Public Consultation on the Draft Guidelines on the Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business (pharmacy) to facilitate compliance with Regulations 4(1), 4(4), 4(5), 5(1)(e), 5(1)(f), 5(1)(g), 6, 7 and 8 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

Submissions Received and Formal Responses

	SUBMISSION	PSI RESPONSE	
1.	**Bernard Leddy MPSI, Mari Mina Pharmacy, Ardmore, Co. Waterford**		
	I acknowledge the importance of being able to trace all medicinal products within the supply chain and that both Pharmacies and Wholesalers should have identifiable quality systems to do so. This is essential to preserve the integrity of the supply chain and prevent contamination by counterfeit products. I do, however, feel that the restriction of inter Pharmacy supply to a quantity of a medicinal product sufficient to meet the needs of a specific patient is too restrictive. I fully agree with the record keeping requirements and I am sure that they will form part of any inspection of RPBs but working in mainly rural locations I feel that this restriction is impractical. For example when trying to fill a prescription calling for 28 tablets and you only have 10 on hand it is much more sensible to be able to buy or borrow a full pack from another Pharmacy and this should be allowed. The record keeping requirements will prevent this being abused to transfer a van load of tablets in these circumstances. A bit more flexibility would help.	Regulation 6(4) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) states: '*The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient*.' Therefore transfer of medicinal product between pharmacies should only be to meet an individual patient's prescription needs. Transferring the nearest whole pack of medicinal product to meet this need is acceptable and in many cases preferable. The guidelines have been updated to remove any ambiguity in this regard.	
2.	**The Adelaide & Meath Hospital Dublin, Incorporating the National Children's Hospital *(Tim Delaney, Portfolio Director & Head of Pharmacy)***		
	I particularly welcome the clear and practicable guidance in relation to the disposal of returned patients' drugs.	Noted with thanks.	
3.	**Mark O'Connell MPSI, Supervising Pharmacist, Boots, Bloomfield Shopping Centre, Dun Laoghaire**		
	I am concerned that the storage guidelines does not recommend an Standard operating procedure (SOP) / ISO standard on cold storage with respect to cleaning / maintaining products in cold storage: the need to have an appropriate separate cold storage device(s) to store products when cleaning, and the regularity or standard needed to provide cold storage product for medicinal or clinical use with respect to microbial control, cleanliness and have in place detailed auditible protocol for such procedures- when cleaned, with what and SOP used	Agreed. The guidelines have been updated to include guidance on maintaining cold storage while cleaning the fridge. The updated guidelines state *'While the fridge is being cleaned due care should be taken to preserve cold storage conditions, to ensure the quality of the medicinal products is not adversely affected*.' The guidelines also state '*The refrigerator should be cleaned regularly as part of a general cleaning rota and cleaning records should be maintained. Refrigerator cleaning procedures should be in line with the manufacturer's instructions.*'	

	Such guidance as recommended frequency, what detergent / anti-microbial agents and limitations on temperature monitors to use would be invaluable tool to aid pharmacists implement the guidelines.	The frequency with which a fridge is cleaned and how it is cleaned should be determined in each pharmacy and should be adequate to maintain a clean fridge and reduce the risk of microbial contamination. It is not the intention of these guidelines to provide such specific detail. It has been stated in the guidelines that fridge temperature should be maintained at 2-8 °C, therefore, temperature monitors, which are alarmed, should signal if the temperature falls outside the required range.
4.	**Diabetes Federation of Ireland *(Kieran O'Leary)***	
	Can you please consider the inclusion of medical devices/equipment perhaps under the section on the safe disposal of unwanted medications. Under this section, you encourage facilitation for safe disposal of unwanted medications by encouraging patients to return them to the pharmacy. Should this not also apply to devices? After all we need to encourage patients to safely dispose any equipment they used to administer the drugs which the pharmacist supplies i.e. the responsibility of the pharmacist must extend to the devices they supply, needles, lancets, disposable pens etc. As far as I can see this is not addressed anywhere in the document. Pharmacists should ensure patients have sufficient and appropriate information on the safe disposal of medicinal products, e.g. in the event of a course of treatment not being completed. Patients should be facilitated and encouraged to return unwanted or expired medicinal products to the pharmacy for disposal. Pharmacists should inform patients that it is not appropriate to dispose of waste medicinal products in their household waste or through the mains water drainage system.	Noted. It is not the intention of this guidance document to address the sourcing, storage and disposal of medical devices, only medicinal products. The '*Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care'* (available on the PSI website www.pharmaceuticalsociety.ie.) contain some information on medical devices. The PSI may issue further guidance on medical devices in the future. While pharmacists need to be cognisant of their responsibilities in relation to medical devices, these guidelines only deal with the sourcing, storage or disposal of medicinal products. The PSI may issue further guidance on medical devices in the future.
5.	**Bon Secours Hospital, Glasnevin, Dublin 9 *(Margaret McCahill, Pharmacy Department)***	
	How is a pharmacist supposed to know why a medicinal product is	The guidelines state: '*The pharmacist should, where possible, inform the practitioner why the medicinal product is unauthorised, e.g. the medicinal product was recently withdrawn from the Irish market.. .'*.

	unlicensed? Also, unauthorized medicines are often initiated in hospital. The patient's GP then transfers the hospital prescription onto a GMS prescription form so it is difficult for the pharmacist to establish the actual prescriber who initiated the medicine, especially as many discharge prescriptions are written by house doctors	Although, pharmacists may not always be aware why a medicinal product is unauthorised, where they are aware or would reasonably be expected to be aware, the practitioner should be informed of this information. It is the responsibility of any practitioner, Consultant, GP etc., who prescribes an unauthorised medicinal product, to ensure any medicinal product they prescribe is appropriate for the patient under their direct responsibility. If a medicinal product is initiated in hospital contact with the original prescriber can often be facilitated by the practitioner in primary care, e.g. a GP may provide the pharmacy with a copy of the original hospital prescription or the practitioner's contact details.
6.	**Marie McConn MPSI Reg No. 4807**	
	1. August is a peak holiday month and the timeframe for submissions on this is therefore too short. Given that the topic is of direct interest to every practising community pharmacist, I would urge you to consider extending the Consultation Period. Below is a necessarily rushed submission. 2. If it was circulated in Word format it would facilitate people making notes in red on the text and returning them. This would be more convenient for me, as the person making the submission, rather than having to prepare a document with appropriate references, headings, numbering etc. Below, I have used your numbering system and considered each document in the order I received them. I only realised near the end that the numbers recur in each document, but I think you should be able to follow it. 3. It is very hard to argue with individual standards when one reads them. All of us want to practice to the highest standard, but	The deadline for submissions to the public consultation on the '*Guidelines on Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business'* was extended to Friday 17th September. The extension of the deadline facilitated stakeholders who wanted to draft a submission, but who may have been on leave in August, to do so. Noted. Noted.

	proportionality has to play a part at some stage.	
	4. 3.1.1 A list of wholesalers. The pharmacy will have a Suppliers Ledger. Surely this is sufficient. Invoices and Delivery dockets may be sent by the pharmacy to their auditor or book-keeper. Therefore they will not always be available. We are already obliged to "keep" them for 2 years if CD, 7 years for Revenue. Surely this is adequate without imposing another standard.	A list of authorised manufacturers and wholesalers, from whom medicinal products are sourced, should be maintained in each pharmacy. The exact mechanism by which this is maintained is at the discretion of the relevant pharmacist. Invoices or delivery dockets etc., should be maintained to permit the supplier of each consignment of medicinal products, and the medicinal products therein, to be clearly identified. Copies of such documents are appropriate where there is no other legislative requirement to keep the originals. The guidelines have been updated to reflect this.
	5. 3.1.3. If breaking packs is allowed, it is inevitable that pharmacies will be left with broken packs for which they have no further use. If a neighbour has a use for them, it should be possible for me to off-load them, in an exchange situation, to a pharmacy who knows they will be able to get rid of them. On cost grounds, and environmental grounds, i.e. there should be no avoidable dumping of product. I am sure you are trying to legislate against some form of informal wholesaling, but you are going to a level of detail that is disproportionate, when you state that the item must be borrowed on a patient specific basis. In addition, in a borrowing / exchange situation, the need for duplicate records of receipt and supply is also OTT (over the top). It could even be confusing, as there is then a need to reconcile Pharmacy A's supplies record with Pharmacy B's receipts record.	Noted. However, the transfer of medicinal products between retail pharmacy businesses other than to meet an immediate patient need is not permissible. Regulation 6 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) sets out from whom medicinal products may be sourced i.e. authorised wholesalers and manufacturers. Regulation 6(4) of these regulations state: '*The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient*.' Therefore the transfer of medicinal product between pharmacies should only be to meet an individual patient's prescription needs (unless the pharmacy holds the appropriate wholesale licences). It is important that detailed records are maintained to ensure the traceability of medicinal products.
	6. 3.2.3 Exempt Medical products. I may not know why the product is Unlicensed, so how can I tell the GP? Also, sometimes, when I have told patients that the product is exempt, I have provoked a	The guidelines state: '*The pharmacist should, where possible, inform the practitioner why the medicinal product is unauthorised, e.g. the medicinal product was recently withdrawn from the Irish market.. .*'. Although, pharmacists may not always be aware why a medicinal product is unauthorised, where they are aware or would reasonably be expected to be aware, the practitioner should be informed of this

		level of anxiety which has caused the patient not to take the medicine. This has been very regrettable in some cases where I know the patient would have benefitted from the medicine. Professional discretion should have a role. After all I am a trained professional. Also, regarding Broken Bulk, could I suggest that the PSI could make a statement authorising us to dispense in whole packs in these situations, given that the medicines tend to be less regularly used, and a tighter borrowing policy as outlined above will mitigate against one's ability to get rid of unused portions of packs.	information. A patient has the right to know a medicinal product is unauthorised. The guidelines have been updated to state: *Patients should be made aware of what this means and be given the necessary reassurance, as appropriate.* Pharmacists can only dispense a medicinal product to a patient on foot of a practitioner's prescription and in accordance with that prescription. These requirements are outlined in the Misuse of Drugs Regulations 1988 (as amended) and the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended). If the intentions of the prescriber are unclear he or she should be contacted for clarification.
	7.	3.3 Recalls. When Recalls go to patient level, or even to pharmacy level, many companies have a policy of not crediting broken packs. It would be helpful if the PSI included a recommendation on this in this document.	Noted. However this is not within the remit of the PSI.
	8.	If all products are in sealed packaging, there should be no need to store medicinal products separately from non-medicinal. Common sense dictates that heavy products are stored low down, as do H&S Guidelines, but one has to have regard to reasonable space restrictions. Most people will only have one store. Medicinal foods such as Ensure and the like are going to end up in people's stores as well. I know you mean food for consumption in the pharmacy, but it would be helpful to state that. Common sense also dictates that animal feed supplements and other products with strong odours should be separate from regular stocks.	Noted. It is good pharmacy practice to store medicinal products separately from non-medicinal products. However, the guidelines have been updated to state: '*the storage of medical devices or health related items with medicinal products may, in certain circumstances, be appropriate.'* The guidelines have been updated to clarify that this statement does not refer to the storage of medicinal foods. Noted. This is what is currently stated in the guidelines.
	9.	3.3.1. I have a large safe. It can fit my total CD requirements, easily 6 - 8 bottles of Methadone, some coin bags and a cash box. I think that's fine. I can't see the need to have 2 safes. Access to the key is controlled, but one has to have regard to safety and welfare of staff in a raid situation. I think this should	As stated in the guidelines: '*The controlled drugs safe or cabinet should be used solely for the storage of medicinal products. This restricts access to the safe and reduces the frequency with which the safe is opened and closed; therefore, increasing the security of the storage of CD2 and CD3 medicinal products'.* Noted. The safety and security of pharmacy staff and/ or patients is

	be reflected in any guideline. I don't want any dead heroes on my staff. Also, if a Garda Superintendent has to certify my safe every 2 years, someone had better tell them. Because I think someone called in once, within the 21 years I am here. I got no certificate.	paramount. Security should be assessed using the PSI's '*Pharmacy Security Assessment Template: Guidance Document for Retail Pharmacy Businesses*'. The PSI also recommends contacting a crime prevention officer. It is the responsibility of the pharmacy owner to ensure that their controlled drugs safe or cabinet complies with all legislative requirements outlined in the Misuse of Drugs (Safe Custody) Regulations, 1982 (as amended) and, where necessary, appropriate certificates are obtained and retained in the pharmacy.
	10. 3.5. I don't have any appreciable Veterinary business, but I think the requirement for a separate fridge for Vet products is OTT. One of the first things a pharmacist learns (or used to learn) in the pre-reg year, was to read the label. This should remove any scope for confusion between the two types of product. Live vaccines whether human or veterinary might be a different matter, but that is a reasonably rare situation.	It is important that a pharmacy which supplies refrigerated veterinary medicinal products stores such products in a separate fridge. Separate storage will minimise the risk of contamination and/ or inadvertent dispensing of veterinary medicinal products to humans. This is also a requirement in other countries, e.g. Canada.
	11. 3.6. I don't see why High Tech meds should be stored separately from regular dispensary meds. For example, Revatio and Viagra have the same active ingredient. Why should one be stored separately? Keeping documentation with the product strikes me as a bad idea. Our system is to have a file for each patient. When the product comes in the docket is put on the patients file. When it is dispensed the docket is attached to the patient's claim form. It simply can't be retained on the premises because it has to be sent to the PCRS in order to claim for payment.	The PSI's High Tech Practice Notice states: '*This scheme (the High Tech Scheme) operates as a **patient-specific pharmaceutical care programme** with a nominated pharmacy responsible for a specific patient and their complete and complex medication and health needs. Care delivery must ensure that patient-specific dispensing occurs with a particular product obtained for a particular individual patient*'. This patient-specific pharmaceutical care programme should include the storage of high-tech medicinal products in a patient-specific manner. The guidelines have been updated to state that documentation related to High-Tech medicinal products, e.g. suppliers' invoices, copies of prescriptions etc., should be stored in a patient-specific manner, e.g. with the medicinal products or in a dedicated High-Tech file.
	12. 3.6. I can see some merit in storing Exempt products separately, but keeping paperwork with them is again inadvisable in my view. Not all Exempt meds are patient specific. I have 2 people on Versatis patches, 3 people on Amitryptilline, 3 people on Colchicine. Of course I keep a stock. I have to break bulk in the case of Colchicine and the bottle is tiny. How could I wrap an	Noted. Unauthorised medicinal products should only be ordered on a patient specific basis. Such medicinal products may be ordered on behalf of one or more patients.

	invoice around a 4cm bottle? Copying prescriptions used to be illegal and I fail to see why it is necessary. There are requirements to file them under the various Prescription regulations anyway. For business reasons, all wholesalers invoices need to be checked off against the statement. These guidelines seem to suggest that we should have a separate file for CD invoices, Exempt invoices, High Tech invoices etc. This would make checking the statement a nightmare.	The guidelines have been updated to state that documentation related to 'Exempt' medicinal products, e.g. suppliers' invoices, copies of prescriptions etc., should be stored in a patient-specific manner, e.g. with the medicinal products or in a dedicated 'exempt' medicinal product file. Filing copies of invoices is appropriate where there is a valid reason to file the original invoice in an alternative location. The guidelines have been updated to reflect this.
	13. 3.1.2. Waste. I submit that it is impractical and inadvisable to state that waste meds should not be stored in the dispensary. The dispensary is under the direct supervision of a pharmacist. Putting out of date Psychotropic medicines into another area is actually opening them up to illicit use.	All waste medicinal products must be segregated from pharmacy stock, appropriately labelled and stored in a designated area of the pharmacy under the control of the pharmacist and inaccessible to members of the public. As stated in the guidelines, they should not be stored in the dispensing/ working area of the pharmacy; this usually encompasses the majority of the dispensary but may vary depending on the layout and specific structure of each pharmacy. Waste medication should not be stored in these areas to ensure it is not inadvertently re-used.
	14. 3.1.3. As far as I know, the waste disposal people won't take liquids. Also, the question arises as to the safety, or potential chemical reactions which might occur if multiple waste liquids are mixed together. The guidelines are silent on this.	It is each pharmacist's responsibility to discuss with their waste management company how they should appropriately dispose of all waste medicinal products, including liquids. Normally when disposing of liquid medicinal products they should remain within an intact container prior to placing them in the disposal bin. Waste bins containing liquids should have sufficient absorbent material in the bin to absorb the bin's entire liquid content. The guidelines have been updated to include this information.
	15. 3.1.5. If patient labels are to be removed from packaging, then companies need to start making readily removeable labels, which could be undesireable in terms of where the product is actually being used by a patient. But rendering labels illegible prior to destruction could take hours.	Noted. However, it is important that pharmacists ensure patients' confidentiality is maintained at all times. The guidelines have been updated to state *'Returned medicinal products which contain confidential patient information, e.g. patient specific labels, should be treated in a manner which maintains patient confidentiality*.'
	16. 3.2.4. and 3.2.5. Suppliers of medicinal waste bins generally	

	exclude CDs from the list of what they will take. In fact, if they spot check the bin and find identifiable CDs they levy a charge on the customer. Mixing it with a substance what does this mean? I have heard compost suggested before. Will they take contaminated compost? Also, there will be a time consideration for any authorised person to witness destruction. For example punding 50 MST in a mortar and pestle, then breaking 8 ampoules and extracting the contents, then pouring some liquids into something, then adding an inert substance. All this could take some time. Will that be fair for the person doing the witnessing. Do they have time to do this. It could easily take 1 to 2 hours. If a PSI Inspector calls unannounced, the pharmacy is extremely unlikely to have the time to avail of their services in this regard. An announced visit would facilitate preparation for this element of our function. 17. These guidelines impose requirements for multiple SOPs. SOPs on checking off orders, cleaning, storing, returning, checking dates, patient waste, temperature monitoring, humidity monitoring, medicine destruction, CD destruction, there were more. Again, I think some regard needs to be had here to proportionality. As I said at the start, everyone wants to operate to the highest standards. However, there needs to be some regard to proportionality. Smaller, independent pharmacies tend to have regular staff, the supervising pharmacist and superintendent pharmacist tend to be the same person. This person tends to be full-time and permanent and tends to be more hands on in every aspect of day to day work. Higher levels of documentation may be necessary in larger outfits, with staff changing in shifts, but they tend to have back office support which will facilitate all this record keeping. I am not advocating that a slipshod approach should be adopted. Simply that some level of proportionality	Pharmacists should check with their waste disposal company what waste medicinal products they will accept. The destruction of controlled drugs results in a 'destroyed material' which is not classified as a controlled drug. Therefore, waste disposal companies should accept such products for disposal. The guidelines have been updated to include this information. Noted. However, as with all aspects of managing a retail pharmacy business the superintendent and supervising pharmacists should decide how best to destroy and dispose of medicinal products. They should refer to legislation, consult with the disposal company(s) and ,where CD2 controlled drugs are involved, consult with an authorised person. The legislation sets out the range of authorised persons (Refer to Appendix 1 of the Disposal Guidelines). Noted. Under Regulation 4(1)(a) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), the pharmacy owner "shall provide and maintain such... **procedures** for the storage, preparation, dispensing, compounding, sale and supply of medicinal products..."Written policies and procedures help ensure patients receive high quality care when using the professional services of a retail pharmacy business. The PSI has highlighted the important sourcing, storage and disposal procedures that a pharmacy should develop SOP's for, however, procedures should be generated for each individual operation carried out in the pharmacy practice that impacts patient care and safety. It is important that superintendent and supervising pharmacists put comprehensive policies and pharmacy specific procedures in place, irrespective of the staffing arrangements in the pharmacy. Such policies and procedures will help to ensure the pharmacy operates consistently, whether the supervising pharmacist or another registered pharmacist is present in the pharmacy; therefore, ensuring

	needs to be maintained. Our primary role is to meet, dispense, advise and support patients and we need to have time for this!	patients receive a consistent level of patient care. Policies and procedures are also a useful tool for training new staff and regular review of such documents can aid in maintaining the quality of pharmacy practices. Once in place policies will only need to be reviewed either when an element of the process changes or annually.
7.	**Willie Roban, Hazard Substance Manager, HSE**	
	Thank you for sending me the Draft Guidelines on Sourcing, Storage and Disposal of Medicines, I have looked at the section dealing with waste management/disposal The advice is general in nature. The pharmacist/owner of the undertaking is legally responsible for the waste as a generated of the waste, holder of the waste and occupier of the premises. there is a lot more waste legislation that applies amend maybe helpful to pharmacists if it was set out in a table with a short summary of each piece of legislation (similarly to what we did in the Healthcare Waste Awareness Handbook).	The guidelines have been updated to clarify pharmacy owners and pharmacists' responsibilities as generators and holders of medicinal product waste. It is not the intention in these guidelines to give details of all the waste legislation which may be relevant; however, the guidelines have been updated to include further information on waste legislation and to direct pharmacists to the Irish Statute Book, the Environmental Protection Agency website etc. The HSE's Waste Management Awareness Handbook 2011 has been reviewed and the guidelines updated where appropriate.
	The advice on waste packaging needs to be enlarged to include photos of the sharps and pharmaceutical bins, The Department of Health and Children set out a standard colour code for these bins and this is used throughout the health services public and private they should check out the Segregation Packaging and Storage Guidelines for Healthcare Risk Waste, Department of Health and Children, 3rd Edition 2004	This document, and the 2010 document, have also been reviewed and information has been included where appropriate, e.g. information on the colour coding of waste packaging.
	It is also important for pharmacist to know that all waste packaging must be UN approved and must state this on the box, they must also carry a UN hazard identification number this number indicates the type of material in the container along with a identification label showing the hazard class the material belongs to.	This information has been included in the updated guidelines.
	The Draft mentions that waste training should be supplied to pharmacy staff, however, it does that outline what this training should involve, the	Noted with thanks. Pharmacists and pharmacy owners should ensure they have sufficient knowledge of the legislation and the PSI's

	HSE has developed a number of training programmes around the management of healthcare risk waste, one in particular directed at healthcare risk waste in the community i.e. general practitioners, public health nurse, dentist the Society should look at the module it may fit the bill on training.	guidelines to ensure they can carry out the disposal of medicinal products in a manner which will not result in any danger to public health or risk to the environment.
	There should be a dedicate storage area for medicinal waste, in new pharmacies it should be included in the fit-out or design stage. As you know at present the DUMP project gives pharmacies in the old South Western Area Health Board region a medicinal waste collection four times a year, it means a lot of waste stored between collections. The HSE have been involved in the design of on-site waste storage facilities and storage containers some of the waste storage container designs may suit pharmacies.	The guidelines state that a dedicated area for the storage of medicinal product waste should be provided and have been updated to also state that the storage area should be of sufficient capacity to allow for the safe storage of all waste medicinal products.
	The transport of medicinal waste: Medicines can be dangerous for carriage particularly cytotoxic drugs, some medicines are also flammable. the Carriage of dangerous goods regulations requires that the consigner of a hazardous goods (those consigning hazardous material for road transport) are responsible for identifying and classifying the material before it can be accepted for transport, it will be important for the Society to find out if medicinal waste comes under the scope of the carriage of dangerous goods regulation, is the pharmacist the consigner of the waste and what legal obligations would this put on the pharmacist/owner of the business. I would advise that the Society discuss this issue with the Health and Safety Authority.	The PSI has, following contact with the Health and Safety Authority (HSA), the Environmental Protection Agency (EPA) and the National TFS Office, updated the guidelines in relation to the transport of dangerous goods, as appropriate. The guidelines also refer pharmacists to the HSA, local authorities, the EPA, the NTFSO and their waste management company if they require further information on their requirements under, for example, the Carriage of Dangerous Goods by Road Regulations (S.I. No. 288/289 of 2007).
8.	**Mater Misericordiae Hospital, The Sisters of Mercy, Dublin 7 *(Ciaran Meegan, Head of Pharmacy Services)***	
	As Head of Pharmacy Services and Superintendent Pharmacist, Mater Misericordiae University Hospital (MMUH), I would like to comment on two sections of the above guidelines. These are listed below. 1. Draft Guidelines on the Storage of Medicinal *ProductsSection 3.6*	All retail pharmacy businesses must comply with the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) and the guidelines written to facilitate compliance with the regulations. In particular care settings, e.g. where a retail pharmacy

	Storage of 'High Tech' and 'Exempt' Medicinal Products ***"High Tech Medicinal Products and 'Exempt' medicinal products are stored separately from other medicinal products in a patient-specific manner".***	business is located within a hospital, it may be appropriate to put alternative policies and procedures in place in respect of specific aspects of the guidelines. Such policies and procedures should take account of all legal and professional responsibilities. For certain aspects of practice it may be necessary to work with other healthcare professionals to put interdisciplinary policies and procedures in place. Where such alternative policies and procedures are in place, in particular care settings, the PSI expects that the superintendent pharmacist, supervising pharmacist, any relevant registered pharmacist and/ or the pharmacy owner to act in the best interest of patients and to ensure the integrity of the final link in the supply chain for a medicinal product, from the manufacturer to the patient, is maintained. Any deviation from the guidelines and the justification for such deviation should be recorded. The guidelines have been updated to reflect this.
	This would be quite difficult to implement for a number of reasons: • The MMUH Pharmacy stores medications for use in a 700-bed hospital. Most of the High Tech and 'Exempt' medicinal products stored are for use within the hospital, which is not the 'Retail Pharmacy Business'. It is not possible to know which medications will be used for the 'Retail Pharmacy Business' and which will be used for the Hospital Pharmacy.	Noted. It is not necessary to store medicinal products for use within the hospital separately from those used for outpatients/ staff etc., except in the specific circumstances outlined, i.e. 'high-tech' and 'exempt' medicinal products ordered on behalf of a specific patient. There should be a patient specific filing system which contains invoices, or copies of invoices and copies of prescriptions for patients receiving 'exempt or' high-tech' medicinal products through the retail pharmacy business.
	• The volume of stock held is very large. Medications are currently stored in such a way that allows them to be appropriately accessed in a safe and convenient manner. The introduction of these guidelines would change this and potentially introduce significant medication errors into a currently safe and efficient process.	Noted.
	• Many of the medications are stored in a robotic system. This system stores drugs according to barcodes - it would not be	Noted. However, the use of a specific system, e.g. a robotic system, is not an appropriate reason not to store medication in accordance with the guidelines. A superintendent pharmacist operating in a specific

	possible to store the 'Exempt' and 'High-Tech' medications separately in the robot. ***"These medicinal products should be stored in a patient specific manner and all relevant documentation should be kept with the 'exempt' medicinal product, e.g. supplier's invoice, copy of prescription"*** This would be extremely difficult to implement for a number of reasons: • As soon as a prescription is received for one of these medications, it is dispensed to the patient therefore it would not be possible to keep any prescriptions beside the 'Exempt' and High Tech medicinal products kept on the shelves. As mentioned above, the vast majority of these medications are actually for use within the Hospital and are not actually dispensed but rather are supplied to wards. • Suppliers Invoices are currently stored in the Finance Department of the Hospital, not the Pharmacy Department. It would not be practical to store the invoices next to the medications in a Hospital Pharmacy. 2. Draft Guidelines on the Storage of Medicinal Products *Section 3.1.3 Stock Management* ***"In exceptional circumstances, if a medicinal product is removed from its original packaging it should be labelled with its name, strength, marketing authorisation number, batch number, expiry date, the name of the supplier (wholesaler or manufacturer), and packaged with a copy of the patient information leaflet"*** I would suggest that the requirement for including the marketing authorisation number is probably unnecessary if the brand is specified, as the marketing authorisation number can be linked. Similarly, I wonder why the name of the supplier is required, as the manufacturer is implicit when a brand name is included. I feel that the addition of these to a label	care setting, e.g. a hospital pharmacy, may, however, put alternative policies and procedures in place regarding, for example, the storage of exempt medicinal products for supply to inpatients etc. The guidelines have been updated to state that documentation related to 'exempt' or 'High-Tech' medicinal products, e.g. supplier's invoices, copies of prescriptions etc., dispensed through a retail pharmacy business, should be stored in a patient-specific manner, e.g. with the medicinal products or in a dedicated 'high-tech' or 'exempt' file. Pharmacies in particular care settings should have appropriate policies and procedures in place for all types of supply, i.e. to inpatients and where relevant to outpatients and staff. Copies of such documents are appropriate where there is no other legislative requirement to keep the originals. The guidelines have been updated to reflect this. The inclusion of the marketing authorisation number is necessary. As stated in the sourcing guidelines, there are varying routes through which a particular medicinal product may be authorised, the medicinal product may, for example, have an Irish or a parallel import

	will make the label very cluttered, thus hard to read and as Chairman of the Irish Medication Safety Network am certain that it would unquestionably lead to medication errors. While I acknowledge the value of including a patient information leaflet with all medications it should be considered that not all repackaged medications are handed to patients and therefore do not actually require a PIL. It would simplify matters if the guidelines recommended that where a medicine has been repackaged, a PIL must be inserted if that repackaged medicine is dispensed to a patient.	authorisation etc. If a medicinal product is recalled, it is important to know the route of supply and the Marketing Authorisation number of the medicinal product. It may be appropriate to include certain information on a second label if necessary. A medicinal product should always be packaged with a patient information leaflet when the product is stored within a pharmacy or dispensed to a patient. It would also be good practice to include a patient information leaflet (or the Summary of Product Characteristics for the medicinal product) with all medication going to ward level to ensure all healthcare staff have access to the relevant information, as appropriate.
	<u>Recommendations</u> As outlined above it would be extremely difficult for the MMUH Pharmacy Department (and all hospital pharmacies) to comply with Section 3. 6 of the Guidelines on Storage of Medicinal Products within a Retail Pharmacy Business. The recommendations on the storage of paperwork included in this document are probably an unnecessary addition to the process. I wonder how the storage of paperwork impacts on any legal, safety or appropriate storage issues and would see this as a housekeeping/filing issue for each Retail Pharmacy Business to decide themselves and probably too prescriptive for a guideline document. If it is felt that the inclusion of these details is necessary from a legal, safety or storage perspective then I would suggest that the guidelines would be amended to state that this section does not apply to the Retail Pharmacy Business of Hospital Pharmacies. Additionally, as stated above, I would feel that there is no need to include the manufacturer's authorisation number and name of the supplier on the label of a repackaged product. Unless this is necessary from a legal perspective, I would suggest that these details are omitted. I	Noted. As outlined previously. Maintaining and retaining appropriate paperwork, particularly for high risk medicinal products, i.e. both 'exempt' and 'high-tech' medicinal products, is necessary to ensure the traceability of such products. Such products should be dealt with in a patient-specific manner and required documentation may be requested during inspections. A superintendent pharmacist operating in a specific care setting, e.g. a hospital pharmacy, may, however, put alternative policies and procedures in place regarding, for example, the storage of 'High-Tech' medicinal products for supply to inpatients etc. Noted. As outlined previously.

	also suggest that the patient information leaflet is only required to be inserted when the medication is being dispensed to a patient. In conclusion, I am very happy to make these suggestions to the PSI regarding the guidelines. I am sure that it is clear that these guidelines actually amplify some of the inherent differences between hospital pharmacy practice and those of a "retail pharmacy business". I think that this is an excellent opportunity for the Regulator to clearly identify to practitioners that there are different professional practices in different aspects of the profession. Please do not hesitate to contact me if you wish to discuss these comments in more detail and would be delighted if I can in any way be of assistance in the redrafting of these guidelines.	Noted. Noted with thanks.
9.	**Oonagh Hassell MPSI, Reg: 7196**	
	I commend the introduction of increased traceability and accountability in the supply of medicinal products. I have made an SOP for the inter-pharmacy exchange of medicinal products, but I was wondering, what happens when one pharmacy in a group orders stock for another pharmacy, as in Rep orders. Is this then not permissable under the new guidelines? With the recent cuts that pharmacy has received, sometimes the only cost-effective ordering procedure is to do it between shops that are owned by the same person. If quality and traceability is maintained between two pharmacies in terms of ordering for both, is it then ok? This did not seem to be addressed in the draft guidelines.	Regulation 6 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) sets out from whom medicinal products may be sourced i.e. authorised wholesalers and manufacturers. Regulation 6(4) of these regulations state: '*The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient*.' Therefore the transfer of medicinal product between pharmacies should only be to meet an individual patient's prescription needs (unless the pharmacy holds the appropriate wholesale licences). It is important that detailed records are maintained to ensure the traceability of medicinal products. Provided that appropriate policies and procedures are in place, medicinal products may be ordered on behalf of a number of pharmacies. Any such methods of ordering must be agreed between the relevant superintendent, supervising and registered pharmacists

		and such medicinal products must be delivered directly from the wholesaler or manufacturer to the retail pharmacy businesses which will be storing and dispensing the medicinal products.
10.	**Ilse Maria Nolan PhD, Novartis , Dublin 4 (*QA Responsible Person/Regulatory Affairs Officer*)**	
	I wonder if you could help me please with a question relating to the Draft Guidelines on sourcing, storage and disposal of medicines. In relation to section 3.2.3..the following is mentioned: "Pharmacists should be aware, and should ensure prescribers are informed, that the IMB does not permit 'exempt' medicinal products to be sourced and supplied if an authorised alternative is available in Ireland." Could you please advise if this is a requirement under current legislation, and if so, could you please provide the reference?	The guidelines have been updated to state 'Pharmacists should be aware, and should inform prescribers, that 'exempt' medicinal products should not be sourced or supplied if a suitable authorised alternative is available in Ireland.' This has been altered following consultation with the IMB. It is in patients' best interests that where authorised medicinal products are available, an unauthorised medicinal product is not supplied.
11.	**Cicely Roche, Senior Lecturer in Pharmacy Practice, TCD School of Pharmacy and Pharmaceutical Sciences (In personal capacity)**	
	I welcome your public invitation to make comment on the draft guidelines on Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business and wish to make some brief comments/suggestions regarding the proposals. **a) Draft guidelines on the Sourcing of Medicinal Products for sale or supply in conducting a Retail Pharmacy Business (to facilitate compliance with Regulations 5(1)(g), 6 and 8 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008.)** 3.1.4 : Policies and procedures • Final sentence: '*Procedures should be reviewed and updated regularly, e.g. when any element of the process changes and, at a minimum, annually*' seems to require amendment to reflect that, while a quality assurance system requires	Agreed. This was the intention of the guidelines; the wording has been updated to ensure greater clarity in this section.

	regular review (usually a minimum of annually) of policies and procedures, and documentation provided to confirm that such reviews have occurred, it would not be entirely appropriate to require that the policies and procedures be <u>updated</u> a minimum of annually. (Some policies/procedures may require update at much more infrequent intervals.)	
	3.2.3 : Medicinal products exempted from the requirement to be authorised – 'Exempt' Medicinal Products: • (paragraph 2)…. As a practitioner, I would never be certain that a medicinal product has <u>never</u> been authorised in Ireland – and believe it would be unreasonable to expect me to have that information. I could not, therefore, insert a corresponding record into the patient's file. (It is accepted that a practitioner will sometimes/generally be in a position to confirm that a product has been recently withdrawn.)	Agreed. Your concern has been noted and the wording reviewed. The guidelines state*: 'The pharmacist should, where possible, inform the practitioner why the medicinal product is unauthorised, e.g. the medicinal product was recently withdrawn from the Irish market..* the remainder of this sentence has been removed. '. Although, pharmacists may not always be aware why a medicinal product is unauthorised, where they are aware or would reasonably be expected to be aware, the practitioner should be informed of this information.
	b) Draft guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business (to facilitate compliance with Regulations 4(1), 4(4), 5(1)(e), 5(1)(f), 6(3) and 7 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008.) 3.1.1 : General Guidance • Typographical (storage *of* medicinal products)	Noted with thanks and changed.
	3.1.2 : Storage areas • I would respectfully suggest that reference to the avoidance of displaying Medicinal Product in 'Retail Pharmacy' premises windows be specifically mentioned (either here or elsewhere in the guidance documents.)	It is important medicinal products are not stored in inappropriate locations, e.g. windows. This will be dealt with in more detail in future guidelines on the premises requirements of a retail pharmacy business.
	3.8 : Policies and Procedures • Final sentence (as per sourcing guidelines) : '*Procedures should be reviewed and updated regularly, e.g. when any element of the*	

	process changes and, at a minimum, annually' seems to require amendment to reflect that, while a quality assurance system requires regular review (usually a minimum of annually) of policies and procedures, and documentation provided to confirm that such reviews have occurred, it would not be entirely appropriate to require that the policies and procedures be <u>updated</u> a minimum of annually. (Some policies/procedures may require update at much more infrequent intervals.)	Agreed. This was the intention of the guidelines; the wording has been updated to ensure greater clarity in this section.
	c) Draft guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business (to facilitate compliance with Regulations 4(5) and 6(3) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008.) 3.1.1 : I would respectfully suggest that reference to a time-frame for disposal of Medicinal products would merit consideration. Without such guidance, there could be a risk that medicines pending disposal would accumulate in Retail Pharmacy Businesses, not least due to the financial cost of disposal. 3.1.6 & 3.2.6: Policies and Procedures • Final sentence (as per sourcing guidelines) : '*Procedures should be reviewed and updated regularly, e.g. when any element of the process changes and, at a minimum, annually*' seems to require amendment to reflect that, while a quality assurance system requires regular review (usually a minimum of annually) of policies and procedures, and documentation provided to confirm that such reviews have occurred, it would not be entirely appropriate to require that the policies and procedures be <u>updated</u> a minimum of annually. (Some policies/procedures may require update at much more infrequent intervals.)	The guidelines already state: '*When full and sealed, the bins should be removed from the pharmacy promptly by an appropriately authorised waste management company for incineration*.' and waste medication if it '*cannot be processed immediately.. should be segregated from pharmacy stock, clearly labelled 'Medicines for Destruction' and stored under the control of the pharmacist in a specifically designated area of the pharmacy, pending timely processing for disposal'*. The guidelines have also been updated to state waste medicinal products '*should never be allowed to accumulate in the pharmacy*'. Agreed. This was the intention of the guidelines; the wording has been updated to ensure greater clarity in this section.
	3.2.3 : Storage of Waste Controlled Drugs • I do not recognise, in context, the phrase 'non-conforming controlled drugs' and would respectfully suggest that the term	Non-conforming controlled drugs are controlled drugs which are unfit for sale or supply, for example, if a controlled drug is damaged or has

	be defined in the guidelines.	been stored outside the terms of its Marketing Authorisation. A definition has been included in the updated guidelines to increase clarity.
	It is assumed that waste management companies are satisfied with proposal for denaturing CD's in a manner that the material signed for by the pharmacist does not subsequently contain 'controlled drugs' *per se*. (see attached extract from earlier submission to PSI – Appendix 1). It is also assumed that the PSI and the Gardai have confirmed appropriate means by which safes for CDs (Safe Custody Regulations) may be certified.	Pharmacists should check with their waste disposal company what waste medicinal products they will accept. The destruction of controlled drugs results in a 'destroyed material' which is not classified as a controlled drug. Therefore, medicinal product waste disposal companies should accept such products for disposal. The guidelines have been updated to include this information. A member of an Garda Siochana (not below the rank of Superintendent) can certify that a safe or cabinet '*meets the constructional and other specifications which are necessary to render the unit fit for purpose as outlined in IS 267: 1985 and the Schedule of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No. 321 of 1982) and that the unit, therefore, provides an appropriate degree of security.'*
	Furthermore, it seems appropriate that reference should be made to medical devices under the heading of 'medicinal products'. It is not entirely clear that these guidelines have been written with medical devices in mind. Finally the recommendations of the Shipman reports are foremost in mind reading some of these guidelines. It seems an opportunity to address some of those recommendations, e.g. guiding pharmacists to have those to whom they supply controlled drugs sign for receipt. This submission is offered in a personal capacity, in the interests of pharmacy practice. Please feel free to contact me if you require any further details.	Noted. It is not the intention of this guidance document to address the sourcing, storage and disposal of medical devices, just medicinal products. The '*Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care'* (available on the PSI website www.pharmaceuticalsociety.ie.) contain some information on medical devices. The PSI may issue further guidance on medical devices in the future. These are not guidelines on the supply/ dispensing of medicinal products; this comment will be considered when drafting guidelines on the sale and supply of medicinal products. Noted with thanks.

12.	**HPAI *(Elaine Conyard, President)***	
	Attached please find a range of comments received from some of our colleagues working in hospital pharmacy in relation to the Draft Guidelines on the Sourcing, Storage and Disposal of Medicines.	Noted
	As you can see there are many comments reflecting a degree of ambiguity about how to balance and organise the work associated with a Retail Pharmacy Business (RPB) and a hospital pharmacy department within the one location.	Noted
	Issues which require particular attention are the management of returns, the management of paper records, communications with prescribers and labelling requirements which are not compatible with current IT systems. However as you can see from the attached document there are a number of other issues also.	Noted. These will be addressed individually below.
	Given the range of uncertainty in relation the hospital sector of RPBs it may be that written feedback alone would not suffice to sort these issues out and that face-to-face discussion may be more productive. There is much interest among hospital pharmacists in endeavouring to comply with both the spirit and the letter of the law, but it needs to be done in a manner which does not take from our multidisciplinary care of our inpatients and its provision in a cost-effective manner.	Noted. The PSI intends, in the future, to address hospital specific practice issues and develop further guidance for this area.
	We would therefore welcome the opportunity to have clarified the many ambiguities which exist, prior to the formal signing off of these guidelines.	
	• P4 – the retention of documentation e.g. invoices and delivery dockets, is only possible in some hospital pharmacies for a limited period of time as they pass to the Finance function for payment. How this can be managed needs clarified. How long documentation for each consignment should be held in Pharmacy?	Copies of invoices are appropriate where there is no other legislative requirement to keep originals at the retail pharmacy business premises. The guidelines have been updated to reflect this. Further clarification regarding the length of time documentation should be retained for will be outlined in future guidelines on record keeping.

	• P5 – medicinal products previously dispensed or supplied must never re-enter the supply chain. What is the position of ward returns and medication transfer from one ward to another via pharmacy (e.g. short-dated stock)? This is done regularly in hospital to minimise wastage and reduce costs. In some cases the medication may be held for clinical reasons and patients may be recommenced – do they then require 'new' stock? Hospital pharmacies routinely accept returns of medication that have been dispensed to wards. The draft guidelines do not explicitly deal with returned medications from wards but the statement would imply that it is not allowed. If that is the case, it would have a huge financial impact on hospital drug costs.	Reuse of medicinal products should only ever occur within a defined premises, which is a single entity, with a single quality system in place. Medication which has been removed from its primary packaging during the dispensing process should never be accepted back into pharmacy stock and should be disposed of. It may, depending on the circumstances, be appropriate to reuse medication, still in its original packaging, which was previously supplied to wards etc. If a hospital pharmacy is reusing such medication, the relevant pharmacists must ensure the hospital has appropriate policies and procedures in place. The superintendent and supervising pharmacists must be satisfied that medication has been stored appropriately, e.g. stored at appropriate temperatures etc. (all storage areas should be temperature monitored). It is also imperative that there has been no unauthorised access to the medication, i.e. only healthcare professionals have had access to the medication, to ensure that the integrity of the medicinal product is maintained. Issues such as this will be dealt with in future by the Pharmacy Practice Development Committee of the PSI.
	• P5 – medical samples should not be stocked or supplied. In hospital pharmacy samples are often held for the particular use of a Consultant and supplied on request from that Consultant – can this no longer happen?	If medical samples are stocked on behalf of a Consultant doctor there must be robust interdisciplinary policies and procedures in place to ensure, for example, the traceability of the medicinal product. Such products should not form part of regular stock, and should only be stored, in the hospital pharmacy, on behalf of a practitioner. Medical samples should be stored in a designated area of the pharmacy, separated from general stock.
	• P9 – informing the prescriber of the reason that a product is exempt – in many cases the reason is not notified to the pharmacist. Also the amount of time and number of prescribers involved could make this simply unworkable in a hospital situation.	The guidelines state*: 'The pharmacist should, where possible, inform the practitioner why the medicinal product is unauthorised, e.g. the medicinal product was recently withdrawn from the Irish market.'* Although, pharmacists may not always be aware why a medicinal product is unauthorised, where they are aware or would reasonably be expected to be aware, the practitioner should be informed of this

		information.
	• P9 – Is it not the responsibility of the prescriber to explain to the patient and record in the notes the reason why an exempt is being used? It is not usual in many hospitals for a pharmacist to have access to these patients.	A pharmacist, as an autonomous healthcare professional, must be satisfied that they have appropriately discharged their responsibility to a patient. They may do so in collaboration with the multidisciplinary healthcare team, if appropriate.
	• P9 – the last line of this page should read if a *suitable* authorised alternative is available. Not all authorised products may be suitable from a clinical perspective	Agreed. The guidelines have been updated to reflect this.
	• P10 – appropriate level of supply of exempt products – in hospital these can often be stock items thus depending on usage, significant amounts may need to be held in stock.	Noted. It is accepted that, where a a pharmacy department is located in a hospital, it may be appropriate to maintain a higher level of stock of unauthorised medicinal products to ensure such products are available when needed urgently.
	• P10 – where no PIL is available in English then it is likely that the rest of the information (livery and labelling) is the same. How is the pharmacist to counsel the patient in these cases?	A pharmacist should not supply a medicinal product unless, in accordance with regulation 9 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), they review the appropriateness of the medicinal product for the patient, ensure the patient has sufficient information and advice on its proper use and storage and they offer to discuss with the patient all such matters as the pharmacist, in the exercise of his or her professional judgement, deems significant.
	• P10 – The requirement for the pharmacist to procure good quality exempt products should be highlighted as not all exempt products may be of the same quality.	The guidelines have been updated to state all 'exempt' medicinal products must be sourced from manufacturers or wholesalers authorised within the EEA. The guidelines already state pharmacists must check that the manufacturers and wholesalers they use are authorised to supply such products. Pharmacists should ensure that all medicinal products they supply are of an appropriate quality.
	• P11 – In relation to product withdrawal this may not be possible to patient level as the software e.g. Cliniscript does not hold batch numbers and expiry dates except the current ones. The difficulty in this respect was obvious in relation to the Heparin withdrawal last year. It would be	Systems in the relevant hospitals should be reviewed, as a matter of urgency, to ensure recall procedures are put in place which ensure if a medicinal product is recalled it is possible to inform all affected patients and if necessary retrieve all stock of the medicinal product. If

	very difficult for a hospital to identify which patients received a particular batch of a product as ward stock may contain multiple batches.	the pharmacy is not aware which patients have been affected, all patients should be contacted. As stated in the guidelines 'The recall procedure should … consider all aspects of a potential recall or withdrawal situation including those that extend to patient level.' Where necessary software providers should be contacted to discuss the hospital's requirements.
	Storage: • P13 – What is meant by an auditable system?	Audit is the process of checking that the documented systems and procedures in place in the pharmacy are working and are effective. An Audit is a quality improvement tool; an objective measure of the effectiveness of procedures. Any process within the pharmacy can be systematically checked or 'audited'. An Audit may help identify areas of underperformance in a pharmacy's procedures which can then be addressed during the routine procedures review.
	• P15 – All stock holding areas need to be part of the RPB – how is this to be managed in hospitals where the RPB is designated separately to the hospital pharmacy workingarea? Do two sets of stock need to be held separately?	All areas of a premises used for the operation of the retail pharmacy business, including storage areas, should be registered as part of the retail pharmacy business. It is not necessary to store medicinal products for use within the hospital separately from those used for outpatients/ staff etc., except in the specific circumstances outlined, i.e. 'high-tech' and 'exempt' medicinal products ordered on behalf of a specific patient.
	• P16 – What are non medicinal products? Are these items without a PA?	Many items are non-medicinal products, e.g. dressings etc., all such items would not have a PA. Not all medicinal products have a PA, for example, medicinal products may have an EU or PPA number.
	• P16 – Who is responsible for the provision of the appropriate storage areas? Is this the pharmacy owner?	As stated in the Regulation of Retail Pharmacy Businesses Regulations 2008. '*The pharmacy owner shall provide and maintain such staff, premises, equipment and procedures for the storage…. of medicinal products, including veterinary medicinal products, that he or she stores, ….in his or her retail pharmacy business, as are necessary to avoid deterioration of the products'* . It would also be expected that, in

		the interest of patients, superintendent and supervising pharmacists would raise any issues regarding storage areas with the pharmacy owner.
	P17 – Where medication is removed from its original packaging label details are required. Most hospitals use Cliniscript which does not have the facility to record all this information on the label i.e. market authorisation number and supplier. If added in then the label with be extremely crowded and possibly unsafe. Each original pack has only one PIL but the contents may be divided up into several portions. There will not be a PIL for each portion. This also has implications for pre-packing down which is done in virtually every hospital pharmacy but does not include PILS. It should be specified that a PIL is only required where packed down medication is being given directly to the patient.	This is an issue which should be discussed with your software provider. It may be appropriate to include certain information on a second label if necessary. A medicinal product should always be packaged with the patient information leaflet, or a copy of the leaflet, when the product is stored within a pharmacy or dispensed to a patient. It would also be good practice to include a patient information leaflet (or the Summary of Product Characteristics for the medicinal product) with all medication going to ward level or ensure all healthcare staff have access to the relevant information.
	• P17 – Does all the information pertaining to stability data have to be retained in the pharmacy – does relevant referencing not suffice e.g. www.imb.ie?	Such information should be retained in the pharmacy. Referencing a website is not sufficient as information on websites can change.
	• Page 17 of the draft states that medicinal products should be retained in the manufacturer's original packaging and only removed in exceptional circumstances. Many hospital pharmacies have a policy of pre-packing medications down to smaller quantities when dispensing to wards for reasons of safety, convenience and cost efficiency. This practice would appear to be non-compliant with the new guidelines.	The guidelines refer to retaining medicinal products in the manufacturer's original packaging during storage, repackaging during the dispensing process will be dealt with in more detail in future dispensing guidelines.
	• P18 – Returns is a significant issue as per sourcing for hospital pharmacy – it needs clarification.	As outlined previously.
	• P20 – Where a domestic fridge is fit-for purpose – is it prohibited?	All pharmacies must use a purpose-built pharmaceutical refrigerator for the storage of cold chain medicinal products.
	• P25 – What is the rationale for storing 'high tech' products separately from other items? Where storage is alphabetically this could cause confusion in a hospital where high tech items may not be managed differently from other items until the time of discharge. Also where the use of robotics exists based on bar-codes, the potential for confusion is even greater as there may now need to be two supply area for the same medication – one for inpatients and one for the RPB. This needs	The PSI's High Tech Practice Notice states: '*This scheme (the High Tech Scheme) operates as a* ***patient-specific pharmaceutical care programme****...* This patient-specific pharmaceutical care programme should include the storage of high-tech medicinal products in a patient-specific manner. A patient specific filing system, containing

	clarification.	invoices, or copies of invoices and copies of prescriptions for patients receiving such medications through the retail pharmacy business should be maintained. A superintendent pharmacist operating in a specific care setting, e.g. a hospital pharmacy, may put alternative policies and procedures in place regarding, for example, the storage of such medicinal products for supply to inpatients etc. The guidelines have been updated to reflect this.
	• P25 – The organisation of storage in a pharmacy department in hospitals means that documentation is not kept on the same shelf as the medication. Thus for exempt medical preparations prescriptions are stored in a separate location and invoices are usually retained in the Finance department or eventually in long term storage facilities.	The guidelines have been updated to state that documentation related to 'exempt' or 'High-Tech' medicinal products, e.g. supplier's invoices, copies of prescriptions etc., dispensed to patients through the retail pharmacy business, should also be stored in a patient-specific manner, e.g. with the medicinal products or in dedicated 'exempt' and 'High-Tech' files. Copies of such documents are appropriate where there is no other legislative requirement to keep the originals. The guidelines have been updated to reflect this.
	• As the majority of hospitals do not operate the high tech scheme, it does not make sense that there would be a need for a high tech prescription to be with the product. Some hospitals need to stock reasonably large quantities of certain high tech and exempt medications to cater for their patients and it does not seem reasonable that these should all be stocked in a patient-specific manner in that setting. • Should a number of exceptions be made where a RPB is situated alongside or within a hospital pharmacy department?	There should be a patient specific filing system which contains invoices, or copies of invoices and copies of prescriptions for patients receiving 'exempt or' high-tech' medicinal products through the retail pharmacy business. All retail pharmacy businesses must comply with the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) and the guidelines written to facilitate compliance with the regulations. In particular care settings, e.g. where a retail pharmacy business is located within a hospital, it may be appropriate to put alternative policies and procedures in place in respect of specific aspects of the guidelines. Such policies and procedures should take account of all legal and professional responsibilities. For certain aspects of practice it may be necessary to work with other healthcare professionals to put interdisciplinary policies and procedures in place. Where such alternative policies and procedures are in place, in

		particular care settings, the PSI expects that the superintendent pharmacist, supervising pharmacist, any relevant registered pharmacist and/ or the pharmacy owner to act in the best interest of patients and to ensure the integrity of the final link in the supply chain for a medicinal product, from the manufacturer to the patient, is maintained. Any deviation from the guidelines and the justification for such deviation should be recorded. The guidelines have been updated to reflect this.
	Disposal: • P31 – Storage of products for disposal which needs to be segregated to another specifically designated area of the Pharmacy, could be problematic. Most hospital pharmacies do not have spare space and this could necessitate building such a location. The volume of items in a hospital setup in significantly greater than that in a community pharmacy.	Noted. However, all waste medicinal products must be segregated from pharmacy stock, appropriately labelled and stored in a designated area of the pharmacy. This area should be under the control of the pharmacist, inaccessible to members of the public and of sufficient capacity to allow for the safe storage of all such products. As stated in the guidelines, they should not be stored in the dispensing/ working area of the pharmacy; this usually encompasses the majority of the dispensary but may vary depending on the layout and specific structure of each pharmacy. Waste medication should not be stored in these areas to ensure it is not inadvertently re-used or doesn't create a hazard for staff.
	• P32 – as in previous sections further clarification on the management of returned items previously supplied needs to be received in relation to current practices across hospital pharmacy.	Noted. Please refer to the comments on page 22 of this document in relation to this issue.
	General: A very significant number of policies and protocols are required to be drawn up in order to comply with these guidelines. In some cases an amendment to current hospital policies may suffice but in other cases two policies may need to exist in parallel – one for the RPB and one for the hospital function. This has the potential for confusion and error. It is also likely that hospitals may have to draw up policies for situations which will never occur in the RPB based in a hospital and these can be	Noted. All of the procedures outlined in the sourcing and storage guidelines will help ensure patient safety. Further procedures should also be generated for each individual operation, carried out in the pharmacy, which impacts on patient care and safety. It is necessary to have different procedures in place if differing practices exist within the one pharmacy. If a situation never occurs in a particular setting it is not necessary to draw up a procedure, except for contingency or

	extremely difficult to make relevant and safe unless tried in practice. As with other draft guidelines which have emanated from the PSI for comment, it appears that the impact of hospital practice on a RPB based in a hospital has not been fully considered. This significantly disadvantages hospital pharmacists in endeavouring to comply with their legal responsibility. Some way of having broad application of legislation to all situations needs to be sought, rather than have guidelines almost exclusively directed at community pharmacy without consideration of the other variations of the RPBs in existence. Certain aspects of the guidelines either need to be more 'generic' in nature, or specific application should be indicated for each of the various scenarios pertaining to RPBs.	emergency procedures. Noted. As outlined above, all retail pharmacy businesses must comply with these guidelines. In particular care settings, e.g. where a retail pharmacy business is located within a hospital, it may be appropriate, in some circumstances, to put alternative policies and procedures in place. Such policies and procedures should take account of all legal and professional responsibilities…..
13.	**IPU *(Pamela Logan, Director of Pharmacy Services)***	
	1. Introduction The Irish Pharmacy Union (IPU) is the representative and professional body for community pharmacists. Its mission is to promote the professional and economic interests of its members. Members of the Union aim to provide the best possible professional pharmacy service to all members of the public. They are committed to delivering a quality, accessible, personal and professional service that puts the patient first and has as its primary goal the optimisation of the health and well-being of society. Pharmacists are accountable for their professional conduct and strive to maintain the confidence and respect of their patients, customers, the State and other professionals in the healthcare field. The Union welcomes the opportunity to make a submission to the Pharmaceutical Society of Ireland (PSI) on its draft guidelines on Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business.	Noted.

	2. Timing/Format of the Guidelines The Union welcomes the decision by the PSI to extend the deadline for submissions to 17 September 2010 as August is a key month for staff holidays. In this context, the PSI may wish to consider not issuing any future draft guidelines for consultation during the summer months or over the Christmas period. These recent draft guidelines are the third published for consultation by the PSI this year. It would be helpful to the Union and its members if the PSI could provide a work plan for the next 12 months on what further draft guidelines it hopes to publish for consultation, so that the views of members can be sought, fully considered and collated for submission. It would also be useful if future guidelines were circulated in „Word" format to facilitate people making highlighted comments in the text. **3. Overview** Pharmacists are fully committed to providing a professional service to their patients but a balance must be struck between meeting the needs of patients and maintaining paper trails and written procedures. Pharmacists are getting increasingly concerned about the ongoing imposition of bureaucracy and paper trails in pharmacy practice. These guidelines alone require in excess of 20 different types of procedures and processes to be developed. It is vital that pharmacy does not become dominated by having written procedures rather than the more fundamental requirement in pharmacy to have skilled, well trained and alert staff at the interface with patients which is the ultimate guarantee of patient safety. It is fully accepted that there is a need for Standard Operating Procedures (SOPs) that cover some fundamental operations of a pharmacy but the documenting of every procedure has the added risk that the important gets lost in the ever growing paper pile.	Noted. It is the intention of the PSI to continue to develop and publish guidance under the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) as outlined in the PSI Service Plan 2011, available on the PSI website www.thePSI.ie. The PSI intends to develop guidelines, under the regulations, on the supply of prescription and non-prescription medicines, premises and equipment, management and supervision and record-keeping and intends to inform pharmacists and other stakeholders of the sequence in which draft guidelines will be issued as early in the process as possible. Under Regulation 4(1)(a) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), the pharmacy owner "shall provide and maintain such... **procedures** for the storage, preparation, dispensing, compounding, sale and supply of medicinal products..." Both written policies and procedures, which are adhered to, and skilled, trained staff help ensure a pharmacy operates safely and effectively and that patients receive high quality care when using the professional services of a retail pharmacy business. The PSI has highlighted some of the important areas of practice, that a pharmacy should develop policies and/ or procedures for, in relation to the sourcing, storage and disposal of medicinal products. All of the procedures outlined will help ensure patient safety. Further procedures should be generated where possible for each individual operation carried out in the pharmacy practice which impacts on

	The Union would ask the Society, therefore, to review their current approach in this area and recognise that there is a need for balance and reasonableness in all of these changes and, above all, to recognise that pharmacists" first priority is to provide timely, professional and cost effective services to their patients. While the Union is fully committed to supporting high pharmacy standards, it is vital that the important does not get lost in a paper melee. We make some specific points on the draft guidelines in the remainder of this submission. **4. Storage of Medicinal Products** The Union would like to make the following comments on specific issues dealt with under *Draft Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business*. ***Humidity Monitoring*** The draft guidelines require that, where particular humidity storage requirements are prescribed, humidity monitoring should be incorporated as part of the monitoring of the storage area. When PSI inspectors have visited Retail Pharmacy Businesses, inspectors have requested that the pharmacy monitors humidity on a daily basis. 4 The PSI should issue pharmacies with standards for measuring humidity, e.g. how is humidity measured, what is the range to monitor, etc., and guidance on what type of humidity monitor to use and also consider the associated costs. ***Controlled Drugs Cabinet*** The Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), Paragraph 4(4), require that the CD cabinet meets the requirements of Regulation 5 of the Misuse of Drugs (Safe Custody) Regulations 1982 (S.I. No 321 of 1982) (as amended by Regulations 26(2) of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988)). In order to comply with these regulations, the cabinet must meet the	patient care and safety. There should be adequate pharmacist manpower available on a whole-time basis in each pharmacy to fulfil these and other requirements under the Pharmacy Act 2007. Noted. As outlined above. . The guidelines state: *'The labelled storage requirements of medicinal products may, infrequently, prescribe particular humidity storage requirements. Where particular humidity storage requirements are prescribed, humidity monitoring should be incorporated as part of the monitoring of the storage area*.' If medicinal products with specific humidity storage requirements are stocked pharmacists should monitor humidity in the pharmacy, thus a max/min hygrometer would be required. The hygrometer should be capable of monitoring the normal environmental parameters of humidity and in particular the pharmacist should be able to demonstrate, through recording humidity in a humidity log, that the daily humidity in the pharmacy does not fall outside the specific humidity requirements of any medicinal product stocked. As with all equipment/ instruments used for monitoring within a retail pharmacy business, if a hygrometer is required, it should be fit for purpose and should be verified/ validated as such prior to use. All such instruments should also be regularly calibrated.

	specifications set out in the standard specification for Burglar-Resistant Cabinets for the Storage of Controlled Drugs 1985 (I.S. 267:1985). The cabinet must **either** be marked permanently with (i) the manufacturer‟s name and address, (ii) the capacity of the cabinet in cubic metres, (iii) the type approval test reference number and (iv) the inscription "I.S.267: 1985" **or** a member of An Garda Síochána (not below the rank of Superintendent) may issue a certificate which will last for 2 years.	Noted. The PSI is aware of the legal situation regarding controlled drugs safes. Further information on this will be outlined in the forthcoming equipment guidelines. The storage guidelines have also been modified to improve clarity.
	It has been brought to our attention that I.S. 267:1985 is not available in Ireland. Consequently, it is not possible for safe manufacturers to inscribe the cabinet with this standard. This leaves the pharmacist with only one option – to get a member of An Garda Síochána (not below the rank of Superintendent) to issue a certificate. Members have reported that when they have contacted the Gardaí to obtain a certificate, many Gardaí are not aware of this requirement and are reluctant to sign a certificate. We would suggest that the PSI produce an updated standard which can be given to both manufacturers of CD cabinets, so that they can inscribe the cabinet appropriately, and also brief the Gardaí so that they are aware of the requirements and advise them on the matter.	Noted. The requirements relating to controlled drugs safes/ cabinets are outlined in legislation. Amended legislation would be required to alter the methods by which a controlled drugs safe can be certified. A controlled drugs safe is acceptable if, when examined by a member of an Garda Síochána, not below the rank of superintendent, it does not depart from the constructional and other specifications which are necessary to render the unit fit for purpose, as outlined in IS 267: 1985 and the Schedule of the Misuse of Drugs (Safe Custody) Regulations1982 (S.I. No. 321 of 1982), and the member of an Garda Síochána issues the appropriate certificate. The PSI collaborates with an Garda Síochána on many matters including certifying controlled drugs safes.
	Veterinary Medicines The draft guidelines propose that veterinary medicinal products requiring 2-8C storage should be kept in a separate animal medicines refrigerator reserved solely for this purpose. Whilst this may be a reasonable requirement for a pharmacy which has a significant veterinary business, it is neither practical nor efficient for a pharmacy which deals in a small amount of veterinary medicines to have a separate fridge for veterinary medicines. We would ask that the PSI guidelines reflect some practicality in this matter.	It is important that a pharmacy which supplies refrigerated veterinary medicinal products stores such products in a separate fridge. Separate storage will minimise the risk of contamination and/ or inadvertent dispensing of veterinary medicinal products to humans. This is also a requirement in other countries, e.g. Canada.
	High Tech/Exempt Medicines We do not feel that it is practical to require that documentation for High Tech medicinal products or Exempt medicinal products be kept with the	The guidelines have been updated to state that documentation related to High-Tech medicinal products, e.g. suppliers' invoices, copies of prescriptions etc., should be stored in a patient-specific

	medicinal products. Pharmacies have a comprehensive, logical, filing system for suppliers‟ invoices, copies of prescriptions, etc., and it does not make sense for paperwork for these products to be stored in a different manner. Likewise, it is not practical to store such paperwork in the fridge with the product. **5. Disposal of Medicinal Products** The Union would like to make the following comments on specific issues dealt with under *Draft Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business*. ***Storage of Waste Medicines*** The draft guidelines require that waste medicinal products should not be stored in the dispensing/working area of the pharmacy. The Union would argue that, as long as these medicinal products were segregated from normal stock and clearly labelled „Medicines for Destruction‟, there would be no issue with them being stored in an area of the dispensary where they would be under the control of the pharmacist. Equally, as explained further in the next paragraph, the PSI should ensure that the HSE has a nationwide system in place for the disposal of such waste. ***Patient Counselling*** The draft guidelines suggest that patients should be encouraged to return unwanted or expired medicinal products to the pharmacy for disposal. Whilst many pharmacies provide this service as a gesture of goodwill to their patients, it is unfair to expect pharmacies to cover the considerable cost of such disposal. Some HSE areas provide a DUMP scheme through pharmacies in their area but many more do not. The Union has, for many years, called for a national DUMP scheme to be put in place. Indeed, this was a recommendation of the Joint Committee on Health and Children in their report on the Adverse Side Effects of Pharmaceuticals. The PSI should be cognisant of the costs involved in expecting pharmacies to provide such a service and should liaise with the	manner, e.g. with the medicinal products or in a dedicated High-Tech file. Similarly, documentation related to ‘exempt‘ medicinal products, e.g. suppliers’ invoices, copies of prescriptions etc., should be stored in a patient-specific manner, e.g. with the medicinal products or in a dedicated ‘exempt’ medicinal product file. Filing copies of invoices is appropriate where there is a valid reason to file the original invoice in an alternative location. The guidelines have been updated to reflect this. All waste medicinal products must be segregated from pharmacy stock, appropriately labelled and stored in a designated area of the pharmacy, under the control of the pharmacist. This area should be inaccessible to members of the public and of sufficient capacity to allow for the safe storage of all such products. As stated in the guidelines, they should not be stored in the dispensing/ working area of the pharmacy; this usually encompasses the majority of the dispensary but may vary depending on the layout and specific structure of each pharmacy. Waste medication should not be stored in these areas to ensure it is not inadvertently re-used or doesn’t create a hazard for staff. As pharmacists’ primary concern, as outlined in the statutory Code of Conduct, is patients’ health, care, safety and wellbeing, pharmacists should accept the return of waste medicinal products in patients’ best interest. Where large volumes of medicinal products are concerned pharmacists should, insofar as is possible, aid patients in disposing of such products or provide information on alternative methods of disposing of waste medicinal products.

	Department of Health & Children and the HSE to ensure that a DUMP scheme, funded by the HSE, is put in place nationally before imposing such a requirement on community pharmacies. **6. Standard Operating Procedures** The draft guidelines impose requirements for a significant number of SOPs to be put in place as part of the implementation of these guidelines. The Union has noted 22 separate SOPs and we feel it is worthwhile to highlight them: **a**. Steps to be taken to verify the authenticity of suppliers (Page 4) **b**. Inter-pharmacy exchange of medicinal products (Page 5) **c**. Ordering, receipt, checking and entering into stock of medicinal products (Page 5) including: • Receipt and examination of new stock • Verification that each medicinal product is appropriately authorised • Verification that the medicinal product is intact and within its shelf life • Prioritisation of fridge stock and CDs **d**. Processes involved in ensuring all medicinal products sourced are appropriately authorised (Page 9) **e.** Steps to be followed when sourcing medicinal products (Page 9) **f.** Procedures for ordering exempt medicinal products (Page 10) **g**. Medicinal product withdrawal/recall procedure (Page 11) **h.** Storage of personal medication (Page 16) **i.** Procedure outlining the repackaging/labelling process (Page 17)	Noted. As stated above, under Regulation 4(1)(a) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), the pharmacy owner "shall provide and maintain such... **procedures** for the storage, preparation, dispensing, compounding, sale and supply of medicinal products..." Written policies and procedures, which are adhered to, help ensure a pharmacy operates safely and effectively and that patients receive high quality care when using the professional services of a retail pharmacy business. The PSI has highlighted the important policies and procedures that a pharmacy should develop, in relation to the sourcing, storage and disposal of medicinal products. All of the procedures outlined will help ensure patient safety. Further procedures should be generated for each individual operation carried out in the pharmacy practice which impacts on patient safety and care. There should be adequate pharmacist manpower available on a whole-time basis in each pharmacy to fulfil these and other requirements under the Pharmacy Act 2007. While some of the procedures outlined, e.g. the medicinal product withdrawal/ recall procedure, will need to be set out in a dedicated SOP, a number of procedures could potentially be combined, e.g. steps to be followed when sourcing medicinal products could include a subsection on steps to be taken to verify the authenticity of suppliers. Other procedures will only apply in certain circumstances, e.g. a humidity monitoring procedure.

	j. Policy identifying which medicinal products must never be removed from the primary packaging (Page 17) **k.** Procedure for checking the stability of all medicinal products subject to repackaging (Page 17) **l.** Procedure for checking the stability of liquids and creams once opened (Page 17) **m.** Measures in place to control non-conforming medicinal products (Page 18) **n.** Regular and systematic checking of expiry dates (Page 18) **o.** Storage and disposal of waste medicinal products (Page 18) **p.** Humidity monitoring (Page 19) **q.** Environmental temperature monitoring (Page 20) **r.** Receipt of medicinal products requiring refrigeration (Page 22) **s.** Receipt of CD2 and CD3 medicinal products (Page 23) **t.** Procedures for pharmacy-specific methods of storing medicinal products (Page 26) **u.** Segregation and disposal of patient-returned medicinal products and expired or non-conforming medicinal products (Page 32) **v.** Segregation and disposal of patient-returned CD2 medicinal products and expired and non-conforming CD2 medicinal products (Page 35).	It is important that superintendent and supervising pharmacists put comprehensive policies and pharmacy specific procedures in place, irrespective of the staffing arrangements in the pharmacy. Such policies and procedures will help to ensure the pharmacy operates consistently, whether the supervising pharmacist or another registered pharmacist is present in the pharmacy; therefore, ensuring patients receive a consistent level of patient care. Policies and procedures are also a useful tool for training new staff and regular review of such documents can aid in maintaining the quality of pharmacy practices. Once in place policies will only need to be reviewed either when an element of the process changes or annually. Having appropriate policies and procedures in place should ultimately speed up pharmacy processes.
	Whilst the Union acknowledges the appropriateness of setting standards in community pharmacies, the PSI should consider practicalities, costs and the workload involved for a single pharmacist pharmacy to produce such a suite of SOPs. We would hope that the PSI would acknowledge	As stated above, there should be adequate pharmacist manpower available on a whole-time basis in each pharmacy to fulfil these and other requirements under the Pharmacy Act 2007.

	the professionalism of community pharmacists and that practicality and common sense would prevail in the methods used to apply such standards. We would be concerned that the onerous requirements involved in producing so many SOPs would result in many pharmacies spending their time writing and reviewing SOPs instead of advising and counselling patients. This has the added risk of critical SOPs not getting the attention they deserve and pharmacists, and their staff, drowning in paper and procedures. We would also expect that the implementation date of these and any further guidelines should reflect the time it will take most pharmacies to produce even just a selection of these SOPs. **7. Conclusion** In conclusion, whilst the Union accepts that all pharmacies should meet the appropriate standards in sourcing, storing and disposal of medicinal products, the Union would expect that the PSI be cognisant of the practicalities from a pharmacist's perspective in relation to the large number of SOPs required to implement these guidelines. There is now a serious risk of SOP overload and critical patient care issues losing out to the maintenance of written procedures and practices. The PSI should seriously review the level of bureaucracy now being imposed on pharmacists and prioritise what they view as the critical SOPs. The Union looks forward to working with the PSI on the production of a more practical version of these guidelines which will incorporate the issues addressed in this submission. The Union is available to meet with the PSI to discuss the issues raised above or, indeed, any other relevant issues.	The guidelines on the '*Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business'* have been developed to assure the quality, safety and efficacy of medicinal products sold and supplied through pharmacies and to ensure that the disposal of medicinal products occurs in a manner which will not result in any danger to public health or any risk to the environment. Compliance with the guidelines, including having the required procedures in place, will enhance patient safety. Noted.
14.	**IPHA *(Dr. Rebecca Cramp, Scientific and Regulatory Affairs Manager)***	
	The Irish Pharmaceutical Healthcare Association (IPHA) represents the international research-based companies who are responsible for developing, manufacturing and bringing innovative medicines to the Irish market.	Noted

	It is IPHA's opinion that unless all actors in the medicine supply chain source, store and dispose of medicines appropriately potentially serious issues may arise concerning the quality of medicines available on the Irish market. We are also concerned about the maintenance of full traceability of the product from manufacturer to end-user, the management of product recalls and the prevention of counterfeits in the supply chain.	Agreed. This is also the position of the PSI.
	Therefore, we welcome the requirement that a pharmacy should operate a comprehensive, auditable system for the control and maintenance of an appropriate level of legitimate stock, held within appropriate storage conditions and facilities and that pharmacies must only source medicinal products from an authorised manufacturer or an authorised wholesaler.	Noted.
	In particular, we welcome the statement that if a pharmacist or pharmacy owner suspects that they are being offered a counterfeit, defective or inappropriately authorised medicinal product, the product should not be ordered and the supplier should be reported to the IMB. Section 3.1.2 of the Guidance also states that '*If a pharmacist or pharmacy owner suspect they have been supplied with a counterfeit, defective or inappropriately authorised medicinal product, the product should be segregated from legitimate pharmacy stock, i.e. stored in a designated area of the pharmacy and clearly labelled. The medicinal product must not be used for sale or supply, pending review and clarification with the IMB'.* In the event of a pharmacist receiving a defective product, our members will be contacted directly. However, we suggest that this paragraph be expanded for the pharmacist to contact the manufacturer as well as the IMB in the case of suspicion of counterfeit or inappropriate authorization also so that the earliest detection of such issues is ensured.	Noted. The IMB in correspondence with the PSI have stated that, as the regulator of medicinal products, they are the appropriate organisation to contact and should be notified as soon as possible.
	We strongly concur with the statement that a person conducting a retail	Noted.

	pharmacy business must take extra care when ordering dual pack registered medicinal products and confirm that the products are appropriately authorised for sale in Ireland.	
	Recent studies on dispensing and dosing errors, reimbursement issues, and cases of counterfeits in the legitimate supply chain have highlighted the need to establish more clearly and effectively the identity of each medicine pack and to trace its origin. The World Health Organisation (WHO) estimates that 8% to 10% of the medicines in the global medicine supply chain are counterfeit, reaching as high as 25% in some countries. Counterfeit medicines are entering Europe's legitimate supply chain in increasing numbers. More than 8.8 million counterfeit medicines packs were seized at Europe's borders in 2008, a 118% increase on the previous year. According to the WHO, around one percent of medicines in Europe are now counterfeit. To date Ireland has had few incidences of counterfeits attempting to enter the legitimate supply chain; however, continued vigilance is required.	Information noted with thanks. The PSI agrees that continued vigilance against counterfeit medicines entering the supply chain is required. The pharmacist, as the final link in the medicinal product supply chain, plays a critical role in preventing counterfeit medicinal products reaching patients.
	Thus while IPHA agrees with the statement on page 17 that *'During storage, medicinal products should be retained in the manufacturer's original packaging'*, we are concerned that in the next sentence the guidance goes on to permit removal from the original packaging in *'exceptional circumstances'.* We do not envisage any 'exceptional' circumstances where the benefit of removing medicines from the original packaging would outweigh the risks and therefore we suggest that this section be removed or the *'exceptional circumstances'* clearly defined. Removal from the original packaging can involve removing the security seal and damaging unique identification codes designed to ensure product traceability. Such practices make it hard to distinguish real medicines from fakes.	The guidelines state that medicinal products should remain in the manufacturer's original packaging except in exceptional circumstances. While agreeing that this is the ideal situation and noting IPHA's concerns, it is recognised that, during the dispensing process, sometimes it is necessary to break original packs. For example, if most of an original pack is dispensed in the original pack it is necessary that any remaining medicinal product is packaged appropriately for storage within the retail pharmacy business.
	We concur that *'Medicinal products must not be removed from the primary protective packaging at the time of dispensing'*. However, the	It is not appropriate to limit the removal of medicinal products from their primary protective packaging to situations where such removal is

	draft guidance goes on to state that such removal is permissible *'in cases where repacking is required to assist patient compliance'* and we suggest that the guidance be reworded to only enable such removal '*in <u>limited specified</u> cases where repacking is <u>requested</u> to assist patient compliance'*. The reality is that as long as removal from original packaging and breaking of seals in the distribution chain is allowed, patient safety will be at risk and the potential for more incidences of counterfeits entering the legitimate supply chain will only increase.	requested by the patient to assist his or her medication compliance. Removal may also occur where deemed appropriate by a pharmacist using his or her expertise and professional judgement, e.g. if a patient is not taking their medication correctly and packaging in a monitored dosage system may assist compliance etc. However, pharmacists must check the stability of all medicinal products subject to repackaging.
	One of IPHA's principle objectives is to ensure that patients use medicines appropriately and safely and we have undertaken extensive patient education initiatives advocating this. It is clear that such safe use is achieved through the strict National and European regulatory processes and the provision of appropriate information about medicines to consumers. Package leaflets are an important source of such information for patients. In recognition of the importance of this information, Directive 2001/83/EC, as amended, requires that package leaflets reflect the results of consultations with target patient groups to ensure that they are legible, clear and easy to use. The leaflet contents are also based on the report on benefit-risk of medicines carried out by the European Medicines Agency and frequent public consultations.	Noted.
	Therefore we believe that the PSI guidance should mandate that the pharmacist provide the appropriate package leaflet with all dispensed product formats *(i.e. in the aforementioned case if the pharmacist was to repackage to 'assist patient compliance' then it would be mandated that the relevant package leaflet be provided)*. Not providing such essential information would introduce the very real possibility of a serious medication error and given that the leaflet is already provided as part of that original pack its current absence in the dispensed pack, as observed in some pharmacies, is difficult to justify. For parallel imported products in particular ensuring the provision of the leaflet in English is essential.	Noted. This will be dealt with in more detail in future dispensing guidelines.
	In the case of the storage of non prescription, schedule 5 controlled	Noted. The finalised guidelines '*Non Prescription Medicinal Products*

	drugs (CD5s), while we agree that it is important that these are not available for self selection and that the sale is made under the supervision of the pharmacist, as outlined in law, it is also important that the balance is retained between this, maintaining convenient access for the pharmacist and ensuring that the patient is aware of their availability. Given the value of self care to patients we believe that a full range of appropriate, regulatory authority approved, non prescription medicines should remain available to them. Finally, we welcome the requirement that the disposal of medicinal products within a pharmacy must be carried out in a manner which will not result in any danger to public health or any risk to the environment. However, we note that with the exception of controlled drugs there appears to be no requirement to keep records in relation to the disposal or destruction of medicines. We believe that to ensure full traceability and as a further tool to ensure the appropriate supply of medicines, disposal and destruction records should be kept for all medicine supplies and that this PSI guidance, as with all guidance issued by the PSI, be accompanied by an appropriate education and inspection approach by the PSI. To conclude, the Association wishes to emphasise the crucial role that pharmacists play in ensuring the safe supply of legitimate medicines. It is only through ensuring awareness, vigilance and appropriate intervention when necessary that we can all continue to ensure the safe supply of high quality, legitimate medicines to patients in Ireland.	*Containing Codeine: Guidance for Pharmacists on Safe Supply to Patients'* have been in force since August 1st 2010. CD5 controlled drugs must not be accessible to the public for self-selection, as set out in regulation 5(e) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). All supplies of non-prescription codeine medicines should be in accordance with legislation and the PSI's codeine guidelines and must adhere to pharmacists ethical and professional obligations. Noted. The guidelines have been updated to clarify what records should be maintained for the disposal of all medicinal products. Agreed
15.	**Conor Phelan MPSI, Reg: 4974**	
	I refer to draft guidance to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the sourcing of medicinal products for sale or supply in conducting a retail pharmacy business and thank you for engaging in this consultation process	A retail pharmacy business (pharmacy) may only source medicinal products for sale or supply in conducting that particular pharmacy and may not supply medicinal products to another pharmacy except in the

	• Regulation 6 (4). I submit that paragraphs 1 and 2 should not apply in the case of transactions between retail pharmacy businesses where the responsibility and accountability for the clinical and professional management of pharmacy practices lays with the same superintendent pharmacist. • I am also unsure as to the wisdom of a pharmacist say who is discontinuing his/her business not being in a position to sell his stock to anyone other than his/her supplier . In this event if the product will re-enter the supply chain why can the retail pharmacy business not sell his stock directly to another retail pharmacy business where the superintendent pharmacist is willing to accept personal responsibility for the medicinal products in question. • 3.13 Short-dated stock: If short-dated stock is identified and appropriately marked then I do not think it should be necessary to remove it from stock and transfer to a specifically designated area. For example, we affix a coloured label to all shortdated stock to ensure it is readily identified and this I submit is perfectly satisfactory. • 3.1.6. This may be pedantic but how do you monitor environmental temperature in all parts of a premises. I submit that it would be preferable if ..the supervising pharmacist should satisfy him/herself that appropriate storage conditions are maintained by monitoring temperature and humidity at appropriate locations within the premises paying particular attention to windows etc… • I do not understand why it is necessary the monitor the min/max temperature at a specific time each day. Isn't it surely sufficient to do it each day?	limited circumstances outlined in regulation 6(4) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), i.e. inter pharmacy transfer of medicinal products to meet an immediate patient need (unless the pharmacy holds the appropriate wholesale licences). This is a requirement of legislation. The transfer of medicinal products from one retail pharmacy business to another is not permitted, by legislation, except in the limited circumstances outlined above. However, where a transfer of the ownership of a retail pharmacy business is made, the transfer of any medicinal products held in stock at the time, are considered as having been lawfully transferred to the new owners. Short dated stock, marked in accordance with a pharmacy's procedure, may remain in active stock. However, pharmacists must pay particular attention to medicinal products which are close to their expiry date and all medicinal products must be removed from stock prior to their expiry date and transferred to a specifically designated area for disposal. A medicinal product must not be dispensed if the duration of treatment extends beyond the expiry date of the medicinal product.The guidelines have been updated to clarify this. Agreed. This was the intention of the guidelines; the wording has been updated to ensure greater clarity in this section. Noted. However, to ensure the maximum and minimum temperatures are monitored in every twenty four hour period, the temperature should be monitored at a specified time each day.

	• 3.6. I submit that the requirement to store High Tech and exempt drugs in a patient specific manner will lead to unnecessary stock-holding and should be removed	The PSI's High Tech Practice Notice states: '*This scheme (the High Tech Scheme) operates as a* ***patient-specific pharmaceutical care programme*** *with a nominated pharmacy responsible for a specific patient and their complete and complex medication and health needs. Care delivery must ensure that patient-specific dispensing occurs with a particular product obtained for a particular individual patient*'. This patient-specific pharmaceutical care programme should include the storage of high-tech medicinal products in a patient-specific manner. 'Exempt' medicinal products should also only be ordered on a patient specific basis and stored in a patient-specific manner.
16.	**Sibéal Nic Suibhne MPSI, Mid-Western Regional Hospital, Co. Limerick**	
	Comment 1 Section 3.1.3 I would like the following two pieces of legislation to be clarified in light of these new draft guidelines. In correspondence from the IMB we are told that a hospital may not supply to a retail pharmacy business but a retail pharmacy business may supply a hospital. It is often the case that a hospital may need to supply a medicinal product to a retail pharmacy business for a patient who has been discharged from hospital where the retail pharmacy business may not be able to source that product in a timely fashion. It is not apparent from these pieces of legislation that a retail pharmacy business may supply another retail pharmacy business. A retail pharmacy business is not listed is as an exemption from the need for a wholesalers authorization in the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 6(c) (ii). It does not concur with the Medicinal Products (Prescription and Control of Supply) Regulations 2003. <u>Medicinal Products (Prescription and Control of Supply)</u> <u>Regulations 2003</u> *"supply by way of wholesale dealing" means the supply of a medicinal product to a person who obtains the product for one or more of the*	A retail pharmacy business (pharmacy), whether a hospital or community pharmacy, may only source medicinal products for sale or supply in conducting that particular pharmacy and may not supply medicinal products to another pharmacy. Regulation 6 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) sets out from whom medicinal products may be sourced i.e. authorised wholesalers and manufacturers. Medicinal products may only be transferred from one pharmacy to another in the limited circumstances outlined in regulation 6(4) of these regulations: '*The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient*.' Therefore the transfer of medicinal product between pharmacies should only be to meet an individual patient's prescription needs (unless the pharmacy holds the appropriate wholesale licences). It is important that detailed records are maintained to ensure the traceability of medicinal

	following purposes – *(a) supply in the course of a pharmaceutical business, or* *(b) administration in the course of a professional practice, or* *(c) for or in connection with a service provided by a hospital.* <u>Medicinal Products (Control of Wholesale Distribution) Regulations 2007</u> *'sale by wholesale' means sale or supply for the purposes of sale in the course of a business or for administration to patients in the course of a professional practice and cognate words shall be construed accordingly. Such term shall also include all activities consisting of the procuring, holding or exporting of medicinal products other than activities involving the sale or supply of such products to the public;* *Requirement for authorisation to sell medicinal products by wholesale* *5. Subject to the provisions of these Regulations, a person shall not sell by wholesale, or offer or keep for sale by wholesale, any medicinal product unless he or she is the holder of a wholesaler's authorisation.* *Exemptions* *6. The provisions of Regulation 5 shall not apply to—* *(a) the sale by wholesale of a medicinal product by a person who has manufactured or imported it under and in accordance with the provisions of a manufacturer's authorisation;* *(b) the supply of an investigational medicinal product in accordance with Regulation 11 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004).* *(c) (i) the sale by or under the personal supervision of a pharmacist in a dispensing pharmacy, to a person to which this subparagraph applies, for administration to patients in the course of a professional practice or service.* *(ii) the persons to which subparagraph (i) applies are a registered medical practitioner, a registered dentist, a registered dispensing optician, a registered optometrist, a registered veterinary surgeon, a person who is acting as a pre-hospital emergency care provider and a person lawfully entitled to obtain medicinal products for administration to patients in the*	products. Noted. The Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007) sets out a number of specific exemptions from the requirement for authorisation to sell medicinal products by wholesale. One of these exemptions applies in respect of

	course of a business as a hospital. **Comment 2 Section 3.2.3** "A medicinal product can only be defined as 'exempt' when it is supplied to the order of a registered practitioner for use by a patient under their direct care" This comment above does not make sense. **Comment 3 Section 3.1.1.** It would be useful to have guidance on how a pharmacist establishes that a wholesaler is authorized to supply medicinal product to a retail pharmacy business. I am aware of the listing on the IMB website. I attach information from the RPSGB regarding the export of medicinal products which suggests that pharmacy business may export medicinal products from the UK with no wholesaler authorization from the MHRA so long as it is less than 5% of its business. It is not clear from the regulations below what a competent authority is in another member state. Is it permissible for a retail pharmacy business in Ireland to source medicinal products from a pharmacy business in the UK registered with the RPSGB? *Retail Pharmacy Regulations 2008 states:* *Sourcing of medicinal products* *6. (1) A person carrying on a retail pharmacy business shall obtain his or her supplies of medicinal products (including medicinal products on a general sales list) from persons—* *(a) who are themselves the holders of a manufacturer's authorisation or a wholesaler's authorisation in respect of such products, or* *(b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.*	the sale by or under the personal supervision of a pharmacist in a dispensing pharmacy (which is defined to include a hospital pharmacy), to a person lawfully entitled to obtain medicinal products for the purpose of administration to patients in the course of a business as a hospital. Please refer to the IMB Guidance Note for the Notification System for Exempt Medicinal Products 2008. This Guidance Notice states: 'An '*exempt medicinal product' is defined as "a medicinal product to which paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007, or any equivalent legislation in any EEA State other than the State, applies*". The aforementioned Paragraph 2 of Schedule 1 states that an exempt medicinal product may be sold or supplied "..*in response to a bona fide unsolicited order, formulated in accordance with the specifications of a practitioner for use by his individual patients on his direct personal responsibility, in order to fulfil the special needs of those patients*…".This means that a medicinal product can only be defined as "exempt" when it is supplied to the order of a registered doctor or registered dentist for use by his individual patients under his direct personal responsibility.' The most up to date versions of all IMB guidance documents are available on the IMB website. As stated in the guidelines, '*A list of authorised manufacturers and authorised wholesalers from whom medicinal products are sourced should be maintained by each pharmacy. There should be a written procedure in place which outlines the steps to be taken to verify the authenticity of suppliers. A list of all Irish authorised manufacturers and wholesalers is available from the Irish Medicines Board (IMB) website [www.imb.ie]. In reviewing the authority of the supplier to supply medicinal products it is important to take into consideration the particular category of medicinal product involved. In relation to wholesale suppliers the information available on the IMB's website*

		includes the particular categories of medicinal products that the wholesaler can supply.' The authorisation status of wholesalers and manufacturers based in other EU/ EEA countries can be checked with the competent authority in the relevant country, e.g. the Medicines and Healthcare products Regulatory Agency (MHRA) in UK etc. Where there is difficulty in checking this information with the relevant competent authority in the relevant EEA country, the matter should be referred to IMB. It is the responsibility of the pharmacy owner, superintendent pharmacist and supervising pharmacist to ensure all medicinal products available for sale or supply in their pharmacy are authorised to be on the Irish market. The guidelines have been updated to reflect this.
17.	**National Working Group on Medication Management for Designated Centres for Older People *(Margaret Buckley)***	
	Submission on behalf of National Working Group on Medication Management for Designated Centres for Older People	
	• PSI to be commended on excellent document	Noted with thanks.
	• Very clear guidelines on sourcing, storage and disposal of medicinal products	
	• Purpose of this guidelines document is to provide information for Retail Pharmacists to facilitate compliance with the requirements of legislation however the guidelines have implications for other members of the interdisciplinary team	Noted. The guidelines provide guidance to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the sourcing, storage and disposal of medicinal products within a retail pharmacy business. However, the PSI is aware that all members of an interdisciplinary team, who work with medicinal products, will need to be aware of the contents of these guidelines.
	• Guidelines are also very relevant and informative for nurses who are involved in sourcing, storage and disposal of medicinal products – legislation and guidelines have implications for nurses involved in	

	these activities.	
	• Guidelines are particularly relevant for nurses working in designated centres for residential care for older people, where nurses sometimes have to take on an expanded role due to lack of a comprehensive pharmacy services at local level. • May need additional interdisciplinary guidelines to provide clarity for nurses who have such an expanded role, e.g. where there is not a 24 hour pharmacy service and nurses may be required to leave the designated centre to source medicinal products out of hours. There are a number of other situations where nurses are required to take on some responsibilities that would generally be considered to be those of a pharmacist where a 24 hour pharmacy service is available.	As outlined in legislation it is the responsibility of superintendent pharmacists, supervising pharmacists, other registered pharmacists and pharmacy owners to ensure a retail pharmacy business is conducted in compliance with the legislation. Pharmacists should collaborate with other health care professionals, e.g. nurses and doctors, to develop robust interdisciplinary policies and procedures for joint areas of working, as appropriate.
	• May need further discussion on how guidelines apply and clarity of roles and responsibilities of Pharmacist/Director of Nursing/other RGN grades/Medical Practitioner with differing levels of pharmacy service e.g.: o Pharmacist on site o No pharmacist on site	Noted.
	• Note references in document to development of policies and procedures & provision of training & maintenance of training records for people involved in the processes (3.1.4); (3.2.2) (3.8); (3.16) & (3.26) implications for: o Interdisciplinary development of such policies and procedures o Interdisciplinary education and training o Roles & responsibilities re development of policies & provision of training o Issues re resources and supports to implement the	Noted.

	guidelines Additional Issues arising • Is there an obligation on the retail pharmacist to take returned unused medicines from a designated centre for residential care and take responsibility for their destruction? • Would it be desirable to develop a standard template for a contract for provision of pharmacy services for HSE?	As pharmacists' primary concern, as outlined in the statutory Code of Conduct, is patients' health, care, safety and wellbeing, pharmacists should accept the return of waste medicinal products in patients' best interest. Where large volumes of medicinal products are concerned pharmacists should, insofar as is possible, aid in the disposal of such products, or provide information on alternative methods of disposing of waste medicinal products.
18.	**Mental Health Commission *(Rosemary Smyth)***	
	1. The Mental Health Commission would like to thank the Pharmaceutical Society of Ireland (PSI) charged with developing guidelines for the purpose of facilitating better compliance with Regulations under Section 18 of the Pharmacy Act 2007, for inviting the Commission's views on this very important area.	Noted with thanks.
	2. The Mental Health Commission mandate is to promote, encourage and foster the establishment and maintenance of high standards and good practices in the delivery of mental health services and to take all reasonable steps to protect the interests of persons detained in approved centres under the Mental Health Act 2001.	Noted.
	3. The Mental Health Act 2001 (Approved Centres) Regulations 2006 came into effect on 1st November 2006. Compliance with the regulations is linked with registration of an approved centre. Therefore, approved centres are obliged to comply. Article 23 specifically refers to Ordering, Prescribing, Storing and Administration of Medicines. The Inspector of Mental Health	Noted.

	Services reported in 2009 that there was 89% compliance with this article a 23% improvement from the previous year (66%).	
	4. The Commission has developed a *Quality Framework for Mental Health Services* (MHC, 2007). The quality framework comprises of 8 themes, 24 standards and 163 associated criteria. The framework promotes an empowering approach to service delivery, where services facilitate an individual's personal journey towards recovery. Staff skills, expertise and morale are key influences in the delivery of a quality mental health service. This includes knowledge of and compliance with relevant legislation and regulations.	Noted.
	5. The Commission welcomes the publication of the guidelines as they will ultimately enhance patient safety and assure the quality and safety of medicinal products supplied. The Commission also welcomes guidance on the safe disposal of medical products avoiding danger/harm to the health of individuals.	Noted with thanks. The guidelines on the '*Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business'* have been developed to assure the quality, safety and efficacy of medicinal products sold and supplied through pharmacies and to ensure that the disposal of medicinal products occurs in a manner which will not result in any danger to public health or any risk to the environment. Compliance with the guidelines will ultimately significantly enhance patient safety.
	6. The Commission recommends that all medical products no longer required should be destroyed or otherwise disposed of in accordance with safety, legal and environmental requirements. An example of a practical initiative is the Disposal of Unwanted Medicines Properly (DUMP) project. DUMP actively seeks to reduce the amount of deaths through overdose and accidental poisoning, by collecting and ensuring the safe disposal and destruction of unused medicines. The project recommends that collection points for unwanted or unused medicines be located at pharmacies. This potentially has very real benefits in terms of suicide prevention, child accident prevention, environmental protection as well as collecting valuable information on prescription and over-prescription patterns.	Agreed and information noted.

19.	**Pharmaceutical Society of Northern Ireland (PSNI) (***Richard Price, Policy Advisor)*	
	The Pharmaceutical Society of Northern Ireland noted with interest the recent consultation by the Pharmaceutical Society of Ireland on draft guidelines on sourcing, storage and disposal of medicinal products within a retail pharmacy business. Thank you for the opportunity to make comment on the draft.	
	On reviewing the draft, we consider that the guidance is well presented, thorough and takes on board the main issues of practice which should be highlighted in such guidance. We commend the fact that the guidance brings together in one document the essential elements of the legislation, appropriate standards and the associated guidance. However, at first sight, and from experience of some past regulatory initiatives at the Pharmaceutical Society of Northern Ireland, it is possible that some pharmacists could consider the guidelines to be overly prescriptive (rather than comprehensive). The Pharmaceutical Society of Ireland should therefore consider means and mechanisms of allaying such a perception.	Noted with thanks. The guidelines on the '*Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business'* have been developed to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), specifically to assure the quality, safety and efficacy of medicinal products sold and supplied through pharmacies and to ensure that the disposal of medicinal products occurs in a manner which will not result in any danger to public health or any risk to the environment. Compliance with the guidelines will ultimately significantly enhance patient safety.
	Further to this, we have some specific comments to make and also reference some guidance in place in Northern Ireland guidance which I hope can be of some assistance to you and your team in the final drafting stages.	
	In general terms, compliance with guidance should be expected. However, there may be some instances where compliance is neither possible nor practical. In such cases, it should be expected that the pharmacist or other responsible person / body has acted with due diligence. in a manner deemed reasonable by peers, and that any deviation was justified and recorded.	All retail pharmacy businesses must comply with the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) and the guidelines written to facilitate compliance with the regulations. In particular care settings, e.g. where a retail pharmacy business is located within a hospital, it may be appropriate to put alternative policies and procedures in place in respect of specific aspects of the guidelines. Any deviation from the guidelines and the justification for the deviation should be recorded.
	It would be reasonable to expect the guidelines to apply to all	It is not the intention of this guidance document to address the

	pharmaceutical products e.g. medicines, devices, dressings / wound management products and nostrums (if permissible).	sourcing, storage and disposal of medical devices, only medicinal products. The '*Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care'* (available on the PSI website www.pharmaceuticalsociety.ie.) contains some information on medical devices. The PSI may issue further guidance on medical devices in the future.
	Exempted medicines Whilst it would be good practice to keep the relevant records with the product(s), this may not always be practical, for example for fridge items. In such cases records could be kept separately, but should be kept separate to other records, be easily identifiable as to what they are and also traceable to the product to which they relate. Similarly there should be an indication on the product e.g. by way of label or tag to track the product back to the appropriate record.	The guidelines have been updated to state that documentation related to 'Exempt' and High-Tech medicinal products, e.g. suppliers' invoices, copies of prescriptions etc., should be stored in a patient-specific manner, e.g. with the medicinal products or in a dedicated file. The guidelines have also been updated to state that where documentation is stored in a dedicated file the medicinal product should be marked in a way which allows the medicinal product to be tracked back to the appropriate record.
	Interpharmacy loans It is recognised that there are times when this is necessary for safe & effective patient care. Any transfer must not constitute 'wholesale dealing' and should only be sufficient to meet the needs of the individual patient(s). The current situation in the United Kingdom, where experience of medicines shortages has increased in the last 12 months, has highlighted this issue as one of concern, and where clear guidance is needed. Any transfers which take place must be recorded and appropriate invoices etc. kept.	Agreed, this is the legal requirement. Regulation 6(4) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) states: '*The provisions of paragraphs (1) and (2) shall not apply in the case of occasional transactions between retail pharmacy businesses involving the exchange of medicinal products with a view to meeting the immediate prescription needs of an individual patient*.' Therefore transfer of medicinal product between pharmacies should only be to meet an individual patient's prescription needs (unless the pharmacy holds the appropriate wholesale licences).
	Unlicensed medicines Whilst it may be more difficult for those in primary care rather than secondary care to be aware of the reasons for which a medicine is classified as unlicensed, such information should be available from the local or regional Medicines Information Centre. If the Centre produces regular Bulletins etc. it may be of use to request they include an update	Noted with thanks.

	on medicines likely to be used off licence or which are unlicensed and the reason(s) why etc.	
	Policies / SOPs etc. These should be reviewed if any change in that area occurs or at least annually and updated if necessary. A change or review may not necessarily mean a change in policy / procedure or an updating of the policy. The date of review and name of the reviewer should be noted. All appropriate staff must be made aware of amended policies & required to indicate this.	Agreed. This was the intention of the guidelines; the wording has been updated to ensure greater clarity in this section.
	Storage It may be of interest to PSI to examine any useful or comparable components of the PSNI's recently produced Standards for Registered Community Pharmacy Premises In Northern Ireland (Jan 2010)1. A key feature of the Standards document is the inclusion of an audit checklist for pharmacists to make use of when reviewing their compliance with the Standards.	Noted. An audit checklist has been drafted and will accompany the finalised guidelines.
	Disposal and waste management The area of waste management is complex and any guidance issued must be in accordance with other legislation, including European regulations. It appears to be difficult to currently reconcile all elements of legislation to allow the safe disposal of medicines whilst enabling pharmacists to comply with their wider duty of care in this area and in Northern Ireland we have found that discussion with other authorities, such as the Health and Safety Executive, is essential before guidance is issued in this area.	Information noted with thanks. The PSI has liaised with the Health and Safety Authority, the Environmental Protection Agency and the National TFS Office regarding the Guidance in this area.
	Also, in relation to patient returned medicines (& indeed, out of date medicines) it may be worth noting (if appropriate in RoI) that an exemption to the re-use of medicinal products could come into effect in the event of a national health emergency. This has recently been the	Noted with thanks.

	case in the UK as a result of pandemic contingency planning. **Pharmaceutical stock - counterfeit medicines** In Northern Ireland, a pharmacist must ensure that if he suspects he has been offered or supplied a counterfeit or defective medicine, this is reported to the Medicines & Healthcare products Regulatory Agency (MHRA), the Department of Health, Social Services and |Public Safety (DHSSPS) Inspectorate, the Pharmaceutical Society of Northern Ireland (PSNI) the Veterinary Medicines Directorate (VMD) or the marketing authorisation holder, as appropriate to the individual situation. Any such stock must be segregated from other pharmacy stock and must not be sold or supplied for the treatment of any person(s) or animal(s). By way of reference material in this area, a useful article appeared in the Pharmaceutical Journal of 20 February 2009 in relation to Counterfeit Medicines2. Additionally, MLX 357 (MHRA)3 and other MHRA & RPSGB guidance may be of use4. **Other Reference Material** Further PSNI, Northern Ireland & UK references which may be of value for PSI to consider before finalising these guidelines include: • PSNI Premises Standards http://www.psni.org.uk/documents/521/Community+Pharmacy+Premises+Standards.pdf • Responsible Pharmacist Regulations and Associated Standards and Guidance http://www.legislation.gov.uk/uksi/2008/2789/contents/made http://www.psni.org.uk/documents/352/Standards+on+the+Responsible+Pharm_.pdf • DHSSPSNI Guidance The Department for Health, Social Services and Public Safety produce a	The IMB, as the regulator of medicinal products, is the appropriate agency to contact regarding counterfeit medicines. The IMB will inform other relevant agencies as appropriate. Noted with thanks. All information accessible via the links provided has been reviewed and the guidelines updated where appropriate.

	range of pharmaceutical guidance including many on issues related to Controlled Drugs5. http://www.dhsspsni.gov.uk/pas-destruction-controlled-drugs-guide-accountable-officers.pdf • National Pharmaceutical Association (NPA) Guidance & SOPs e.g. Delivering Medicines Safely & Effectively, SOPs for range of pharmacy procedures http://www.npa.co.uk/Resources/Publications/?cat=180 I hope that the comments made by our Committee are useful to you and your team as you finalise the guidelines. I should be happy to clarify any points made or provide any further information if I can.	Noted with thanks.
20.	**Boots Ireland *(Mary Rose Burke, Superintendent Pharmacist)***	
	Introduction Boots is a leading provider of pharmacy services in Ireland, employing over 120 pharmacists in 49 registered retail pharmacy businesses across the country. We are committed to the provision of professional services to the highest standards and welcome the opportunity to contribute to the development of practice guidelines. In responding to this document, Boots has made a number of specific observations and comments relating to individual points in the document and may be reviewed in the information below. By way of general commentary, Boots wishes to note the following: 1. Boots acknowledges that the guidelines will provide useful assistance and guidance to many pharmacists and pharmacy owners and supplement the provisions of the Regulation of Retail Pharmacy Businesses Regulations, 2008. However, it is considered that the document's provisions may be excessive in parts as to what is	Noted. Noted. The guidelines have been prepared with a view to publication in accordance with regulation 14 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) which allows the PSI Council publish detailed guidelines for the purpose of facilitating better compliance with these Regulations. Compliance with the regulations and guidelines ensures the integrity

	required to further explain and interpret the regulations. The regulations themselves are clear and concise and in some instances, the guidelines may be considered to be unnecessarily expanding the scope of their provision (see point 2 below). The individual comments in the attached document further elucidate this observation.	of the final link in the supply chain for a medicinal product, from the manufacturer to the patient, is maintained. This assures the safety, quality and efficacy of medicinal products sold and supplied through pharmacies. Compliance also ensures medicinal product disposal, within a pharmacy, is carried out in a manner which will not result in any danger to public health or any risk to the environment.
	2. In some instances, these guidelines appear to require pharmacists to duplicate the functions that are in many instances assigned in statute to other bodies or agencies. For example, in the matter of sourcing non-"exempt" medicinal products, it could be interpreted that the guidelines do not appear to properly acknowledge the role of the IMB in its regulation and licensing of wholesalers in the jurisdiction. Regulation 6 clearly sets out the requirements as regards the sourcing of medicinal products. However, the ensuing guidance appears to advocate pharmacists and pharmacy owners undertaking their own process of verifying wholesaler's authenticity. It may be preferable for the guidance to restrict itself to the recommendation that pharmacies only source medicinal products from wholesalers currently licensed with the IMB, without further qualification.	The guidelines acknowledge the role of the IMB, however, It is the responsibility of the pharmacy owner, superintendent pharmacist and supervising pharmacist to ensure all medicinal products available for sale or supply in their pharmacies are authorised to be on the Irish market. The guidelines state: '*The authorisation status of any medicinal product or of any wholesaler or manufacturer can be clarified with the IMB*.' They also state *'A list of all Irish authorised manufacturers and wholesalers is available from the Irish Medicines Board (IMB) website [www.imb.ie]. In reviewing the authority of the supplier to supply medicinal products it is important to take into consideration the particular category of medicinal product involved. In relation to wholesale suppliers the information available on the IMB's website includes the particular categories of medicinal products that the wholesaler can supply.*' The guidelines have been updated to clarify how a pharmacist can check the authorisation status of wholesalers and manufacturers based in other EU/EEA countries.
	3. The guidelines in many instances recommend the production of further written policies and guidelines in respect of many routine activities in a retail pharmacy business. Several examples of this are highlighted in the commentary to the guidance in the attached document. There is undoubtedly a need for such policies and procedures in certain circumstances. However, the rationale or the necessity for such written procedures and policies for many routine and regular tasks in the pharmacy needs to be more carefully considered. When contemplating recommending the need for written policies and procedures, it is considered that there are a number of important matters which should be taken account of as follows:	Under Regulation 4(1)(a) of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), the pharmacy owner "shall provide and maintain such... **procedures** for the storage, preparation, dispensing, compounding, sale and supply of medicinal products..." Both written policies and procedures, which are adhered to, and skilled, trained staff help ensure a pharmacy operates safely and effectively and that patients receive high quality care when using the professional services of a retail pharmacy business. The PSI has highlighted the important policies and procedures in relation to the

	a. What is the level of expertise and training of the person undertaking the task or directly supervising it; b. What is the nature of the task – how detailed it is and what are the complexity of the various steps therein c. What are likely adverse effects on the health and well being of those attending the pharmacy in the context of it not being properly executed In the context of these guidelines and determining the need in various instances for written procedures and policies, it would be useful be apply the three tests as outlined above. The conduct of all activities in the pharmacy is at all times under the direct supervision of a pharmacist who is expertly trained in the safe and effective conduct of the pharmacy and in most instances has at least three years' experience. Appropriate recognition and confidence in the professional ability and capacity of a pharmacist and their ability to effectively and safe execute routine activities without having recourse to written down procedures should generally be reflected in PSI guidance. The activities of a pharmacy are in the main routine and regular and conducted in an environment that is readily observed and monitored by the duty pharmacist. The typical pharmacy environment is not analogous to that of a large production facility in a modern pharmaceutical plant. In citing the need for written procedures and policies, the PSI should balance its need to have safe and effective processes in the pharmacy with its acknowledgement of the training and expertise of the pharmacist to deliver a professional service and the nature and complexity of the task being delivered. **DRAFT GUIDELINES ON THE <u>SOURCING</u> OF MEDICINAL PRODUCTS FOR SALE OR SUPPLY IN CONDUCTING A RETAIL PHARMACY BUSINESS** **<u>3. Guidance</u>** 3.1.1 Sourcing from Authorised Manufacturers or Wholesalers	sourcing, storage and disposal of medicinal products. All of the procedures outlined will help ensure patient safety. Further procedures should be generated for each individual operation carried out in the pharmacy practice which impacts on patient safety. There should be adequate pharmacist manpower available on a whole-time basis in each pharmacy to fulfil these and other requirements under the Pharmacy Act 2007. It is important that superintendent and supervising pharmacists put comprehensive policies and pharmacy specific procedures in place. Such policies and procedures will help ensure the pharmacy operates consistently, whether the supervising pharmacist or another registered pharmacist is present in the pharmacy; therefore, ensuring patients receive a consistent level of patient care. Policies and procedures are also a useful tool for training new staff and regular review of such documents can aid in maintaining the quality of pharmacy practices. Once in place policies will only need to be reviewed either when an element of the process changes or annually. Having appropriate policies and procedures in place should ultimately speed up pharmacy processes.

	'A list of authorised manufacturers and authorised wholesalers from whom medicinal products are sourced should be maintained by each pharmacy. There should be a written procedure in place which outlines the steps to be taken to verify the authenticity of suppliers. It is important that these verification procedures are applied retrospectively for existing suppliers and are performed prior to sourcing medicinal products from new suppliers' The IMB is the competent authority charged with the regulation of wholesaling in Ireland. If a wholesaler is licensed by IMB, then it would appear unnecessary for a RPB to undertake a further process of verification of wholesalers in the manner suggested. 3.1.2 Medicinal Products which should not be Sold or Supplied *'If a pharmacist or pharmacy owner suspect they have been supplied with a counterfeit, defective or inappropriately authorised medicinal product, the product should be segregated from legitimate pharmacy stock, i.e. stored in a designated area of the pharmacy and clearly labelled. The medicinal product must not be used for sale or supply, pending review and clarification with the IMB'* How likely is it that a pharmacist's suspicions would be aroused in this regard? Counterfeit medicines are unlikely to be generally readily identifiable. If the medicine is properly sourced from a licensed wholesaler in the State, then it is unlikely that a simple physical examination is going to give rise to suspicions as to its counterfeit nature 3.1.2 Inter-Pharmacy Exchange of Medicinal Products *'It is important to take extra care when dealing with controlled drugs, due to the nature of the medicinal products involved and the legal requirements for record keeping, requisitions, etc. Any CD2 medicinal products entering or leaving the pharmacy in the manner outlined must*	Verification of the authenticity of suppliers may be via the IMB website or by contacting the IMB directly (e.g. if querying the authenticity of suppliers of Dual Pack medicinal products). It may also be necessary to contact the competent authority in another EU country. Further information on this is outlined above and in the guidelines. In the interest of patient safety, if a pharmacist or pharmacy owner suspect they have been supplied with a counterfeit, defective or inappropriately authorised medicinal product, the product should be segregated from legitimate pharmacy stock, i.e. stored in a designated area of the pharmacy and clearly labelled, and must not be used for sale or supply pending review and clarification with the IMB. For example, if a medicinal product is examined on receipt for an appropriate authorisation number and if such a number is not present '*the medicinal product must not be used for sale or supply, pending review and clarification with the IMB'*

	be recorded in the controlled drugs register' It should be clarified at this point whether the current Misuse of Drugs Regulations allow for the inter pharmacy exchange of products containing substances controlled by the regulations in the manner outlined. It is our understanding that the regulations do not. Furthermore, the regulations would not appear to give authority for entries to be made in the controlled drugs register in the manner prescribed on foot of the ad-hoc inter pharmacy exchange of controlled drugs. It is suggested that this guidance be reviewed within the terms of the existing Misuse of Drugs regulations. 3.1.3 Policies and Procedures *'Superintendent and supervising pharmacists should ensure that there are written policies and procedures in place which outline the steps to be followed for the ordering, receipt, checking and entering into stock of medicinal products. The procedure for the receipt of medicinal products should state the processes involved in the receipt and examination of new stock, prior to its addition to existing pharmacy stock. These checks should include, but are not limited to, verification that each medicinal product is appropriately authorised, appropriately intact and within its shelf life'* Where replenishment of POM's are concerned, this is a routine activity that occurs twice or three times a day in a pharmacy. It is important for the PSI to acknowledge that every pharmacy is under the direct control of a pharmacist at all times who is expertly trained in the fundamentals of stock management and control. In light of this, is it appropriate that this most basic routine activity, which each pharmacist by virtue of their training is completely competent in, should be the subject of a written policy and procedure? As trained professionals, pharmacists should be credited with the ability to conduct many routine activities in a pharmacy	The guidelines state: '*It is important to take extra care when dealing with controlled drugs, due to the nature of the medicinal products involved and the legal requirements for record keeping etc.'.* The inter-pharmacy transfer of controlled drugs should only occur where there is an immediate patient need and where waiting for the next delivery of controlled drugs would negatively impact on a patient's health, care, safety or wellbeing. The Misuse of Drugs Regulations 1988 (as amended) do not prohibit the inter pharmacy transfer of controlled drugs in such circumstances. It is necessary that CD2 controlled drugs entering or leaving a pharmacy are recorded in the controlled drugs register. The guidelines have been updated to expand on the requirement for a requisition in such cases. Noted, it is accepted that ordering and receiving medicinal products is a routine activity. However, as stated above, both written policies and procedures, which are adhered to, and skilled, trained staff help ensure a pharmacy operates safely and effectively and that patients receive high quality care when using the professional services of a retail pharmacy business. A pharmacy specific procedure is necessary to ensure all pharmacists operate in a consistent manner and to ensure patients receive a consistent level of patient care. Policies and procedures are also a useful tool for training new staff and regular review of such documents can aid in maintaining the quality of

	without needing to be guided by a written policy. 3.2 **<u>Medicinal Products which may be Sold or Supplied from a Pharmacy</u>** 3.2.2 Policies and Procedures '*In addition to the information outlined in section 3.1.4, there must be written procedures in place which outline the processes involved in ensuring all medicinal products sourced are appropriately authorised. This can be achieved by using authorised suppliers and checking each medicinal product on receipt for an authorisation number and appropriate packaging. The authorisation status of any medicinal product or of any wholesaler or manufacturer can be clarified with the IMB'* The rationale for including this is unclear. The IMB regulates wholesalers. In all circumstances other than in the case of exempt products, wholesalers can only supply properly authorised products into pharmacies. Accordingly, if a product is sourced from an authorised wholesaler, then the onus is on the wholesaler to ensure the product supplied is properly authorised. If wholesalers were not so doing, the IMB would respond accordingly. This being the case, the need for a written procedure in the pharmacy in this regard would appear unnecessary. 3.2.3 Medicinal products exempted from the requirement to be authorised - 'Exempt' Medicinal Products *'Patients should be appropriately informed of the unauthorised or 'exempt' status of the medicinal product. They should be made aware of what this means and reassured that their practitioner has decided that the 'exempt' medicinal product prescribed is the most appropriate treatment for their individual condition'*	pharmacy practices. Once in place policies will only need to be reviewed either when an element of the process changes or annually. Having appropriate policies and procedures in place should ultimately speed up pharmacy processes. Such procedures help ensure the integrity of the final link in the supply chain for a medicinal product, from the manufacturer to the patient, is maintained. This assures the safety, quality and efficacy of medicinal products sold and supplied through pharmacies. There is an onus on the pharmacist to ensure they only obtain medicinal products from authorised Irish wholesalers or manufacturers, or wholesalers or manufacturers authorised to supply into Ireland. There is also an onus on pharmacists to ensure that any medicinal product they receive is from a wholesaler or manufacturer authorised to supply the medicinal product and, in so far as is possible, check that the medicinal product is appropriately authorised. If wholesalers or manufacturers are supplying medicinal products inappropriately this will be regulated by the IMB and where a pharmacist is aware of such a situation he or she should inform the IMB.

	It is not considered appropriate for this guidance to delegate the reassurance of a patient to a pharmacist on behalf of a prescriber. It is considered that only the prescribing practitioner could reassure a patient that any treatment regimen initiated by him/her is "most appropriate treatment for their individual condition"	The guidelines have been updated to state: *Patients should be appropriately informed of the unauthorised or 'exempt' status of the medicinal product. They should be made aware of what this means and given the necessary reassurances, as appropriate….'*
	3.3 Withdrawal or Recall of Medicinal Products from the Market *'A medicinal product withdrawal/recall procedure should be developed, documented and regularly reviewed to ensure that a pharmacy can quickly respond to a request from the competent authority (the IMB) to withdraw or recall any medicinal product from sale. The recall procedure should be regularly challenged to verify effectiveness and should consider all aspects of a potential recall or withdrawal situation, including those that extend to patient level'*	
	It is considered more appropriate that this be amended to more closely reflect what is required in the Regulations, namely that each pharmacy owner and superintendent pharmacist co-operates with the IMB in the matter of recalls and follows exactly the directions issued by the IMB and or licence holder in respect of each recall. Each recall is unique in its circumstances therefore rather than requiring a pharmacy to prepare a generic written procedure for a process most have no experience of or expertise in, it might be more appropriate to limit the guidance to that required under the regulations.	Noted. There should be a recall procedure in place which can then be adapted, as appropriate, to each individual recall situation. Pharmacists need to have such procedures in place in advance of a recall situation to ensure when a medicinal product is recalled that the recall can be *'actioned as soon as possible following notification of the recall or withdrawal'*.
	DRAFT GUIDELINES ON THE STORAGE OF MEDICINAL PRODUCTS FOR SALE OR SUPPLY IN CONDUCTING A RETAIL PHARMACY BUSINESS **3.1 Storage of Medicinal Products** 3.1.4 Stock Management *'The stability of certain medicinal products, including some liquids or creams, may be altered once they have been opened. The pharmacy*	

	should have a procedure in place for checking the stability of such products' What precisely is understood by this statement? It might be more appropriate to explicitly state that pharmacists should comply with the manufacturers directions with regard to the shelf life of opened medicinal products. 'A documented procedure for the regular and systematic checking of *expiry dates should be in place. Short-dated stock should be identified and appropriately marked. All medicinal products which are close to their expiry date should be removed from stock and transferred to a specifically designated area'* The purpose of this statement is not clear. If a medicinal product's expiry date allows for it to be dispensed for a programme of treatment and still remain in date, then it is considered that it should remain part of the pharmacy's normal stock; if it does not fulfil this requirement, then it should be removed for destruction. It could be considered impracticable and confusing to advise having some form of double location of the same product on the basis of expiration date within the pharmacy. **<u>3.3 Storage of Medicinal Products which are Controlled Drugs</u>** 3.3.2 Controlled Drug Stock Management *'When a delivery is received by the pharmacy, the invoice or delivery note should be examined for the presence of CD2 and CD3 medicinal products; these should be removed immediately, entered into the CD register, if applicable, and placed in the safe or cabinet. The controlled drugs delivery docket should then be signed by the pharmacist and returned to the wholesaler. There should be a written procedure in place, which deals specifically with the receipt of CD2 and CD3 medicinal products'*	Noted. The procedure for checking the stability of such products should include checking the medicinal products Summary of Product Characteristics and/ or contacting the manufacturer, as appropriate. Agreed, short dated stock, marked in accordance with a pharmacy's procedure, may remain in active stock. However, pharmacists must pay particular attention to medicinal products which are close to their expiry date and all medicinal products must be removed from stock prior to their expiry date and transferred to a specifically designated area for disposal. A medicinal product must not be dispensed if the duration of treatment extends beyond the expiry date of the medicinal product.The guidelines have been updated to clarify this. Noted. It is not clear where this has been dealt with previously in the

	This could be amended to state that each pharmacy should adhere to the preceding requirements as outlined in the paragraph with respect to the receipt into the pharmacy of controlled drugs. **<u>3.6 Storage of ' High Tech' and 'Exempt' Products</u>** *'Exempt' medicinal products previously referred to as 'unauthorised' or 'unlicensed' medicinal products should be stored separately from authorised medicinal products. These medicinal products should be stored in a patient specific manner and all relevant documentation should be kept with the 'exempt' medicinal product, e.g. supplier's invoice, copy of prescription'* In the absence of some requirement relating to cross contamination, it is unclear as to the underlying rationale for this. All pharmacies endeavour to operate a stock management system that is uniform in application for all medicinal products without exception. This recommendation will likely disrupt this for many pharmacies. Because a product is exempt or reimbursed under the High Tech scheme, would not appear to warrant its exclusionary storage in the manner prescribed. A patient's treatment regimen should be considered in the whole and this guidance may militate against this. In the absence of a persuasive rationale such as a stability or cross contamination concern, then it is considered that this provision should be omitted. **DRAFT GUIDELINES ON THE <u>DISPOSAL</u> OF MEDICINAL PRODUCTS WITHIN A RETAIL PHARMACY BUSINESS** **<u>3.1 Disposal of Medicinal Products</u>** 3.1.5 Patient Counselling *'Pharmacists should ensure patients have sufficient and appropriate information on the safe disposal of medicinal products, e.g. in the event of a course of treatment not being completed. Patients should be facilitated and encouraged to return unwanted or expired medicinal*	storage guidelines. The PSI's High Tech Practice Notice states: '*This scheme (the High Tech Scheme) operates as a **patient-specific pharmaceutical care programme** with a nominated pharmacy responsible for a specific patient and their complete and complex medication and health needs. Care delivery must ensure that patient-specific dispensing occurs with a particular product obtained for a particular individual patient*'. This patient-specific pharmaceutical care programme should include the storage of high-tech medicinal products in a patient-specific manner. Unauthorised medicinal products should also only be ordered on a patient-specific basis and the medicinal products should be stored in a patient-specific manner.

	products to the pharmacy for disposal' The disposal of medicines constitutes a significant cost for many pharmacies. Accordingly, it is considered appropriate that this statement be qualified as follows: 'Patients should be facilitated and encouraged to return unwanted or expired medicinal products to the pharmacy *where they were dispensed or purchased from* for disposal'. **<u>3.2 Disposal and Destruction of Controlled Drugs</u>** 3.2.5 Disposal of Controlled Drugs *'Once the destruction criteria have been met, the resultant mixture must be disposed of into a medicinal product waste bin. Such waste should never be disposed of in regular waste and should never enter the mains water drainage system. The waste should be removed by an appropriately authorised disposal agency for incineration. Details of the waste management company should be retained in the pharmacy'.* It is our understanding that those companies who engage in the removal and destruction of medicinal products specifically preclude the inclusion of controlled drugs in their waste bins. This is because waste medicines are sent abroad for incineration and if they contained controlled drugs, notwithstanding that the controlled drugs therein they may have been rendered unsuitable for use, under the existing Misuse of Drugs regulations, the company would have to hold an export licence for their transfer abroad. Unless, the regulations have been amended to include an appropriate exemption, this provision would appear to be advocating a practice outside the current provisions of the law.	As pharmacists' primary concern, as outlined in the statutory Code of Conduct, is patients' health, care, safety and wellbeing, pharmacists should accept the return of waste medicinal products in patients' best interest. Where large volumes of medicinal products are concerned pharmacists should, insofar as is possible, aid patients in disposing of such products or provide information on alternative methods of disposing of such products. The destruction of a CD2 controlled drug medicinal product results in a 'destroyed material' which is not classified as a controlled drug and negates the requirement for an export licence to allow removal this from the jurisdiction for incineration, i.e. once the drug has been rendered unusable and unrecoverable from the final product it would no longer be considered a controlled drug and therefore would not require an export licence. Therefore, medicinal product waste management companies should accept such material for disposal by incineration.
21.	**An Bórd Altranais *(Eugene Donohue, CEO)***	
	An Bord Altranais appreciates the opportunity to review Pharmaceutical Society of Ireland's Draft Guidelines for Sourcing, Storage and Disposal of Medicinal Products within a Retail Pharmacy Business. The draft	Noted with thanks.

	guidelines appear to be very comprehensive in providing guidance to the pharmacist regarding the medication management activities of sourcing, storing and disposing of medications for retail pharmacy services. The document clearly outlines the need and content for policies and procedures for these activities. An Bord Altranais particularly notes the PSI's reference to policies and procedures for identifying staff involvement, provision of appropriate training and review of procedures on at least a minimum annual basis. (Refer to page 6 – 3.1.4, page 26-3.8, p 35 3.2.6). The inclusion of this guidance is appreciated as the Board acknowledges that medication management responsibilities are sometimes shared by health care professionals (i.e. nurses and midwives) when or where the services of the retail pharmacy may not always be available (e.g. residential care facilities for the older person) and alternative systems (i.e. stock medication dispensing) are in place. An Bord Altranais believes these draft guidelines facilitate the development and safeguarding of accountable practices by the retail pharmacy and its staff. And as a consequence safety risks to patients can be reduced and/or eliminated in the medication management cycle. It would be beneficial to all health care professionals involved in medication safety to be aware of the implications of these guidelines in relation to their own practice setting and how they may influence or impact medication management policies and systems in health care organisations in support of robust governance structures. The Board would be interested in discussing this aspect with PSI once the guidelines have been finalised. As an additional observation the information relating to patient education and counselling should consider the role of the carer and/or nurse as there may be situations whereby the patient lacks capacity for receiving and understanding medicines information. (Refer to page 10 - 3.2.3, page 18 - 3.1.4, page 31 - 3.1.4). Again thank you for the opportunity to contribute to this important	Noted. The guidelines provide guidance to facilitate compliance with the requirements of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) in relation to the sourcing, storage and disposal of medicinal products within a retail pharmacy business. However, the PSI is aware that all members of an interdisciplinary team, who work with medicinal products, will need to be aware of the contents of these guidelines. As outlined in legislation it is the responsibility of superintendent pharmacists, supervising pharmacists, other registered pharmacists and pharmacy owners to ensure a retail pharmacy business is conducted in compliance with the legislation. Pharmacists should collaborate with other health care professionals, e.g. nurses and doctors, to develop robust interdisciplinary policies and procedures for joint areas of working, as appropriate. Noted. The minimisation of risks to patients related to the sourcing, storage and disposal of medicinal products within a retail pharmacy business is the primary aim of the guidelines. Noted, the guidelines have been updated to acknowledge that the provision of information and the related counselling, as set out in regulation 9 of the Regulation of Retail Pharmacy businesses Regulations 2008 (S.I. No. 488 of 2008), may sometimes involve the patient's carer rather than the patient themselves.

	work.	
22.	**Irish Medicines Board (IMB)** ***(Dr. Caitriona Fisher)***	
	<u>General Comments</u> As general comments, we would suggest consecutive numbering if the document is to remain structured in three separate sub-documents and the addition of a glossary. It might also be useful for pharmacists if a list were appended or otherwise made available, showing all the procedures which the guidelines require or recommend. This might assist pharmacists in developing an implementation plan to meet the requirements. All IMB comments were made by way of track changes and so are indicated here by italicised text. (PSI comment) **<u>Sourcing of Medicinal Products</u>** <u>3.1.1 Sourcing from Authorised Manufacturers or wholesalers</u> Paragraph 4 Original: Documentation should be available in the pharmacy which permits the supplier of each consignment of medicinal product received by the pharmacy to be clearly identified, e.g. supplier invoices, delivery dockets. Changed to: "Documentation should be available in the pharmacy which permits the supplier *and medicinal products within* each consignment received by the pharmacy to be clearly identified, e.g. supplier invoices, delivery dockets. *Such documentation should also be maintained so as to ensure full traceability.*"	A contents page has been included. The numbering hasn't been altered as there are three separate stand-alone guidelines grouped together as they are interrelated. Noted. An audit checklist, which includes details on policies and procedures, has been drafted and will accompany the finalised guidelines. The guidelines have been updated to increase clarity in this section of the guidance.

	3.1.2 Medicinal Products which should not be Sold or Supplied Paragraph 2 "If a pharmacist or pharmacy owner suspect they have been supplied with a counterfeit, defective or inappropriately authorised medicinal product, the product should be segregated from legitimate pharmacy stock, i.e. stored in a designated *quarantine* area of the pharmacy and clearly labelled. *The word quarantine has been inserted.*	The guidelines have been updated to include the word quarantine in this section of the guidance and in the recall section of the guidance.
	3.1.3 Inter-Pharmacy Exchange of Medicinal Products Paragraph 2 "This documentation should include details of the medicinal product(s) involved, quantity supplied, batch number, expiry date, supplier (wholesaler or manufacturer), date of supply, details of the lending and recipient pharmacy and the reason for the exchange. When stock is obtained from another pharmacy, every effort should be made to assure the quality of the medicinal product obtained. Only the amount of stock required to meet the immediate patient need(s) should be transferred." *We suggest inserting a statement that on receipt of a recall letter this documentation should be checked and if units supplied are the subject of the recall, the pharmacy supplied should be alerted immediately and a copy of the recall letter provided as soon as possible* Paragraph 3 "It is important to take extra care when dealing with controlled drugs, due to the nature of the medicinal products involved and the legal requirements for record-keeping, requisitions, etc. Any CD2 medicinal products[4] entering or leaving the pharmacy in the manner outlined must	Agreed. This suggestion has been included in the recall section of the guidelines.

	be recorded in the controlled drugs register." *We suggest inserting a statement on the need for the receiving pharmacy to formally requisition the product(s) and the need for the supplier to provide a receipt with the product(s).* <u>3.2.3 Medicinal products exempted from the requirement to be authorised - 'Exempt' Medicinal Products</u> Paragraph 1 Original: Notwithstanding the marketing authorisations outlined above, Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) includes an exemption from the requirement for a medicinal product to be authorised for sale or supply. This exemption allows a practitioner, i.e. a registered doctor or a registered dentist, to prescribe unauthorised medicinal products for individual patients who are under their direct responsibility, in order to fulfil the special needs of those patients. Such products are defined as 'exempt' medicinal products. These products were previously known as 'unauthorised' or 'unlicensed' medicinal products. A medicinal product can only be defined as 'exempt' when it is supplied to the order of a registered practitioner for use by a patient under their direct care. Changed to: Notwithstanding the marketing authorisations outlined above, Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) includes an exemption *for the supply of unauthorised ('exempt') medicinal product in response to a bona fide unsolicited order from a practitioner. This exemption allows the supply of exempt (unauthorised) product in response to a prescription from a practitioner*, i.e. a registered doctor or a registered dentist, to prescribe unauthorised medicinal products for individual	Agreed. The guidelines have been updated to improve clarity in this section of the guidance. The guidelines have been updated to improve clarity in this section of the guidance.

	patients who are under their direct responsibility, in order to fulfil the special needs of those patients. Such products are defined as 'exempt' medicinal products. These products were previously known as 'unauthorised' or 'unlicensed' medicinal products. A medicinal product can only be defined as 'exempt' when it is supplied to the order of a registered practitioner for use by a patient under their direct care.[6] *We suggest re-wording as shown to clarify the precise circumstances under which the legislation permits supply of exempt medicinal products.*	
	Paragraph 2 "Pharmacists should be aware, and should ensure prescribers are informed, that the IMB does not permit 'exempt' medicinal products to be sourced and supplied if an authorised alternative is available in Ireland." *We suggest deleting this statement as this is not a formal IMB position. We also suggest adding the following to the end of this paragraph:* *"In circumstances where a pharmacist has dispensed an exempt medicinal product in response to a prescription for an authorised product which has previously been in short supply, the pharmacist should routinely check if the product has become available again, rather than continue to supply an unauthorised equivalent."*	The guidelines have been updated to state 'Pharmacists should be aware, and should inform prescribers, that 'exempt medicinal products' should not be sourced and supplied if a suitable authorised alternative is available in Ireland.' It is in patients' best interests that where authorised medicinal products are available an unauthorised medicinal product is not supplied. Agreed. A modified version of this sentence has been included in the guidance.
	Paragraph 5 "Any 'exempt' medicinal product ordered must only be sourced from manufacturers and wholesalers authorised to supply such products. A list of manufacturers and wholesalers used should be available in the pharmacy." *It might be useful to add that the manufacturers and wholesalers on this list must be authorised within the EEA.*	Agreed. The guideline has been updated to include this information.

	3.3 Withdrawal or recall of Medicinal Products from the Market Paragraph 2 "A medicinal product withdrawal/recall procedure should be developed, documented and regularly reviewed to ensure that a pharmacy can quickly respond to a request from the competent authority (the IMB) to withdraw or recall any medicinal product from sale. The recall procedure should be regularly challenged to verify effectiveness and should consider all aspects of a potential recall or withdrawal situation, including those that extend to patient level" *We suggest clarifying that recall notices usually come from the marketing authorisation holder and should include a statement that the recall has been agreed by the IMB.* **Storage of Medicinal Products** 3.1.3 Stock Management Paragraph 2 "Any medicinal product received in packaging that is damaged or discoloured, should be segregated on receipt and returned promptly to the supplier. Consideration should also be given to returning any short-dated medicinal product received. It is important that the return is appropriately documented, through completion of the supplier's 'returns form' or other appropriate means, *and is made as soon as possible after receipt.*" *We suggest adding this clarification – "and is made as soon as possible after receipt.*" Paragraph 5	Agreed. This has been clarified in the updated guidelines. Noted. However, the guidelines already state that such products should be returned '*promptly*' to the supplier.

	"Medicinal products must not be removed from the primary[4] protective packaging at the time of dispensing, except in cases where repacking is required to assist patient compliance. Certain medicinal products must never be removed from the primary packaging, as their stability will be impacted. There should be a policy in place which identifies these medicinal products. *There should also be a procedure in place for checking the stability of all medicinal products subject to repackaging.* This procedure should include checking the medicinal product's Summary of Product Characteristics and/or verifying the medicinal product's stability with the marketing authorisation holder. Relevant stability data may also be available from various other sources. A pharmacist should satisfy themselves of the validity of any stability data used. Documentation outlining the relevant stability information for each medicinal product should be retained in the pharmacy" *It might be useful to clarify the extent of re-packaging envisaged given the difficulties retail pharmacists may have in sourcing relevant stability data.*	Noted. However, pharmacists should ensure that if a medicinal product is repackaged, that the repackaged medicinal product is appropriately stable.
	Paragraph 10 "Patient-returned, expired and non-conforming medicinal products should be stored in a specifically designated area of the pharmacy, segregated from general stock and clearly labelled 'Medicines for Destruction', pending timely removal for disposal and destruction.[5] There should be a procedure in place outlining the process involved in the storage and disposal of waste medicinal products." *This paragraph might be cross-referenced to the guidelines on disposal.*	This paragraph is already cross referenced to the Disposal Guidelines.
	<u>3.2.3 Stock Management</u> Paragraph 1 "When medicinal products requiring refrigeration are received from	

	suppliers, they should be checked on receipt and placed in a refrigerator." *We suggest highlighting that this should be an immediate check on receipt.* <u>3.3.2 Controlled Drug Stock Management</u> Paragraph 1 "When a delivery is received by the pharmacy, the invoice or delivery note should be examined for the presence of CD2 and CD3 medicinal products; these should be removed immediately, entered into the CD register, if applicable, and placed in the safe or cabinet. The controlled drugs delivery docket should then be signed by the pharmacist and returned to the wholesaler. There should be a written procedure in place which deals specifically with the receipt of CD2 and CD3 medicinal products." *We recommend adding that any discrepancies in the receipt are noted. This procedure is legally required to be completed within 3 days of receipt.* <u>3.5 Storage of Veterinary Medicinal Products</u> Paragraph 4 "Certain veterinary vaccines are live vaccines and these should not be kept in close proximity to other veterinary medicinal products, human medicinal products or food." *Perhaps 'attenuated' should be added after 'live'.*	This has already been highlighted elsewhere in the guidelines (Section 3.1.4 of the Sourcing Guidelines). The word immediate is now also included here, to reiterate the importance of dealing promptly with refrigerated medicinal products. The guidelines have been updated to state any discrepancies should be noted on the controlled drugs delivery docket, which should be signed by the pharmacist and returned to the wholesaler. Agreed.

	<u>Disposal of Medicinal Products</u> <u>3.1.3 Disposal of waste Medicinal Products</u> Paragraph 2 "Medicinal products should never be disposed of in regular waste and should never enter the mains water drainage system. Medicinal product waste bins should not be overfilled. When full, the bins should be removed from the pharmacy promptly by an appropriately licensed disposal agency for incineration. Details of the waste management company should be retained in the pharmacy." *It is important that evidence of the medicinal products having been destroyed be routinely obtained from the waste management company. Typically a destruction certificate will be provided which details the waste consignment and the date of destruction.* <u>3.2 Disposal and Destruction of Controlled Drugs</u> Paragraph 1 "There are specific requirements for the destruction and disposal of Schedule 2 (CD2) controlled drugs, i.e. medicinal products specified in Schedule 2 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988)(as amended). Requirements, additional to those detailed in Section 3.1, are outlined below." *Please note that the legal disposal and destruction requirements apply to S2 to S4 inclusive* <u>3.2.2 witnessed Destruction</u> Paragraph 1 Original: Pharmacists who maintain a stock of CD2 medicinal products can only destroy such products in the presence of an authorised witness,	Agreed, the guidelines have been updated to reflect this. Certain requirements pertain only to CD2 medicinal products and certain requirements pertain to CD2, CD3 and CD4 medicinal products. The guidelines have been updated to include references to CD3 and CD4 medicinal products where appropriate.

	e.g. a member of an Garda Síochána or a PSI Inspector. The authorised witness must record that the controlled drug has been destroyed. This destruction should be recorded either in the CD register or in a specific controlled drug destruction record book which is also retained on site. If the destruction is not directly recorded on the relevant page in the CD register, there should be a reference to the page/ book where it is recorded inserted on the relevant page. Changed to: "Pharmacists who maintain a stock of CD2 medicinal products can only destroy such products in the presence of an authorised witness e.g. a member of an Garda Síochána or a PSI Inspector. The authorised *person must* witness and record that the controlled drug has been destroyed. This destruction should be recorded either in the CD register or in a specific controlled drug destruction record book which is also retained on site. If the destruction is not directly recorded on the relevant page in the CD register, there should be a reference to the page/ book where it is recorded inserted on the relevant page." *Please note that the legal term is authorised person. It would be worth emphasising that these persons must be authorised by the Minister for Health and Children to witness the destruction and include examples given.* Paragraph 2 "At a minimum a record of the name, strength and form of the medicinal product, the date of destruction, the quantity destroyed and the signature of the authorised witness is required. If a member of an Garda Síochána is witnessing the destruction it is recommended that they also record their Garda number. The balance in the CD register and/or destruction record book should be adjusted down to reflect the quantity destroyed, as appropriate. The destruction of the medicinal product should be carried out in accordance with any directions given by the	The guidelines have been updated as suggested. This information is already included in the guidelines. Appendix 1 lists all the persons that the Minister has authorised to witness the destruction of controlled drugs.

	authorised witness. (A full list of authorised persons/witnesses is outlined in **Appendix 1**.) *It is recommended that the guidelines include a requirement for the record to include a brief description of the destruction method followed.* <u>3.2.3 Patient-returned Controlled Drugs</u> Paragraph 2 "If a pharmacist is unable to destroy such CDs on receipt, they should be clearly labelled as 'Patient-Returned CDs for Destruction'. They should be stored securely in a specifically designated area of the CD safe/cabinet and segregated from normal CD stock, to avoid the potential for re-use. It is recommended that the destruction of patient-returned CD2 medicinal products be witnessed by a second pharmacist or another responsible member of the pharmacy staff." *We consider that it is important to consider that this would include any product in S2 to S4 inclusive.* <u>3.2.4 Destruction Criteria</u> Paragraph 1 "When destroying a CD2 medicinal product, there are two main criteria to be fulfilled to ensure that the final product is no longer considered to be a controlled drug • It must be no longer usable • and the active ingredient must be irretrievable from the final mixture." *This requirement also applies to S2 to S4 inclusive.* Paragraph 2 & 3	The guidelines have been updated to state that the record should include a brief description of the destruction method used. The guidelines have been updated to state: '*The destruction of patient-returned CD2, CD3 and CD4 medicinal products should be witnessed by a second pharmacist or another responsible member of the pharmacy staff.'* The guidelines have been updated to include references to CD3 and CD4 medicinal products where appropriate.

	Original: There are many ways to satisfy the destruction criteria to render the medicinal products unusable, pharmacists can: • grind up tablets with a pestle and mortar; • dissolve or cut capsules and, if necessary, grind up the contents; • cut patches or remove the backing from patches and fold the patch over on itself • open and empty ampoules; • mix liquids with solid matter. Empty ampoules or glass bottles should be placed in a sharps bin. Having rendered the medicinal product unusable it should be mixed with a product which will render the drug substance unrecoverable from the final mixture. A controlled drug denaturing kit may be used for this purpose or an alternative suitable product. Changed to: There are many ways to satisfy the destruction criteria *as follows. The* pharmacist can • grind up tablets with a pestle and mortar; • dissolve or cut capsules and, if necessary, grind up the contents; • cut patches or remove the backing from patches and fold the patch over on itself • open and empty ampoules; • mix liquids with solid matter. Empty ampoules or glass bottles should be placed in a sharps bin. *We consider that it is important to highlight that from the perspective of street level abuse, grinding tablets etc. does not render them unusable. It is the breaking up of the dosage unit and subsequent mixing which in effect makes it unrecoverable & unusable. An alternative wording is suggested*.	The wording in the guidelines has been updated to increase clarity. The guidelines now state: '*There are many ways to satisfy the destruction criteria. To render a controlled drug unusable as a medicinal product, pharmacists can:'* Noted. The guidelines have been updated to increase clarity. The first destruction step renders the controlled drug medicinal product no longer useable as a medicinal product.

	"Having broken down the dosage unit, it should be mixed with a product which will render the drug substance unrecoverable from the final mixture *and as such unusable*. A controlled drug denaturing kit may be used for this purpose or an alternative suitable product." Paragraph 4 "Any method of destruction employed should safeguard the environment and the health of pharmacy staff and members of the public. Appropriate safety precautions should be taken when destroying CD2 medicinal products, including the wearing of appropriate personal protective equipment." *This applies to S2 to S4 inclusive.* <u>3.2.6 Policies and Procedures</u> "There should be written policies and procedures in place outlining the processes involved in the segregation and disposal of patient-returned CD2 medicinal products and the segregation and disposal of expired or non-conforming CD2 medicinal products. These procedures should state the persons involved in the process and be signed by such persons. It is recommended that a pharmacist carry out all matters in relation to the disposal and destruction of CD2 medicinal products. If other staff are involved in the disposal of such products, they should be trained and records of such training maintained. All procedures should be reviewed and updated regularly, e.g. when any element of the process changes, and at a minimum annually." *We consider that this should reflect throughout S2 to S4 inclusive* <u>Appendix 1</u> "4. Persons employed or engaged as inspectors in connection with a scheme for the licensing of manufacturers or wholesalers of medicinal products under the Irish Medicines Board Act, 1995 (No. 29 of 1995) *as amended"*	Agreed. A similar sentence has been included in the updated guidelines. The guidelines have been updated to include references to CD3 and CD4 medicinal products where appropriate. The guidelines have been updated to include references to CD3 and CD4 medicinal products where appropriate. Agreed. The guidelines have been updated as suggested.

	We suggest this 'as amended' is added as the 2006 Act amended the 1995 Act. "6. Persons appointed as inspectors by the Irish Medicines Board." *We wonder if this is already covered by point 4.*	This information is taken directly from the Schedule which authorises persons for the purposes of article 22 of the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) and, therefore, has not been modified.