the moment this is only alluded to (..do not use for more that 3 days unless told to do so by your doctor.) This warning should be "*boxed" and highlighted in a different colour than the box colour.* In this regard at least the warning currently on Nurofen Plus is better than on Solpadeine which is in the same colour and style as information on the box and consequently is hard to see. **A uniform policy for all pharmacies instead of a "pharmacy specific" policy should be implemented**. Under 1. In the Guidance section mention is made of a pharmacy specific policy. There was an excellent "Protocol for the sale of codeine-containing medicines" which was issued by IPHA and the IPU in 2008. This one page document contains all the information one needs to train staff and implement policy in this area. Surely a pharmacy specific approach will just lead to greater differences in policy in this area when uniformity between pharmacies is what's needed. I feel that the section in this that deals with abuse/misuse could be strengthened especially in regard to putting an *onus on the pharmacist to inform the other pharmacies in the locality of a person abusing codeine - if needs be through a "cascade" system.* **The concept of Visual Self Selection** I feel that this is a new and nebulous concept. *Storing these products in the dispensary out of sight is a nonsense suggestion.* Once the products cannot be self selected, are not in any way advertised and are sold under the direct supervision of the pharmacist by properly trained staff, then that should be enough. At present *most dispensaries are open plan* and there is direct supervision by the pharmacist for these sales. It could be	Noted. However, initiatives here are for the product manufacturers and the IMB as the licensing authority to consider. Sales protocols are an important part of the procedures that will need to be put in place in a pharmacy to ensure adequate control of the supply of these products and adherence to the finalised guidance. However, all and any such protocols currently in place will need to be updated in light of the guidance. Noted. Noted. The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise a direct involvement in the supply and enable him or her to use their professional judgement as to the appropriateness of the supply and intervene professionally in the supply as may be necessary.

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	contended that these open plan dispensaries lend themselves to "visual self selection" of Tylex, Sopladol or any other medicines. Solpadeine and Nurofen Plus are two of the best selling OTC medicines and in the vast majority of cases are used correctly. To remove these products to dispensary only would be a *major inconvenience to pharmacies and the public who use them correctly*. It will lead to the *farcical situation* of the products been stored under the counter just for ease of access by pharmacy staff.	The Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restrictions are imposed which requires that those products would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved. Patient information and education is a critical component of the safe use of any medicine however these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists to exert control over their supply and ensure the rational use of these products.
	A public awareness campaign regarding Codeine addiction should be run. Perhaps this could be funded by the companies who sell codeine containing products. The issue of potential addiction should be publicised and the public advised that these are not "first line " products and that simpler, safer and cheaper products might be more appropriate. A *helpline* for people with codeine addiction could be set up to advise people of where to seek help etc. *It goes without saying that these addiction facilities would have to be set up first!* I'm aware of no specific help or course for people suffering with codeine addiction and feel that the expectations put on pharmacists in section 4 Abuse/Misuse Are too great and more that a bit "pie in the sky".	Noted. The competent pharmacist should be in a position to address all of these issues and that the health services and others involved in this area including those involved in continuing education of health care professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed

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17.	**The Drug Treatment Centre Board,** ***Mary Egan MPSI, Pharmacist*** ***Dr. John O'Connor Consultant Psychiatrist / Clinical Director***	
	Non – Prescription Medicinal Products Containing Codeine Having worked for a number of years in retail pharmacy (and still doing the odd locum), I am fully aware of the problem we have with OTC Codeine based products! I spent time in the U.K and Northern Ireland and have not seen the same level of abuse of such products, which begs the question, why so much here? Is it a cultural thing, advertising? Whatever it is, it's still unclear. In reference to the draft, I am glad to see these combination products will be 'out of view' to the public, therefore eliminating self selection and easy access. At least if the product is out of sight, it will give the Pharmacist a better opportunity to question appropriately and make a professional judgement based on what they've heard. The W.H.A.M questions are a handy tool to cover all the important information required. With regard to the general public, there is a case of knowing too much and not knowing enough. In terms of the former, they (the customer(s)) are fully aware of the effects of long term use but unfortunately, are willing to jeopardise their own health just to feed their cravings. This is a huge problem and this is what addiction is. This leads onto a problem with tolerance, forcing the user to consume higher doses to achieve the same high as before. In reference to the latter they are happy to continue taking a product as long as it 'agrees' with them and are not fully aware of the long term damage it may be causing. Because codeine is legal, there are many addicts who underestimate how addictive and dangerous the drug can be. The draft also refers to the first line treatments, those being the single agents, aspirin, paracetamol, ibuprofen. A lot of the time, these are by-passed in favour	Noted Noted. The intention here is to place these products under the direct control of the pharmacist. Noted. These comments support the important role and contribution that pharmacists have in counselling patients and ensuring the safe supply of such products. Noted. These comments support the important contribution to the correct management of pain that pharmacists have in

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	of the combination products. It is at this point, a Pharmacist's intervention is key, perhaps explaining how the single agents may be just as effective and taking these 'combination product's may not give any additional benefit. In an ideal world, no more than three days usage is what is recommended and this too has been stated in the guidelines. If you use a lot of opioid painkillers, you may find that you need more and more to feel the same effects, as mentioned earlier. One can become mentally and physically dependent, or addicted to how they make you feel. Dependent users who quit using opioids get withdrawal symptoms like craving, runny nose, yawning, sweating, restless sleep, weakness, stomach cramps, nausea, vomiting, diarrhoea, muscle spasms, chills, irritability and pain. The worst symptoms pass within a few days but it can take months to feel normal. It is best to stop using under supervised care i.e. Doctor / Pharmacist.	counselling patients and ensuring the safe supply of such products.
	It is clear to see the effects prolonged use of these product's can have on one's health and this draft guidance for pharmacists on safe supply by The Standards and Practice Committee of the PSI Council is very much welcomed by Pharmacist's across the country.	Noted
	However, as much as these guidelines are necessary, I personally don't think they're enough to stop this silent addiction that has swept the country. I think more radical measures need to be put in place i.e. make the customer sign a register when they purchase a codeine based product. This does two things 1) It helps the Pharmacist keep tabs on the frequent user's and 2) makes the customer more reluctant to purchase, signing a codeine register would certainly not appeal to most.	
	More importantly, we feel the whole legal status of these combination products needs to be addressed. To put it simply, they need to be reclassified from P to POM. In The U.S for instance, codeine is not an option OTC, given on a prescription only basis. It's not until a more stringent legal category is applied, will we see the end of this ongoing serious problem and the sooner these changes are made the better.	This decision lies with the IMB as the licensing authority.

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18.	**Mary Gallwey MPSI, Co Cork**	
	To whom it may concern. Leaving the final decision to the pharmacist on duty in any one pharmacy to decide whether a customer should purchase a codeine containing product could lead to confusion. One pharmacist may say no in a particular situation and another pharmacist may sell the product. Putting the onus on the pharmacist can be compared to the publican deciding when not to serve the drunkard. Perhaps more information for the public e.g. Joe Duffy show, more news paper articles. Warnings similar to cigarette packs. From all the years I have worked in pharmacy very few well known customers will return when I suggested "to go easy on the solpadeine". Embarrassment sends them to another shop. Maybe signing for these products in ALL pharmacies will help deter the overuse. A register in all shops. To help going forward maybe placing these products on prescription will help. A last resort. Guidelines will not work because of inconsistencies. Making the public more aware on(a regular basis) will reinforce the addiction nature of these products. Many people commence taking solpadeine for that migraine headache not knowing better. Very few of these people would believe that they may be getting a "codeine headache" instead. I feel I can speak from experience after 28 years. I probably have heard most of the excuses even from people I know very well. All community pharmacists want to work with their customers. The customer comes first. It is easier to loose a customer than gain one. We want this problem solved for everyone's sake. Remember the paracetamol pack size became uniform and that seems to have helped reduce suicide. Uniformity will be required. We must all sing from the same hymn sheet!	These products have been authorised and placed on the market and regulated in a manner which authorises pharmacists to exert control over their supply. The guidance document attempts to include all relevant points for the supply of these products to ensure consistent practice. This may be the outcome if the current controls and guidelines prove not to be sufficient, however this decision lies with the IMB as the licensing authority to assess and consider the risk-benefit ratio for a product Patient information and education is a critical component of the safe use of any medicine however these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists to exert control over their supply and ensure the rational use of these products. These comments highlight the important contribution to the correct management of pain that pharmacists have in counselling patients and ensuring the safe supply of such products.

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19.	**Niamh Murphy MPSI, McCabe's Pharmacy**	
	MCCABES PHARMACY along with our colleagues appreciate that there are ongoing concerns regarding the misuse and abuse of codeine containing products and as health care professionals we have a duty to improve awareness and help limit this problem.	Noted.
	We vehemently disagree that the proposed guidelines will in fact address the issue in hand and suggest that there are other ways to tackle the problem. The proposed guidelines seem to suggest that pharmacists need help in exercising their professional judgement when dealing with sales of these products and that said guidelines are being put in place to help us with this. This is a direct insult to pharmacists and our ability to use our professional judgement. It questions our capabilities in this area. It completely undermines our whole training where the safety of our patients and the safe use of medicines is instilled in us from day one in university. From that day on, we have been given the skills and have practiced the skills in dealing with patients who may be misusing medications both prescription and non prescription. The safe use of codeine and indeed all medicines is of paramount importance to the pharmacist and is inherent in us from day one. The introduction of these proposed guidelines will not change that.	Noted. This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products.
	We can assure you that in MCCABES PHARMACIES, as with our colleagues, there are <u>already</u> procedures in place to ensure the safe supply of these products. There are strict in house protocols that enable the pharmacists to "discharge their professional obligations to patients" when it comes to the sale of codeine containing products. For example: - In MCCABES PHARMACY we have produced an additional **<u>warning sticker</u>** that is attached to all Codeine containing products on OTC. This warning is bright, is on the front of the packet and gives the necessary information; that the product contains codeine which can be addictive and should not be used for more than 3 days. The pharmacy staff have been trained to highlight this to the patient at the point of sale. This has been in place in MCCABES PHARMACY since February 2009. - In addition training programmes within MCCABES PHARMACY, as with	Noted. Sales protocols are an important part of the procedures that will need to be put in place in a pharmacy to ensure adequate control of the supply of these products and adherence to the finalised guidance. However, all and any such protocols currently in place will need to be updated in light of the guidance

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	our colleagues, include instruction on the safe sale of pain killers (which includes codeine based products) and when to refer to the pharmacist. Sales of multiple items is strictly policed and refused when the product contains codeine. - All pharmacy staff are trained to a level whereby they know how to sell codeine based products correctly. These staff undergo an in house OTC training module at the end of which they sit an exam where the pass rate is 95%. Failure to achieve this score results in the staff member having to re-sit the exam. Coupled with this there is a strict WWHAM protocol in place to ensure that the OTC teams and pharmacists are working together to ensure safe supply of ALL medicinal products including those containing codeine. - The pharmacists in MCCABES PHARMACY have written Performance Contracts which include these protocols. The pharmacists are held accountable for ensuring these protocols are in place. Our CHIEF PHARMACIST audits all standards in the pharmacies on a monthly basis and the pharmacists' performance in this area is closely monitored. - The Lay-out of MCCABES PHARMACIES and indeed all modern pharmacies mean that the pharmacist can hear and witness OTC sales. The OTC staff and pharmacist work together as a team to benefit the patient and ensure sales are of the highest standard. - Pharmacists are available to the patient 100% of the time when a patient wishes to speak to them regarding the safe use of codeine based products. They are extremely vigilant in monitoring sales of these products and will always intervene when a patient is using for more than 3 days or buys too frequently. They always exercise their professional judgement and will stop or refuse a sale where ever there is a suspicion. To add to this, our pharmacy union are active in keeping the public informed of the dangers of pain killers and in particular those containing codeine. MCCABES PHARMACY welcomes changes that can mean an increased public awareness of the dangers of codeine and procedures to help police these sales however even with the new proposed storage suggestions whereby the	This is a regulatory requirement under the Regulation of Etail Pharmacy Businesses Regulations 2008, Regulation 4(2) This is a regulatory requirement and professional obligation under regulation 10 of the above regulations. Noted. Noted. The placement of these products under the direct control of the pharmacist is intended to enable the pharmacist to exercise a direct involvement in the supply and enable him or her

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	products are out of the publics physical and visual access, there is no evidence to suggest and nor do we believe that these proposed rules will enable the pharmacist to control the abuse and misuse of codeine based products. If patients wish to buy in excess they simply have to visit several pharmacies to achieve their goal. We sincerely hope that the suggested guidelines are evidence based. Is there for example concrete evidence to suggest that "hiding" codeine based products in pharmacies nationwide will indeed actually have a positive impact on the abuse and misuse of OTC codeine based products. **In summary** - Pharmacists are already policing and supervising the sale of Codeine base products OTC and always exercise their professional judgement in doing so. We believe that the proposed guidelines will make no difference to the abuse and misuse issue and hence are unnecessary. - We feel there is a need for the PSI to establish EVIDENCE of the extend of existing Codeine abuse - We feel there is a need for the PSI to establish evidence that "hiding" these products will lower the amount of abuse - What input, if any will the public have on these protocols given that consecutive surveys amongst the public call for further deregulation of medicine sales? We do however recognise the role of the pharmacist in helping to increase public awareness of the dangers and would welcome more practical solutions to the issue by way in house awareness days and public campaigns.	to use their professional judgement as to the appropriateness of the supply and intervene professionally in the supply as may be necessary. The Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition it must be noted that because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed which requires that those products would not be available to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved. The draft guidance document was released for public consultation. Patient information and education is a critical component of the safe use of any medicine. However, these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control over their supply. These

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		comments highlight the important contribution that pharmacists have in ensuring the safe supply of such products and counselling patients on their correct use.
20. **Mervyn Moriarty MPSI, Kenmare, Co. Kerry**		
	Read draft guidance and it looks good. Maybe it would be worth considering that a record be kept of each sale of codeine containing OTC products, this would act as a deterrent to those people who abuse and constantly frequent different pharmacies in order to obtain a supply of OTC codeine. I know this would be time consuming but some countries like New Zealand operate this sort of system. Customers should also be offered the smaller pack size before offering the larger packs. Also I think pharmacies should be prohibited from selling OTC products containing codeine such as Solpadeine and Nurofen Plus tablets at prices below the RRP. Most notably one of the larger chains has both of the above products at permanently lower prices.	Noted. This would require a regulatory intervention which is outside the remit of the PSI. Agreed Noted.
21. **Noelle Lynskey MPSI, Hayes & Hayes Community Pharmacy, Co Galway**		
	In principal, I welcome the guidelines but unfortunately, I feel that to carry out the guidelines properly, a register of purchase is the most practical way of monitoring and recording the transaction. This problem, because of lack of any regulation to date, is widespread and an addiction for many patients. Here, we have worked with longterm patients in	Noted. To require this is a regulatory intervention which is outside the remit of the PSI. The guidance is what is expected at a minimum in the supply of these products, additional measures may be taken by pharmacists in their own practices to monitor or audit supplies from their place of practice Noted. See above comment in relation to register. It is possible that if the draft guidelines are not adhered to and the control exercised by pharmacists does not effectively result in the safe

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	helping them to withdraw, in consultation with GP's etc. We also have had the embarrassment of refusing to serve patients who travel 20-30 miles. The problem is greater than just taking them off the shelf in the OTC area. (we have never had a self service OTC area for Codeine products). The guidelines in dealing with distressed, dependent patients are not really practically applicable. However, a register may help to highlight the problem-give time for consultation and conversation without confrontation. Ideally, prescription only category is required. Also, legislation re confining Paracetamol is also required. This is a step in the right direction-but too small a step to make any real difference.	use of these non-prescription medicinal products containing codeine that those products will become prescription-only in this country however this decision lies with the IMB as the licensing authority. This is outside the remit of the PSI.
22. **Prof. Anita Maguire, School of Pharmacy, University College Cork**		
	The School of Pharmacy at UCC welcomes the development of guidance for the supply of non-prescription medicines containing codeine which will aid pharmacists in this important area. In addressing this and other issues it is critically important that the profession in Ireland aims to adopt best international practice. Our Clinical Practice group has engaged in some research in this area and in discussing the draft guidance with them they have indicated further steps which might be taken, including recording names of patients. I understand Prof Kennedy will follow up with you on this issue.	Noted. Noted.
23. **Prof. Julia Kennedy School of Pharmacy, University College Cork**		
	The document whilst welcome and outlines what pharmacists should be doing at this juncture in time, is utterly disappointing in its lack of vision and courage. As a Society you know full well, codeine is a problem. Why else the document? What is outlined in the present document is the bare minimum of what should already be best practice. The production of this document in itself is tacit acknowledgement that these minimum standards are not being adhered to in any meaningful manner to any great extent.	These products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control over their supply. The guidance is what is expected at a minimum to ensure the safe supply of these products.

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	Pharmacists have clearly shown as evidenced by the research carried out in this University that they many have largely abdicated responsibility with respect to codeine, sales continue to increase, and the two most abused products are Solpadeine® and Nurofen Plus®. These products have the highest codeine content, and no matter in whatever form, either capsules, tablets or soluble formulations, account for >90% of all codeine sales and more damningly, the larger pack sizes are the ones sold most often and in many instances, actively promoted by owners because of deals.	Research noted.
	As pharmacists we need to have a useful drug at our disposal for judicious use as a pharmacist prescribed/recommended medicine. If the current rate of codeine misuse continues, largely through either abdication of professional responsibility or through sheer monetary considerations, thus showing a lack of responsibility in the recommendation of this medicine, then we are in danger of losing this OTC classification. That would be of considerable disadvantage to patients who do benefit from short courses of this medicine for a variety of conditions which are self limiting and do not necessitate a visit to their GP or dentist. We would be in the position that patients in the USA are: codeine unavailable as an OTC medicine. That is not desirable. Our research here at UCC shows: • 777 pharmacies responded to a questionnaire regarding the abuse of codeine as an OTC medicine, yielding a response rate of 61.3%. From these replies, 97% of pharmacists in Ireland acknowledge there is a problem with codeine sales. • Some areas of the country have a greater misuse problem than others • It is estimated that an average of 6 incidences (± 5.1) of suspected codeine dependent patients requesting codeine based products occurs every week in each community pharmacy involved in this study. • Nearly 50 pharmacies reported >20 incidences of suspected codeine dependent patients requesting codeine based products every week in each community pharmacy • There was a higher incidence of requests from suspected abusers in urban and city centre/suburban pharmacies than in rural pharmacies • There were definite regional variations reported in the level of suspected codeine dependent patients	This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products. It is possible that if the draft guidelines are not adhered to and the control exercised by pharmacists does not effectively result in the safe use of these non-prescription medicinal products containing codeine that those products will become prescription-only in this country, however this decision lies with the IMB as the licensing authority. Research noted.

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	• The level of abuse in multi-national multiples of pharmacies was seen to be the greatest, and this was significantly greater than any other group. The abuse in national multiples of pharmacies was seen to be significantly greater than that in single outlet pharmacies • When codeine products were sold as pharmacist-prescribed medicines and dispensed as patient specific medicines, i.e. were processed in the same manner as a normal prescription, only two purchasers objected to having their name and address recorded; one was a known abuser and the sale was then refused and another was an American visitor.	
	The guidelines are welcome but do not follow best practice in other countries where abuse of OTC substances has been markedly curtailed by greater pharmacist involvement and the recording of the purchaser's name and address. The latter is a major deterrent to those abusing medicines. The genuine patients have no problem in supplying their name and address. In fact, I understand that a pharmacist in a Boots pharmacy in Dublin has initiated this process and is showing significant benefits from this approach.	Noted. This would require a regulatory intervention which is outside the remit of the PSI. The guidance is what is expected at a minimum in the supply of these products, additional measures may be taken by pharmacists in their own practices to monitor or audit supplies from their place of practice
	In the research projects we have proposed regarding codeine abuse, recording of the patients' names and addresses has been resisted by pharmacists because of the perceived effect on sales. The Registrar himself has witnessed firsthand the collapse of the project because of this. Whilst this is understandable especially in straitened economic times, this is not a valid reason for the Society not moving to mandate that pharmacists record all codeine purchasers' name and addresses. Arguments will be promoted along the lines of patient privacy and all manner of sorts of considerations in this vein. These arguments, are, in the interests of patient safety and showing the profession to be taking responsibility for a potent medicine, to be resisted at all costs.	Noted. See above comments.
	National Identity Cards have been suggested in this country in the near future. A culture of secrecy and *"hands off"* surrounding peoples' business may be part of the national psyche, but we have very recent and costly examples, both in human and financial terms, in this country of where a *"softly, softly/hands off"* touch and turning the blind eye have had major consequences for innocent people. It is time that changed and to hide behind it is no excuse for failing to introduce a measure which has been clearly shown to work in other countries	

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	where the abuse has hitherto been a problem. There is a problem with codeine. Pharmacists have clearly not been fulfilling their professional obligations. Recording names and addresses in other countries has been shown to be effective in reducing abuse and in isolated instances in this country. Patient safety is **the** major consideration in this debate. It is time to show real leadership and not pussyfoot about. We would be more than happy to present the data to the Council of the PSI to help them be better informed about this problem, as the Guidelines as proposed would reflect that the extent of the problem is not fully appreciated or willing to be faced. The Guidelines are a small step but in reality will have little or no impact on those who are misusing or abusing codeine products.	
24.	**Rosarie Lynch, MPSI, Lucille Vernon, MPSI, Pharmacy Department, Louth County Hospital**	
	We wish to make the following comments in response to the consultation on the document "Non-Prescription Medicinal Products containing Codeine: Draft Guidance for Pharmacist on Supply": Pages 2 and 3 both refer to codeine as a Schedule 5 controlled drug. We note that the first paragraph explains that the document is in the context of 'non-prescription medicinal products containing codeine'. However, we feel it would be useful to acknowledge that prescription only products containing codeine are also available and that this guidance does not apply to such, although the principles of prudent codeine use and appropriate patient education should be applied regardless of the situation.	The scheduling reference for codeine is to be updated. See above comments This guidance applies to non-prescription medicinal products containing codeine.
25.	**Ross McEntegart MPSI**	
	Allow me to congratulate you and the Society, and especially the Standards and Practice Committee, on your excellent consultation document "Non-Prescription Medicinal Products containing Codeine: Draft Guidance for Pharmacists on Safe Supply", and thank you for inviting the membership and	Noted.

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	the public to comment upon it. It is regrettable that such a document should prove necessary, but there is undoubtedly a problem extant in Ireland today, and it is incumbent on us all to do what we can to reduce and, hopefully, eliminate it. For the most part, I agree with the document. However, there are just points with which I would like to raise issue. 1. Section 4 (a): A pharmacist "…should take all reasonable attempts to ensure that the patient is facilitated in accessing services which will assist in the management of their addiction." My problem with this sentence isn't so much the sentence itself or even the sentiments underpinning it, but rather to point out that such services are virtually non-existent in this country at present. It makes little sense to me should I have an obligation placed upon me to direct patients to services which don't exist. I feel that the Society could perhaps assist in this by lobbying the authorities to introduce such a service. 2. Section 2: "Therefore codeine medicines must be stored in an area of the retail pharmacy business where patients cannot self-select the product - either visually or physically. The recommended location is in the dispensary, out of sight of the public." I agree totally that patients should not be in a position to "self-select" such products. However, I vehemently disagree with the Society's apparent equation of 'visible' with 'available for self-selection'. If the definition of 'available for self-selection' were to include 'visible' then that would throw up the following problems: a) There is an implicit accusation and assumption that a pharmacist is unwilling or unable to say "No" to any patient who asks for anything that they can see. Not only *can* I say "no", I do, when appropriate to do so.	Agreed. It is envisaged that the competent pharmacist should be in a position to address all of these issues and that the health services and others involved in this area including those involved in continuing education of health care professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed. The intention here is to place the products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-

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	b) There has been a definite move over the last 10-15 years towards open plan dispensaries. The regulatory framework for this has become more and more stringent; it began as a suggestion, later became a condition and so on. The upshot of this is that a customer standing at the counter of almost any pharmacy in the country will be able to see a large range of prescription only products. If 'visible' = 'available for self selection', then by extension this would imply that the patient can self-select any of the products they can see in the dispensary. Since this would plainly be nonsense, then by application of logic it becomes plain that the definition of 'self selection' *cannot* include 'visible'. To put this another way: Premise: If a product is visible, then it is available for self selection. Fact: Many prescription only products are visible. Conclusion: many prescription only products are available for self selection. The conclusion is evidently invalid, but the fact is valid. Therefore the Premise *must* be invalid. I trust that the Society will see the unarguable logic in this e-mail, and remove the ridiculous and unworkable word 'visually' from the Guidelines before they come into force.	prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.

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26. **Mark Sajda MPSI, Sam McCauley Chemist**		
	We are delighted that the Pharmaceutical Society of Ireland are addressing the safe supply of non-prescription products containing codeine. The safety concerns around the misuse of non-prescription medicines containing codeine are well established and an improvement in the method of supply is welcome.	Noted.
	Sam McCauley Chemists Ltd. have always ensured that customers are questioned using the WWHAM protocol and that if the pharmacist is not happy with the request, then the customer will be refused the medicine. UK research shows that pharmacists are confident in their ability to identify customers who they suspect to be misusing OTC medicines and that they employ various strategies to limit access to medicines that might be misused.[3]	Noted.
	We would be concerned that these codeine containing products '*should be stored in a retail pharmacy business out of the view of the public'* as being a retrograde step. Pharmacists more than ever have improved their operating procedures to ensure that they are in the first instance concerned for the health and well-being of the patient. The New Pharmacy Act has ensured that Superintendent and Supervising Pharmacists are fully aware of their professional obligations and they should be allowed to use relevant protocols to ensure the safe supply. As per the guidance on principle one of the Code of Conduct pharmacists should be allowed '*to ensure the safety of the patient in all circumstances by decision making, which may at times conflict with the stated requirements of the patient.'* By requiring that these products be hidden from sight will only serve to make patients more devious in their attempts to access these medicines and make the decision making process more difficult. Many patients may find, that their legitimate attempts to purchase these medicines, becomes difficult and embarrassing, and particularly in the border counties may decide to travel to Northern Ireland to purchase these. This may result in patients purchasing larger quantities than necessary to make the	The intention here is to place the products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition, because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine), further restrictions are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a

[3] RPSGB submission to the All Party Parliamentary Group on Drug Misuse inquiry into the misuse of prescription-only and over the counter medicines

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	journey worthwhile, perhaps leading to increased usage. This will further be reinforced by the advertising of these products on UK television channels which are seen by the vast majority of Irish television viewers. These products work extremely well for the vast majority of patients and only a very small minority of patients abuse the product. By restricting the visibility of the product will only serve to inconvenience the vast majority of patients whilst at the same time making those that do abuse codeine containing products ever more devious in their attempts to purchase them. Instead of moving these products out of the view of the general public the Pharmaceutical Society should focus on education of the public with improved labelling regarding warnings of overuse and allow time for the new written protocols to be observed. Increasing supplies of medicines are being purchased overseas via the internet and by restricting these products further will only serve to remove the intervention of the pharmacist in cases where these medicines are being abused. To conclude we are very much of the opinion that improved protocols and education will reduce the misuse of non-prescription medicines containing codeine but would be against these medicines being stored out of the view of the general public with the exception of some of the codeine based cough bottles.	manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved. The matters raised here are for the manufacturers and the IMB as the licensing authority to consider It is not suggested that the products would cease to be available and even today the potential for securing products via the internet exists. We note that the IMB regularly warns the public on the risks posed by the supply of medicinal products via the internet Patient information and education is a critical component of the safe use of any medicine however these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control over their supply. These comments highlight the important contribution that pharmacists can make in ensuring the safe supply of such products and counselling patients on their correct use.

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	Furthermore we would see a place for clear labelling on OTC medicines that contain addictive substances and training programmes for all medical professionals to raise further awareness.	Noted. However, some of the suggestions here are outside the remit of the PSI.
	Finally we would have liked more time to have been allocated to review this very important issue rather than the few weeks given and note that when the Medicines and Healthcare products Regulatory Agency in the UK did a similar public consultation there was a period of two years allocated. They concluded that '*codeine should continue to be available at pharmacies with strengthened warnings regarding overuse in the context of headache, and of the possibility of dependency and withdrawal effects with all codeine containing products.*'[4]	Noted. The MHRA review was a review of the licensing of these products and hence was a very different type of review. No legislative change is envisaged arising out of this initiative.
27.	**Sean Reilly MPSI, Reilly's Pharmacy, Clondalkin & Thomas St., Dublin**	
	At the outset I would declare a vested interest that combination containing analgesics are the largest selling lines in both value and volume terms in my practice. IMS data shows this is in line with the national norm.	Noted.
	While the issue of codeine abuse is not a theoretical one, credit should to be given to Irish pharmacists for the manner in which they dealt with it to date. Codeine in cough bottles was the problem and most if not all Irish pharmacists refused to stock it or confined it to prescription long before the Pharmaceutical Society was in a position to effective regulate. Twenty years ago I recall getting requests for it on a daily basis now we are asked maybe once a year, individuals who wish to abuse now know it is not supplied in Dublin. It didn't require regulation to deal with that problem then and it shouldn't now. However should unscrupulous pharmacists emerge in the future, it should be challenged with the new fitness to practise mechanism.	While we recognise many pharmacists have used many measures such as those included in this guidance to address the potential misuse of medicinal products over the years this guidance is intended to to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products.
	I disagree with the two points of the proposed draft • "Non-prescription medicinal products containing codeine should be out of the view of the public". • Non-prescription 'combination' products, containing codeine and paracetamol, aspirin or ibuprofen, should be supplied only as 'second line'	The intention here is to place the products under the direct control of the pharmacist in a manner which would require his or her direct involvement in their supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene

[4] http://www.mhra.gov.uk/home/groups/es-foi/documents/foidisclosure/con2024350.pdf

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	products for the treatment of pain relief I submit proposed guidance is flawed in that: While I have no problem with the strictest restrictions on products where codeine is the sole or primary ingredient the case is completely different in combination analgesic products. These are effective, safe, popular and trusted. Restricting them beyond prudent use, which pharmacists are currently supervising, • will drive GMS patients to surgeries and • increase illicit imports from abroad. Furthermore these are restrictions that none of the organisations the consultation document refers to (MHRA[1], RPSGB[2] or PSNI[3]) implemented to deal with their concerns. In my view there is not a lot of hard science on the misuse of combination analgesics, concerns based mainly on anecdotal evidence outlined in the British All Party Parliamentary Group on Drug Misuse inquiry (see APPDMG report) A broad review of the evidence available is outlined in MHRA PUBLIC ASSESSMENT REPORT of Sept 09 [1]. In it's opening statement it states "taken in the correct manner and for the right purposes, codeine and DHC are very effective and acceptably safe medicines" I suspect the general public would expect hard scientific information is presented and accepted before they are restricted or prevented from obtaining occasional supplies of useful OTC medication. As a community pharmacist I (and not the Pharmaceutical Society) regularly have to field questions as to why oral fluconazole, low dose aspirin and post coital contraception, etc. is not available in this jurisdiction OTC. Removing these combination analgesics from view is going to further alienate Irish pharmacy from its patients.	professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.

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28. **Garvan Mulligan MPSI, Mulligans Pharmacy, Co. Waterford**		
	I am writing this letter, as superintendent pharmacist to twelve pharmacies, in response to the draft guidance by the Standards and Practise Committee of the PSI Council on the safe supply of non prescription medicines containing codeine.	
	I agree with the guidance in principle, but I wish to make the following points. 1. These guidelines appear too restrictive. It must be remembered that a pharmacist has undergone more than four years education and training and must be allowed to use their professional judgement and expertise to enable them to give each patient the correct advise. To ensure correct supervision of codeine sales, it is vitally important to empower the professional judgement of the pharmacist and ensure that all pharmacists have systems/protocols in place so that they can supervise and be aware of <u>all</u> sales of products containing codeine. 2. The PSI definition of self select is too restrictive. These products should not be able to be physically selected by the patient, but they should be visible to the patient. It is the professional judgement of the pharmacist which should be the deciding factor on the suitability of a product for a patient. 3. A bigger area of concern that the PSI should address are the large amount of paracetamol and aspirin available for self select in supermarkets. Who is supervising these sales? Who is informing these patients of the risks of paracetamol and aspirin?	These products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control and their professional judgement over their supply. The guidance is what is expected at a minimum in ensuring the safe supply of these products. This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products. This is outside the remit of the PSI
	In conclusion, the PSI should be empowering the professionally trained and educated pharmacist to discuss and educate patients of the most suitable medication for their ailment.	This is what is envisaged in this guidance. These comments highlight the important contribution that pharmacists have in ensuring the safe supply of such products and counselling patients on their correct use.
	Also the PSI should restrict the sale of all medicines to pharmacies only and thus help safeguard patient safety.	This is outside the remit of the PSI

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29. **Tom Taaffe, MPSI**		
	Submission to Expert Group, PSI in respect of recent guidance on supply of OTC Codeine-containing analgesic products;	
	The guidance as published in the Irish Pharmacy Journal (Nov/Dec 2009, p139-p140) advises Pharmacists of the dangers to customer/patients of Codeine habituation as a result of OTC sales of Codeine-containing products, advises that advertising of such products is prohibited forthwith and advises that strict protocols of supply are to be drawn up to deter future inappropriate sale(s).	Noted
	Essentially, the PSI and IPU (in concert with the IMB) should launch a series of initiatives to remind the public that prolonged and excessive use of such analgesics represents a substantial health risk. This can be achieved by a campaign on TV and Radio and **clear warnings** on packs to the effect that excessive or prolonged use of OTC analgesics containing Codeine is counter-productive and can cause 'addiction or overuse headache if used continuously for more than three days' (if we agree with the MHRA advice). This warning should be very similar to the health warnings placed on cigarettes. Under the current rules, it appears that a Pharmacists may at his/her own discretion sell two packs of a product such as panadol, panadeine, solpadeine or nurofen plus i.e. a total of 2 x 24 (48 dosage units in total). This contradicts the thrust and spirit of the current guidance and must be examined closely with a view to moving away from a judgement call to a clear assertion that 1 x 24 pack of OTC analgesics is the maximum permitted per purchase.	Patient information and education is a critical component of the safe use of any medicine however these products have been authorised and placed on the market and regulated in a manner authorises pharmacists as the healthcare professional that is responsible for exerting control and their professional judgement over their supply. These comments highlight the important contribution that pharmacists have in ensuring the safe supply of such products and counselling patients on their correct use. Some comments here are more appropriate for the product manufacturers and the IMB as the licensing authority
	If Pharmacists advise patients about the problems resulting from a more prolonged period of usage i.e. beyond the maximal advised three days, the risk exists for challenges to that assertion. The IMB has refrained from making a clear statement that excess to a three-day usage could be habit forming or result in overuse headache. The IMB has not made it clear that it expects the responsible manufacturers to alter PIL's and on-pack instructions given the current advice. Until such changes are made, it is difficult to imagine that OTC codeine-sale volumes with diminish significantly and that the above advice will have it's intended effect; to alter the pattern of usage of codeine-containing medicines to a more moderate and sustainable level consistent with optimal public health.	This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products.

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	Allied to such a campaign, we need to explore ways of determining current codeine use in our pharmacies and current codeine use by specific individuals so as to give them guidance on how to get the best effect from codeine, advise them of the potential danger of inappropriate use and hence re-enforce the warning(s) present on the amended packaging (and prevent a pattern of systematic codeine abuse). We must establish a sound methodology for identifying customers who are at risk from codeine-addiction or trial systems to monitor such customers. These measures may seem to be challenging to enact but they may be critical in the promotion of pharmacists' role to the wider public by demonstrating that we, as a profession, facilitate the correct use of medicines for our patrons above any commercial considerations. We must be pro-active and tackle such potential difficulties robustly and effectively before elements in our media launch such a campaign (without us) and portray our profession as one that's more concerned with maintaining medicines sales than protecting our communities. Again thanks for the opportunity to submit a contribution to the future direction of policy, practice and regulation in this core area for the Pharmacy Profession and the wider community.	Noted.
30.	**Ultan Molloy MPSI, Healthwest Pharmacy, Co Mayo**	
	Having worked in community pharmacy in Ireland, the UK and Australia for 12 years, my preference would be to have products that contain codeine returned to prescription only status. I am a community pharmacist in a rural setting and on a number of occasions refused supply to patients who are either abusing or misusing these products. They can likely then just go to another pharmacy and purchase them and this leaves me in a very difficult situation in terms of that patients perception of my actions, and this subsequently can undermine further professional interactions with the patient. Many patients who are abusing / misusing these medicines, and who want them, know what answers to give when asked by pharmacy staff in order to facilitate their purchase of the medicine. There is	This may be the outcome if the current controls and guidelines prove not to be sufficient however this decision lies with the IMB as the licensing authority to assess and consider the risk-benefit ratio for a product. This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products and hence ensure more consistent practice in relation to these products.

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	presently no way to track a persons use of these products.	
	There is a lack of education among patients and primary care providers with regards to appropriate use and the dangers associated with abuse / misuse of these medicines. GP's for the most part do not have sufficient knowledge or experience to treat codeine addiction effectively, in my experience, even in the unlikely event that the patient is prepared to admit they have a problem with medicine abuse / misuse. There is a significant number of patients who are abusing / misusing this class of medicines at present.	These issues ought to be addressed and the health services and others involved in this area including those involved in continuing education of health care professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed.
	The idea of local networking between pharmacies with regards to "problem patients" raises issues of patient confidentially. In the event that such a network was to be put in place between pharmacies / GP's there would be other significant issues. These include patient identification, information dissemination among staff and issues of confrontation with patients due to the perception of many patients that they should be readily available to them.	Noted.
	At a minimum they should be removed from general display to an area out of sight of members of the public and any sale should be made by the pharmacist only.	Noted.
31.	**Vanessa Smith MPSI**	
	I am currently working a s a supervising pharmacist and I feel that there is a definite overuse of products containing codeine in this country. I have read the recent draft of codeine restrictions and the RPSGB's advise which is very similar. By trying to restrict sale for prolonged periods is not always possible as patients go to different pharmacies to purchase these products. It is too difficult to identify regular users until they get very regular. When people from other countries mainly America realise that there is codeine products available for sale in this country, they are quite amazed. I feel these products should just be made prescription and this would cut out a lot of the addiction.	This may be the outcome if the current controls and guidelines prove not to be sufficient however this decision lies with the IMB as the licensing authority to assess and consider the risk-benefit ratio for a product.

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32.	**Conan Burke MPSI, Burkes Pharmacy, Co Sligo**	
	I would like to make some observations about the draft guidelines on the sale of codeine products.	
	I do not think the interpretation of self-selection to include visual selection is appropriate. To my mind this is really creating a new schedule of medicines - in the dispensary but not prescription drugs. I do not think this is the right approach. I fully acknowledge that there are problems with some OTC drugs in terms of abuse, inappropriate use, addiction. In my opinion either these products are suitable for OTC sale or they are not. Control should be based on proper legislation or licensing of the product. there are many products that have been deemed no longer suitable for OTC use with their current ingredients - in the past Diarrest which contained codeine was reformulated to contain Loperamide. Recently antihistamine containing products such as Teedex and Dozol have been licensed only for sale for over 2 yr olds. The OTC use of antihistamines such as Diphenhydramine as OTC sedatives have never been licensed in Ireland unlike the UK where the product Nytol is widely marketed and sold. We have many problem OTC products - either addictive or subject to misuse - laxatives, Nicotine replacement therapy, sedative antihistamine therapies including cough bottles and travel sickness tablets, and caffeine containing medications. many others are borderline e.g. dextrometorphan, pseudoephedrine, xylometazoline, ibuprofen, paracetamol etc. Are we to subject all of these problem OTC products to be hidden from sight.	The existing legislation i.e. the Pharmacy Act 2007 and the RPB regulations (in force since 29th November 2008) currently require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restrictions are imposed which require that those products would not be accessible to the public for self-selection (regulation 5(e)).
	Why do we have products licensed that contain a combination of ingredients which may cause addiction or be commonly subject to inappropriate usage for example combinations of codeine, caffeine and antihistamines. Why does the IMB allow the licensing of these products. Why must Pharmacists have to control the use of these products after the fact. If there is such concern about codeine - why is it not returned to prescription status. It is my understanding that that is the case in other countries! I would have no objection to this being the case here. What is the wisdom in combining two addictive substances caffeine and codeine with paracetamol which causes irreversible liver damage in overdosage?	These comments are for the IMB as the licensing authority. These products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control and their professional judgement over their supply.

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	I do not want to be surreptitiously reaching into the dispensary for codeine products. Leave me with prescription or non-prescription. I do not want a third way. Legislate or license and leave it at that.	
33.	**Rory O'Donnell MPSI, O'Donnells Pharmacy, Co Donegal**	
	I would like to state at the outset that I welcome the move by the PSI to issue draft recommendations on the sale/supply of OTC products with an abuse potential. It is an issue that requires much consideration and appropriate practice.	Noted.
	It is clear that Schedule 5 Controlled Drugs should not be available for self selection nor be the subject of retail promotion, advertising or the like. I would argue however if this stipulation carries to the visibility of the product, given that many dispensaries are open plan and the majority of medicines are visible to the public.	Argument noted. Transferring the products into the dispensary would bring these products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restrictions are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.

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	I agree that pharmacy sales of codeine could be monitored and in some way logged in cases where abuse is suspected. I am not sure how this can be done on a practical basis without the use of networked Information and Communications Technology, however. I believe an opportunity to address this could be explored with stakeholders such as the Irish Pharmacy Union, Irish Medicines Board, Health Services Executive and perhaps the three pharmacy computer vendors currently in the marketplace. The desired outcome of more appropriate and controlled codeine sales/supply must be borne in mind. This outcome may backfire in the short to medium term in border counties where patients are free to access supplies of codeine products in another juristiction. I am not sure if this can be addressed through an all- island approach, perhaps this is worth pursuing with the PSNI.	Noted.
	Finally, the result of this initiative could facilitate the introduction of a broader "pharmacist prescribed" category of medicines, which would necessitate a greater degree of record keeping and pharmacist's personal involvement than the current "P" medicines category. This might facilitate the reclassification of a number of medicines with well established international safety records and thereby make better use of pharmacist resources and ability. A recent presentation by the PSI to the Oireachtas Health Committee seemed to advocate such a move also.	Noted. However, these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control and their professional judgement over their supply.
	The problem of Codeine addiction is well known in the healthcare professions. The IPU has recently produced a sales protocol on codeine products and has run a number of health promotions on chronic daily headache. The PSI's recent launch of a consultation on same has increased public awareness and focussed the minds of pharmacy even further on this growing problem. This is to be commended.	Noted.

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34.	**Conor Phelan MPSI, Phelans Pharmacy, Co. Cork**	
	I refer to the draft guidance for pharmacists on supply of non-prescription medicinal products containing codeine and wish to comment as follows. I would query firstly why it is necessary to have a pharmacy-specific policy (guidance 1(b). Clearly each superintendent must consider any proposed policy and if thought appropriate why could the same policy (such as the one recently produced by IPU and IPHA) be used in multiple outlets. This avoids placing an unnecessary administrative burden on individual superintendent pharmacists. Secondly, I would query the advice 3(i) that patients should be counselled in the course of each supply in respect of potential side effects. I think this should be left to the pharmacists discretion and professional judgement particularly if it is a repeat sale under medical supervision where the patient has been previously counselled in this respect. My third and main comment is as follows: The 2008 Retail pharmacy Businesses Regulations do not define the term self-selection and your draft guidance document states that self-selection means the patient cannot self-select the product – either visually or physically. This is the first time I have come across this interpretation of self-selection and I am concerned as to the implications of same. A strict interpretation would mean that if patients can visually self-select (i.e. see medicinal products that are subject to prescription control under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended) and medicinal products that are controlled drugs listed in Schedule 5 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) then there is a breach of the regulations. We will then have to redesign pharmacies to ensure all the above medicines and therefore the pharmacist are out of sight of the public.	Superintendent pharmacists are responsible for policies in pharmacies under their jurisdiction. While the policies they put in place will reflect good pharmacy practice and legal requirements they will also reflect their own professional judgement including their knowledge of the practice and patient cohort. The Regulation of Retail Pharmacy Businesses Regulations 2008 highlights that it is the pharmacist that must be satisfied, in each supply of a non prescription medicines, that the purchaser is aware of what the appropriate use of the medicinal product is and that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and/or misuse. The intention here is to that these products must be under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restrictions are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and

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	One would hope that common sense would prevail but this common sense should be incorporated into the guidelines. Perhaps if the guidelines stated that products should not be visually displayed within 2 metres of the public area this would cover it. In summary, it should not be the case that just because it can be seen it is deemed to be available for self-selection.	where the potential for the pharmacist professional intervention is most likely to be achieved.
35.	**Martin Styles MPSI, McSweeney Group Ltd**	
	I fear that it will be necessary to make all Codeine preparations POM for effective control to be achieved.	This may be the outcome if the current controls and guidelines prove not to be sufficient, however this decision lies with the IMB as the licensing authority to assess and consider the risk-benefit ratio for a product.
	Education of the medical profession is necessary. Astonishingly, many doctors still recommend Codeine Linctus for "chesty" coughs.	Noted. The guidance document from the PSI is directed towards pharmacists, however these matters ought to be addressed and the health services and others involved in this area including those involved in the continuing education of health care professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed.
	UK based TV and magazine advertising for Codeine preparations should be controlled as much as possible.	Noted. This is unfortunately a reality on the global stage.
	I would advocate the banning of names such as "Plus", "Extra" and "Max Strength" as these encourage the public to make inappropriate choices. Likewise, packaging should be more sober, similar to designs used for POM packaging. Strongly worded warnings of the side effects (including constipation) and addictive properties of Codeine should be included on all packaging, similar to the warnings on cigarettes.	Noted. However initiatives here are for the IMB as the licensing authority to consider.

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36.	**Martin Henman, School of Pharmacy and Pharmaceutical sciences, Trinity College Dublin**	
	The arrangements for codeine usage are a matter for all of the institutions of the health service and for society as a whole to address. The opportunity to make a submission on these proposals is welcome. Most of the proposals are a valuable contribution to public health.	Noted.
	Introduction A minority of countries around the world allow codeine-containing products to be available without prescription. The present regulations in Ireland are of long standing and were devised when the procedures for the supply of medicinal products were very different and when attitudes to self-medication and to medicines were very different. In that time, some countries, notably The Netherlands and Sweden, rescheduled all codeine products as prescription preparations. In Ireland, there has not been a substantive discussion involving all of the health care and industry groups, nor has there been any significant attempt to engage patients, patient groups, the public, or policy makers.	Noted.
	While much of the material presented in the PSI proposal is correct, the risks to the public from combination preparations vary significantly with the ingredients and the summary presented could be misleading; for example, ibuprofen poses a risk to patients when misused in chronic rather than acute circumstances, as Australian case reports have demonstrated. The Irish Medicines Board has authorised the preparations on the Irish market and in consequence has established the Indications for which they can be used and the precautions and side effects that must be taken into account when they are used.	
	The majority of patients use these products appropriately and gain significant benefit as a result. However, as the proportion of the population reporting some degree of dependence and/or abuse of potentially addictive drugs and other substances has increased, so the likelihood that codeine containing products are being abused by this segment of the population must be taken seriously. In particular, UK support groups such as *Overcount* and anecdotal evidence in this country suggest that people can become dependent upon	It is widely recognised that better information on the appropriate referral pathways for patients with addiction problems could be developed. This can be progressed with the appropriate authorities e.g. HSE. This can also be addressed with more inter-professional cooperation and continuing professional development for healthcare professionals.

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	individual products and that these people are not dependent or abusing any other addictive substance(s). This possibility is, in itself, a matter of concern. Support and services for those dependent on licit or illicit substances cannot cope with existing demand (driven primarily by heroin abuse) and the provision of these services is geographically limited. Pharmacists and Community Pharmacies have worked with the HSE in the Methadone Treatment Service but are not routinely informed or engaged by the HSE in services for any other groups of patients with substance dependencies. Although both GPs and Community Pharmacists have expressed their concern about the limited availability of help for patients with benzodiazepine dependency, and although both, in exercising their duty of care would wish to do more, they have not received any more support from the HSE. If pharmacists are to inform patients about services and to refer them to services, they will need to be recognised by the HSE as participants in these activities and should receive a much higher level of assistance to enable them to act effectively. *Medicines supply and the Irish Health Service* Prescription-only medicines and the procedures for their supply have been subject to regular reviews involving most of the relevant stakeholders with the notable exception of one component, the prescription. Each of the stakeholders seems to be clear about the role that these medicines play in health care and about their responsibilities in the medicines supply process. However, not all of them appear to understand the legal requirement that prescription medicines should not be available for patients to select themselves and that dispensaries should not be areas of public access. Notably, a greater proportion of the population care for their symptoms by themselves than seek to have a medicine prescribed to provide that care and many with chronic diseases also choose to use non-prescription medicines in certain circumstances. In recognition of this the DoHC has adopted a policy to promote self care and self medication, and the HSE, which has the responsibility to implement the DoHC's policy, has stated that it accepts that patient's will take more responsibility for their own care. Non-prescription products are categorised by the Irish Medicines Board as exempt from prescription and suitable for distribution through pharmacies or through pharmacies and certain non-pharmacy 'grocery-type' outlets. The Irish Medicines Board evaluates all of the aspects of safety, efficacy and risk	Correct and in addition to prescription only medicines, the regulations also state that non prescription medicines, containing CD5 medicines, should not be available for self-selection.

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	management in making these decisions and its remit and responsibilities in this area have increased significantly recently as it has taken over the functions performed by the Poisons Council in the past. But while the medicines and pharmacy regulators have sought to establish a suitable environment to facilitate this, the HSE's encouragement of selfcare and with it self-medication, HSE plans and actions relevant to self medication are barely visible and their concern seems to focus solely on the extent of direct costs to the HSE or the possibility of cost-shifting.	
	Non-prescription medicines use involves patients, pharmacists, regulators, the pharmaceutical industry, the HSE and the DoHC; but only three stakeholders have been active consistently in regulating this important sector of health care. The relative roles and responsibilities of these stakeholders are very different to those involved with prescription only medicines because the patient is the principal agent, not the prescriber nor the health service. The forces that operate upon patients and the means of influencing their demand for and their use of non-prescription medicines are quite distinct to those that apply to prescription medicines. To ensure that patients and purchasers obtain the right preparation for the appropriate symptoms and are able to use it in a way that maximises the safety and efficacy of the active ingredients is the objective of public policy. Unfortunately, the scope of the legislative, regulatory and informational actions required and the importance of collaborative and co-ordinated working that this is required to attain this objective is not appreciated by the majority the stakeholders, leading to incomplete, ineffective policy strategies.	Noted. However regulation 10 highlights that it is <u>the pharmacist</u> that must be satisfied, in each supply of a non prescription medicines, that the purchaser is aware of what the appropriate use of the medicinal product is and that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and/or misuse.
	Pharmacist's responsibilities and role Pharmacists accept that they have been entrusted with the public policy objective of optimising the use of non-prescription medicines. This is essentially, a quality assurance role. It is entirely appropriate that pharmacy owners, pharmacists and their staff are reminded of their responsibilities under regulation 10 of SI 488 of 2008 and that the particular roles of superintendent and supervising pharmacists should be highlighted. Pharmacists and their staff sometimes use structured questioning protocols (such as 'WWHAM'; Who is it for?; What are the symptoms?; How long have they been present?; Has the patient taken any action?; Are medicines being	Noted.

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	taken?) to respond to patient requests for non-prescription preparations. Yet, in this country and in the UK, patients and other purchasers are often resentful of such questions. This attitude is regularly expressed to pharmacists and is particularly felt by other pharmacy staff who try to adhere to a non-prescription medicines supply protocol. The culture of consumerism places the purchaser as the prime mover and product promotion emphasises the value of the product and its ready availability. These characteristics are reinforced by an environment in which the granting of product authorisation by the medicines regulator supports the notions of safety and efficacy despite the fact that they are subject to significant restrictions; for example in the case of codeine-containing products a three day limit on their use before seeking medical advice. Consumerism does not distinguish between the necessary limitations applied to different types of products nor does it emphasise the role of personal responsibility, whereas in contrast these are core elements of self care and self medication. The emphasis of the HSE and of competition policy on access and cost without concomitant emphasis on the need to utilise the expertise and advice available in pharmacies and of its potential value to patients countermands the HSE's self care policy and exacerbates the notion of non-prescription medicines as items equivalent to any other retail goods with unrestricted availability and unrestricted use. Both of these factors act in opposition to the moderating intervention required by standards of practice of pharmacists. The result is that this important quality assurance procedure is rejected by patients and inadequately provided by pharmacies with unquantified harm occurring to patients, pharmacies, the health service and the products. Similarly the explication of the Control of Advertising Regulations in relation to in-pharmacy promotion and the use of promotional and information materials is especially useful and could be extended to other Pharmacy Sale preparations, since over time, inappropriate practices have developed that reflect patient demand and market dynamics and conflict with the pharmacist's professional responsibilities. It is notable that the UK medicine regulator does not prohibit public promotion of codeine-containing preparations and did not choose to introduce such a restriction in the autumn of 2009, when it issued updated advice to pharmacists. Public promotion in broadcast and other media from the UK and elsewhere is freely available in Ireland and influences public	Noted. However the Regulation of Retail Pharmacy Business Regulations 2008 (S.I. No. 488 of 2008) deems medicinal products containing codeine, CD5 medicines, not suitable for self-selection by patients. Therefore these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control and their professional judgement over their supply.

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	perceptions of the accessibility of medicines as well as demand for medicines. In order to increase the accessibility of pharmacists many pharmacies have remodelled their dispensaries so that the dispensary staff can be seen and can communicate directly with waiting patients without having to leave the dispensary. This, of course makes at least some of the prescription products visible to the public which is pertinent considering the PSI proposals. *The PSI Proposals* Pharmacy Sale products are not meant for self-selection by purchasers. To comply with this requirement these products have usually been kept behind the counter nearest the dispensary where the pharmacist could be made aware of their sale and where other qualified staff work (pharmaceutical assistants and pharmacy technicians) who would have the knowledge and skills to assist the pharmacist and patient and who would know which patients require referral. The interpretation in the PSI proposals that the phrase 'not capable of self selection' means physically and visually is new. Custom and Practice to date throughout Pharmacy in those countries that authorise these preparations and previous interpretation in this country by the former Pharmaceutical Society of Ireland and others limited the meaning of this phrase to physical selection. The PSI proposals do not extend this interpretation to other non-prescription preparations that are subject to the same regulations but do not contain codeine. The result would be to create two distinct categories of products where previously there was one via a re-interpretation of the regulation. This is potentially confusing to the public and unhelpful regulator practice since the IMB and DoHC should be prime movers in any reclassification of medicinal products. *Minimising the potential for harm* While the PSI proposals address the pharmacist and alter the availability of the products, they do not and cannot address other components of the problem; • pharmacist's reluctance to question patients	The intention here is to place the products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement, as to whether the supply is appropriate or not, and intervene professionally in the supply as necessary. In addition the requirement under regulation 4(4), which requires each retail pharmacy business to have a patient consultation area will change the nature of the pharmacist-patient interaction and enhance patient confidentiality and the counselling role of the pharmacist. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a

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	• patients' resistance to questioning • lack of clear public policy about the role of non-prescription medicines and the quality assurance role of the pharmacist and of the Community Pharmacy for medicines • insufficient promotion to the public of the role of pharmacists and pharmacies in self medication and in the stewardship of non-prescription medicines • lack of support for pharmacists and pharmacies in a public health role • the unintended effects of competition policy • understanding of consumerism • transnational advertising and its influence • inadequate treatment services for those with substance dependencies • insufficient collaboration between the HSE and Community Pharmacy in public health	manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.
	Potential problems with the proposals Regulations need to be perceived as necessary, reasonable, sufficient, understandable and applicable. Unless this is the case, those who must implement them will not accept the challenge of doing so. Any change in regulations must also promote the desired behaviour and be practical to implement and be feasible to enforce. Although most of the proposals have value and are appropriate the most novel of them is likely to have a number of unintended effects that could negate much of the benefit gained from the others and damage the capacity of the Community Pharmacy sector to support patients in self care across a wide range of conditions. If the proposal to remove from public sight codeine-containing medicines implemented by pharmacists without any other related interventions by other stakeholders, in particular the DoHC and the HSE, it present the problem as one belonging to pharmacy and to the product manufacturers. The proposal does not address patient's behaviour and instead seeks to use pharmacists as agents of change. Patients who may benefit from the use of a codeine-containing product may be discouraged from requesting it. For those who do request a product it may promote confrontation with Pharmacists since hiding non-prescription products that are well known and have been approved as safe and effective by the IMB will make pharmacists appear as paternalistic and their questions as unnecessarily intrusive. This will tarnish the perception of pharmacist's in	This a competency issue for pharmacists and a critical element to be addressed through their education, training and continuing professional development. The role and obligations of the pharmacist are clearly laid out in the regulations. Noted. The PSI will consider this in terms of its future communications with the public.

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	supporting patients in self care in these and in other circumstances. Instead of engaging a patient on the condition to be treated these proposals will focus the attention of most patients and purchasers upon the terms for the supply of the products and convey an image of the pharmacist as a supplier of goods rather than as a carer. This will establish an inappropriate context for the conversation that the pharmacist is being asked to initiate. Those who have become dependent on codeine-containing products will evade the restrictions; this already happens with paracetamol products. Although there is a restriction on the amount of paracetamol that can be purchased, patients may go to several pharmacies or to several check-outs in a large supermarket to circumvent the restriction. Even though dependency is not a problem with paracetamol these behaviours are adopted by patients and the open availability of the products makes this evasion possible. Dependent patients will go to greater lengths to obtain supplies as anecdotal evidence about codeine-containing products from Australia and the UK suggests. In these circumstances, patient attitudes and behaviour are the primary problem and pharmacist behaviour the secondary problem, tackling one but not the other will not solve either, instead both must be addressed. Logically, seeking to minimise the potential harm from the misuse of codeine, draws comparisons with the arrangements for alcohol and tobacco; both are used widely and frequently and safely by many people, but neither of these has any therapeutic value and both produce serious and extensive harm in our society. Yet both are freely available for self selection by adults and are on display to everyone, simply because they are not medicinal products. This contradiction also shapes the public's attitudes and opinions about medicines. The proposed merger of the IMB and the Office of Tobacco Control perhaps follows from a change in the thinking of policy makers about products with a potential for abuse. *Proposals* There is no doubt that there is a consensus that measures are needed to address the potential abuse of codeine-containing products. In order to alter non-prescription medicine use patients, patient groups, the public, all of the health care and industry groups and policy makers must be engaged. The problems that must be addressed to make the necessary, reasonable,	The draft guidance aims to facilitate compliance with legislative requirements and ensure CD5 medicinal products are under pharmacist control. The suggestion is not that these products would be no longer available but that they would only be supplied to patients that, in the professional judgement of the pharmacist, require them. The aim of the guidance is to guide and support pharmacists in discharging their professional role in the safe supply of these products. Following a review the authorities in Australia are introducing

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	sufficient, understandable regulations that are implementable and enforceable are multifactorial. Consequently a multiagency, multilevel approach is the only one that will bring substantive, sustainable benefits. The industry body, IPHA, has proposed that discussions about policies for non-prescription medicines should be held by a group of all stakeholder representatives and this possibility should be explored. It is notable that the UK and Australia have taken action over codeine-containing products but that neither of them has adopted the approach suggested here. Nevertheless there are ideas in their policies that could be explored in this country; the UK medicines regulator has amended both the Summary of Product Characteristics and the Patient Information Leaflets of codeine-containing products and in particular it has included an explanatory section in the PIL on the recognition of addiction; in Australia a pharmacy IT system for sharing information (NotifyRx®) about product use between pharmacies was proposed as a measure on the basis of the successful use of a similar system for psuedoephedrine containing products. It is to be hoped that the outcome of this consultation process will be the convening of a strategy and implementation group drawn from each of the stakeholders to propose measures within a short period that have their support. The initiatives that are likely to emerge from such a group will have not only tackle this problem but have significant capacity for generalisation to other non-prescription medicines. If however this is not the outcome, then close collaboration between the HSE, Pharmacy bodies, Patient groups, IMB and the Pharmaceutical Industry would be the next best option. The PSI may decide to proceed with its proposals and they would have widespread support inside and outside the Profession of Pharmacy for all but the putting out of sight of the products. If this option is pursued, the PSI must use its authority to persuade the DoHC, other agencies and Patient groups of the need for them to support publicly the pharmacist's in this role and to take complementary steps to address the issues most apposite for them. *References* Medicines Healthcare Regulatory Agency. MHRA Public Assessment Report. Codeine and dihydrocodeine-containing medicines: minimising the risk of addiction. 2009	stricter scheduling and controls of codeine as of 1st May 2010. In addition in Canada, where these products are also available without prescription, similar controls are in place. These products are restricted within the pharmacy and can only be supplied by the pharmacist.

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	Smith S, Henman M, Schroeder K, Fahey T, Over-the-counter cough medicines in children: neither safe or efficacious?, *British Journal of General Practice*, 58, (556), 2008, p757 - 758 Switch-on to self care. Roundtable meeting report. Irish Pharmaceutical Healthcare Association. 2009 Wafaizy M, Sheilds E, Hughes CM & McElnay JC. Societal perspectives on over-the-counter (OTC) medicines. Family Practice; 22: 170-176. World Health Organisation. The role of the pharmacist in self-care and self-medication. Report of the 4th WHO Consultative Group on the Role of the Pharmacist. The Hague, The Netherlands. WHO/DAP/98.13. WHO, Geneva, 1998.	
37.	**David Carroll MPSI, Boots Store, Grafton Street, Dublin**	
	I would like to warmly welcome the new guidelines for supply of codeine-containing medicines. It has long been my view that there is a significant overuse and misuse of these products in countries such as Ireland and Britain where they are not subject to prescription control. In particular, I noted the recent findings of a very large survey of self-described codeine addicts where approximately 70% of them had never been told the medicine was addictive and a similar proportion were taking more than the recommended dosage on a continuous basis.	Noted.
	We have been conducting an ongoing trial in my pharmacy where codeine sales were very tightly restricted by means of a specific protocol where customers would be read out a short 30 second summary warning of the side-effects of codeine, its addiction potential, how it should be used for no more than 3 days, etc. I am attaching all of the relevant documents (3 attachments) in use in our store as a formal submission to this consultation process, though I am aware that the PSI is already aware of what we have been doing.	Noted.
	In particular, I strongly welcome the PSI's proposal to have all of these medicines stored in the dispensary out of sight. While it will undoubtedly be an inconvenience to many pharmacists, it will have the effect of ensuring all the sales go through the pharmacist and therefore regular users will be more easily	Noted

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	identified. I feel it is important to insist on the dispensary as the location, as opposed to just shoving it in a drawer outside, in order to ensure the pharmacist is involved in all transactions. I also greatly welcome the proposal for pharmacies to have an agreed protocol in place for these sales, which incorporates various aspects of advice and information, as this is what we have in place in our store already. I understand the PSI's need not to be over prescriptive in setting out the exact wording of the protocol. However, I would be concerned if it was left too loose as a recommendation. I note the codeine guidelines recommended by some other organisations are very loosely-worded eg telling people that some of the effects of codeine withdrawal are restlessness and irritability is most unlikely to worry anyone and in fact it has the effect of greatly downplaying the serious problem of codeine addiction. The PSI should be aware that, in my opinion, some previous guidelines done in association with an organisation like the IPHA, with all due respect to them, is equivalent to Alcoholics Anonymous drawing up new guidelines in association with the Licensed Vintners Association! It is obvious from reading over them that while they give important information, they are not tough enough to realistically make an impact on codeine sales. No doubt, that was the aim. If we are going to introduce a strict protocol with the aim of ensuring appropriate and only appropriate sales of these medicines, then it needs to be strict, it needs to have a strong impact on the patient, and it needs to be universally implemented. Many pharmacists have congratulated me about the strict protocols I have put in place around codeine but almost every single one of them said there is no way they would do the same in their stores because of the impact it would have on sales. In some states in the USA, where codeine is on prescription, there is a specifically worded protocol which must be gone over with the patient every time a prescription is being dispensed. In our store, the protocol takes 25 seconds to read. It's not a big deal. So I would urge you to insist on a few key phrases which must be included in the protocol, and to insist that this set protocol is used at every single sale. Finally, I want to make a suggestion around pack sizes. Despite all our efforts here, the sales of 2 products in particular are huge - Nurofen Plus 24s and Solpadeine Soluble 24s. There is an obvious overuse of these medicines that is	Noted. This will be considered when finalising the guidance. Noted. However some of the comments here are more relevant to the IMB as the licensing authority.

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	very difficult to address adequately. If we are serious about the use of these medicines being no more than for 3 days, then Nurofen Plus should be restricted to a 16 pack and Solpadeine to a 20 pack to ensure that one pack can not be used for 3 days or more. (3 days of Nurofen Plus is 18 tablets, 3 days of Solpadeine is 24 tablets) Moreover, I believe the PSI should introduce a restriction, like we have in our store, of no more than one single pack of a codeine containing medicine per transaction. This would stop people buying 2 x 24 Nurofen Plus, or 24 Nurofen Plus and 24 Solpadeine. Furthermore, in Britain, they are introducing new labelling regulations which, similar to the warning on cigarette packs, will clearly warn the patient with a short sharp phrase such as "Warning: Addictive. No more than 3 days." This should be considered by the PSI also as I believe it will be highly effective. Finally, even if all of these are introduced, I still think there will be a problem with these larger pack sizes and I would urge the PSI to consider even tighter restrictions for these products to encourage people to only buy the smaller pack sizes. For example, this could involve insisting that all pack sizes of 16 or more are recorded on the dispensary computer, which would further emphasise how seriously sales of these packs should be taken, as well as providing an excellent way to monitor regular use. Again this may be a pain to implement, but if we are to be allowed sell more and more currently prescription-only items, record keeping is going to be increasingly required. It is good practice anyway and something pharmacists will have to get used to. In summary, I want to warmly welcome these proposals from the PSI. I believe they are long overdue and are very necessary. In fact, as I've stated, I believe there are further modifications that could be made to tighten up supply even more as I've outlined above. I have no doubt that there will be great resistance to their introduction and the PSI must stand firm. The most difficult aspect of what I have done in my store is that the customer can go to any other pharmacy and pick up their codeine product without any interaction or restriction at all. Having a uniform policy in place across the country will be very welcome. Please note this submission is in my personal capacity as a pharmacist and does not necessarily reflect the views of the company I work for. However, they have been hugely supportive of the restrictions I have put in place in my store and I have no doubt they will welcome a strict and uniform countrywide regulation of these medicines.	Noted.

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	Research **The development of a protocol for the sale of codeine-containing medicines in community pharmacy: a practice report** **David Carroll, Supervising Pharmacist, Boots, Grafton Street, Dublin** In 2008, combination analgesics contributed more new sales than any other sub-sector in the Irish OTC market.. In particular, sales of analgesics containing codeine grew strongly and this has been raised as a concern within the Irish healthcare community This concern is not new, with the potential for misuse or abuse of 'over-the-counter' codeine products being repeatedly highlighted as an issue which needs to be considered in countries where codeine is available without prescription. The advantages of using compound analgesic preparations containing paracetamol or aspirin with a low dose of an opioid analgesic (e.g. 8mg of codeine phosphate per tablet) have not been substantiated and their use can lead to increased side effects. In my pharmacy, I had become increasingly concerned that a high proportion of our analgesic sales were made up of products containing codeine. As a result, I decided to revise our protocols for the sale of codeine containing medicines (CCMs), with the aims of educating customers on their appropriate use and reducing the level of codeine use. Because actual use could not be measured (i.e. I could not follow patients home to see how much codeine containing medicines they used), the sales figures for CCMs were used as a proxy measure for codeine use. This paper describes the steps that I and my pharmacy staff took in developing a new protocol and shares some insights into the issues that arose from our actions. **Development of a new protocol** Although we already had protocols in place for the appropriate sale of prescription-exempt medications in our pharmacy, we decided to introduce additional safeguards for the sale of CCMs in October 2008. This involved limiting the sale to a maximum of 24 tablets per transaction and telling all customers that the product should not be used for more than three days continuously. In addition, there was more proactive monitoring of repeat customers, with pharmacists intervening in sales where customers were found to be making regular purchases. Whilst these measures went some way to	Research Noted.

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	increase patient awareness, it was felt that they were not sufficient to alert customers to the specific concerns relating to codeine. The warning about the three day limit often appeared to get lost in the haze of conversation and questioning which arose during customer transactions. Moreover, the intervention did not result in any reduction of CCM sales, which we took to indicate no change in use. **Codeine register** Following a review of this initial intervention I felt it was necessary to provide more specific information to customers on the concerns relating to CCMs. It was also decided that a register should be established, with a requirement for each customer to sign for each purchase. This would ensure that customers understood the possible side-effects and problems which could arise from misuse of CCMs and would be a valuable aid in identifying regular users. At the end of March 2009 we revised the protocol to include these measures. Every time a CCM was requested, the healthcare assistant informed the customer that we had a new protocol and provided some information to the customer about CCMs (as per the Patient Information Summary) after which the customer was requested to sign the register to confirm that they had received this information. The Patient Information Summary consisted of direct extracts from the patient information leaflets of two well known codeine containing brands including warnings about side-effects and the effects of prolonged, regular use. If a customer refused to listen to the information, or to sign the register, the sale would not proceed and the pharmacist would be asked to intervene. This process was used for every sale of CCM, no matter how long the queue was, how rushed the customer was or what time of day it was. **Patient objections** A few days into the trial we made a couple of amendments to the process. Firstly, we recognised that the term 'codeine register' caused difficulties with some customers. It was suggested, for example, that we were keeping a register of codeine addicts. As a result we changed the heading on the register to 'sale of medicines register. (Figure 1) and there were no subsequent objections. Secondly, we felt that the protocol as it stood still did not provide enough information to the customer about the lack of evidence for an	

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	additional analgesic effect from codeine. As stated in the BNF, "*combining a non-opioid with an opioid analgesic can provide greater pain relief than a non-opioid analgesic given alone. However, this applies only when an appropriate dose combination is used. Most combination analgesic preparations have not been shown to provide greater pain relief than an adequate dose of the non-opioid component given alone. Moreover, combination preparations have the disadvantage of an increased number of side-effects*." A single sentence summary of this information was included in the Patient Information Summary, and was followed with a warning about the possible side-effects and withdrawal symptoms (Figure 2). After these amendments, it was felt that the information was more practical, possibly more stark, and at least gave an opportunity for the sale to be redirected to an alternative non-codeine painkiller rather than making the transaction simply an information-giving exercise. **Outcomes** After two weeks of the trial, the weekly sales of CCMs had reduced by 12.35% with significant increases in the sales of paracetamol and ibuprofen. As a proportion of overall analgesic sales, CCMs had decreased by 11%, which we took to be indicative of reduced codeine use, while sales of paracetamol had increased by 4% and ibuprofen had increased by 7%. Two months into the trial, the downward trend of codeine sales was still continuing, with paracetamol sales 19% above levels before the start of the trial and ibuprofen up by 32%. **Impact on sales** While we had expected to suffer a significant reduction in analgesic sales, we were surprised to find that the trial had no effect on overall sales. Most importantly, we had ensured that absolutely 100% of our customers who purchased CCMs were made fully aware of both the potential side-effects and the problems associated with taking it on a continuous basis. All of these people were informed of alternative analgesics that would give them an equivalent degree of pain relief without any of the problems associated with codeine. Therefore we felt that we had taken very firm steps to ensure the safe and appropriate use of medicines in our pharmacy, and had demonstrated that we placed the health and well-being of our customers above any interest in maintaining sales figures. The vast majority of people who purchased CCMs had no problem with the new protocol. By the time 2,000 customers had signed our register, we	

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	had recorded just 19 complaints from customers -- fewer than 1% of the total. The majority of these arose in the second week when people returned to buy a CCM and complained to us that they had signed the register previously. This provided an opportunity for the pharmacist to intervene to ascertain why they needed another pack so soon. Every one of these customers admitted to taking codeine regularly though only a couple acknowledged that they may have a problem with it. Excuses ranged from 'allergy to paracetamol' to dislike of the taste of other analgesics and inability to swallow them because of their shape. A small number of healthcare professionals refused to sign as they said that they "know all about it and buy it regularly" while one man claimed his doctor told him to take it to help with his depression since he neither drank nor smoked. Two customers reacted very aggressively, shouting at staff. Notably, all of the customers who reacted negatively to the protocol admitted in one way or another that they are regular users of CCMs and so, even though the sale was ultimately refused and they may not decide to come to our pharmacy again, at least we can be sure that we gave them sound advice and we can hope that our intervention may encourage them to reconsider what they are doing and possibly seek professional help. **Positive customer feedback** On the other hand, we have received a number of instances of positive feedback including six people who admitted that they knew they had a problem but that since nobody had confronted them about it they were reluctant to deal with it. All of these people had consultations with the pharmacist who advised them on how to deal with codeine withdrawal and 4 of the 6 returned to us some weeks later to tell us that they were now off codeine completely and thanked us for our help. Two customers who happened to observe us reading out the protocol to other people made a point of speaking to the pharmacist about their situation: one of them had undergone a four month withdrawal programme from codeine under their doctor's supervision, while the other person had been prescribed methadone for a period to help them withdraw. Interestingly, one American lady commended us on our protocol and told us that in her state, even though CCMs are restricted to prescription-only, they have a similar protocol to ours which the pharmacist must go through each time he dispenses the prescription. She felt that in the absence of prescription regulations here, we were taking all the necessary steps to ensure	

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	the safe and appropriate use of CCMs. There was some initial resistance amongst the healthcare staff to the idea of maintaining the register. They had concerns over the amount of time this would take and how it would be perceived by customers. Following implementation, however, they have recognised the benefit to customers, and were particularly heartened by the fact that CCM sales were being reduced as a result of their interaction. The protocol is running very smoothly now and has become part of our routine. The information takes approximately 25 seconds to read to the customer and therefore has not had a significant impact on workload. **Conclusions** I feel this initiative has helped contribute to patient safety in my pharmacy while emphasising the positive role of the pharmacists in guaranteeing the safe and appropriate use of medicines. As a result, we have decided to implement it on a permanent basis. Clearly we cannot influence what happens to the people who are regular users of CCMs who are refused a sale in our store and who simply go to the next pharmacy up the road. However, we can ensure that the message is conveyed to them clearly and professionally, and we can hope that they will reconsider what they are doing and seek professional help. Although I feel that this initiative has been effective, it only goes a small way to addressing the wider issue of codeine misuse. A more effective measure would be to introduce a national protocol for the sale of codeine, and I would welcome such an initiative. Given the concerns that have been raised regarding the levels of CCM use in Ireland it would be useful to have consistent standards across pharmacies to ensure that the general public receives a clear, unambiguous message about codeine use. However, if this were to happen, greater support mechanisms would be needed for the rehabilitation of individuals who have developed codeine dependency and referral pathways would need to be established from pharmacies. Such issues need to be considered at a national level. In the meantime, I hope that the insights provided in this article prove useful to other pharmacists who may be considering revising their protocols for the sale of codeine containing medicines.	

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	References: 1. Euromonitor International. *OTC Healthcare in Ireland*. 2009 [cited May 2009]; Available from: http://www.euromonitor.com/OTC_Healthcare_in_Ireland?print=true. 2. Hughes, G., McElnay, J., Hughes, C. and McKenna, P., *Abuse/misuse of non-prescription drugs.* Pharmacy World & Science, 1999. **21** (6): 251. 3. Ford, C. and Good, B., *Over the counter drugs can be highly addictive.* BMJ, 2007. **334**: 917. 4. Ó Cionnaith, F., *Call to end over-the-counter sales of codeine*. Irish Examiner, Thursday, April 23, 2009 5. Matheson, C., Bond, C. and Pitcairn, J., *Misuse of over-the-counter medicines from community pharmacies: a population survey of Scottish pharmacies.* The Pharmaceutical Journal, 2002. **269** (66-68) 6. Section 4.7: Analgesics, from the British National Formulary. March 2009. BMJ group and RPS Publishing. **OTC medicines containing CODEINE** The dose of codeine in these medicines has not been shown to provide greater pain relief than paracetamol or ibuprofen on their own.† It may however cause side-effects such as euphoria (feeling "high"), nausea and constipation. † They should only be taken when necessary and not for more than 3 days. ‡ Prolonged regular use may lead to dependence (addiction) and result in withdrawal symptoms such as rebound headache once the drug is stopped. †‡ If you find you need to use this product all the time, it is important to consult your doctor. ‡ † ref. BNF 56, Sept 2008, 4.7 Analgesics ‡ ref. Patient Information Leaflets, Solpadeine (Mar 2008) & Nurofen Plus (Feb 2008)	

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38.	**Brendan Hayes MPSI, Portumna, Co Galway**	
	A: Commentary of the Codeine Sale Guidelines, as published for consultation Commentary - Page 1: The 'Background' material is scant, not quoting any scientific evidence, more anecdote. *"The safety concerns around the misuse of non-prescription medicinal products containing codeine are well established".* References?	Noted.
	The guidance includes the following key points: • "Non-prescription medicinal products containing codeine should be stored in a retail pharmacy business (pharmacy), out of the view of the public, to facilitate the legislative requirement that these products must not be accessible to the public for self-selection". Comment: Inadequate reason. The real reason should be mentioned. The same reason that cigarettes were recently obscured from view in grocery shops, the opposite reason as to why 'merchandising managers' ensure that large areas of eye-level shelf space is allocated to high profit items in retail stores….. visual location and display increases sales.	Noted. The intention here is to place the products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene professionally in the supply as necessary.
	• "Non-prescription 'combination' products, containing codeine and paracetamol, aspirin or ibuprofen, should be supplied only as 'second line' products for the treatment of pain relief, when single ingredient products, such as paracetamol, aspirin or ibuprofen, have not shown to be effective. • Non-prescription medicinal products containing codeine should only be used in accordance with the terms of their marketing authorisations, which all state that the product be used for short-term use, no longer than three days". Comment: Maximum dose of Nurofen Plus is 2 tablets 3 times daily, which equals 6 tablets daily over 3 days, equaling 18 tablets in total. Therefore, in accordance with the above mentioned authorization, Nurofen Plus should have marketing guidelines attached to it requiring that the maximum pack size be 18 (currently sold in 12's and 24's), and that no more than one pack be sold to any one patient per 3 days, similar to the terms of the current paracetamol legislation. Maximum daily dosage of Solpadeine is 8 daily, therefore the currently 24 pack size is compliant with the above '3 days supply' recommendation.	Noted. However some of the comments here are more relevant to the IMB as the licensing authority.

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	• "Patients need to be fully advised of the correct use of these products and the risks associated with their misuse. It is also essential that patients be facilitated in obtaining medical assistance for any health problems related to their misuse that may arise". Comment: There needs to be a PSI led SOP for the actions proposed above. The wording 'be facilitated' is a nebulous term lending itself to misinterpretation between pharmacies and practicioners.	Noted.
	Commentary - Page 2: "*Codeine phosphate is a mild to moderate analgesic and has weak cough suppressant activity*." Comment: [Quote reference].	Reference is given. IMB Drug safety Newsletter 2004
	"It is considered important that patients consult their doctor if a need to use codeine medicines all the time is experienced". Comment: Suggest more directive wording. Patients must be alerted to the need to consult their doctor if they are using codeine medicines repeatedly or continuously.	Patients must seek medical advice if the product is needed for longer than 3 days.
	Commentary - Page 3: *"Furthermore, Regulation 5(e) of those Regulations requires that any medicinal product which is a Schedule 5 controlled drug (which includes medicinal products containing codeine) must not be accessible to the public for self-selection".* History has proven that it is very difficult for regulations to define what constitutes a display which does not provide self-selection access to potential purchasers of a given product. Retailers / manufacturers are devising a range of 'work-arounds' in order to defeat this code proposal. For a good example, visit the Unicare Pharmacy in Donnybrook, Dublin, which after a recent shop-fit has installed see-through perspex flaps on shelves for pharmacy-only sale OTC products displayed within the main body of the pharmacy. These flaps include the wording, in small print "Supervised sale only", as if the wording itself ensures compliance with that very provision. This regulation 5(e) provision is inadequate, and any new guidelines should attempt to remove any doubt as to what is intended, should loose all ambiguity and state words to the effect that all codeine containing pharmacy products shall be stored in the dispensary of a pharmacy, and shall not be visible to the public.	Noted The guidelines are to facilitate compliance with the regulatory provisions.

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	Commentary - Page 4 *"As a consequence of these provisions, any form of advertising of a medicinal product that is a controlled drug, that is directed at the public is prohibited. This would include any form of window displays, in-pharmacy promotional displays, promotional leaflets and shelf stickers."* The practice of manufacturers and wholesalers employing professional merchandising companies to ensure that Solpadeine and Nurofen Plus are actively merchandised is pharmacy is widespread. Some chains provide 'planograms' guiding store managers as to how head-office wants its Solpadeine products to occupy 5 shelf-facings, at eye level directly behind the OTC counter. I suggest that such visual display be also included in the above page 4 commentary. In fairness if section 2 of these guidelines are complied with unambiguously my concerns above will not apply as all codeine containing OTC products will be stored within the dispensary area of community pharmacies.	Noted.
	Commentary - Page 5 1(a): the only effective method this can be achieved with consistency, continuity and transparency is by ensuring that the provisions applying to record-keeping for prescription medicines are extended to codeine containing non-prescription medicines. Anything less smacks of a regulatory body which wishes to give the impression of concern and activity, while in actual fact, not being brave enough to enact guidelines which would yield defined controls, definite results, a defined difference to the public, standardizing pharmacy practice protocols across the profession in Ireland, and making the application of pharmacy practice easier in Ireland.	This is beyond the remit of the PSI. However each pharmacist may implement their own procedures to monitor the supply of these products.
	Commentary - Page 6 Regarding 3(b) and 3(c): Clause 3(c) contradicts clause 3(b), in that the only way 3(c) can be complied with is if the pharmacist interviews the patient directly. An interview by any other staff member "under the supervision" of the pharmacist will not satisfy. In fact, the knowledge required to be imparted to the patient by section 3 is so prescriptive as required by 3(a)-(i), compliance with this code can only be achieved if the patient is interviewed personally by a pharmacist.	Noted.
	Commentary - Page 7 Regarding section 4 (a) Over the years working in my community pharmacy we have tried to keep records of patients have had a record of repetitive use of	This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional

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	codeine. Such patients had been interviewed, with little or no success. In practice, what has happened is that patients when they find that they are under the glare of the spotlight in a given community pharmacy because their repetitive use of codeine has been identified, simply move and start purchasing in another pharmacy or 12. Section 4(b): now we're getting to something. A concrete direction from the PSI to pharmacists. The trouble is it really doesn't go far enough. I will explain in my next section on new proposal for OTC codeine control in Ireland. **B: A recommendation for a substantially changed guideline which would in my opinion offer a real opportunity for society to deal with reality of OTC codeine abuse and addiction in Ireland.** The stated aim of the guidelines published for consultation: The "background" preamble to the published guidelines contains, I presume, the aim of these codeine guidelines. "Consumption of quantities of these medicines in excess of the recommended dose, or over a prolonged period of time, may cause tolerance and dependence, as well as the risk of other adverse effects. Furthermore, the consumption in excessive quantities of 'combination products', i.e. those containing codeine and another analgesic such as paracetamol, aspirin or ibuprofen, also increases the risk of harm from these other substances." "This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products." The published guidelines will fall short of achieving this aim. **I suggest a new set of stated aims:** 1. To take cognizance of the anecdotal evidence of addiction of patients to OTC codeine products currently available only through community pharmacies in Ireland, and provide meaningful protocols for the dispensing of such products from Retail Pharmacy Businesses (RPB) in Ireland. 2. To retain codeine products as being OTC available answering a genuine health need, while at the same time ensuring a higher level of vigilance at the point of purchase to the benefit of the patient. 3. To provide a vehicle for the collection of codeine related data and ongoing review of same, which will in itself an act as an evidence base	obligations to patients seeking advice, guidance and assistance in respect of the use of these products and hence ensure more consistant practice in relation to these products. Noted Noted. See above comments.

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	for the development of codeine sale directives/regulations/codes into the future. **I suggest the following means to achieve these aims:** In order to achieve this purpose, there must be traceability concerning codeine products, from invoice to sale. Therefore, a. invoices containing codeine products would have to be retained for a period of 2 years following purchase (this is already a requirement by the revenue commissioners regarding taxation accountability) b. All sales of codeine containing products would have to be recorded with the relevant details – see details later. c. Records of such sales transactions must be collated centrally/nationally in order to provide data for statistical analysis and academic research to provide evidence for any further actions deemed necessary in the area of codeine. **Proposal** **A.** Non-prescription medicinal products containing codeine should be stored in a retail pharmacy business (pharmacy), in accordance with the legislative requirement that these products must not be accessible to the public for self-selection. They must therefore be stored out of patient view, in the dispensary of the pharmacy. **B.** The PSI will require that all requests for purchase of codeine containing products be interviewed personally by a pharmacist. Having interviewed the patient, the pharmacist will write a prescription in writing for the patient which will include the following details i. Name ii. Address iii. D.o.B iv. PPS No. v. Therapeutic indications – relief of pain in such conditions as rheumatic and muscular pain, migraine, headache, menstrual pain, toothache, backache and for symptoms of the common cold and influenza vi. Recommended duration of treatment following which medical advice should be sought. vii. Acknowledgement that the patient has been advised of the importance of adhering to the recommended dosage and	

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	duration of use. Patients should be informed that chronic use and consumption of quantities in excess of the recommended dose, or for a prolonged period of time, may lead to tolerance, psychological and physical dependence and may result in the development of symptoms such as restlessness and irritability upon cessation of this medicine. viii. Acknowledgement that the patient has been advised of the risks associated with overdose and/or prolonged use. ix. For products which also contain paracetamol or ibuprofen, acknowledgement that the patient has been advised that these substance have the potential to be harmful in overdose quantities. x. Acknowledgement that if patients experience the need to use codeine medicines over a prolonged period of time (i.e. more than 3 days) for pain relief or other effect, the patient is being referred forward be to a registered medical practitioner / HSE approved addiction councillor for appropriate advice. xi. Acknowledgement that the patient has been counselled in the course of each supply in respect of other potential adverse reactions or side effects, including nausea, constipation, dizziness and drowsiness (which may impair their ability to drive safely);regarding the contraindications for use, drug interactions, or existing medical conditions which may preclude the use of these medicines; the need for safe storage of these medicines. **C.** Following the consultation above and the decision being made to dispense a codeine containing OTC product, the details of the prescription will be entered on the patient medication record (PMR). Most community pharmacies in Ireland currently use computer software in order to record the complete patient medication history. Most pharmacies, however, only use this software to comply with the legal requirement for the recording of prescription-only items. I propose that codeine containing OTC products would be included in this requirement. Given the extensive search and statistical software available nowadays on pharmacy practice software, this simple act of requiring that all sales of codeine-containing products be recorded on the PMR would empower and a whole range of evidence-based analysis of codeine use in Ireland.	

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	D. This being done, all the information concerning codeine transactions in any given community pharmacy would be immediately available to officers of the PSI, HSE, the IMB, and indeed to academic researchers where required and authorized. As the Pharmacy Regulator will be aware, all community pharmacists holding contracts with the HSE must submit their end-of-month claims for reimbursement online to the Primary Care Reimbursement Service (PCRS). I propose, that for the purposes of centralizing and gathering information on the use of OTC codeine products on a national basis, one additional 'codeine' file would be compiled on individual pharmacy computers and sent to the PCRS on a monthly basis.	
	E. The PCRS would forward these files on a monthly basis to the PSI. This would serve to collate all information on codeine transactions within the RoI each month. Ongoing review of national codeine sales would provide evidence for future actions in this area.	Noted
	Other considerations: • The PSI should do everything possible therefore to enable an easy transition to this new culture of recording OTC codeine containing products as if they were prescription-only products. The PSI should, as already mentioned, initiate discussions with the main software developers, (Helix, McLernons, Prometheus, etc.,) and the computer section of the drugs reimbursements board of the GMS. Instead of the PSI requiring as on page 5.1(b) of the proposed guidelines that "a pharmacy specific policy addressing the supply of medicines containing codeine should be developed, with specific patient consultation protocols included", I suggest that the PSI themselves should develop these protocols which would include all of the requirements for compliance as laid out on page 6, section 3 (a)-(i), and serve as a checklist for practitioners to enable compliance. This would also standardize the practice across all of the pharmacies in Ireland so that patient recognition and compliance with these new codeine sales guidelines would be enabled. Having had these discussions, (involving the PSI, the IPU, the GMS, patients organisations) a date for implementation should be selected and a national information campaign launched leading up to the date of implementation In order to prepare both practitioner and patient and therefore ease the implementation and manage the change	Noted.

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	• An additional issue which should be considered by the PSI would be whether or not it should be necessary for pharmacies to retain all invoices pertaining to codeine purchases for possible examination. There has been a history in retail pharmacy of bonus-ing of both Nurofen Plus and Solpadeine, the biggest selling and best-known codeine containing OTC products. Manufacturing companies and pharmaceutical wholesalers try to increase their sales by offering preferential terms to pharmacies with the highest sales in such products. I believe that such incentives should be included page 7, section 6 of the proposed guidelines in that they constitute an unwelcome incitement to sell. This incitement to sell constitutes a conflict of interest between the pharmacist's Code of Conduct – especially Principles 1-3, which claim to hold the needs of the patient as the paramount professional purpose – and the desire to make the retail pharmacy business profitable. • There may be resistance from pharmacies reluctant to implement this much higher level of pharmacovigilence. For pharmacy owners, these new proposed guidance notes would involve significant work/time input from staff and would predictably result in a decrease in sales of codeine containing products, as a result of the deterrent that the interview procedure will cause to patients. The resistance to change might be mitigated by the HSE reimbursing pharmacists for recording the relevant data on patients PMR's and allowing central analysis of same. Bear in mind, there is already a proposal for extra work to be imposed on community pharmacy administration with the DoH announcement of the introduction of prescription fees for GMS patients. If there was a nominal fee paid per 'codeine entry' (whether dispensed on not) this would encourage the cooperation of pharmacists and allow for the development of a reliable codeine database for the RoI. • If being asked to refuse sales of codeine, pharmacists must have a national list of addiction councillors available to them in order to inform patients where next they might seek assistance. This list should be published and updated on both the PSI website and the HSE website. I'm sure the IPU would also provide a link to it. • Among the concerns of Irish community pharmacists is that patients not managing to receive codeine in one pharmacy, will travel on to the next pharmacy and the next, until their supply needs are met. Every community pharmacist knows that such 'codeine tourism' exists. If the PSI were to be able to collate a list of PPS numbers and patients who engaged in such a practice,	This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products and hence ensure more consistent practice in relation to these products.

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	warnings relating to codeine over-use / abuse could be attached to the PPS numbers of patients in a return file and sent back to pharmacies along with their usual GMS update file making them aware of repeat codeine abusers. This would close the pharmacovigilence circle, thereby making the aims of these guidelines meaningful. • An additional bonus to including OTC codeine on the PMR would be that the codeine entry would automatically be subjected to all of the usual drug interactions checks being implemented automatically by the software provider program. Indeed, I would not be surprised if the process of recording codeine on a regular basis was found by pharmacy practitioners to be so useful that they might start recording sales of *all* pharmacy-only OTC products on patient medication records (pseudoephedrine, anti-histamines etc.). Sections 4 and 5 of page 7 of the draft codeine guidelines can now become much more than PSI aspirations.	
39.	**An Bord Altranais**	
	An Bord Altranais is the statutory body which provides for the registration, control and education of nurses and for other matters relating to nurses and the practice of nursing. It sees its overall responsibility to be in the interest of the public. As the regulator of nurses and midwives it appreciates the opportunity to review and comment on the Pharmaceutical Society of Ireland's draft guidance on the safe supply of non-prescription medicines containing codeine. The draft guidance document for pharmacists appears to be comprehensive in its advice for the pharmacy profession for this important public safety and health care concern. The guidance information gives reference to the medicines and professional legislation which clearly details the regulatory requirements for the practitioner. The subsequent six points of professional guidance state the expectation of the PSI for retail pharmacy business/practice. The various issues addressed under point 3 – supply of medicines containing codeine by a pharmacist in a retail pharmacy business, and point 4 – suspected abuse and/or misuse; are critical in highlighting the significant issues of patient/consumer education and medication safety.	Noted These comments are welcomed

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	The interdisciplinary focus for healthcare provision in the community and acute care setting is mentioned in the document. An Bord Altranais advocates safe and quality medication management practices for all health care professionals and welcomes this guidance drafted by the PSI for its members. An Bord Altranais would like to highlight that the introduction of nurse/midwife prescribing and the continued expansion scope of practice for nurses and midwives in the provision of patient care may also influence the consultation/referral services and collaboration available to the retail pharmacist in providing health care and education to the patient. An Bord Altranais looks forward to the publication of the PSI's guidance on the subject of the safe supply of non-prescription medications containing codeine as it is important that this topic receive continued professional and public attention.	Noted Noted.
40. **Mary Berney**		
	I read about your new proposals vis-a-vis medications containing codeine for pharmacists in The Irish Times the other day. In addition to your proposals, I would like to suggest that codeine should not be prescribed/given/sold to those who are taking anti-psychotic medication, sleeping tablets etc. ever. I'd like to see a much greater awareness about the dangers of codeine, even when taken at normal levels – the packaging and advertising for codeine should change and contain clear warnings about the dangers of codeine mixing with other medications and being a factor which can cause sudden death. Doctors should warn patients that if they take certain medication (e.g. anti-psychotic medication etc.) they should not take codeine/paracetemol/ etc. as well. Further research should be done on the numbers of people who die each year with codeine in their bodies. If you wish to have further feedback on why I hold these views, please don't hesitate to contact me.	Noted These comments highlight the importance of counseling patients when supplying codeine medicines to ensure their safe use. Patients should be counseled in the course of each supply in respect of potential adverse reactions or side effects, including nausea, constipation, dizziness and drowsiness (which may impair their ability to drive safely). They should also be counseled, as appropriate, regarding the contraindications for use, drug interactions, or existing medical conditions which may preclude the use of these medicines. The need for the safe storage of these medicines should also be referred to.

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41. **Kathy Maher MPSI, Donore Pharmacy, Co Meath**		
	I am writing to express my views about on the draft recommendations by the PSI on the sale/supply of codeine based product.	
	I agree that codeine based products should not be for self-selection though I would disagree that visual display would be classified as self-selection. Certainly the criteria for sale should be strictly adhered to and pack sizes reduced perhaps further.	The intention here is to place the products under the direct control of the pharmacist in a manner which would require his or her direct involvement in the supply. This action would enable the pharmacist to exercise their professional judgement as to whether the supply is appropriate or not and intervene professionally in the supply as necessary. It is worth noting that the Pharmacy Act 2007 and the RPB regulations require that all medicines be supplied by or under the personal supervision of a pharmacist and that all non-prescription medicines be the subject of appropriate counselling (regulation 10). In addition because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine) further restriction are imposed by the regulations which require that those products (CD medicines) would not be accessible to the public for self-selection (regulation 5(e)). When all of these requirements are taken into account, the outcome is that the CD products concerned may only be supplied in a manner where the advice of the pharmacist is obtained and where the potential for the pharmacist professional intervention is most likely to be achieved.
	Codeine product sales should e tracked and if abuse I suspected-a tighter regulation in the management of these patient, liasing with general practitioners more. Perhaps as series of CPD events through joint initiatives between ICCPE, IPU and PSI could help address some of these issues.	Noted. It is envisaged that the competent pharmacist should be in a position to address all of these issues and that the health services and others involved in this area including those involved in continuing education of health care professionals should ensure that there is a full understanding of the problems, the services available and the way in which those services may be accessed.

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	I would be apprehensive about making these products subject to prescription control. My pharmacies are close to the Northern Ireland border and I have experience of a large number of patients that currently travel North to purchase medicines available across the counter there and not here-Emergency Hormonal Contraception being one of the biggest. A lot of my NI pharmacy colleagues would also talk about the amount of cross border sales they have particularly on weekends. This could be an issue that could be addressed with PSNI?	Noted
	In terms of codeine-based product sale/supply, I would anticipate that a new regulatory category could be introduced-a pharmacist prescribed category, and have possible paper trail with that. Or a 'pharmacist personal sale'.	Noted. The existing legislation, the Regulation of Retail Pharmacy Business Regulations 2008 (S.I. No. 488 of 2008), deems medicinal products containing codeine (CD5) medicines not suitable for self-selection by patients..Therefore these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control and their professional judgement over their supply.
	Codeine addiction is well documented and anecdotal evidence is also there. The fact that it is being addressed by the PSI is broadly welcomes and highlighting this in the media (as the IPU have done recently) will also help. I think this is best tackled with the joint approach of the IPU/PSI, then rollout joint media campaigns.	Noted
42. **Uniphar Plc**		
	Uniphar Plc, who market the product Uniflu Plus recognise the importance of ensuring the safe use of analgesic products containing codeine. We believe the safety issue surrounding the misuse of Codeine containing products is related specifically to the overuse of Pain Killers containing Codeine. Uniflu Plus is specifically indicated for the treatment of Cold and Flu and, as such, is intended for use over a short period of time. There is no evidence of the abuse of Uniflu Plus and this is supported by the clear seasonal pattern of the sales of the product. These are attached.	Noted

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	In addition we can confirm from checking our medical information enquiries log that adverse reactions are extremely low. Available only from Pharmacies, Uniflu Plus is a cost effective and accessible medication used across all socioeconomic groups. The seasonal sales patterns to community pharmacies in different locations consistently support this point of view. Appropriate local community based treatment options such as Uniflu Plus obviate the need for flu related GP consultations in many instances. Effective local symptomatic relief discourages patients from moving about and reduces risk of spread of infectious viral illness. Cold and Flu over the counter products are not marketed as 'Pain Killer' products. In most cases these products are grouped together and displayed as a discrete section within the OTC area of pharmacies. Some pain killer products have been abused for some time in the Irish territory and are broadly known to have an abuse potential. Policy changes relating to the use of codeine may disincline the appropriate use of flu treatments by bona fide flu patients and actually promote the misuse potential to addicts and potential addicts. Increased patient anxiety related to the use of flu products may precipitate increased traffic to GP surgeries, as patients seek reassurance related to these changes;- and at a time when the public health services are already struggling to cope with seasonal illness. It is for these reasons that we believe the new guidelines should not apply to Uniflu Plus We feel this is an unnecessary imposition. Uniflu Plus contains: • Paracetamol 500mg • Diphenhydramine Hydrochloride 15mg • Phenylepherine Hydrochloride 10mg • Caffeine 30mg • Codeine Phosphate Hemihydrate 10mg • Ascorbic Acid (Vitamin C) 300mg Attachments. Patient Information Leaflet – Uniflu plus. Seasonal Sales trend 2008/09.	The existing legislation, the Regulation of Retail Pharmacy Business Regulations 2008 (S.I. No. 488 of 2008), deems all medicinal products containing codeine (CD5) medicines are not suitable for self-selection by patients. Therefore these products have been authorised and placed on the market and regulated in a manner which authorises pharmacists as the health care professional that is responsible for exerting control and their professional judgement over their supply. It is not suggested that these products would cease to be available. What is envisaged here is that there would be a more direct pharmacist involvement in the supply of codeine medicines with a view to assuring their rational use. These products will be supplied when the pharmacist is satisfied that, in the exercise of his or her professional judgment, the supply of such a medicine is the most appropriate therapy available at the time and that such supply is in the best interest of the patient.