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Response from: The Royal Pharmaceutical Society to Public consultation MLX 375

The Royal Pharmaceutical Society (RPS) welcomes the opportunity to contribute its views on the consolidation and review of UK medicine legislation.

The RPS is the professional body for pharmacists across Great Britain. We are the only body that represents all sectors of pharmacy.

The RPS promotes and protects the health and well-being of the public through the professional leadership and development of the pharmacy profession. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

In formulating this response to the consultation the RPS has completed the appropriate sections of the response template but would like our general comments to be considered alongside the detail provided in the attached proforma. Additionally we would like to highlight that our response has been produced in the spirit of a professional leadership body and not by legal experts. We should also like to note that we have produced the response within the very short timescale of 12 weeks (including Christmas break) which we believe for this level of complexity and size of consultation is inadequate. We must therefore take in good faith the MHRA intention of not introducing any changes which will affect any sectors of pharmacy practice which have not been outlined and explained in the consultation document and Annex E.

We have also noted that the consultation document has omitted to ask any questions on the changes to section 10 (7) (exemptions for pharmacists) and therefore have included our comments on this section at the end.

1. General comments

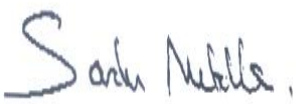
The RPS would like to acknowledge the hard work and commitment the MHRA have shown over the past 3 years in producing this draft set of regulations: The Human Medicines Regulations 2012. We have been supportive of the MHRA aim of consolidating and reviewing

the UK medicine legislation. We accept that regulations by nature lack the detail of implementation and would request that where appropriate additional guidance is produced to support the delivery of these regulations that the RPS is consulted at an early stage with regard to the impact they may have on the pharmacy profession.

With regard to the pharmacy profession a set of consolidated regulations as a framework to work within is a very desirable concept. Whilst we do not wish to diminish this achievement we are however concerned that a review of the regulations to ensure they are fit for purpose does not appear to have taken place. We believe this lack of review is a missed opportunity to align medicine legislation with the changing environment that health care is now delivered within and from, i.e. changes within the NHS structures, multiple legal entities with a hospital setting, the emergence of social enterprise models, out of hours services proved by private agencies and the ever changing technological advancements used to support the delivery of healthcare e.g. telemedicine, shared patient information. The process should also consider if the Definitions used within the Medicine Act are still valid and fit within the current view of how the service is delivered i.e. retail pharmacy business, retail pharmacy premise

Additionally we are disappointed that the consultation does not cover some very important aspects of medicine legislation, namely the decriminalisation of dispensing errors, and provide the much needed clarity in respect to the role of the Superintendent Pharmacist and Responsible Pharmacist. We appreciate the assurance that these areas are intended to be addressed but would ask for greater clarity to the how, and when.

Kind regards,


Lindsey Gilpin Sandra Melville, Mrs Mair Davies

Chair, English Pharmacy Board
Chair, Scottish Pharmacy Board
Chair, Welsh Pharmacy Board

For further information or any queries you may have on our consultation response please contact Jocelyn Parkes Jocelyn.parkes@rpharms.com 029 2073 0311

Annex G – Response sheet

Instructions

- If possible, please send responses electronically to medicines.consolidation@mhra.gsi.gov.uk using the following table. Even if you reply in hard copy, please use this table.

- If any of your answers refer to specific regulations in the draft consolidated regulations, please provide the regulation number and corresponding 'j-number' (this is shown in square brackets after the regulation number) in the relevant columns.

- Please provide any other observations in the second table below. Use one row per comment, and add more rows if necessary.

- Please also complete and return the confidentiality template at Annex H.

Respondent details

Please provide your details as requested below. The second and third pieces of information would assist us in delivering the Government's commitment to engage with small, medium and micro businesses.

- Please provide your name and (if relevant) the organisation or body you represent: Jocelyn Parkes, Royal Pharmaceutical Society , 1 Lambeth High street ,London, SE1 7JN, 020 7735 7629

- Please tick this box if you or the body you represent are in the NHS or public sector: ☐

- If you represent a private sector company, please indicate the number of employees in the company by ticking the relevant box below:

9 or less ☐ 10-49 ☐ 50-249 ☐ 250 or more x

Question Number	Question	Response	Regulation number (if relevant)	J-number (if relevant)
1	Are there any benefits and costs of consolidation other than those outlined in the impact assessment? If so, what are they?	The RPS would like to acknowledge the hard work and commitment the MHRA have shown over the past 3 years in producing this draft set of regulations. With regard to the pharmacy profession a set of consolidated regulations as a framework to work within is a very desirable concept. However we are concerned that a review of the regulations to ensure they are fit for purpose does not appear to have taken place. We believe this lack of review is a missed opportunity to align medicine legislation with the changing environment that health care is now delivered within and from, i.e. changes within the NHS structures, multiple legal entities within a hospital setting, the emergence of social enterprise models, out of hours services provided by private agencies and the ever changing technological advancements used to support the delivery of healthcare e.g. telemedicine and shared patient information. Additionally we are disappointed that the consultation does not cover some very important aspects of medicine legislation, namely the decriminalisation of dispensing errors, nor does it provide the much needed clarity in respect to the role of the Superintendent Pharmacist and Responsible Pharmacist or supervision. We appreciate the assurance that these areas are intended to be addressed but would ask for greater clarity and accountability to the how, and when. The RPS acknowledges that a full review of 43 year old legislation is an onerous task but we believe the benefit of such a review outweighs any difficulties in undertaking the task. We would suggest that the review is split into two, firstly a review of the legislation that is pertinent to medicine licensing requirements in respect to aligning the legislation within the context of EU legislation and secondly a review of the legislation pertinent to access to medicines and pharmacy.		

		Health and the implementation of health policy and strategy is a matter for the devolved governments but we believe overarching UK legislation should be written to support this implementation in all home countries. It is vital that the Medicine Act is not amended piecemeal to correspond to individual countries policy intent. In respect to cost of consolidation, any legislative changes will have a knock on effect on the people and resources that are used to teach educate and advise on the law. This effect cannot be articulated accurately as a financial cost but it must be acknowledged that the proposed changes outlined in this consultation will have a considerable resource, effort and cost by virtue that that teaching material, assessments, training, textbooks, advisory services and published guidance will have to be reviewed and updated to reflect the changes.		
2	What other evidence is there of the benefits and costs of consolidation for you or your organisation?	As above		
3	Please review the sections relevant to your industry and/or body and provide comments on the accuracy of our assumptions. In particular, we would like to know the following:	As above		
3a	Approximately how much time does your firm or body currently	The RPS provides support, advice and leadership to its members. This includes advice on law and ethics and the impact of the law on their specific area of practice. The professional advice and guidance we provide to our		

	spend every year understanding the regulations as they are currently drafted?	members is based on the framework of the Medicines Act. Additionally we provide advice and information to a vast array of stakeholders on the practise of pharmacy. The sum total of time taken to amass this knowledge and understand the ramifications of the regulation is therefore extremely significant.		
3b	What change in this annual amount of time would you expect as a result of the consolidated regulations?	As above		
3c	Roughly how much time do you think your firm or body will take in familiarising itself with them?	As above		
3d	Where relevant, how much time do you estimate your firm or body will require to alter your own guidance material in response to the consolidated regulations?	As above		
3e	What is the approximate wage rate of the staff who will engage in understanding regulations and revising guidance?	As above		
3f	Is our assumption that	Most small and independent community pharmacy contractors rely on their		

	small and micro businesses generally rely on their trade and professional bodies for regulatory information correct?	professional body to provide legal and ethical advice to support their daily practice. This advice is based on observations on legislation and our understanding of legislation. It is outside the scope of a professional leadership body to offer definitive legal opinion and in such cases members are referred to the General Pharmaceutical Council. However the RPS supports all of its members in understanding and working within the legal framework of the Medicines Act. Pharmacists work in many different practice settings in the NHS and in private health care and they seek individual advice from their professional leadership body on how the Medicines Act applies to their particular circumstance and working environment. This advice is provided within the scope of professional advice and not definitive legal opinion.		
4	Do you agree with the structure of the draft regulations? Why, or why not?	We support the structure of the regulations which is logical, but as with most legal documents is not particularly user friendly to non-legally trained persons. J172 could be extended to place a mandatory obligation on manufacturers to give adequate notice of planned product withdrawals or anticipated shortages.		J172
5	Do the draft regulations introduce any changes other than those outlined in this document?	As per general comments, we have drafted our response within a very limited timeframe for such a large complex document. We have focused our response on questions raised and have taken in good faith the MHRA intention of not introducing any changes which will affect any sectors of pharmacy practice which have not been outlined and explained in the consultation document and Annex E. We would ask that if any changes or drafting errors have been introduced, that the MHRA consults again on those issues and does not view a lack of input at this stage as being compliant with the change. Additionally we would ask for clarity on J203A , the wording now seems to		J203a

		suggest that the current sec 9 & 10 exemptions for radiopharmaceuticals would in future also include nurses. If this is the position we would not support this change.		
6	Are there any drafting errors in the draft regulations?	As above. 9b: the word “prepared” appears in j203a. There is a error on page 97 “relevant” not “relevent”. The drug name Amiodarone is misspelt in the document.		J203a
7	Are there any provisions in the draft regulations that could be made clearer?	We have made specific comments at the end of the response form.		
8	What should we do to help users prepare for the entry into force of the consolidated regulations?	Legal documents are by nature often difficult to interpret by non-legal people, and as such the MHRA should consider issuing a lay explanatory guide on new regulations, similar in nature to the guidance notes produced on the Veterinary Medicine Regulations to introduce a consistent approach. Additionally it should consult the relevant bodies including the RPS on what additional support guidance is needed to underpin the changes. As with any legislative change there must be sufficient time between the publication date and the implementation date, we would suggest at least an implementation time frame of 12 months for the proposed changed within this consultation. The MHRA could then use this lag time to run or fund a series of briefing events across the UK to cover key aspects of the legislative changes.		
9a	Should we add more requirements to Reg 3 [j002B] for medicinal products	No.		

	that fall outside the scope of the consolidated regulations? If so, what?			
9b	We have replaced the term “prepared” that was used in a few of the exemptions in the Medicines Act 1968 with “manufactured”, as we believe that term covers the making of any product. Do you see any difficulties with this?	We do not support the change in terminology, as although it appears to be more relevant to EU legal directives, it will cause confusion for practise in the UK. In the working practices of the UK the word “manufacture” and “prepared” are interpreted differently and are not interchangeable. By removing the word “prepared” from the regulations there is a danger that the operations undertaken by or under the supervision of a pharmacist such as extemporaneous dispensing will be considered in the same legal framework as those undertaken by a licensed manufacture. This will lead to unrealistic expectations and inappropriate standards being placed on practitioners with regard to simple dispensing exercises. Additionally this change may cause confusion for those purchasing products, as they may think they are buying a product manufactured and tested according to current standards of EU GMP when in fact they are purchasing an extemporaneously prepared product made under the supervision of a pharmacist (e.g. in the case of a licensed specials manufacturer that is also a registered pharmacy).		
9c	Is the provision too narrow or too broad in any respect?	We would ask for clarity within this provision as to the position of dispensing doctors.		
10	Is the new definition of advertisement sufficient to cover all relevant forms of advertising?	We support the new definition of advertising, and would suggest that the activities of cold calling by telephone or spam / junk email are included in the definition.		

11	Do you agree with the proposals for the two simplifications in relation to herbal medicines? Why, or why not?	We support the proposal to transpose the definition to “herbal medicinal product” as this appears to be a logical step to consolidate the regulations in this area. We are unable to comment on the second simplification as we have insufficient knowledge to know if this is a redundant provision to the Act.		
12	Do you agree with the proposal to remove the requirement to dispense certain medicinal products in fluted bottles? Why, or why not?	We support the proposal to remove the requirement for dispensing into fluted bottles for certain medicines. The ability to acquire fluted bottles has been problematic as their use within pharmacy has diminished. Additionally they no longer offer any additional patient safety benefit as people do not understand the applied connotation of their use. Additionally we would suggest that the MHRA uses this opportunity to introduce a manufacturing licence requirement for child proof packaging for all liquid preparations.		
13	Do you agree with the proposal to remove statutory warnings, including for paracetamol? Why, or why not?	We support the proposal to remove statutory warnings as they appear to offer no additional patient safety benefit that cannot be achieved by the introduction of non-statutory warnings. We support any measures taken by manufactures to improve patient understanding of their medicines and would suggest that if new wording is suggested for warning labels the wording is reviewed by patient groups and professionals to ensure clarity and lack of ambiguity. In respect to the statutory warnings on paracetamol we support the flexibility on non-statutory warnings which can quickly accommodate any changes to its indications. However in light of recent studies we are concerned about the removal of the statutory wording to the maximum daily dose, the warning for not taking other preparations containing paracetamol and that the medicine contains paracetamol and the quantity it contains.		
14	Do you agree with the proposals to change	We support the proposed changes as it would enable the expertise of former members of the medicine advisory board to be used appropriate. Additionally		

	the persons appointed process? Why, or why not?	the 1 year time frame seems an appropriate gap before taking up the post.		
15	Do you agree with our proposals to remove exemptions that are obsolete or no longer relevant? If not, why?	We agree with the proposal to remove the provision that allows pharmacists to sell or supply Amyl Nitrate. However we do not support the removal of the provision which would relax restrictions on the sale or supply of medicines to people who are employed or engaged in connection with schemes for testing the quality and quantity of medicines supplied in the NHS on the basis that this provision is obsolete or no longer relevant. (Paragraph 9.4 of MLX 375) NHS pharmaceutical quality assurance and quality control personnel continue to carry out testing of the quality of medicines supplied in the NHS and the current medicines act provisions should be retained.		
16a	Do you agree with our proposal to extend to other organisations concerned with research the provisions allowing sale or supply of medicines to universities and institutions concerned with research or higher education. Why, or why not?	We have reservation about extending to other organisations ***concerned with research*** the provisions allowing sale or supply of medicines to universities and institutions concerned with research or higher education. The organisations would have to be clearly defined in law, with a definitive list being available in the public arena for the profession to refer to when approached to make such a sale or supply. Additionally the supply should be through a named person / or job role within the organisation, to ensure a safe chain of supply and accountability for safe storage and custody of medicines.		
16b	If such a change were introduced, should it be subject to the exclusion of any	We are unable to comment on the classes of drugs that should be available prior to knowing the details of the intended use and the other organisations referred to.		

	classes of medicines in addition to controlled drugs? Why, or why not?			
17	Should the limit on the size of ampoule in which water for injection can be supplied be extended to 5ml? Why, or why not?	We support the recommendation to extend the size of ampoules in which water for injection can be supplied. The introduction of the 5ml ampoule will allow flexibility of supply, ease of administration and improved patient safety with the use of plastic rather than glass ampoules / containers.		
18a	Should the existing exemption allowing the administration of Adrenaline by injection by any person for the purpose of saving life in an emergency be amended to allow injection up to and including 1 in 1000?	We support increasing the range of Adrenaline preparations available to be used in an emergency, however we have concerns that the wording “up to and including” is too vague, as this wording will allow inclusion of Adrenaline 1 in 10000 which is an intravenous preparation that should only be used by experienced practitioners, and its inclusion would offer more risk than benefit for patients. We would also suggest a more generic wording to allow for brand changes and substitution if there is a supply problem.		
18b	Should an increased range of Adrenaline preparations be subject to any limitations on the route of administration. Why, or why not?	If the range of Adrenaline is increased, guidance should be issued to ensure patient safety is paramount and this should include appropriate route of administration, that the containers are clearly identifiable in strength and route of administration and that there is an auditable process in place to minimise the risk of administration errors. Additionally if the range of Adrenaline is increased to allow the intravenous 1 in 10000 preparation to be available then this should only be used by experienced practitioners in controlled situations where monitoring is available (Ref BNF 3.4.3.).		

19	Should Paracetamol and Ondansetron be added to the list of medicines that can be administered parentally by registered ambulance paramedics on their own initiative? Why, or why not?	We support the proposal for Ondansetron as it would allow greater access to the medicine in a timelier manner; however we are concerned that the licensing agreement may not reflect its use in this circumstance. In respect to Paracetamol we are concerned that patient safety could be compromised for quicker drug access. Many patients take paracetamol routinely for pain and may have ingested their daily dose prior to the ambulance arrival, in a confused or vulnerable patient this information may not be conveyed to the ambulance paramedic and additional Paracetamol be given leading to a potential overdose.		
20	Should people be allowed to obtain water for injection for purposes other than parenteral administration without a prescription? Why, or why not?	We support the proposal to extend the availability of water for injection. This would enable a pharmacist to use their professional judgement to supply sterile water that is required for other circumstances.		
21	Should pharmacists be allowed to sell or supply water for injection without a prescription for purposes other than parenteral administration or for use as a dilutent where no dilutent has been specified by the prescriber? Why, or why not?	Yes – as above.		
22	Should holders of the	We would support the proposal to enable quicker or timely access to		

	Council's Advanced Life Support (ALS) certificate be allowed to administer Adrenaline and Amiodorone in emergencies involving cardiac arrest? Why, or why not?	emergency medicines. We would suggest that additional guidance is produced to ensure patient safety is paramount and the containers are clearly identifiable and auditable to minimise the risk of administration errors. Additionally the guidance should reflect medicine management issues such as storage and safe custody of a POM.		
23	Do you agree with the proposal to retain the general structure and requirements of PGDs in their current form, and to retain the principle that only registered health professionals should be able to use PGDs?	We support retaining the general structure and requirements of PGDs. PGDs have been a useful mechanism in allowing access to medicines, particularly in "see and treat" services e.g. emergency hormonal contraception / stop smoking services. There is clear evidence of patient benefit in continuing with this legal mechanism. But legislation must keep pace with the evolution of the health care environment to ensure that PGDs can be used appropriately to develop and deliver safe, effective services that comply with the law. There is a need to urgently review some aspects of PGD legislation to ensure that it is future proofed and fit for purpose in the ever changing health care environment. For example, the authorisation of PGDs can cause practical difficulties in changing NHS structures and urgent consideration needs to be given to how PGDs can be approved by healthcare organisations who are social enterprises. (See comment under 10.16) We would agree that prescribing on a one to one basis is the preferred way for patients to receive medicines. However, there has been lack of progress with the introduction of non-medical prescribing. This continues to cause barriers to service development and may lead to inappropriate use of PGDs as a result. Therefore, this must be separately addressed.		
24	Should NHS bodies	We support the supply of medicines in accordance with written directions		

	be able to supply medicines in accordance with the written directions of an independent nurse, pharmacist or optometrist prescriber? Why, or why not?	from non-medical prescribers as this gives equal legal prescribing rights to non-medical prescribers. The wording does need future proofing or clarifying as there are currently proposals to extend prescribing rights to other healthcare professionals. We would however ask for more clarity on labelling requirements when supplies are made under this mechanism to ensure patient safety is not being compromised and a full audit trail is available.		
25	Should independent hospitals, clinics etc. in England continue to be allowed to use PGDs but by reference to them being registered for the following regulated activities in England? • treatment of disease, disorder or injury • assessment of persons under the Mental Health Act 1983 • surgical procedures • diagnostic and screening procedures • midwifery services. Why, or why not?	For English independent hospitals, clinics etc we support this proposal as the Health and Social Care Act 2008 (HSCA) has superseded the Care Standards Act 2000 and this is not currently reflected in PGD legislation. The use of PGDs in these regulated activities could help ensure timely and equitable access to the appropriate prescription only medicines by their patients in these settings. We would suggest that the MHRA should refer to the PGD website to help ensure that independent hospitals, clinics etc are aware of additional PGD guidance and resources to help ensure that PGD use is safe and legal. Health and the implementation of health policy and strategy is a matter for the devolved governments but we believe overarching UK legislation should be written to support this implementation in all home countries. It is vital that the Medicine Act is not amended piecemeal to correspond to individual countries policy intent. The Care Standards Act is still applicable in Wales, as many companies work across borders it is difficult to work within and especially uphold compliance with the differing legislation. As the Medicine Act is intended to be UK wide then we would request that the MHRA consults with the appropriate organisation in the devolved countries ie Healthcare Inspector Wales, and Health Improvement Scotland to gain UK agreement with such specific legislation.		
26	Should dental practices and dental	We support this proposal - as 25 above.		

	clinics registered with the CQC or private dentists registered with its equivalent in Wales be able to sell, supply or administer medicines under PGDs? Why, or why not?			
27	Do you agree with the proposal to facilitate the optimisation of medicines use? Why, or why not?	We strongly support this proposal. This proposal would enable pharmacist to use their professional judgement to supply medicines to patients in a quick and efficient manner whilst acting within the prescriber's intent and clinical indication. We understand that this change removes only the requirement to try to contact the prescriber and in no way changes the current position with regards to generic substitution As the professional leadership body we are happy to work with the MHRA in producing any underpinning guidance that is necessary to implement this proposal.		
28	Do you agree with our proposal for keeping the consolidated regulations up to date? Why, or why not?	We are supportive of the consolidated regulations and would suggest that the MHRA looks to review the Regulations to ensure they are fit for purpose in the every changing health care environment. From a professional stance a set of consolidated regulations are welcomed and we would request that they are regularly reviewed to ensure that all the medicine legislation is encompassed within one set of regulations.		

Further comments (please use a separate row for each comment and insert more rows if necessary)

Number	Further comment	Regulation number (if relevant)	J-number (if relevant)
4.21	The RPS is disappointed that section 10(7) of the medicines act is to be repealed but understand the reason for this is to bring the UK in line with European legislation. To meet the needs of specific patients, pharmacies have been able to provide small quantities of stock to other healthcare professionals for onward supply to meet patient need under section 10(7). Whilst we acknowledge that the MHRA have retained the general implications of this exception we would ask for clarity for the implied intention of the new wording within the exception. In particular we consider that pharmacists will need clarity about: • How will 'small quantities' be interpreted by the Regulator • How will 'occasional' be interpreted by the Regulator • What is meant by a 'single legal entity' • Can NHS bodies still supply another NHS body on another site but within the same legal entity organisation e.g. large hospital supplying a smaller community hospital • Can NHS bodies supply to non NHS bodies e.g. a hospital to a hospice, community pharmacy to care home, community pharmacy to prison pharmacy • Can small supplies of stock be made in anticipation of need for, as yet, unidentified patients We would like pharmacies to have the ability to continue to supply to other agencies in a way that meets immediate patient need. We also understand and support the situation that after the repeal of 10(7) supply to other agencies with the intent of further onward supply should be regulated as wholesale dealing. MHRA have indicated that professional guidance will be required to support the implementation of this		J226

	exception and the RPS offers its support and expertise in developing such guidance which, we expect, will clarify the issues identified above. This supporting guidance needs to be issued in a timely manner to enable those pharmacies currently using the section 10(7) exemption to change their working practice. Should this not be possible within the legal timescales, we would request that a “bedding in” period be declared by the MHRA so that current supply routes that would not fall within the guidance can find suitable alternatives through regulated wholesale supply.		
	Packaging and package leaflets The current provision to supplying patient information leaflets (PILS) with all medical products cause practical difficulties for pharmacy without corresponding benefit for the patient when making the supply through monitored dosage systems(MDS) or multi-compartmental compliance aids (MCAs). We would ask that the MHRA considers the need for a more pragmatic approach when supply is made through an MDS or MCA to a patient who receives the medicine on a regular basis, particularly when they are in a residential care setting. There is a practicality difficulty for the pharmacy in supplying PILS to regular MDS patients, in that they do not have enough PILs to send out on each occasion (weekly). We acknowledge that PILS can be printed from the internet “medicines.org.uk website.” However on a practical basis this is not ideal as not all PILs are available for printing and the quality of printed material can be variable. The supply of a PIL is also problematic within a hospital environment as the bulk stock for ward requires several PILs to be produced which may not be the most use friendly for the staff who require the information. Additionally for the patient and / or care homes there is a big bundle of paperwork that is supplied to them which makes locating the right information when needed difficult and thus patients then tend to throw away all the paper work. A sensible and pragmatic solution is required which continues to provide information to patients regularly but without imposing excessive bureaucratic burden to the pharmacy and inconvenience to the patient without corresponding benefit.		J602c

	Labelling Additionally we would ask that the MHRA considers a more flexible approach to the labelling requirement of MDS and in particular MCA which tend to be smaller in style and therefore more difficult to label appropriately. These tend to be used more often by patients in the community requiring less support than those using MDS. The current regulations can cause practical and aesthetic issues in trying to attach full labels to these aids in accordance with the legal requirements. The end result can be difficult for both patients and carers, or other health professionals to read, which could have safety issues. Depending on the MDS supplied and the amount of tablets contained within the system it might be appropriate to label the MDS fully or where there is insufficient space, to label the MDS with basic information, such as name and quality of medication, and then supply the addition information and cautions on an accompanying card for the named patient or similar practice adaptation to suit the care setting.		
	Emergency supply Currently it is not possible legally to make an emergency supply to a patient representative as the legal requirements state that the pharmacist must interview the patient. We would request this is reviewed to allow a pharmacist to use their professional judgement in making an emergency supply and act in the patient's best interest. When an emergency supply is needed it is often requested by a parent / spouse / career and in these incidences the pharmacist should be allowed to use their professional judgement and act in the patient's best interest to make the supply if needed and appropriate.		J527
	Electronic prescribing /Faxed Prescriptions We would ask that the MHRA considers a change in wording within the legislation to accommodate for the increasing use of electronic means of producing / requesting a patient's medicine. A small change in wording of the Act needs to be made to allow' at the request of a doctor' to mean a written record transferred by fax or secure email as well, so that these supplies would then fall within the legal requirements of the Medicines Act.		

	In practice faxed prescriptions are a routine part of business for many pharmacies, especially at weekends when out of hours doctors do a consultation over the phone and fax a prescription to a convenient pharmacy, particularly in rural areas. Hospitals often fax NHS prescription forms for MDS patients to community pharmacies to allow enough time for the pharmacy to prepare the patients medicines in preparation for their discharge. In both examples the NHS prescription forms are posted to the pharmacy as the patient is usually housebound and the medicines delivered or picked up by carers. Additionally the prison service use faxed prescription as a means of obtaining supply from a central pharmacy hub with the original prescription being sent to cover the supply. These practices offer practical solutions to patients in need of medicines and we would ask that the Regulations are changed to reflect this.		
	Restriction on paracetamol quantities Currently the Medicines Act restricts the sale of paracetamol to the pack size of paracetamol. We would request that the MHRA reviews this and considers restricting the sale of paracetamol to total quantity sold in a single transaction. This change would stop the practice of non pharmacy outlets selling multiple packs of the small pack of paracetamol and restrict the total qualities sold to any one individual.		J502
	Collection points for medicines We are concerned about the application of J516 which could allow any registered pharmacy to setup multiple collection points (automated or otherwise) without restriction. Whilst collection points serve a legitimate purpose in some scenarios we would request that there are safeguards in place to ensure they form part of the overall pharmaceutical care needs of the patients they are intended to serve. Namely their introduction should be supported by a pharmaceutical needs assessment for their use, and ensure patient safety is not compromised when collecting their medicines. Additionally patients must have access to pharmaceutical advice when they collect their medicines.		J516
10.16	**Patient Group Directions – views in advance of informal consultation** **Organisational and structural changes in the NHS and PGD Authorisation** We accept the need for a separate piece of work to review the legislation for authorisation of PGDs,		

10.17 10.19	but would ask that it is viewed as a priority by the MHRA. The shape of the new NHS commissioning and delivery landscape in England is rapidly evolving with some areas being far more advanced than others. Early pathfinder sites are now emerging with some expecting to be functioning as early as April 2012. These sites could then gain formal accreditation by October 2012, with the consequential knock on effect of PCTs in these areas being disbanded. In addition, the rate of establishment of Community Health Services across England who are social enterprises is increasing and many of these organisations rely on PGDs to deliver their services e.g. family planning and sexual health clinics. These organisations currently rely on PCTs to authorise PGDs on their behalf. **Pharmacy** We note that the issue of adding pharmacy technicians to the list of health professionals who can use PGDs requires more detailed consideration which cannot be completed within the timescales for the consolidation and that the MHRA will progress this separately. We would suggest that the MHRA should at the same time consult on the need to add other registered health professions to this list to ensure that the list reflects needs across all healthcare provision .e.g. registered operating department practitioners. **Unlicensed medicines** Whilst we agree that in principle unlicensed medicines should not be supplied/administered under a PGD, there is a one notable exception, Tuberculin PPD (Mantoux test). Tuberculosis services all use the unlicensed Mantoux , and as such have to use Patient Specific Directions (PSDs) not PGDs as a means of supplying the test. The use of PSDs is not appropriate in this instance as it is not always possible for prescribers to individually assess each patient and we would therefore ask for either an impact assessment on the decision not to change the law or a licensed product should be made available so that practice could take place under PGD and safer systems of work could be implemented.		
	Schedule 7 Qualified Persons We would ask the MHRA to consider including the experience under a manufacturing specials licence to count towards QP training as this would allow more QPs to be trained and retained in the NHS. This		J005

	may include changing the wording in part 1 of Schedule 7 from **authorised** to **licensed**. A hospital pharmacy holding a Specials licence is 'licensed', but not authorised i.e. it has a manufacturing specials licence (MS) not a manufacturer's authorisation (MA). At the moment NHS candidates generally have to rely on experience under a manufacturer's authorisation for investigational medicinal products (MIA(IMP)) to fulfil the practical experience criterion and it is hard for candidates to obtain this experience.		