

**Submissions received during public consultation on the Draft Guidance on the Delivery of Prescription-only medicines from a Retail Pharmacy Business**

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	SUBMISSION	PSI RESPONSE	
1.	Ryan's Pharmacy Kickham Street Thurles		
	<p>Firstly I would like to separate the delivery of POM into two categories:</p> <p>a) delivery from a community pharmacy to a patient who lives in the nearby area and therefore has access to the services of the pharmacy on a continual and ongoing basis with short notice.</p> <p>b) delivery from a pharmacy located in an area outside the community to which the patient does not have ready access e.g. countryside delivery using courier services etc..</p> <p>In the first instance I deliver to a nursing home and to patients who cannot make their way to the pharmacy as the need arises but I do not deliver to patients outside me own area or to people whose medical history I do not know.</p> <p>I find it strange that you might be considering a situation where the local service can be bypassed and the delivery of medicines from long distances. Ireland has a a huge number of pharmacies and one of it's strengths is the availability of local choice. Local pharmacies know their patients and their needs and can respond quickly and effectively to their changing circumstances. In a situation where a patient is using a remote pharmacy for its regular and on-going medication and then uses a local pharmacy to implement changes or for one off medication seems to me to be a very unsafe practice due to lack of past drug history and patient understanding. In practice patients want to implement changes to medication immediately which cannot be done using a remote pharmacy. The</p>	<p>Noted. None of this is disputed.</p>	

	<p>regularity of medication changes increase with a persons age and infirmity.</p> <p>Your remit is to look after the interest of the patient. As patients get older (no matter what their level of education) their use of local services increase. There is no substitute for local services and when the time comes the understanding and in many cases friendship and trust that has been built up over the years between patients and their local pharmacist becomes invaluable. Your proposal ignores this reality and puts at risk local services for virtually no gain.</p>	
<b>2.</b>	James Cassidy, Siopa an Cheimiceora Gaoth Dobhair, An Bun Beag	
	<p>Further to the recent invitation for submissions on draft guidance for delivery of prescription medicines I would like to make the following points :</p> <ol style="list-style-type: none"> <li>1) In their own draft guidelines the PSI accept that the <b><i>“It can be concluded that ‘Supply by mail order’ is prohibited in Irish law as it is considered that personal face-to-face interaction between pharmacists and their patients regarding prescription-only medicines is the most appropriate means by which these important medicines are supplied to patients. “</i></b></li> <li>2) The draft guidance also clearly states what is prohibited <b><i>“Any supply made (i.e. each and every supply) of a prescription-only medicine to a patient, after solicitation of the custom by the pharmacist and without the pharmacist and patient and/or carer or representative being simultaneously present and where the pharmacist and patient use a means of communication at a distance</i></b></li> </ol>	<p>Noted. In view of the fact that activities referred to are prohibited the material has been removed.</p>

***(e.g. telephone, email, text message, video conferencing etc.) to convey both the custom solicitation and the order for the supply “***

I must point out that it is physically impossible for a pharmacist to provide the personal face-to-face interaction with patients or their carers where a remote delivery service is used. Permission of such a service is an acceptance that this is no longer a requirement which would be a gross abdication of the role of the PSI in ensuring the highest standards within our profession with a view to optimising patient safety.

I would contend that the only possible way a delivery service could meet the needs of the patient would be to have it performed by a qualified pharmacist who had been personally involved in the checking and dispensing of the original prescription.

I would further point to the fact that mail order is prohibited in any case where supply has been solicited – If this was to be the case then any pharmacy involved in such a service would have to give a formal undertaking not to advertise or solicit such custom. Recent events where certain operators have advertised online , instore and in the media show how pointless any such aspiration would be. Even if such commitments were made , the constant media briefing and covert advertising / placement of such a service would be guaranteed to render any such

Noted. By virtue of regulation 9 pharmacists have an overriding obligation to review the prescription and counsel patients for every prescription received and supply of medicines made.

Noted.

commitments worthless as they would be used to evade such accusations on technicalities. Any rational assessment of potential delivery services will conclude they will be advertised and solicitation of custom will be necessary if the venture is to have any chance of success – the commercial entities behind all such ventures also know this.

E.G. [REDACTED]  
[REDACTED]  
[REDACTED]

I further note that from the pharmacy act :

28.— The conditions referred to in section 26 (1(b) are—

(a) that the part of the business that consists of the management and administration of the sale and supply of medicinal products is under the personal control of a registered pharmacist who has a 3 year minimum post-registration experience and who has provided the registrar with a statement—

It is impossible to separate the delivery chain i.e. courier company , from “ ***the part of the business that consists of the management and administration of the sale and supply of medicinal products.***” Clearly this cannot be under the direct supervision of the registered pharmacist , and would also be impossible for officers of the PSI to inspect should any concerns arise. Consequently I again

Noted. Whatever system of arranged delivery is used, the pharmacist retains full responsibility for ensuring that the system used is suitable having regards to the nature of the medicines concerned and the integrity of the supply chain through which the medicines are delivered.

<p>return to the view that the only way a delivery service can be acceptable is if it is always carried out by a qualified pharmacist who has been involved in the earlier dispensing process.</p> <p>Furthermore , no current delivery service ( including current wholesaler services to retail pharmacy ) has a record of the accuracy required for patient prescription services. There are also major issues around the ability of any courier company to identify the recipient of any medicine delivery is a legitimate patient and I have no faith in the ability of any courier company to do this adequately.</p> <p>I would also ask the PSI to consider the practicalities of an organised delivery service in the real world. Any large scale operation with a formal delivery service will be an entirely commercial operation , designed to offer large scale distribution of medicines for a profit. We have already seen many examples of inappropriate quantities of prescription medicines delivered and such a service will simply not be viable for multiple deliveries of low value items. For this reason it is certain to drive supplies of three and six month supplies which is undesirable as it reduces the Pharmacist – Patient interaction which often picks up issues which require changes to medication and/or referral of patients.</p> <p>Finally , any permission of a courier or other prescription delivery service ( unless carried out by qualified pharmacists ) will open the door for mail order pharmacy which has been resisted for good reason and is prohibited by Irish law. The PSI have difficulty carrying out the required inspections of current pharmacy services , and simply would not be equipped to inspect ,monitor or control such</p>	<p>Noted as above</p> <p>Noted. The important role of the pharmacists is recognised throughout and the ultimate guidelines will reflect this.</p> <p>Noted. By virtue of the prohibition of supply of prescription-only medicinal products by mail order, contained in regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), the question of supply by mail</p>
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	<p>dispensing services adequately. This gap in the regulatory process , added to the inherent patient safety issues from widespread delivery services mean that the PSI must resist any attempt to legitimise any such delivery service.</p> <p>We have enough reports from the IMB about the current problem with illegal mail order supplies of medicine into the country without opening another Pandora’s box.</p> <p>I have attached a copy of an earlier complaint made to the PSI re advertised delivery services and the response received.</p> <p>I would be grateful if my communication could be circulated to all of the members of the council of PSI , and for an acknowledgement of receipt of my submission.</p>	<p>order and mail order pharmacies does not arise.</p>
<b>3.</b>	<b>David Burke</b>	
	<p>I would have serious concerns about delivery of medicines in this manner, such as courier type services. If this model is permitted mass delivery of medicines could occur from a central warehouse with a follow up phone call to advise patients. Direct face to face</p>	<p>Noted with thanks.</p>



	<p>contact is necessary to counsel patients on their medicines. Pharmacists should not be put in the position to decide whether delivery like this is appropriate, the pharmacists first concern is their patients and most if not all agree that face to face counselling is the safest way to practise pharmacy. With repeat prescriptions this is equally necessary to ensure patients are taking their medicines as required and are not experiencing any adverse effects. Also one could envisage mass stockpiling of medicines if repeat prescriptions are being delivered across the country without face to face consultations with pharmacists. The draft guidance states that there is increased risk of errors with delivery services as the patient does not present in the pharmacy, I agree and believe that to protect the public they should not be allowed. Thank you for the opportunity to provide feedback on the consultation process for delivery of medicines.</p>	
4.	<p><b>Gary O'Brien, Pharmacy Student</b></p>	
	<p>I am a fourth year pharmacy student in UCC and am writing to you about the delivery of medicines issue.</p> <p>I really do believe that the legislation already in place where by a pharmacist is the only person allowed deliver medicines to a patient is the best and safest method. I feel the proposal of leaving delivery men/women continuously delivering medicines to patients ( especially on a large scale ) dangerous and quite frankly, a retrograde step for the pharmacy profession. Pharmacists know medicines are sensitive things hence why some are subject to prescription and other restrictions from the public. As you know,</p>	<p>Noted. Many pharmacies have traditionally provided a delivery service for dispensed medicines whenever this was necessary in the interest the health, care and convenience of the patient. This guidance document therefore sets out certain of the precautions that might be taken in order to assure the security and safety of delivery systems from the point of view of the patient.</p>

	<p>some medicines have special storage conditions and there are certain things about specific medicines that pharmacists would only be aware of. Pharmacists currently spend over 5 years studying medicines to deliver them in a safe and appropriate manner to patients. By permitting anyone to supply medicines, it really is leaving the patient at risk. Who knows what short cuts or neglect a delivery man might avail of on delivering medicines with an economic point of view in mind. No one understands how important medicine delivery is like a pharmacist and if this is allowed, it could be the next big "pharmacy sector" mistake waiting to happen at the cost of patient safety.</p> <p>Also, not to mention the raids that may occur on delivery vehicles for the tablets they may contain.</p> <p>I really hope no change occurs in the legislation. What would be the point of a student pursuing such an respected profession when its controlling body is decreasing its status.</p>	
5.	<p><b>Irish Medicines Board (IMB)/ Health Products Regulatory Authority (HPRA)</b></p>	
	<p>In response to a request from the Pharmaceutical Society of Ireland (PSI) for comments to its recent draft guidance document on the delivery of prescription-only medicinal products from a retail pharmacy business, the Irish Medicines Board (IMB) wishes to make the following comments. From the outset, however, the IMB is cognisant that the interaction between the pharmacist and the patient in supplying medicinal products is a practice issue under the auspices of the PSI.</p>	<p>Noted with thanks</p>

	<p><i>Comment 1</i></p> <p>The title of the guidance document and the intended audience, together, could give the impression that the focus of the guidance relates to the ethical and practical considerations a pharmacist should take into account for the physical delivery of prescription-only medicinal products to patients. This would be consistent with previous Practice Guidance documents issued by the PSI in both anticipation of and response to emerging issues. The focus of the document, however, seems to be placed on a discussion of practice and ethics issues relating to supply by mail order rather than addressing the delivery process to ensure that medicinal products are supplied safely and in a manner that ensures efficacy is maintained.</p> <p><i>Comment 2</i></p> <p>In the boxed section <i>‘What is prohibited under ‘supply by mail order’</i> on page 2, it is stated that pharmacists <i>‘should be circumspect when offering a delivery service to patients’</i>. It is the offer of prescription-only medicinal products and not the offer of a delivery service that is covered by the prohibition of supply by mail order, as detailed in Regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulation 2003, as amended.</p> <p><i>Comment 3</i></p>	<p>Agreed. The guidance document has been revised to take account of this including a change in the title to refer to the delivery of all dispensed medicines from a pharmacy.</p> <p>Noted. Since the activities referred to in this box are prohibited, this material has been removed.</p>
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	<p>Following a brief review of how a similar issue is dealt with in the UK, it is clear that major pharmacy groups offering an internet service advertise its availability but not a price list of prescription medicines to the public. This would appear to be consistent with the provisions of Directive 2001/83/EC, as amended, regarding the prohibition on advertising of prescription medicines but enables a delivery service to be advertised by pharmacies. Perhaps the document could be reviewed having regard to this.</p> <p><i>Comment 4</i></p> <p>It may also be appropriate to address the situation of counselling the patient when a prescription is renewed or a revised prescription is written. As acknowledged in our first paragraph above, this is a practice issue that is entirely within the remit of the PSI.</p> <p><i>Comment 5</i></p> <p>In relation to a delivery service, we fully endorse the need to ensure its security and that the labelled storage conditions are observed throughout and that the integrity of the product is ensured. Should products requiring refrigerated storage be delivered in this way, it is essential that validated transport systems are used and that preservation of the required storage conditions is verified in each case.</p>	<p>Noted. There are differences between the position in the UK and in this country arising out of the nature of the health service entitlements under the NHS where price is not important. Furthermore by virtue of 86.2 of Directive 2001/83/EC and the national implementing regulations on the advertising of medicines factual information regarding the prices of prescription-only medicines may be lawfully displayed.</p> <p>Agreed, this has been addressed in the guidelines.</p> <p>Agreed</p>
6.	<b>Brodericks Pharmacy, 84 Barrack Street, Cork.</b>	
	DRAFT GUIDANCE ON THE DELIVERY OF PRESCRIPTION ONLY	

<p>MEDICINES FROM PHARMACIES</p> <p>“We are committed to the safety of the Patients and the Public as our highest priority” - PSI</p> <p>The PSI has requested submissions from the public and pharmacists re the above. Here are some of the points I feel very strongly about.</p> <p>☐ The concept of delivering medicines by anyone other than Pharmacists themselves falls very far short of giving the best care and advice to patients.</p> <p>☐ ..From the code of conduct that we sign each year; "the health, well being,care and safety of their patients is the primary concern of every pharmacist"</p> <p>How can you fill this obligation if you don't meet the patient?</p> <p>☐ There is also the opportunity for a Patient to get multiple supplies more easily by attending more than one prescriber, and using more than one remote Pharmacy to deliver six months worth of medication. We all have had instances of customers who shop around to more than one Prescriber and more than one Pharmacy concurrently. More often than not, we have instincts in these situations, when faced with the Patient and script that all may not be as it seems. Remote supply would very much facilitate this type of patient in their efforts to have more medication in their possession than is safe.</p> <p>☐ A Pharmacist should ensure that suitable controls and accountability mechanisms are in place, appropriate to the area of practice, to govern the management of the supply and distribution of</p>	<p>Noted</p> <p>Noted, the requirement concerned is both a regulatory and a professional one which must be reflected in any system of supply.</p> <p>Noted</p> <p>Noted, the pharmacist is responsible for the decision to supply in</p>
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<p>medicinal products which have a potential for abuse and dependency. (from the code of conduct)</p> <p>How can a pharmacist supervise his/her Patients Controlled drugs, sleeping tablets, benzodiazepines, mood altering drugs etc. if they offer 6 months supply by courier?</p> <p>☒ Increased likelihood of Polypharmacy. Courier pharmacy doing deliveries and local Pharmacy doing emergency supplies. Neither knowing the full treatment of the Patient.</p> <p>☒ Pharmacies, their staff and premises are among the most strictly regulated anywhere in the world. We are required to monitor our dispensaries temperature, humidity, prove cold chain storage and provide garda verification for the storage of our controlled drugs. Would a courier be able to operate to those standards?</p> <p>☒ OTC drugs like Solpadeine and Nurofen plus have guidelines attached to them so that they are NOT over-used and abused. (3 days at a time....One pack only of 24 tablets) How then can it be acceptable to allow the dispensing of 6 months of any Prescription medicine to patients delivered by courier? The propostion is dangerous and ludicrous.</p> <p>In conclusion I would implore the members of the Council who have resposibility for this matter to ensure the safety of patients, and continue with the UNDERSTOOD POLICY to date that Medicines cannot be delivered by Mail order/Courier or any other means which dilutes the professional input of the Pharmacist</p>	<p>the first instance and it would not be appropriate for such drugs to be supplied in the manner described.</p> <p>Noted. See above.</p> <p>Noted. Couriers provide the method of delivery to standards required by the pharmacist.</p> <p>Noted. See above.</p> <p>Noted. The PSI can only go as far as the law permits and agreed professional standards support.</p>
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	<p>in making sure the Patient gets the right drugs at the right time and in the correct quantity.</p> <p>Anything less will dumb down the profession and ultimately result in a decreased standard of Patient care,</p>	
7.	Michael Tierney, Tierney's pharmacy, Rathdrum, Co. Wicklow.	
	<p>Chapters.</p> <ol style="list-style-type: none"> <li>1.. About me.</li> <li>2.. What do pharmacists do?</li> <li>3.. Do I do deliveries?</li> <li>4.. Nursing/residential home guidelines.</li> <li>5..Currently what is happening nationally?</li> <li>6..The dangers of courier deliveries. <ul style="list-style-type: none"> <li>A..Delivery of large amounts at a time.</li> <li>B..Delivery by courier and other non-qualified staff.</li> </ul> </li> <li>7..Recommendations.</li> </ol> <p><u>About me.</u></p> <hr/> <p>My name is Michael Tierney. I am a qualified pharmacist and have over 35 years experience as a pharmacist. During that period I have worked as an employee pharmacist, a locum pharmacist and an</p>	

<p>owner-contractor pharmacist. I have also filled the roles of supervising pharmacist and superintendent pharmacist.</p> <p>In addition I have a Diploma in Pharmacy Management and am the author of a book titled “Pharmacy Business Management” I have had a number of articles published in the IPU review and I am part of a team that designed and implemented the new VAT scheme for pharmacy. Last year I was presented with the “Helix Excellence in Community Pharmacy award”</p> <p><u>What do pharmacists do?</u></p> <hr/> <ul style="list-style-type: none"> <li>*Pharmacists dispense prescriptions.</li> <li>*Pharmacists check that the prescribed medications are suitable for the patient.</li> <li>*Pharmacists check that the dosage of prescribed medication is correct.</li> <li>*Pharmacists check the prescribed medication for interactions that may be on the current prescription and for possible interactions from any other medication that the patient may be on.</li> <li>*Pharmacists explain the purpose of the prescribed medication to the patient.</li> <li>*Pharmacists explain the prescription directions to the patient.</li> <li>*Pharmacists explain to the patient how to use their medication. eg a pharmacist will explain inhaler technique to a patient.</li> </ul>	<p>Noted.</p> <p>Noted</p>
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<p>*Pharmacist will advise their patients of things they should and should not do. eg Patients on Warfarin should be advised not to use Miconazole products such as Daktarin oral gel.</p> <p>eg. Pharmacists advise their patients on Statins who are prescribed certain anti-biotics to stay off the Statin whilst they are on the anti-biotic. This often occurs if a patient sees an emergency doctor who may not be aware of the patient's other medication.</p> <p>*Pharmacists are available to answer any patient queries or questions. This may not always happen but the pharmacist should always be available to help the patient.</p> <p>*Pharmacists explain possible side effects to patients.</p> <p>*Pharmacists explain possible interactions to patients.</p> <p>*Pharmacists check for errors on prescriptions.</p> <p><u>Do I do deliveries?</u></p>	<p>Noted.</p>
<p>Yes I occasionally do deliveries.</p> <p>If I am short of a medication I may deliver the shorts to a patient. Some local patients are infirm and in those cases I would also do deliveries.</p> <p>I think it is necessary that on occasions like the ones I have just described that pharmacists be allowed to do local deliveries. My other pharmacist or myself always do these deliveries ourselves. All our deliveries would be local and would be completed by a</p>	<p>Noted. These are all good practices.</p>

<p>pharmacist.</p> <p>It would be my recommendation that if deliveries are to take place that they should be local and should be done by a pharmacist.</p> <p><u>Nursing/residential home guidelines.</u></p> <hr/> <p>My understanding of the guidelines for drug deliveries to nursing/residential homes is that all such deliveries should be made by a pharmacist. The reasoning for this is that a pharmacist must be able to advise and help the patients in such a home. If the patients are unable to understand such advise then the pharmacist must advise the nurse in charge. In cases like this the pharmacist must discuss side effects, interactions etc with the nurse in charge.</p> <p>In my opinion this recommended pharmacist delivery of drugs to nursing/residential homes is correct and is in the best interest of the patient.</p> <p>I believe that the requirement for delivery of drugs in the regular community should be the same. ie delivery by a local pharmacist locally.</p> <p><u>Currently what is happening Nationally?</u></p> <hr/> <p>Some pharmacies are doing drug deliveries by courier and by delivery van. Most of these deliveries are by non-qualified staff.</p> <p>Some pharmacies are offering to and delivering six months supply</p>	<p>Noted.</p>
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<p>*The presence of a large amount of drugs in a household may be tempting to children.</p> <p>*the presence of a large amount of drugs in a household may be tempting to those suffering from depression or from suicidation tendencies.</p> <p>*the storage conditions of 6 months supply of medication in a household may not be correct. (Temperature, fridge control, light sensitive medication, humidity and security of drug storage in the home).</p> <p>*the prescribing Doctor may wish to change either the medication or the dosage of that medication.</p> <p>*Patients may think that they can return this medication for credit.</p> <p>*A pharmacist must promote compliance in patients taking medication. Compliance is hard to promote if the patient has 6 months supply of medication in the home.</p> <p>* There are logical reasons for the restrictions in the sale of Paracetamol. Why would it make sense to restrict the sale of Paracetamol and allow the 6 month supply of prescribed medication by courier or remote supply.</p> <p>*When suicides and accidental poisoning of children increases due to the widespread availability of 6 months supply of drugs in the home, I want to be able to say that I tried to stop it. The responsibility will be with the PSI, both council and executive. I don't want to take the responsibility of the accidental death of</p>	<p>Noted. Adherence to the guidance should prevent issues in relation to inappropriate supplies being made.</p>
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even one child.

\*Drugs are not sweets. In fact nobody would purchase 6 months supply of sweets at a time.

\*The supply of 6 months at a time gives the impression that all medicines are safe. Medicines are not safe; all medicines have interactions and side effects and dosage limits.

B..Delivery by courier and other non-qualified staff.

\*A medication delivery by a courier means that the patient is less likely to have received advice about their prescription.

\*Drug interactions may not be picked up if a patient uses 2 different pharmacies. ie a local pharmacy and a courier pharmacy.

\*A local pharmacy being used for emergency supply may have no knowledge of the content of the courier delivery.

\*Deliveries fall well short of the ideal of best professional care which a pharmacist provides to the patient or to the patient's carer.

\*Drugs may be left with a child, a neighbour or even in a box beside the front door.

\*The health, well being, care and safety of their patients is the primary concern of every pharmacist. These obligations are not being fulfilled by courier delivery using non-professional staff.

\*The practice by a pharmacist of her/his profession must be

<p>directed to maintaining and improving the health, wellbeing, care and safety of the patient. A pharmacist must employ her/his professional competence, skills and standing in a manner that brings health gain and value to the community and the society in which she/he lives and works.</p> <p>A patient is a person who stands in such a degree of relationship to a pharmacist that the pharmacist ought to reasonably apprehend that such a person's health, well being and care are likely to be affected by the acts or omissions of that pharmacist.</p> <p>Does remote or courier dispensing fulfil the duties and obligations of the pharmacist to the patient. I believe that remote dispensing does not fulfil the obligations of the pharmacist to the patient.</p> <p>*A pharmacist must ensure that their professional judgement is not impaired by personal or commercial interests including incentives, targets or similar measures.</p> <p>In dealing with patients we cannot allow commercial interests to supersede our duty of professional care for the patient. I believe that the only motive for courier deliveries is commercial. There are sufficient pharmacies nationwide to allow for universal local access to medication.</p> <p>*Whilst some patients may not wish to discuss their medication, they should still have the opportunity to raise a query with a pharmacist on each dispensing. Courier delivery by a non-pharmacist removes that opportunity.</p> <p>*A pharmacist should ensure reasonable care and expertise is</p>	<p>All pharmacists must in all areas of their interactions with patients and the public uphold all aspects of the Code of Conduct, and primarily maintain and promote the health, care, safety and wellbeing of patients and the public.</p> <p>Commercial incentives</p>
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<p>employed before providing a product or service. Courier delivery by a non-pharmacist does not provide care and expertise to the patient.</p> <p style="text-align: center;">*The following are taken from the Code of Conduct.</p> <p>The pharmacy act 2007 specifies that pharmacists act in a manner that is focused on the safety and interests of their patients.</p> <p>A pharmacist must ensure that the health of the patient is their primary focus. (from the code of conduct)</p> <p>A pharmacist must be cognisant of the well being of the patient. (from the code of conduct)</p> <p>A pharmacist must endeavour 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. (from the code of conduct)</p> <p>A pharmacist must provide a proper standard of practice and care to those for whom they provide professional services.(from the code of conduct)</p> <p>A pharmacist should encourage the rational and proper use of medicines. (from the code of conduct)</p> <p>These duties and obligations to the patient cannot be fulfilled if the</p>	<p>In the provision of any service to patients pharmacists must be mindful of their responsibilities under the Code of Conduct, in particular their responsibilities under Principle three to 'Ensure that their professional judgement is not impaired by personal or commercial interests including incentives, targets or similar measures.'</p>
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	<p>pharmacists.</p> <p>5..Local delivery of drugs and medication should be allowed by pharmacists.</p> <p>6..Local should be defined as within 10 kilometres of the pharmacy. Exceptions only with the written approval of the PSI in rare cases.</p> <p>7.. Delivery of drugs and medication that originate outside the jurisdiction should not be allowed. This means that a foreign pharmacy should not be allowed to prepare patient prescriptions which are subsequently going to be relabelled by a domestic pharmacy.</p> <p>8..Local deliveries only.</p> <p>9..A Pharmacist must do the deliveries.</p> <p>10.. Local delivery of medication by a pharmacist must not be any more than 28 days supply at a time.</p> <p>Thank you for allowing me to make this submission. I honestly believe that courier delivery of up to 6 months supply of medication is not in the interest of patients. I honestly believe that pharmacists only, should make local deliveries in the interests of patient safety and well being.</p>	<p>choice that determines what pharmacy a patient wishes to attend.</p> <p>Noted.</p>
<b>8.</b>	<b>David Jordan MPSI</b>	

Submission dated 28/5/14

The opening paragraph states that “The delivery of medicines has always been permitted”. I would hold that this statement is inaccurate in so far as that the delivery of prescription only medicines has never been expressly permitted nor has it never been expressly forbidden. This changed with Regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003.

From the draft guidance there are three elements that define a supply by mail order.

Firstly there must be “after solicitation of custom by the supplier.” According to Merriman Webster to solicit is to ask for. In this instance it would be to ask for custom. This covers all forms of advertising. So that once a pharmacy has used any form of advertising then it would meet this requirement. The definition in the regulation does not require the addition of a delivery service to the solicitation of custom to meet this definition.

Secondly the requirement that “any supply made,.....without the supplier and the customer being simultaneously present” can only be met by the customer (the patient) or their carer being physically present in the pharmacy. The supplier in every instance is the Retail Pharmacy Business (RPB). This is the entity in law that receives payment for the prescription. The Pharmaceutical Society of Ireland (Retail Pharmacy Businesses) (Registration) Rules 2008 states that “premises”, in relation to a retail pharmacy business

Noted. Pharmacists have been facilitating patients by arranging the delivering of dispensed medicines from their pharmacies for many years.

Noted. Since the activities referred to in this section is prohibited, this material has been removed.

means a fixed premises,

That is to say that by the supplier the regulations imply a fixed premises.

I would take this to mean that a RPB may only operate and dispense prescription only medicines (POM) from a fixed premises. Best practice dictates that transfer of a POM from the Pharmacy to the patient if not carried out personally by the pharmacist should be carried out under their direct supervision. This cannot be done at a distance. If there was to be a transfer to the patient outside of the RPB then it would have to be carried out with a pharmacist employed by the RPB physically present so that he/she can perform this duty personally or directly supervise this operation.

The physical presence is required because of the third element “any supply made,.....using a means of communication at a distance,..”

If the pharmacist is physically present then communication is not at a distance and the third element is not met. My interpretation of this is that if a pharmacist is physically present when transfer takes place outside of the fixed premises then this transfer does not meet the definition of “Supply by mail order” in the regulations. If transfer of POM occurs without a pharmacist being present then any transfer of POM outside of the fixed premises of the RPB meets the definition of mail order pharmacy.

There will always be instances where it is in the patients best interests to have the medicine delivered to their home. But in these instances to ensure best practice and to meet the requirements of Clause 9 this should be carried out by the pharmacist or a pharmacist employee of the RPB. And because of this these situations should be the exception rather than the standard practice.

The regulations are silent in respect of Nursing Homes and other institutions. I would see these as a different case as here transfer is made to another healthcare professional. However as outlined above if these transfers are carried out by a pharmacist employed by the RPB then there should not be any issue.

*Submission dated 9/6/14*

Traditionally delivery of prescription only medicines (POM) would have been understood to mean delivery within a local area. This has changed recently with the advent of the growth in nursing homes and other institutions with a large number of inmates who require POM. Many of these are being serviced from locations which are some distance from the institution. Also we have recently seen the development of a discount model of pharmacy offering delivery services nationwide. On as an aside I note that this pharmacy has advertised that their delivery service has the PSI's imprimatur. Despite requests for clarification on this matter the PSI has remained silent.

As outlined in my first submission it is my opinion that any delivery

The PSI considers that the optimal and safest way for prescription-only medicines to be supplied to patients, is through direct supply to the patient and/or carer following a face to face interaction between a pharmacist and the patient in the pharmacy. However it is acknowledged that it may not always be practical for patients or carers to attend the pharmacy and in some circumstances it may be appropriate for medicines to be supplied by means of delivery to the patient at the patient's residence.

Patients in residential care are entitled to expect the same standard of care as any other patient with respect to delivery services. The PSI has published specific guidance on the care of patients in Residential care/nursing homes.

Noted. PSI must act in accordance with current legislation, there is no legal basis in any area of medicines or pharmacy legislation to restrict delivery to within a local area. It is patient choice that determines what pharmacy a patient wishes to attend.

<p>service which is not carried out by a pharmacist in person meets the definition of “Mail Order Pharmacy” as laid down in the 2008 regulations. Not with standing this I wish to outline the reasons why I feel that delivery by anybody but a pharmacist or at a great distance can result in a poor outcome for patients.</p> <p>It would very difficult to ensure that the patient received proper advice about their medication. Presuming that some counselling was offered via telephone for instance it would be impossible to give proper directions on inhaler technique for instance. All the more so with the multiple types of inhalers now available. Also it would be important to indicate the correct amount of a topical preparation to be applied and where it should be applied. This is of particular importance when dealing with steroid creams.</p> <p>It would be unlikely that there could be timely delivery of medications which would require immediate commencement. Short course antibiotics are the first that spring to mind. Similarly additional or inhalers of a higher strength for exacerbation of various pulmonary conditions. Also anxiolytics for patients who are undergoing a crisis. Presuming that it may be permissible to dispense against a faxed copy pending receipt of the original prescription there would be a significant time delay in delivery to anywhere but local addresses. This presumes that the patient would have access to a fax machine and that confidentiality could be guaranteed at both ends. In all but exceptional cases dispatch of the POM would need to be withheld until receipt of the original prescription form. This is in cases where the patient may send an</p>	<p>Noted. See earlier comments.</p> <p>Noted. It is a statutory requirement that the pharmacist is satisfied that the patient or their carer has sufficient information on the use, storage and disposal of the medicine involved.</p> <p>Noted.</p>
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electronic copy to the pharmacy offering the delivery service and then have the prescription dispensed in another pharmacy. One would immediately think of possible abuse of psycho-active medicines.

In cases where a POM is needed urgently the patient may well choose to have the prescription dispensed locally. In this instance the dispensing pharmacist would have no knowledge of any other POMs that the patient may be taking. The patient may volunteer the information but might only be able to give an incomplete picture. This can also occur in reverse where the remote pharmacy is unaware of any POMs that the patient obtains locally. While this can happen at present it is the general practice that most patients on long term medications attend just one pharmacy. The chances of this occurring if delivery services become widespread is much higher.

Next I wish to touch upon who would actually receives the medication from the delivery person. There is no way of ensuring that the POM will be handed to the patient or their carer. Several scenarios can arise. A child, another family member or a house mate may answer the door. In my own pharmacy I would be reluctant to hand a POM to a minor without being aware of the back ground. Handing the POM over to another family member or a house mate can lead to a breach of patient confidentiality. All of these scenarios may follow when there is somebody to answer the

door. But what if there is nobody home? Is it left with a neighbour? Or is it to be left in the delivery van over night to attempt delivery the following day or returned to the pharmacy to await further instructions. If medications are to be left in the van over night what of the storage conditions. Excessive heat in summer and cold in winter can affect the stability of medicines. And what of the security of controlled drugs. In a pharmacy setting we must store the completed CD POMs in the safe until it is handed over to the patient. Could this be replicated in a couriers van? What would be the status of thermolabile POMs? Would delivery vans be required to maintain a proper cold chain?

Delivery services would introduce a new element to our two tier health service. Patients with medical cards would not be attractive to these pharmacies. The reimbursement rate for ingredients at below cost and a fixed fee of €3.50 per item means that the costs of a delivery service would most likely exceed any possible return.

The costs of delivery would lead to a situation similar to other jurisdictions where several months supply are delivered at one time to reduce costs. This is already discouraged in the PSI's guidelines. It is not in the patients interests to have large quantities of any medication present in the home. The risk of poisonings or over-dosage, either accidental or otherwise is much higher when several months supply are present. This is all the more so in the case of psycho-active medications which may be prone to abuse by the patient and other members of the household. The delivery of several months supply does not encourage the rational and proper

Noted. Many of the views expressed here are supported as an essential part of good pharmacy practice.

use of medicines. There is also an economic cost as frequently medication regimes are subject to change. Unused medicines would have to be disposed of properly giving rise to further costs. It would not be wise (or possibly ethical) to send out further supplies of new POMs when large quantities of discontinued medications are still present in the patient's home. There may also be pressure from patients to have unused medications returned for credit. When they are told that pharmacies are unable to credit them as they cannot re-use them the temptation for the patient to keep them becomes greater. This would further increase the risk of over-dosage or poisoning leading to further costs to the health services.

It is for these reasons amongst others that there is a prohibition on dispensing more than one months supply in the PSI's guidelines. However there does not seem to be any effective way of enforcing this.

The PSI's Code of Conduct for pharmacists states

“The practice by a pharmacist of her/his profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient. A pharmacist must employ her/his professional competence, skills and standing in a manner that brings health gain and value to the community and the society in which she/he lives and works. A patient is a person who stands in such a degree of relationship to a pharmacist that the pharmacist ought to reasonably apprehend that such a person's health, well being and care are likely to be affected by the acts or omissions of



that pharmacist.”

I find it hard for any pharmacist to meet this requirement without actually meeting the patient. The very concept of a remote delivery service falls very short of the ideal of trying to provide the best professional care to patients.

Again, from the Code of Conduct;

" a pharmacist must ensure that their professional judgement is not impaired by personal or commercial interests including incentives, targets or similar measures"

A delivery service for POMs from a remote location can only be driven from a commercial considerations. In such a service the commercial consideration would take precedence over the patient's welfare.

The various pharmacy wholesalers already operate a delivery system for POMs to pharmacies. Even with their experience and professionalism there are still mistakes. Orders go astray, items go missing or arrived damaged and unusable. At least in these situations there is the pharmacist present to intervene before any of this reaches the patient. It goes without saying that any delivery service from the community pharmacy to the patient also runs the same risks as this. The absence of a pharmacist as the final link to

protect the patient gives rise to great risks for the patient.

Any sort of large scale delivery service of POM's from remote locations would undermine the economic viability of many pharmacies especially the smaller ones. Declaration of interest here. I own and operate as my main source of income a small independent pharmacy. Many of the state schemes are now operating at break even at best. The state pharmacy service is effectively being subsidised by the private patients. If the bulk of private prescriptions are cornered by a pharmacies offering a delivery service then the economic base of all pharmacies will be affected. Depending on which figures that you look at this could lead to the closure of up to 700 smaller pharmacies. Earlier I mentioned that patients may need some POMs urgently. If the local pharmacies are closed then this may not be possible. One of the biggest advantages to the state and the public is access to free advice from a healthcare professional from a pharmacy service in practically every town and village in the country. If the economic basis for many of these pharmacies goes then patients will suffer hardship through having to travel further distances and the subsequent delay. The state will face higher costs in poorer patient outcomes and increased social welfare payments for staff of the closed pharmacies. The importance of a rural pharmacy service is recognized in Northern Ireland where the state pays an allowance for pharmacies in remote and disadvantaged areas.

In brief it is in the patient's best interests to have regular contact with their pharmacist. It is also in the state's best interests for the pharmacist to keep regular contact particularly with vulnerable patients. The pharmacist cannot meet their ethical and

	<p>professional obligations as outlined in the Code of Conduct without meeting the patient face to face. While a certain cohort of patients may see a financial benefit in a remote mail order/delivery service in the long run it will lead to poorer patient outcomes and increased costs to the state.</p> <p>Additional points 10/5/14</p> <p>The draft guidance make no mention of distance for deliveries. Is it to be acceptable for a pharmacy in Dublin to deliver to a patient in Cork? Or what distance would be acceptable?</p> <p>Neither does the guidance make any mention of quantities that may be delivered. I presume from other guidances issued by the PSI that one months supply would be the maximum amount which should be supplied.</p>	<p>The PSI must act in accordance with current legislation, there is no legal basis in any area of medicines or pharmacy legislation to restrict delivery to within a local area. It is patient choice that determines what pharmacy a patient wishes to attend.</p> <p>Noted.</p>
9.	<b>DMcDermott MPSI, Moran’s Pharmacy, Firhouse, Tallaght, Dublin 24</b>	
	<p>I am of the opinion that medicines -even those in S1B class- should only be dispensed in monthly amounts and at monthly intervals. This ensures patient build of medicines in community is reduced. This improves safety and reduces incidence of potential overdose whilst maintaining pharmacist to patient monthly interaction. Six monthly bulk suppling of prescriptions should not be encouraged by psi.</p>	<p>Noted and agreed</p>
10.	<b>Boots Ireland</b>	

<p>Boots is a leading provider of pharmacy services in Ireland, employing over 220 pharmacists in 75 registered retail pharmacy businesses across the country. We are committed to the provision of services to the highest standards and welcome the opportunity to contribute to the development of pharmacy practice in Ireland.</p> <p>In responding to this document, Boots has made a number of specific observations and comments relating to individual points in the document, and these may be reviewed below.</p> <p>1. Introduction</p> <p>‘The PSI considers that the optimal and safest way for prescription-only medicines to be supplied to patients is through direct supply to the patient and/or carer following a face-to-face interaction between a pharmacist and the patient in the pharmacy. This direct communication with the patient and / or their carer during a face-to-face interaction allows the pharmacist to evaluate the patient’s overall health and need, perform a full therapeutic review of the prescription and allow appropriate patient counselling to take place. It also allows the pharmacist to assess and verify the authenticity of the prescription.’</p> <p>Boots recognises that the interaction between the patient and / or carer and the pharmacist is vitally important to improve the patient’s understanding of their treatment, and thus achieve patient concordance with their intended treatment and improvement of patient outcomes. The traditional model for achieving this has been a face-to-face interaction between a pharmacist and patient in the pharmacy. This model has many</p>	<p>Noted and agreed.</p>
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advantages. It has allowed patients to build a relationship of trust with the pharmacist. Pharmacists have not been limited to verbal or written communication methods and have the benefit of assessing a patient's non-verbal cues to assist in the determination of a patient's understanding of their health condition and treatment.

The advent of modern technologies such as social media platforms which facilitate real time transfer of information using routes such as video conferencing provides additional opportunities to expand the pharmacist / patient interface beyond the boundaries of the pharmacy. Such technologies could be considered as alternative methods to improve patient access to their pharmacist in circumstances where the patient or their carer is unable to attend the pharmacy. With suitable controls in place to maintain patient confidentiality, the pharmacist and patient retain the ability to use the full range of communication methods available in a face-to-face interaction in the pharmacy while the patient's access to a pharmacist is improved in a situation where the patient is unable to attend the pharmacy in person to avail of the pharmacist's advice.

A face-to-face interaction with the patient where the prescription is presented to the pharmacist for review certainly allows the pharmacist to verify the authenticity of the prescription. However, this is not the only method by which a pharmacist can obtain a prescription or verify its authenticity. For example, at a patient's request, the pharmacist may obtain a prescription directly from the prescriber subsequent to the patient's consultation with their medical practitioner. A prescription may be delivered to the pharmacy by a third party on behalf of the patient. Confirmation of the authenticity of the prescription in the absence of a face-to-face

While, as stated in the guidance, the PSI considers that the optimal and safest way for prescription-only medicines to be supplied to patients, is through direct supply to the patient or their carer following a face to face interaction between a pharmacist and the patient in the pharmacy, it is acknowledged that embracing modern technologies may also be useful in certain circumstances.

Noted

<p>interaction with the patient is possible in each of these circumstances.</p> <p>Although not possible within the current legislative framework, prescriptions may in the future be transferred electronically from the prescriber directly to the patient's nominated pharmacy. This model, which has been successfully implemented in other jurisdictions, is particularly suitable for those patients whose health condition restricts their mobility and therefore limits their ability to readily access a pharmacy. A delivery service coupled with patient counselling by a pharmacist using one of the methods described above may support such patients to continue to live in their community for longer by facilitating the safe and appropriate use of their medicines.</p> <p>In its current format, this guidance document prevents pharmacists from embracing many aspects of modern technology which could facilitate pharmacists to improve patient concordance with their medicines. This restriction to traditional methods of pharmacy practice could in some circumstances be contrary to the best interests of the individual patient. It is submitted that that the Code of Conduct for Pharmacists provides a framework for pharmacists to use their professional skills and competence to make decisions which are 'directed to maintaining and improving the health, wellbeing, care and safety of the patient'. The decision to provide delivery of prescription-only medicines or patient counselling using a means of communication at a distance to individual patients are examples of such decisions.</p> <p>2. Legal and Professional Requirements in the Provision of a</p>	<p>Noted</p> <p>Noted. See earlier comments.</p>
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<p>Delivery Service</p> <p>‘In a delivery service, due to the increased number of steps involved in the dispensing process and the fact that the patient does not present in the pharmacy, there is increased potential for errors to occur and patients to receive the wrong medicine when supplied via a deliver service. Pharmacists should therefore be involved in all aspects of the preparation of medicines for supply via a delivery system and a thorough double checking of all prepared packages, including name and address labelling and sealing should occur’.</p> <p>The provision of a delivery service must be supported by robust standard operating procedures covering all steps of the process. In the design of the procedures for a delivery service, consideration should also be given to situations which may arise in the context of a delivery service which are not seen in the pharmacy environment. This might include policies for situations where patients with limited mobility seek to give access codes / keys to their home to pharmacy staff to ensure access to their medicines, policies for dealing with failed deliveries, additional policies for raising concerns to the appropriate authorities about potential abuse of vulnerable patients which may be more apparent in the patient’s home setting than the pharmacy environment.</p> <p>‘When the supply of a prescription-only medicine to a patient is made via a delivery service, the pharmacist is fully responsible for ensuring the safe delivery of the medicines to the patient and therefore must be satisfied that the route of delivery is suitable..’</p> <p>Boots recognises that the choice of delivery mechanism is</p>	<p>Noted</p>
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<p>important having regard to the protection of patient safety. The delivery mechanism must ensure that the patient gets their medication at the expected time and without compromise of the stability of the medicine. The use of third party delivery agents may present some additional challenges in this regard. Robust service level agreements must be in place to ensure that appropriate storage arrangements during delivery can be maintained, delivery schedules are in place and adhered to and delivery records are available. All delivery service should be audited regularly by the Superintendent / Supervising Pharmacist as appropriate to ensure that all appropriate controls are in place and adhered to.</p> <p>The alternative delivery mechanism where deliveries are made by pharmacy staff members also requires careful consideration. Appropriate insurance arrangements must be in place to cover such a delivery service. Arrangements must be in place to ensure the security of all prescription-only medicines and associated patient data during the delivery process. Consideration should be given to the identification of delivery vehicles and the storage of undelivered medicines in such vehicles outside the pharmacy opening hours.</p> <p>The delivery mechanism chosen must have sufficient capacity to guarantee continuity of supply to patients relying on the delivery service. An appropriate delivery radius which allows patients to readily access their community pharmacist in person should be determined. This is to ensure that patients can access the community pharmacy for other healthcare needs not provided by the delivery service without undue hardship. A contingency plan must be available to deal with unexpected events which might</p>	<p>Agreed. Established policies and procedures of a pharmacy delivery system, if appropriately followed, should address these matters.</p> <p>Noted</p> <p>Noted</p>
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	<p>impact on a delivery service, such as adverse weather conditions, loss of a delivery vehicle etc.</p>	
<p><b>11.</b></p>	<p><b>Tadhg Scanlan MPSI</b></p>	
	<p>I feel that there are many patient safety issues arising from the development of prescription delivery services in Ireland.</p> <p>It is important to specify exactly what is meant by a delivery service in order to ensure that pharmacists are not prohibited from delivering a prescription to patient in an emergency as a result of the development of unwieldy guidelines.</p> <p>Prescription delivery services by pharmacies appear to be running in Ireland on two different levels:</p> <ol style="list-style-type: none"> <li>1) Regular service provided by pharmacists to clients with delivery by pharmacy staff</li> <li>2) Ad hoc service on occasional basis in response to once off need.</li> </ol> <p>The PSI must provide clear guidance for both of these types of services. I note that there are already guidelines in place for delivery to nursing homes and/or health care facilities, where there are other healthcare professionals available to monitor the medications.</p> <p>If a pharmacy decides to provide a structured prescription delivery service for its customers then the service should be carried out by an employee of the pharmacy who should be either a pharmacist, pharmaceutical assistant or a pharmacy technician. This will ensure that when the prescriptions are delivered, to patients or carers, a suitably qualified healthcare professional will be present to answer any questions or queries. It is inappropriate to allow pharmacies to provide delivery services using couriers, An Post or drivers with no dispensary qualifications.</p>	<p>Noted.</p>

<p>Prescription delivery services should be restricted to the normal catchment area of the registered retail pharmacy business. This will ensure that there will be continuation of care for the patient and help reduce the risk of 'prescription tourists'. It will also ensure that any issues arising, or changes to a prescription, can be dealt with appropriately and in timely fashion. Restriction of delivery to the local area will also ensure that patients/carers and the staff carrying out deliveries will be familiar with each other. This is particularly important for elderly patients living alone who could be unnerved by strange vans turning up on their doorsteps.</p> <p>The maximum quantity of medication which can be delivered should be restricted to either one month or the maximum amount specified by prescriber provided it is less than one month. This will reduce the risk of an accumulation of medication being built up in the home and becoming a risk to both patients and other family members. It may be worth considering introducing a condition that the person carrying out deliveries should check to confirm quantities of medication in home in order to monitor compliance. The individual carrying out delivery of prescription medicines should also be in a position to refuse to supply some or all of the prescription if he/she feels that it is in the best interests of the patient to do so. E.g.: in a situation where the patient is intoxicated a pharmacist would refuse to dispense benzodiazepines in the pharmacy, the delivery person should be suitably qualified to do the same when delivering to the home</p> <p>I would suggest that the guidelines in place for the delivery of medication to nursing homes should also be reviewed at the same time as these guidelines are being put in place to ensure that all patients receiving their medication by a delivery service receive the same care and attention that patients presenting directly to a</p>	<p>The PSI must act in accordance with current legislation, there is no legal basis in any area of medicines or pharmacy legislation to restrict delivery to within a local area. It is patient choice that determines what pharmacy a patient wishes to attend.</p> <p>Noted</p> <p>Noted. While the guidelines are in parallel it is hoped that they will be supportive of each other.</p>
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<p>pharmacy expect and receive. I do accept that medication being delivered to nursing homes is generally received by a healthcare professional but all delivery services should be carried out to the same standard.</p> <p>The guidelines should also include specific reference to high risk drugs and how they should be handled. Careful consideration should be given to whether or not the delivery of cytotoxic drugs or controlled drugs is appropriate. The question arises as whether or not it is appropriate to deliver fridge items. There is a risk that pharmacies providing delivery services, especially outside of their local areas, may decide to cherry-pick what items they dispense and leave the high risk drugs to the local pharmacy. This will lead to a situation where patients have incomplete medical records in different pharmacies resulting in possible overdoses, adverse drug reactions and interactions.</p> <p>I am concerned that texting patients or sending email reminders could be seen as solicitation of customer by supplier and while it is completely prohibited in the context of 'mail order supply', I feel that this type of solicitation should be legislated against, not just for targeted prescriptions. It would be appropriate for the PSI to issue a warning to all pharmacists that solicitation of any repeat prescription business by communication at a distance is inappropriate even when carried out under the guise of patient care.</p> <p>In my opinion the number of times a specific prescription can be delivered without there being direct contact between the patient/carer and the pharmacist must be restricted. It would be very easy for a patient to manage to source several months of medication with a perfectly legal prescription without actually seeing any healthcare professionals at all. This position puts</p>	<p>Noted. There are certain medicines that are not suitable for certain delivery systems.</p> <p>Noted</p> <p>Noted</p>
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	<p>vulnerable patients, in particular those with mental health difficulties at risk, especially with the reduction in community care services across the country.</p> <p>I accept that there is a need for delivery services to patients and carers on an occasional basis but this should not be allowed to become normal practice. According to the draft guidelines the optimal and safest way to dispense prescription only medicines is via direct supply to the patient and/or the carer. The PSI must be very cautious when drawing up these guidelines to ensure that it continues to protect public welfare and patient safety, while at the same time working to promote the profession of pharmacy.</p>	<p>Noted</p>
<b>12.</b>	<b>Maxwell Pharmacy Dalkey, Co. Dublin</b>	
	<p>Traditionally delivery of prescription only medicines (POM) would have been understood to mean delivery within a local area. This has changed recently with the advent of the growth in nursing homes and other institutions (such as prisons) with a large number of inmates who require POM. Many of these are being serviced from locations which are some distance from the institution. Also we have recently seen the development of a discount model of pharmacy offering delivery services nationwide</p> <p>I wish to outline the reasons why I feel that delivery by anybody but a pharmacist or at a great distance can result in a poor outcome for patients.</p> <p>It would very difficult to ensure that the patient received proper advice about their medication. Presuming that some counselling was offered via telephone for instance it would be impossible to</p>	<p>Noted.</p>

give proper directions on inhaler technique, or on the correct use of eye drops, especially for the use in the treatment of glaucoma.

Presuming that it may be permissible to dispense against a faxed copy pending receipt of the original prescription there would be a significant time delay in delivery to anywhere but local addresses. This presumes that the patient would have access to a fax machine and that confidentiality could be guaranteed at both ends. In all but exceptional cases dispatch of the POM would need to be withheld until receipt of the original prescription form. This is in cases where the patient may send an electronic copy to the pharmacy offering the delivery service and then have the prescription dispensed in another pharmacy. One would immediately think of possible abuse of psycho-active medicines.

In cases where a POM is needed urgently the patient may well choose to have the prescription dispensed locally. In this instance the dispensing pharmacist would have no knowledge of any other POMs that the patient may be taking. The patient may volunteer the information but might only be able to give an incomplete picture. This can also occur in reverse where the remote pharmacy is unaware of any POMs that the patient obtains locally. While this can happen at present it is the general practice that most patients on long term medications attend just one pharmacy. The chances of this occurring if delivery services become widespread is much higher.

Next I wish to touch upon who would actually receive the medication from the delivery person. There is no way of ensuring that the POM will be handed to the patient or their carer. Several

scenarios can arise. A child, another family member or a house mate may answer the door. In my own pharmacy I would be reluctant to hand a POM to a minor without being aware of the back ground. Handing the POM over to another family member or a house mate can lead to a breach of patient confidentiality. All of these scenarios may follow when there is somebody to answer the door. But what if there is nobody home? Is it left with a neighbour? Or is it to be left in the delivery van over night to attempt delivery the following day or returned to the pharmacy to await further instructions. If medications are to be left in the van overnight what of the storage conditions. Excessive heat in summer and cold in winter can affect the stability of medicines. And what of the security of controlled drugs. In a pharmacy setting we must store the completed CD POMs in the safe until it is handed over to the patient. Could this be replicated in a couriers van? Would delivery vans be required to maintain a proper cold chain?

Delivery services would introduce a new element to our two tier health service. Patients with medical cards would not be attractive to these pharmacies. The reimbursement rate for ingredients at below cost and a fixed fee of €3.50 per item means that the costs of a delivery service would most likely exceed any possible return.

The costs of delivery would lead to a situation similar to other jurisdictions where several month's supply are delivered at one time to reduce costs. This is already discouraged in the PSI's guidelines. It is not in the patients interests to have large quantities of any medication present in the home. The risk of poisonings or over-dosage, either accidental or otherwise is much higher when several month's supply are present. This is all the more so in the

case of psycho-active medications which may be prone to abuse by the patient and other members of the household. The delivery of several month's supply does not encourage the rational and proper use of medicines. There is also an economic cost as frequently medication regimes are subject to change. Unused medicines would have to be disposed of properly giving rise to further costs. It would not be wise (or possibly ethical) to send out further supplies of new POMs when large quantities of discontinued medications are still present in the patient's home. There may also be pressure from patients to have unused medications returned for credit. When they are told that pharmacies are unable to credit them as they cannot re-use them the temptation for the patient to keep them becomes greater. This would further increase the risk of over-dosage or poisoning leading to further costs to the health services.

The PSI's Code of Conduct for pharmacists states

"The practice by a pharmacist of her/his profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient. A pharmacist must employ her/his professional competence, skills and standing in a manner that brings health gain and value to the community and the society in which she/he lives and works. A patient is a person who stands in such a degree of relationship to a pharmacist that the pharmacist ought to reasonably apprehend that such a person's health, wellbeing and care are likely to be affected by the acts or omissions of that pharmacist."

I find it hard for any pharmacist to meet this requirement without actually meeting the patient. The very concept of a remote delivery

service falls very short of the ideal of trying to provide the best professional care to patients.

Again, from the Code of Conduct;

” a pharmacist must ensure that their professional judgement is not impaired by personal or commercial interests including incentives, targets or similar measures”

A delivery service for POMs from a remote location can only be driven from a commercial considerations. In such a service the commercial consideration would take precedence over the patient’s welfare.

The various pharmacy wholesalers already operate a delivery system for POMs to pharmacies. Even with their experience and professionalism there are still mistakes. Orders go astray, items go missing or arrived damaged and unusable. At least in these situations there is the pharmacist present to intervene before any of this reaches the patient. It goes without saying that any delivery service from the community pharmacy to the patient also runs the same risks as this. The absence of a pharmacist as the final link to protect the patient gives rise to great risks for the patient.

It is in the patient’s best interests to have regular contact with their pharmacist. It is also in the state’s best interests for the pharmacist to keep regular contact particularly with vulnerable patients. The pharmacist cannot meet their ethical and professional obligations as outlined in the Code of Conduct without meeting the patient face to face. While a certain cohort of patients may see a financial benefit in a remote mail order/delivery service in the long run it will



	lead to poorer patient outcomes and increased costs to the state.	
<b>13.</b>	<b>B&amp;JD McCormack's Pharmacy, 14 Selskar St, Wexford, Co. Wexford</b>	
	<p>I wish to make a submission to this public consultation process regarding the delivery of Prescription only Medicines via courier,Postal, or any other method which does not involve the direct personal involvement of a Pharmacist. From the outset I must state that I believe that any mode of delivery or supply of medicines to a patient that does not involve the direct involvement and supervision of a Pharmacist is a very bad way of practicing Pharmacy, and the most fundamental aspect that underpins quality patient care is being totally compromised, that is patient safety.</p> <p>Any method of supply of Prescription only medicines that does not directly involve the Pharmacist and the patient is compromising this safety, a courier can not be expected to fulfill the role of a Pharmacist in ensuring that :</p> <p>the correct person who receives the medicines is actually the patient.</p> <p>the advice and consultation which would be required to ensure that the patient uses the medicine to achieve the best possible outcome for the patient given their individual circumstances.</p> <p>the patient can ask questions regarding their medicine, possible interactions with other medicines,food etc, possible side effects and optimum time for taking doses of their medicines.</p> <p>If more than one month of a medicine is supplied, how is it</p>	<p>Noted. Many of the comments have been taken into consideration in the revision of the guidelines</p>

	<p>possible for a remote/courier/delivery system to carry out a full review of a medicine if problem occurs and Pharmaceutical advice re options open to the patient is needed?</p> <p>Also, if a bulk supply of medicines is supplied via delivery, how can the patient ensure that this large amount medicines can be stored safely?</p> <p>How can the patient ensure that the potential six month supply of medicines will be stored in a way that ensures that the medicine will not suffer from spoilage over this time?</p> <p>will will this not have serious consequences for the overall Health system when large quantities of medicines being stored in the home bring about an inevitable increase in poisonings and associated suicide risks?</p> <p>I believe that there are huge safety implications for the health of our nation if the Pharmaceutical Society endorse a policy that compromises and threatens the overall safety of the public by allowing unsupervised delivery of large quantities of medicines without the direct and specific involvement of the Pharmacist in the entire process.</p> <p>I do not see any obvious benefit to the establishment of widespread and unrestricted remote delivery of medicines except for convenience and possible monetary savings for the patient, i believe that this issue is about patient safety, and the setting up of a delivery system can not be in the interests of patient safety for the reasons i have outlined above.</p> <p>For this reason, I hope that the Pharmaceutical Society will put patient welfare first when making any decision regarding guidance on delivery of medicines.</p>	
<b>14.</b>	<b>Lusk Pharmacy, Lusk, Co. Dublin</b>	

<p>To Whom it concerns,</p> <p>My name is Paul Gaynor. I am the pharmacist at Lusk pharmacy, in Lusk, north county Dublin.</p> <p>I am emailing you regarding the submission on prescription deliveries. Clarification on this issue is imperative, due to patient safety, drug stability and environment issues.</p> <p>The Pharmaceutical Society of Ireland have admitted that face to face contact between patient and pharmacist is best practice. How can this happen if the patient lives so far away that regular visits to the pharmacy are not feasible.</p> <p>It was well flagged in the press through adverts for a pharmacy that club membership would allow members to get 6 months of prescription medicines delivered by courier. How can this be good pharmacy practise? Six months of medicine in a household is dangerous. What if the patient's medicine has to be changed through the 6 months? Unused medicines will have to be disposed of, giving rise to an environmental issue and extra unnecessary extra cost to the patient.</p> <p>(Besides, I thought that soliciting such business was illegal.) Extra one off prescriptions such as anti-biotics, would be difficult if the patient wanted to keep his record within the one pharmacy.</p> <p>How will the prescription medicines be delivered? will the courier's van be under the same controls as the dispensary, temperature controls etc?</p>	<p>Noted</p>
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	<p>How long will they be left in the van? will the couruier be trained enough to understand the seriousness of the medicines?</p> <p>Where will they be left if no one suitable is at the delivery address. if such deliveries are permitted what impact will be the impact on our insurance?</p> <p>Closures of rural pharmacies will be inevitable if such practices were permitted, thereby reducing access to essential medicines for the rural community.</p> <p>I would sincerely hope that these issues will be given serious consideration</p>	
<b>15.</b>	Rx+pharmacy, 48/48a Skycourt, Shannon, Co. Limerick	
	<p>I look forward, to the introduction of regulations which will effectively outlaw the posting/couriering/mail ordering of prescription medicines in the Rep of Ireland.</p> <p>Not doing so will prove invidious commercially to all but a handful of corporate bodies and will thus lead to a wholesale diminution of locations and the attendant dilution of professional service levels- this would be ironic, given that we're reminded regularly of the fine professional services we give; maybe it's time for the PSI to educate the public it serves and explain that the services provided in local pharmacies are a little broader than 'cheap' medicines.</p> <p>If the number of pharmacies are reduced, then the counselling role of my profession goes out the window; I'll certainly be spending fewer hours with my reduced patient numbers in my consultation</p>	Noted.

	<p>room-if I'll need one at all!</p> <p>At a time where suicide is sadly on the increase again in Ireland,how will a professional call be made by the pharmacist posting multiple months of medication to what could possibly be a compromised patient?</p> <p>How would the PSI propose to police this new dimension?</p> <p>Does the PSI feel that this is in the best interests of the Irish public-and society as a whole?</p> <p>It is in the public interest to remove local primary care units,such as community pharmacies,which are unlikely to survive an onslaught of mail order 'super dispensaries'?</p> <p>10 years down the line,will the PSI be proud of this particular council' decision to introduce mail-order?</p> <p>Is it a step in the right direction to remove the pharmacist completely from any face interaction with a patient and his/her attendant duty of care?</p> <p>With a vastly diminished number of pharmacies,will my regulator(you)be in a position to properly police the profession with a greatly reduced stream of revenue?</p> <p>What impact will this have on protecting the public?</p>	
<b>16.</b>	<b>Carmel Morey - Qualified Assistant Rx+pharmacy, 48/48a Skycourt, Shannon, Co. Limerick</b>	
	I wish to express my wholehearted support of the ban of couriering/ posting of prescription medicines. This simply would be	Noted.

	<p>unsafe practice. If it came into force it would undermine the profession of the pharmacist / qualified assistant,, at a time when it has never been more greatly required as so many people have not the means to go to the doctor and therefore rely on the expert advice of their pharmacist.</p>	
<b>17.</b>	<b>Brian Walsh, Leo Walsh Pharmacy, Joyce's Shopping Centre, Knocknacarra, Galway, Co. Galway</b>	
	<p>I note with interest the PSIs, “Supply by Pharmacists of Medicines to Patients in Residential Care Settings/Nursing Homes” Practice Notice (1/2010) and the last line of the opening paragraph, “The provision of pharmacy services to these patients must ensure that they receive the same level of professional care as those patients who attend personally at the pharmacy practice”. The draft guidelines also reference the ideal scenario where the patient or their carer presents themselves in the Pharmacy, so why would we want to take a retrograde step and cede the final step of the supply of POMs to a patient, to a courier service. Will the patient receive adequate counselling over the phone? Can inhaler technique be explained sufficiently well to a patient that isn’t standing in front of you? Can a pharmacist figure out that a patient is illiterate, if they are 220 Kilometers away? (We look after such a patient at present!). Practice Notice (1/2010) also states that, “it is essential that the pharmacist personally physically attends on the patient in the home”, surely it is equally as important that the pharmacist attends all patients that would have medicines delivered to them, as unlike a care home where there are other healthcare professionals, most patients living in their own home do not have such health professionals at hand.</p> <p>There are multiple other problems with a courier service too, as I see it. What if the delivery driver arrives and the patient isn’t at home, what happens the package? Is it left with a neighbour? This</p>	<p>Noted. Many of the comments have been taken in consideration in the revision of the guidelines</p>

could cause problems with patient confidentiality. Is it returned to the depot and left sitting in the van? Many of my patients operate on a "just in time" type arrangement and will collect their months prescription on the day before they run out or on the very day they take their last tablet. The patient could be left without their medication for a couple of days. It is OK to say that these eventualities will be contained in any SOP, but the bottom line is whether the patient has their correct medication available to them when they need it.

How are the delivery services going to be monitored & policed by the PSI?

The PSI can obviously inspect our RPBs. It ensures that each individual pharmacist is registered. What about the courier driver? What about the delivery vans? Will they have suitable refrigerated facilities for the transportation of insulins? A locked storage area, sufficiently robust to store Controlled Drugs? Would a courier driver be legally covered for the handling of a Controlled Drug in a prescription?

Viewing a delivery service from a commercial aspect, you would expect anybody operating such a service would try and gain as much economic value from each delivery as they can, which will mean trying to dispense as many months worth of medication as possible into each patients bag. This will lead to wastage and may also lead to overdoses, intentional or otherwise, by the patient.

The practice by a pharmacist of his/her profession must be directed to maintaining and improving the health, wellbeing, care and safety of the patient, therefore it is my opinion that the delivery of medicines should only be executed by a registered pharmacist, after all, it is all about the well-being of the patient and affording them the best pharmacy care available, and unless Fastway or DHL

	start employing pharmacists as drivers, I don't see a courier being suitably qualified to provide a patient with their prescription.	
<b>18.</b>	Parnell Pharmacy, 35/41,Parnell St., Dublin 1	
	<p>I find the principle that the commercialisation of remote supply of medicines is even being considered wrong on so many levels, I don't even know where to begin.</p> <p>Where would it end? A website where one might clicks ones symptoms, clicks a box to accept the associated risks, and waits for a parcel of tablets to arrive from somewhere distant.</p> <p>This is about patient safety, not about being 'modern' or facilitating commercial ventures because the authorities don't want to be seen as luddites.</p> <p>Over the decades, a terrific network of local pharmacies has built up around Ireland where every person in the country has access to good local and personal care.</p> <p>Let me give you an example of my concerns. I have a psychiatric service patient who I shall call Ann (not her real name but she would be happy to go on the record). She is a vulnerable patient. She is known to the local primary care network. People care about her and watch out for her. If she doesn't turn up as expected, she is missed and followed up on. I give her daily tablets for her own protection. In the past couple of years she has attempted suicide by overdose two or three times. She has achieved this by purchasing supplies of paracetamol from newsagents and supermarkets locally. The most recent episode was about eight weeks ago and the hospital has confirmed that she has permanent liver damage. Yesterday she told me that she has begun accumulating tablets again. At I local level, I can now intervene and attempt to save Ann's life. If Ann had access to remote supply of volumes of prescribed medication, I am confident she would be dead at this point.</p> <p>We want to protect vulnerable patients like Ann but if remote</p>	<p>Noted. Many of the comments have been taken in consideration in the revision of the guidelines</p>



	<p>supply was to become a reality, the caring, local networks which have been built over time would be rendered useless over night. I don't want Ann to become 'collateral damage' in a battle for commercial gain.</p> <p>I am appealing to you to use common sense and continue to resist the dangerous practice of remote supply of medication.</p>	
<b>19.</b>	Matt Murphy's Pharmacy, 2 Main st., Macroom, Co. Cork	
	<p>To whom it concerns,</p> <p>"The PSI considers that the optimal and safest way for prescription-only medicines to be supplied to patients, is through direct supply to the patient and or carer following a face-to-face interaction between a pharmacist and a patient in the pharmacy"</p> <p>I agree with your statement entirely but realise in reality it is not always practical or realistic to apply this expectation of care, be it due to disability, geographic or social isolation or more importantly medical need. It would be ridiculous to expect either the carers or parents or families of a nursing home patient to transport in certain cases their relatives to a pharmacy sometimes up to twenty or more miles to a pharmacy and more if it truly was to be of their choosing.</p> <p>In these cases in our case we work closely with the carers and families of the patients to deliver medicines to the home where possible and to the patient if practical. These according to our logs have been done by pharmacists 96.3% of the time. At other instances they were carried out by a technician after telephone consultation with the matron or nurse in charge.</p> <p>We have at numerous junctures dispensed prescriptions delivered them and on brief interaction with the carer realised that there was a problem. This usually goes on in the Pharmacy and the issue can be sorted usually in a timely manner. Envisage the situation whereby a condition has worsened between prescribing ordering payment and delivery and eventual use by the patient in particular</p>	<p>Noted. Many of the comments have been taken in consideration in the revision of the guidelines</p>

with respect to dermatological conditions or anti-psychotics, antibiotics.

Any member of the society who is a Pharmacist or regularly receives deliveries from companies knows how often mistakes are made, orders are delivered incorrectly, not at all to the wrong address etc.

I could continue in a vein of fear mongering as I'm sure many of you could with issues solely regarding to the actually delivery and yet never mention dispensing because that is what will be changing. The old Clause 9 will effectively be gone and dispensing will change to delivery. The effectiveness of PMR's will be greatly diminished is a patient is sourcing medicines from seven or eight different sources at a minimum.

I have outlined brief instances where a single delivery of a medicine can go awry. The risk in my opinion where six months supply of medications will be supplied willy, nilly with no knowledge of patients risk factors is a prescription for disaster for the profession and most importantly for patient care.

In conclusion in my opinion the delivery of medicines by anyone other than a pharmacist to patient is a process that will be fraught with mistakes

13 June 2014

I write to you the delivery of Prescription only Medicines from a Pharmacy.

I have been delivering medicines to many patients for many years. the only safe way I know of is for the Pharmacist to deliver themselves.

	<p>I know this will put huge extra workload on the already overworked pharmacists as well as extra costs on the pharmacy, but it is the only safe method for the patient. Any other delivery method is fraught with danger of mis-delivery and mishandling yours etc Matt Murphy M.P.S.I PSI No. 4433</p>	
<b>20.</b>	Irish Pharmacy Union	
	<p><b>IPU Submission to the PSI on Draft Guidance on the Delivery of Prescription-only Medicines from a Retail Pharmacy Business</b></p> <p><b>1. Introduction</b></p> <p>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 IPU 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.</p> <p>The IPU welcomes the opportunity to make a submission to the Pharmaceutical Society of Ireland (PSI) on its Draft Guidance on the Delivery of Prescription-only Medicines from a Retail Pharmacy Business.</p> <p><b>2. Context of the Guidance</b></p> <p>The IPU understands that the purpose of the PSI in issuing this guidance was to clarify what pharmacies are allowed to do in the context of delivering prescription-only medicines to their patients and what they are not allowed to do. There has been much media attention recently about a particular pharmacy, which purported to offer a prescription delivery service which was more akin to mail order. Whilst the PSI draft guidance clarifies that mail order is</p>	<p>Noted</p>

<p>prohibited under current legislation, the PSI’s explanation in the draft guidance of the obligations on owners, managers, superintendent pharmacists and supervising pharmacists and the professional obligations of pharmacists would appear to have caused much confusion amongst the profession.</p> <p>It is the view of the IPU that the distance supply of prescription-only medicines is not in the interests of patients or the public at large. Medicines are not ordinary items of commerce and their supply to patients and consumers should be undertaken as part of a personal professional pharmacy service. No courier service, no matter how secure, can replicate the patient benefit afforded by a face-to-face consultation with a pharmacist. The requirement for the counselling of patients which is outlined in Regulation 9 of the Regulation of Retail Pharmacy Business Regulations (and, in the case of prescriptions issued on the Community Drugs Schemes, Clause 9 of the Community Pharmacy Contractors Agreement) upholds this view.</p> <p>It is neither reasonable nor realistic to expect the majority of pharmacists to abide by one set of rules which prohibit online or mail order pharmacy, if another, looser, set of rules is perceived to apply to one individual pharmacist. Therefore, it is essential that immediate clarity on the issue be provided by the PSI to the entire pharmacy profession, in order to dispel the uncertainty which now exists about which models of dispensing and supply of prescription medicines are permitted and which are not.</p> <p><b>3. What Pharmacists Can Do</b></p> <p>As the PSI acknowledges in the draft guidance, the delivery of medicines has always been permitted in certain circumstances. Indeed, the IPU has produced guidelines to assist pharmacies in a home delivery service; a copy of these guidelines is in Appendix One of this submission. We make it quite clear in our guidelines that it is a requirement for the pharmacist to have face-to-face</p>	<p>Noted</p>
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We look forward to working with the PSI on the production of final guidance to incorporate the issues addressed in this submission. We are available to meet with the PSI to discuss the issues raised above or, indeed, any other relevant issues.

**Appendix One:**

**IPU Guidelines on Prescription Collection and Home Delivery  
Prescription Collection Service**

A Prescription Collection Service refers to a service whereby the patient's prescription is collected from the surgery by the pharmacy. When providing such a service, the following must be considered:

- ☒ The patient must give written consent to the pharmacy to collect their prescriptions from the surgery. A copy of this consent form should be given to both the patient and the surgery and the original kept in the pharmacy;
- ☒ The patient should be made aware of the timescales involved from them informing the pharmacy that there is a prescription to collect to the dispensed prescription being available for pick-up from the pharmacy;
- ☒ All pharmacy staff involved in collection of prescriptions from surgeries should be made aware of the arrangements of the service;
- ☒ Patient confidentiality and security of the prescriptions should be ensured throughout the collection process;
- ☒ Repeat prescriptions must be requested from the surgery by the patient, not the pharmacy;
- ☒ The pharmacy must ensure that all prescriptions collected from the surgery are covered by written consent from the patient. If prescriptions are inadvertently collected for which there is no consent, they must be returned immediately to the surgery.

**Home Delivery Service**

A Home Delivery Service refers to a service whereby the patient's medicines are delivered to the patient in their home. When providing such a service, the pharmacist still has a professional responsibility to ensure that the patient knows how to take their medicines and all aspects of Regulation 9 and Clause 9 have been considered. In addition, the following must be considered:

- ☒ Each time the Home Delivery Service is provided, the pharmacist must determine whether direct face-to-face contact with the patient is necessary;
- ☒ The pharmacy should obtain consent from the patient to provide the service and a note should be made on the patient's medication record;
- ☒ The way in which the service is carried out should ensure that the medicine is delivered securely and promptly along with any information necessary for the safe and effective use of the medicine;
- ☒ The service should take into account any special security or storage requirements of the medicine;
- ☒ The service should incorporate an audit trail for the medicine from the point it leaves the pharmacy to the point when it is handed to the patient or returned to the pharmacy in the event of a delivery failure;
- ☒ Patient confidentiality and security of the medicine should be ensured throughout the delivery process;
- ☒ Wherever possible, a signature should be obtained to indicate safe receipt of the medicine;
- ☒ A note should be left to inform a patient who was not at home that a delivery had been attempted.

**Important Note**

*The Medicinal Products (Prescription and Control of Supply) Regulations, 1996 (SI No. 256 of 1996) prohibit the supply of medicines by mail order. Supply by mail order is defined in the*

	<p><i>Regulations as meaning any supply made, after solicitation of custom by the supplier, without the supplier and customer being simultaneously present and using a means of communication at a distance, whether written or electronic, to convey the custom solicitation and order for supply. Interpretation of this regulation would imply that it would not be recommended to offer both a prescription collection and home delivery service to the same patient as this would result in no face-to-face contact between the pharmacist and the patient, unless the pharmacist personally delivers the medicine, thus facilitating Regulation 9 and Clause 9. These Guidelines should be read in conjunction with the PSI's Pharmacy Practice Guidance Manual: Dispensing of Prescription Only Medicines</i></p>	
<b>21.</b>	Healthwave Pharmacy, Unit 2.4 Dundrum Retail & Office Park, Sandyford Road, Dundrum, Dublin 16	
	<p>I wish to provide comment on the Draft Guidance on the Delivery of Prescription-only Medicines from a Retail Pharmacy Business (Pharmacy) document published on May 19th last.</p> <p>In the section "What is prohibited under 'supply by mail order'?" it is unclear what constitutes solicitation.</p> <p>As you are aware, many pharmacies send a text message or phone patients each month either a) informing them that their prescription has been prepared automatically or b) asking whether the patient would like their prescription prepared. More pharmacies use an online order form on their website to order prescription medication.</p> <p>Use of a delivery service arises out of the inability for a patient or representative to be present in the pharmacy. Therefore, an electronic form of communication, invariably a phone call, is used by all pharmacies providing a delivery service to establish the patients requirement. It appears from the guideline that while</p>	<p>Noted. These comments refer to mail order and not a delivery service. By virtue of regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) the supply by mail order of prescription-only medicinal products is prohibited and accordingly is an offence. It would not be appropriate for PSI to provide guidance on a prohibited activity. In arranging their delivery systems, pharmacy owners and pharmacists should, therefore, ensure that they do not contravene this prohibition</p>



	<p>delivery is permissible, the pharmacy is prohibited from communicating with the patient even by phone regarding same.</p> <p>Can clarity be provided on</p> <ul style="list-style-type: none"> <li>•the means with which a patient can reorder prescription medication</li> <li>•the means with which a pharmacy can communicate with a patient regarding the reorder of their prescription</li> <li>•whether any of the activities above constitute solicitation</li> </ul>	
<b>22.</b>	McCabe's Pharmacy, Unit 4 The Roof Garden Offices, Clarehall S.C, Malahide Road, Dublin 17	
	<p>We wish to make two observations to the above proposed guidelines:</p> <ol style="list-style-type: none"> <li>1. That the delivery of repeat prescription only medicines should only be made after a direct face to face consultation between the pharmacist and the patient (or carer) for each repeated prescription, that is, each month of a repeat prescription must have full face to face interaction between the pharmacist and the patient (or carer).</li> <li>2. That full practical consideration is given to the delivery of prescription only medicines into institutional settings especially in the instance where the patient is incarcerated and face to face interaction with the pharmacist is not possible. In these instances, regular audit and medicine reviews with the relevant healthcare professionals of the institutions should suffice in place of face to face patient interaction.</li> </ol>	<p>Noted</p> <p>The PSI Guidance on the Supply by Pharmacists in Retail Pharmacy Businesses of Medicines to Patients in Residential Care Settings/Nursing Homes provides guidance in this area.</p>

<b>23.</b>	Tesco Pharmacy Ireland, Tesco Ireland Limited, Gresham House, Marine Road, Dun Laoghaire, Co Dublin	
	<p>Tesco Ireland is a relatively new entrant to the Irish Pharmacy market opening our first Pharmacies in 2011. The pharmacies have been exceptionally well received by our customers and we continue to roll out our pharmacies across our store network to ensure that as many residents of Ireland can receive their prescriptions in the most effective manner.</p> <p>We welcome the lead that the PSI is taking on the subject of home deliveries and ensuring that such deliveries are carried out in the safest and most transparent manner.</p> <p>One of the main growth areas within Tesco Ireland are our home delivery services which are market leading and operate to the highest possible standards. These high standards encapsulate the entire process from selecting the best products, transporting same and delivery using fully trained drivers. There is full traceability of all products from arrival in our stores to delivery to the customer and a full support service is available to deal with any issues.</p> <p>We are going to start a home delivery service to our customers utilising our existing grocery home delivery service. This will involve prescriptions which have been dispensed in one of our pharmacies being delivered to the patient's home address at a date and time of their choosing.</p> <p>The prescription deliveries will utilise the technology already being used so that the dispensing pharmacist will have full visibility of the prescription at all times between the pharmacy and the patient's home.</p> <p>In all circumstances the pharmacist will remain fully available to the patient either by visit to the pharmacy or by phone at the patient's choice. Where a prescription is not suitable for delivery for whatever reason, our pharmacists retain the right to help the patient in the correct manner, whether by signposting to an alternative service provider.</p>	<p>Noted. Any delivery service in development or operation must comply with the PSI guidance on delivery of dispensed medicines from retail pharmacy businesses.</p>

	<p>This new service will enable pharmacies to provide dispensing services to those patients who are currently restricted for various reasons, such as disability or lack of transport. However it will also enable Tesco pharmacy services to reach a far greater population.</p>	
<b>24.</b>	<b>HealthWest Community Pharmacy, Ballindine, Claremorris, Co. Mayo</b>	
	<p>As outlined in the draft guidance "..personal face-to-face interaction between pharmacists and their patients regarding prescription-only medicines is the most appropriate means by which these important medicines are supplied to patients"</p> <p>The reason for this is based on sound communication science. The majority of a message and interaction between two people is both through tone of voice and body language. Patients will open up following a personal interaction and in many cases vital information relevant to the patients use of their medicines and the safety of the patient transpires through this interaction. Counselling of patients on the effective use of inhalers, for example, will mean the difference between therapeutic success and failure and critical health and safety benefits for the patients.</p> <p>There is no substitute for this personal and private interaction.</p> <p>While there may be exceptional circumstances where patients or carers cannot readily access their pharmacy, a delivery of medicines must be the exception rather than the rule. Supplies must be limited to 30 days at a time to ensure that patients have that regular interaction with their healthcare professional who is an expert in the safe and effective use of their medicines.</p> <p>To paraphrase a line from the PSI's own Pharmacy Ireland 2020 document.. pharmacists are not merely a conduit for the delivery of medicines. We are healthcare professionals that patients have</p>	<p>Noted. Many of these comments were taken into consideration in revising the draft guidance.</p>

	access to up to 70 hours per week in many areas who have their health and welfare as our reason for being.	
25.	<p>Our Lady's Children's Hospital, Crumlin, Dublin 12</p> <p>Consultation on delivery of POM from retail pharmacy businesses</p> <p>Our pharmacy department is registered as a retail pharmacy business. Being a national referral centre for many diseases in children, the pharmacy department sources many unlicensed medicines and compounds products extemporaneously where a suitable commercial alternative is not available.</p> <p>Occasionally, there is a need to post medicine to a patient where the patient's needs cannot be met by a local community pharmacy. This may involve an unusual drug and problem with delivery of the order to the community pharmacy or perhaps the bottle was accidentally broken. Ordering of unusual or unlicensed medicines can often be a prolonged process. It would be detrimental to the patient's health not to intervene and send them supply.</p> <p>It might also arise where supply is available only through the hospital but the parents cannot travel to the hospital in time to get supply e.g. anti-retroviral medicines where OLCHC is the national paediatric centre and supply all anti-retrovirals to children.</p> <p>Such patients are nearly always on established medicines that they/their parents are familiar with. If there were any changes, this would be communicated to the parent over the phone.</p> <p>When considering the content of these guidelines, the national bowel screen programme needs to be considered also, where supplies of laxatives are posted from screening centres. I believe that the PSI had discussions with HPAI on this issue.</p>	Noted.
26.	IPHA	

<p>Thank you for the opportunity to comment on the draft guidance on <b>the Delivery</b> of Prescription-only Medicines from a Retail Pharmacy Business to their patients.</p> <p>IPHA has the following comments:</p> <p>Page 3 Section titled ‘In providing a delivery service for prescription-only medicines’</p> <ul style="list-style-type: none"> <li>- The third point “If the patient has a new prescription or change to their prescription, the pharmacists should have a face-to-face consultation with the patient or carer” should be moved up to become the first point as it should be made clear that a face-to-face consultation with the patient, carer or representative is required at the initial prescription. The first point should follow on with the underlined word added in: “On each and every occasion <u>thereafter</u> that the supply of medicines.....” (see attached PDF).</li> <li>- It should be mandatory that any medication delivered to the patient or carer includes the package insert for the medication(s) concerned particularly in the absence of a face-to-face with the pharmacist. This ensures that the product information is readily available to the patient or carer.</li> <li>- It is not specified if/how often audits of pharmacy and delivery practices (by PSI) will take place to ensure robust procedures are in place to safeguard patient safety and product integrity.</li> </ul>	<p>Noted. Many of these comments were taken into consideration in revising the draft guidance.</p> <p>Noted. A patient leaflet should always be included when medicines are dispensed and supplied to a patient</p>
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	<p>Page 4 Delivery mechanism section</p> <ul style="list-style-type: none"> <li>- Feedback from patient to pharmacist to confirm safe delivery and integrity of medication should be in real time.</li> <li>- There should be a vetting process (Garda or similar) for those carrying out the delivery service (on behalf of pharmacy).</li> </ul>	
27.	NMBI	
	<p>The Nursing and Midwifery Board of Ireland (NMBI) appreciates the opportunity to review the Pharmaceutical Society of Ireland’s draft Guidance on the Delivery of Prescription –only Medicines from a Retail Pharmacy Business. The draft guidelines are comprehensive in providing guidance to the pharmacist about what is required by retail pharmacy services in relation to delivery services. The responsibilities of the pharmacist in the provision of the supply of medicines to the person are well addressed in the Introduction section of the guidance.</p> <p>The legislative basis in the draft document (with reference to the Regulations of 2008 and 2003) is well defined for the pharmacist to understand his/her statutory and professional responsibilities for providing delivery services as part of meeting the needs of the individual patient/person for medicines.</p> <p>NMBI strongly supports the PSI guidance statement regarding the factors to consider in the draft text of the Delivery Mechanism section (page 4). Given the collaborative nature of health care and medication management by pharmacists as members of the multidisciplinary team, this guidance may assist nurses and midwives in understanding and acknowledging the regulatory</p>	Noted with thanks.

	<p>standards to pharmacists as required by their regulatory body. NMBI proposes that the final guidance be widely circulated and available as a reference to service providers and settings where delivery services are regularly used in the provision of pharmacy care (such as nursing homes).</p> <p>Again thank you for the opportunity to comment on the Draft Guidance. The NMBI looks forward to the publication and dissemination of this informative document</p>	
28.	<p>Tim Kyne, MPSI</p> <p>The inclusion of the following sentence 'Please note the above guidance has been prepared by the PSI to assist pharmacists and pharmacy owners. They are advisory in nature and do not constitute legal advice.' suggests that the guidance of the PSI, as outline in the draft document, is not compulsory and may therefore be ignored. Clarification on the status of the 'guidance' is required.</p> <p>I believe that 'guidance' should cover the supply/delivery of 'balances of prescriptions, requests from patients for medication to be sent to them while away on holiday either at home or abroad and requests made on behalf of a patient by a temporary carer unknown to the pharmacist'</p>	
29.	<p>Margaret Mullarney, Move4Parkinsons</p> <p>Regarding the public Consultation on draft Guidance on the Delivery of Prescription-only Medicines from a Retail Pharmacy Business (Pharmacy):</p> <p>We would hope that medicines would be available to all people with Parkinson's in the easiest and most accessible manner and the relevant clinical information would accompany the supply of any prescription in plain English.</p>	<p>Noted with thanks.</p>
30.	<p>Collette Finnegan MPSI</p>	

I have read the Draft Guidance on the Delivery of Prescription-only Medicines from a Retail Pharmacy Business. I wish to submit the following, and I trust that my observations will be taken into account in the preparation of the completed Guidance document.

The introduction states “The PSI considers that the optimal and safest way for prescription-only medicines to be supplied to patients, is through direct supply to the patient and/or carer following a face-to-face interaction between a pharmacist and the patient in the pharmacy.” While the guidance notes that follow go some way towards reflecting this statement, I believe that the guidance in its current form is not clear enough in its direction to owners and managers of pharmacies.

Delivery of prescription only medicines at the request of a patient has always been undertaken by community pharmacists, usually on an exceptional rather than on a routine basis. In order to fulfill the legal and professional obligations that underpin the dispensing process, this delivery can only be undertaken by a pharmacist. It is not possible for a non-pharmacist delivering the prescription to the patient’s place of residence to perform the statutory and professional role of the pharmacist. Indeed, if this were to be the case, then the profession of pharmacy would be redundant.

It is my view that the final guidance document needs to be clear in its direction to pharmacy owners and managers, that any delivery of prescription-only medicines, performed by a person other than a pharmacist, is not acceptable in the discharge of their obligation to provide a safe service to patients.

Face- to -face interaction

The recent move by some Retail Pharmacy Businesses (RPB) to attempt to normalise a pharmacy service in which face-to-face

Noted. Many of these comments have been taken into consideration in revising the guidance.



contact between pharmacist and patient is absent, is a danger to the individual patient and to the public generally. I refer to those RPBs which provide a delivery vehicle and non-pharmacist driver to deliver prescription-only medicines, and to those which use commercial delivery channels such as An Post and other courier companies as conduits of prescription-only medicines.

In the course of a face-to-face interaction, the pharmacist is in a position to observe those non-verbal cues that satisfy him or herself that the patient understands the discussion regarding the prescription and specific directions pertaining to the medicines being dispensed. In addition, the pharmacist can observe physiological signs that would cause him to refrain from dispensing the prescription without further review or action (for example an unsteady gait or a tremor, facial pallor or a jaundiced appearance, the smell of alcohol or ketones on the patient's breath, heightened anxiety or agitated behaviour). Indeed, lack of face-to-face interaction can lead to red flag signs and symptoms being overlooked and the patient being placed in danger by the medicines that have been dispensed. Where a carer presents to the pharmacist, in place of the patient, the carer will normally be expected to be familiar with the patient's condition before the pharmacist is satisfied to release the prescription-only medicine to that person.

I submit that where the draft guidance document asserts that "personal face-to-face interaction between pharmacists and their patients regarding prescription-only medicines is the *most appropriate* means by which these important medicines are supplied to patients" should be strengthened to "personal face-to-face interaction between pharmacists and their patients (or the patient's nominated carer) regarding prescription-only

medicines is the *singular* means by which these important medicines are supplied to patients, save in the most exceptional of circumstances.”

This proposed wording leaves pharmacy owners and managers in no doubt as to the proper route of supply of prescription-only medicines.

#### Security

There is a danger to the public at large from the increasing use of non-pharmacist delivery methods for prescription-only medicines. I acknowledge that the draft guidance mentions that the medicine needs to be delivered securely, the subject of an audit trail, and signed for by the patient or carer. However, I believe that these steps remove the ultimate responsibility for the security of the medicine from the pharmacist. The release of any prescription-only medicines, but controlled drugs in particular, into the world of delivery vans and commercial courier companies, is irresponsible and will inevitably result in misappropriation of medicines and in their not reaching the intended recipient.

#### Confidentiality

In the absence of the face-to-face interaction between pharmacist and patient/carer, either in the pharmacy or in the patient’s home, it is not possible to guarantee the confidentiality of personal and medical information. Any aspiration to do otherwise is not executable.

Collette Finnegan, MPSI

12<sup>th</sup> June 2014

Noted. Whatever system of arranged delivery is used, the pharmacist retains full responsibility for ensuring that the system used is suitable having regards to the nature of the medicines concerned and the integrity of the supply chain through which the medicines are delivered.

31.	Eimear Murphy MPSI	
	<p>To whom it may concern,  After reading the draft for providing a delivery service for POMs , I would like to offer my "two cents."  If the pharmacist organises the delivery, does every therapeutic step to which is mandatory, creates a trail for which it can be seen step by step how the prescription is to be delivered etc surely does it not make sense for the pharmacist to make all of the deliveries ?  Can a hired driver realistically explain something appropriately without the correct knowledge ? Will pharmacists bother having the phone conversation with the patient about the medications and how can this be upheld ?  Ok in realising that my email is now full of question marks I shall wrap it up ! I know that I always deliver the medicines to my patients, there aren't that many but I always go, always.</p>	<p>Noted. Many of these comments have been taken into consideration in revising the guidance.</p>
32.	Nora White MPSI	
	<p>I support the introduction of Regulations which will continue to prohibit the mail order of prescription only medicines to patients both from within The Republic of Ireland and from outside the State. Also it is essential that "delivery services" are not seen as a way to circumvent the prohibition of mail order of prescription only medicines.</p>	<p>Noted.</p>
33.	Peter Twomey	
	<p>I would like to thank the PSI for giving us the opportunity to engage in the consultation process. Please find my comments below which I hope will shape final guidance.</p>	

## Introduction

It is acknowledged by the PSI guidance that direct face-to-face contact between the pharmacist and patient/carer is the safest and optimal way of dispensing. This statement should form a central part to deciding when prescription delivery should or should not occur.

- In order to avoid abuse of this discretion, clear instances of when prescription delivery is not appropriate (e.g. delivery for mere convenience when collecting medicines at a pharmacy is possible) should be stated in the PSI guidance. Deliveries should occur only in exceptional circumstances. Delivery to areas outside an appropriate distance from the base pharmacy should be prohibited to negate abuse of the delivery system. Examples of prescription delivery in excess of 200 km from the pharmacy are known. A pharmacy should be required to clearly document the reason why a delivery occurred and this should be included with the daily audit to allow for transparency during inspections.

## Legal and Professional Requirements in the Delivery of a Prescription Service

“Any communication at a distance (e.g. phone call, email, texts etc.) by a pharmacy that is directed to a patient with a view to an order being placed for a prescription-only medicine and where the medicine will be delivered to the patient without face-to-face interaction between the pharmacist and patient is not permissible.”

- Clarification on what falls within the category of “mail order” is required. For example, many pharmacies may

Noted. PSI must act in accordance with current legislation, there is no legal basis in any area of medicines or pharmacy legislation to restrict delivery to within a local area. It is patient choice that determines what pharmacy a patient wishes to attend. Any delivery service must comply with the PSI guidance document.

Noted. These comments refer to mail order and not a delivery service. By virtue of regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) the supply by mail order of prescription-only medicinal products is prohibited and accordingly is an offence. It would not be appropriate for PSI to provide guidance on a prohibited activity. In arranging their delivery systems, pharmacy owners and should not contravene this prohibition. pharmacists should, therefore, ensure that they do not contravene this prohibition

display websites on advertising material. Should these websites contain product names, prices and the offer of a prescription delivery service, I believe there is a danger that the patient is effectively being offered a mail order service.

“On each and every occasion that the supply of medicines (including repeat supplies) to a patient is considered, the pharmacist must use their professional judgement to determine whether the supply is appropriate and whether direct face-to-face contact with the patient or their carer is required.”

- I believe a statement encouraging documentation of such steps including a reason for not engaging in face-to-face consultation is appropriate. This will help ensure that the delivery system is not abused and used in inappropriate circumstances and allow the PSI to assess compliance during inspections.

#### **Delivery Mechanism**

“(The pharmacist is responsible for incorporating) an itemised, verifiable audit trail for the medicine from the point at which it is requested by the patient from the pharmacy to the point at which it is received by and signed for by the patient or their carer/representative”

Considerable risk exists where an unauthorised person may inadvertently receive medicines, particularly in Ireland where many houses do not have a unique name or number.<sup>1</sup>

- The Newfoundland and Labrador Pharmacy Board Pharmacy Practice Guidance states that patients requesting

<p>deliveries of prescriptions to a person other than themselves must provide the pharmacy with a written delegation of authority to a designated agent that is kept on file in the pharmacy.<sup>2</sup> Should the authorised agent not be available for the receipt of medicines, the medicines must be returned to the pharmacy. This approach would be a beneficial addition to Irish guidance to avoid unauthorised receipt of medicines.</p> <p>There exists a danger where children may come into contact with medicines when acting as a recipient, particularly if a child is nominated as recipient. I recently phoned a pharmacy prescription delivery service and was advised that a younger sibling was a suitable signatory.</p> <ul style="list-style-type: none"> <li>• I believe a statement requiring the recipient of a medicine to be of an appropriate age, such as the statement found in the South African Pharmacy Council Guidance (below) is required;<sup>3</sup></li> </ul> <p>“In the absence of an adult (a person above 14 years) to receive the medicine, it must be taken back to the pharmacy”.</p> <p>Many medicines may be subject to abuse or contain toxic ingredients. Should a representative signing for delivered medicines not understand the significance of this, then product may be stored inappropriately leading to safety issues.</p> <ul style="list-style-type: none"> <li>• A prohibition on receipt of controlled drugs and/or highly toxic medicines (e.g. methotrexate) is appropriate to address this. The Pharmaceutical Society of Northern</li> </ul>	<p>Noted. Many of the comments have been taken into consideration in revising the guidance.</p>
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Ireland recommends that delivery of these medicines via a prescription delivery service should not occur where alternative methods of supply are available.<sup>4</sup>

**Stability of products being delivered**

Many products which require cold chain storage or ambient storage temperatures may be exposed to the extremes of temperatures during transportation. These considerations require a detailed understanding of product storage requirements and robust procedures. I believe the PSI guidance should be expanded to reflect this. The IMB Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances, explains the requirement for controlled systems which include temperature logging to ensure product integrity is maintained.<sup>6</sup>

- The PSI guidance should be expanded to outline systems which must be implemented to ensure product integrity is maintained. Ongoing temperature logging and frequent monitoring is a minimum requirement. Furthermore, robust procedures for handling temperature deviations is required. The PSNI states that cold chain products should be included in the delivery service where alternative supply methods are available.<sup>4</sup>

It is general practice in the wholesaling industry that delivery drivers and those involved in transportation of medicines undergo good distribution practice (GDP) training.<sup>5</sup>

- As similar product stability and integrity principles apply to

medicines being delivered on behalf of pharmacies, GDP training should be an essential requirement for all drivers and associated staff.

**In conclusion**

Remote delivery of prescription medicines presents both opportunities and threats. The PSI draft guidance requires considerable expansion to maintain the safety of patients and to ensure the quality of medicines. As demonstrated by examples from pharmacy regulators in other jurisdictions and industry guidance, expanded points indicating the requirement for a specified recipient of medicines, restriction on the collection of medicines by children, avoidance of the delivery of controlled drugs and toxic medicines, and processes and procedures to ensure the principles of GDP are adhered to are required.

**References**

1. Flaherty R. *The Irish Times Online: New Irish postcodes to be sent to 2.2m households in spring 2015.* <http://www.irishtimes.com/news/environment/new-irish-postcodes-to-be-sent-to-2-2m-households-in-spring-2015-1.1776841> (accessed 13 June 2014).
2. Newfoundland and Labrador Pharmacy Board. *NLPB Pharmacy Practice Manual*. St. John's: NLPB; 2014.
3. The South African Pharmacy Council. *Good Pharmacy Practice in South Africa*, 4th ed. Arcadia: SAPC; 2010.
4. The Pharmaceutical Society of Northern Ireland (PSNI). *Supplementary Guidance for Pharmacists in Northern Ireland on the Provision of Prescription Collection and/or Delivery Services*, 1st ed. Belfast: PSNI; 2011.

Noted.



	<p>5. Medicines and Healthcare products Regulatory Authority (MHRA). <i>Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014</i>, 8th ed. London: MHRA; 2014.</p> <p>6. Irish Medicines Board. <i>Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances</i>, IA-G0011-1 ed. Dublin: IMB; 2011.</p>	
34.	Cicely Roche MPSI	
	<p>To whom it may concern,</p> <p>a) Clarity regarding the use of different terms to identify a person that might order or collect a prescription on behalf of a patient would be appreciated e.g.</p> <p>a. Patient and/or their [his/her]carer (introduction, paragraph 2, and various other)</p> <p>b. Signed for by the patient or their [his/her] carer/representative.</p> <p>Clarification as to what is intended by the use of the term ‘carer’ would be of value in all guidelines. However it seems that it may be particularly helpful in the case of these guidelines.</p> <p>By way of explanation: It has been my experience that prescriptions are sometimes collected by helpful neighbours or friends, who would not necessarily have any knowledge or insight regarding a patient’s medication. Notwithstanding that I would release such medication only where I am satisfied that the patient has been counselled as required, I would, nevertheless, not consider</p>	<p>Noted. Interpretation agreed.</p>

<p>'neighbours and friends' to be carers.</p> <p>b) Clarity regarding the difference between 'dispensing' and 'supply' would be appreciated (e.g. page 2, 'prior to the dispensing of each prescription and prior to the supply of the medicinal product concerned' seems to indicate that there are two different interpretations envisaged, in this context of prescription-only medicines).</p> <p>i. By way of explanation: Dispensing, in my approach to practice, includes all aspects of packing, counselling and supply.</p> <p>c) Re 'delivery mechanism, page 4, bullet point 2:</p> <p>i. 'Ordered by the patient' – interpreted literally this would suggest that e.g. one spouse could not phone in to request prescriptions for both husband and wife. Clarification as to whether or not this as intended would be helpful.</p> <p>d) The use of the term 'solicitation' seems to indicate (dictionary definition) that only insistent and/or repeated requests/phonecalls/emails are considered a breach of Regulation 4 (Medicinal Products 2002, as amended). Clarification and/or any further interpretation as per PSI guidance would be appreciated.</p> <p>e) Page 4: Should 'received by the patient for which they are intended' be 'received by the patient for whom they are intended'?</p> <p>Please accept my apologies for my lateness in contributing to this consultation process.</p>	<p>Noted. Agree with interpretation outlined.</p> <p>Noted.</p> <p>Noted. These comments refer to mail order and not a delivery service. By virtue of regulation 19 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) the supply by mail order of prescription-only medicinal products is prohibited and accordingly is an offence. It would not be appropriate for PSI to provide guidance on a prohibited activity. In arranging their delivery systems, pharmacy owners and pharmacists should, therefore, ensure that they do not contravene this prohibition.</p> <p>Agreed</p>
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	Sincerely,	
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	Cicely Roche MPSI	
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The draft guidance for consultation was notified to all registered pharmacists via the PSI newsletter, the stakeholders listed below and placed on the PSI website for any other member of the public to respond to.

List of stakeholders that the guidance was sent to:

Age Action Ireland	Irish Pharmacy Union
Alzheimer Society of Ireland	Medical Council
Asthma Society of Ireland	Mental Health Commission
Aware	Migraine Association
Boots Retail Ireland	Multiple Sclerosis Association of Ireland
Bord na Radharcmhastóirí	National Consumer Agency
Clinical Strategy & Programmes Directorate	Nursing & Midwifery Board Ireland
Consumer Association of Ireland	Nursing & Midwifery Board Ireland
Cystic Fibrosis Association of Ireland	Nursing Homes Ireland
Dental Council	Parkinsons Association of Ireland
Dept of Health	Pharmacists in Industry, Education and Regulation
Diabetes Federation of Ireland	Pre-Hospital Emergency Care Council
Food Safety Authority of Ireland	Primary Care Reimbursement Service, HSE
Health & Social Care Professionals Council (CORU)	Radiological Protection Institute of Ireland
Health and Safety Authority	Retail Excellence Ireland
Health Information Quality Authority	National Director Quality & Patient Safety, HSE
HPAI	School of Pharmacy UCC
ICGP	School of Pharmacy RCSI
Irish Cancer Society	School of Pharmacy and Pharmaceutical Sciences, TCD
Irish Chronic Pain Association	The Pharmaceutical Society of Northern Ireland
Irish Heart Foundation	The Veterinary Council of Ireland
Irish Hospital Consultants Association	Unicare/Doc Morris/Lloyds
RCPI Faculty of Pathology	Allcare Management Services Limited
Irish Medicines Board	National Treatment Purchase fund

Irish Patients Association	Patient Focus
Irish Pharmaceutical Healthcare Association	IPPOSI - Irish Platform for Patients' Organisations , Science and Industry
move4parkinsons	Health Research Board
National Cancer Control Programme	NMIC
Irish Institute of Pharmacy	