ROYAL PHARMACEUTICAL SOCIETY

Response by the Royal Pharmaceutical Society to the European Commission's Concept paper on the Delegated Act on the detailed rules for a unique identifier tor medicinal products for human use, and its verification.

Lindsey Gilpin,

Chair, English Board,
On behalf of the Royal Pharmaceutical Society

Delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification

The **Royal Pharmaceutical Society** (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. 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.

Its functions and services include:

Leadership, representation and advocacy: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.

Professional networking and publications: creating a series of communication channels to enable pharmacists to discuss areas of common interest.

The Royal Pharmaceutical Society (RPS) is committed to making the UK the safest place to take medicines. The elimination of counterfeit medicines in the legitimate medicine supply chain is a key element of this commitment. It is essential that we introduce a robust process that protects by rejecting counterfeit medicines before they reach patients where possible, before they reach patients, but also facilitates recalling packets from patients should they be identified after dispensing.

The RPS believes the Falsified Medicines Directive sets out the requirements for such a system, namely the requirement to inspect suppliers of excipients and active pharmaceutical ingredients, use of a unique identifier, and tamper-proof seal. This concept paper deals with some of these key issues and the success of this consultation will determine the overall success of the Directive.

When leading the implementation of the Directive, we ask the Commission to ensure that the following over-arching principles underpin detailed proposals:

- The purpose of the system is improving patient safety, primarily achieved by reducing the risk of counterfeit medicines reaching patients
- There is a risk-based balance between the requirement to ensure the key aspects of the system are effective but also do not deter practitioners from adhering to its use.
- To ensure adherence, it should be cost-effective and avoid undue delay to the dispensing process
- Existing patient-focused working practices should be supported and the system should not impose undue restrictions on the development of new and innovative services for patients
- Consideration should be given to the future potential to develop the system further to allow new functionality such as a link to payment authorities to facilitate speedier payment for services provided.

Q1. Please comments on points 1 and 2. Where do you see the benefits and disadvantages of each policy option?

Pharmacies handle medicinal products made by hundreds of different manufacturers. In the UK alone, we dispense around 1.26 billion medicines per year. Any variance in technical standards between manufacturers will introduce potential inefficiencies into the dispensing process. It is essential to minimise the additional costs associated with introducing a standardised system, but a consistent, Europe-wide specification is the only acceptable solution.

Q2. Where do you see the advantages and disadvantages of the approach set out in point 2.1.1?

The approach set out in point 2.1.1 seems reasonable, except it is unlikely to be able to recall batches due to errors in the manufacturing process.

Q3. Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2?

The inclusion of additional information in the barcode will facilitate a further accuracy check available to practitioners at the point of dispensing, reducing the potential for dispensing errors and raising levels of patient safety.

Pharmacies already receive information alerts when a product recall is issued, so that any units from the affected batch can be identified and quarantined. Including the batch number within the code will provide an additional safety system for ensuring that patients do not receive stocks of medicines that have been recalled.

Pharmacies must not dispense a drug which has expired, and they therefore have systems in place to prevent the dispensing of stock which has passed its expiry date. Including the expiry date within the code would provide a second check and reduce the relatively small number of incidences where an out of date medicines is inadvertently dispensed.

Further information should be included, such as: change of shape or colour, or anything of a similar nature that must be known by the practitioner and patient can be flagged up to the dispensing pharmacist, so that they can best advise patients.

Q4. Which of the two options set out under point (c) of point 2.1.2 is in your view preferable? Where do you see advantages and disadvantages?

The RPS believes Option 2 is the most beneficial. Even though reimbursement via this system is unlikely to take place in the UK in the foreseeable future, the RPS would like to have it included so it can be utilised as a method of payment at an appropriate time.

Q5. Please comment on the three concepts described under points 2.2. Where do you see the benefits and advantages of each of the three concepts. What are the costs for each concept? Please quantify your reply, wherever possible, by listing examples:
costs for reading devices for the different carriers;
costs for adapting packaging lines of medicines packaged for the EU market.

Radio-frequency identification has an advantage over barcode technology because it is able to identify multiple packs at a single scan. The RPS understands that the margins of error in reading multiple packs will not facilitate the level of security expected by patients and the public. This so-called 'tag collision' can be avoided with the introduction of additional equipment but it involves further expense in addition to this already being the most expensive system under consideration. There may also be interference from metal objects, water or residual radio frequency sources in close proximity to the packs being scanned. The RPS believes this option is not an appropriate option to deliver the scanning of medicine packs.

The use of linear barcodes would save the associated costs of introducing new technology within pharmacies. The RPS understands that this system would be placed under stress if it is asked to carry the additional information identified in Questions 3 and 4. We, therefore believe it isn't an acceptable solution.

The use of all relevant technical information (product code, serial number, batch number, expiry date and possibly reimbursement code) in the available space will prove too challenging for a linear barcode system. The additional information will make the use of linear barcodes difficult due to the available space on many smaller products such as eye drops.

2D barcodes make more effective use of the space available on medicinal products. Even though there are associated additional costs with introducing 2D barcode technology: software, hardware, retraining staff etc, the RPS believes this is the preferable system to be used to deliver the requirements contained within the Directive.

The vast majority of pharmacies within the UK already have a scanner which can read 1D barcodes. Welsh pharmacies (which represent about 5% of the total) already use 2D barcode scanners. The vast majority of pharmacies will need to purchase at least one new scanner, which could be partially set against a pharmacy's ongoing process of IT procurement.

Q6. Regarding point 1, are there other points of dispensation to be considered? How can these be addressed in this policy option?

In rural areas of the UK, it is often the case that a doctor's surgery will dispense the medication that it prescribes. 81 million prescription items per year are dispensed this way in England alone. In addition, some medicines are administered within the GP practice (for example, influenza vaccines which are typically administered by practice nurses).

In order to protect patient safety and avoid weaknesses in the overall anti-counterfeit system, it is essential to apply the same authentication obligations to dispensing practices.

The Commission should be aware that in the UK there are a range of places other than pharmacies from which medicines are supplied to a patient. Wholesalers and pharmacies supply medicines to midwives, hospices, optometrists, chiropodists, podiatrists, certified first aiders, masters of ships, providers of occupational health schemes, commanders of aircraft, mountain rescue teams, sports clubs and others for onward supply or administration to patients. Administration of medicines from some of these points may result in individual tablets being given to patients. It may be possible to check out a specific pack to another point of dispensing, a hospital ward for example, with another recording system used at the point of dispensing to record the names of individuals who receive every tablet or dose from

specific packs. Consideration needs to be given to how such a system can best be integrated with the main verification system described in the Falsified medicines Directive. The view of the RPS is that authentication at the point of supply from the registered pharmacy end the requirements of the Falsified Medicines Directive.

Q7. Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible. This applies in particular to the:

- **Number of wholesale distribution plants**
- **Costs for adapting such plants**
- **Duration of scanning of the serialisation number**
- **Number of pharmacies, including hospital pharmacies**
- **Number of medicinal products dispensed by pharmacies and a hospital pharmacy**

The RPS believes that there must be an understanding by every individual within the medicine supply chain, that every pack will be verified where possible. To facilitate every pack being scanned, delays whilst verifying must be kept to a minimum, in order to avoid undue delay to the person receiving their medicine.

The only certain method of understanding where counterfeit medicines have entered the supply chain would be to scan every pack at every stage in the process, when it moves from one entity to another, or across borders. The RPS understands this will impose an unrealistic level of bureaucracy onto all stakeholders within the supply chain. The best option outlined in the concept paper is option 2, requiring random verification and reducing the potential for counterfeits to enter the supply chain. It is accepted that counterfeit medicines are highly likely to be identified at the point of dispensing without random checks, but it is essential that we can learn from every instance when counterfeit medicines manage to penetrate the legitimate supply chain. To enable this learning process, it is important to be able to trace counterfeit packs back to the point where the supply chain was compromised.

The level of success of a system with random checks depends upon the number of random checks being carried out throughout the process and would not address the need for a robust system of authentication at the point of dispensing.

There are approximately 13,500 community pharmacies in the UK and a further 500 hospital pharmacies, dispensing approx 1billion prescriptions per year.

Q8. Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, wherever possible. This applies in particular to the estimated one-off costs and running costs for a repositories system. Where possible, please provide information on past experiences with a repositories system at individual company level and at national level (taking into account the experiences of Member States and companies).

EFPIA, GIRP, PGEU and EAEPC have set out coherent and reasonable proposals on how relevant actors can take responsibility for delivering the repository system. The actors, who

will all be users of the system, will be highly motivated to deliver an efficient system. The marketing authorisation holders, who are required to fund the database, have an additional incentive to ensure that the system is cost effective. The proposed architecture will allow appropriate interaction at both EU and Member state level. With the alignment of incentives, the proposed stakeholder model provides the best opportunity for delivering the desired outcomes in a cost-effective manner.

An EU governance model presents a number of concerns and does not appear to be a suitable option. A pan-European system, governed by the EU, may not provide adequate flexibility to deal with the considerable differences in practice within Member States. Such a system will face challenges integrating with the huge number of supply chain participants and may lack access to key expertise within the supply chain. A system operating above national boundaries presents serious concern for national stakeholders which may reduce the acceptance of the scheme and present a barrier to adoption.

Systems set up by Governments of individual member states will face a number of problems, including the likely variance of technical standards and difficulties dealing with products moving across borders. The latter issue may introduce weaknesses into the system which could be exploited by counterfeiters. A multitude of national systems will increase the overall costs. While the costs of the repositories will be met by manufacturers, these are likely to be passed onto those who fund the health system across Europe. It is therefore important that consideration is given to the financial impact of decisions made as part of the Delegated Act.

The Stakeholder governance model appears to be appropriate in that it sets out roles and responsibilities for all relevant actors and is likely to be the most cost-effective solution.

Q9. Please comment on point 4.1. Are there other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act?

Three sets of information that are commercially sensitive have been correctly identified, and we propose an additional point:

> Information that allows the total number of interactions with the repository by an individual pharmacy to be identified

It should be recognised that most pharmacies in Europe are owned and operated by individual pharmacists. Allowing any release of the information they supply to the repository, without their permission, would undermine the right of a pharmacist to maintain confidentiality over details of their professional practice and size of their business. There should be an explicit recognition that the pharmacy owns the data that it adds to the repository.

Q10. Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?

This proposed pan-European system is unlikely to win the support and trust of patients if there is any suggestion that their personal data will be stored in the repositories. We can only endorse a system where the personal data from patients is kept within a specific pharmacy and isn't held in a regional/national/European repository.

We support the proposal that re-packaged products should have equivalent safety features applied, so that high standards of security are maintained throughout the system.

Q11. Which approach seems the most plausible from your point of view? Can you think of arguments other than those set out above? Can you think of other identification criteria to be considered?

The RPS believes that a different set of criteria need to be displayed to pharmacists: Active pharmaceutical ingredient, brand, strength and form. Pharmacists will be able to identify any potential discrepancy between description on the pack and the medicine identified by this information.

Q12. Please comment on the quantified approach set out above.

The Directive states that prescription only medicines would require security features, and over the counter medicines would not, unless a risk assessment determined otherwise.

We appreciate that a point of differentiation between the white and black lists must be found and that an arbitrary figure of 2 Euros has been chosen. The RPS believes that counterfeiters will adjust their operations to target those medicines that fall under this point of differentiation but still provide a profit. For the initial period of operation, the process of determining white and black lists must be reviewed frequently in order to be responsive to the ever-changing activities of counterfeiters.

The IT within a pharmacy will be required to manage electronic processes for all medicines available to patients from a pharmacy. The new 2-D scanner will be required to scan all medicines, general sales, pharmacy only, and prescription only medicines, additionally with a differentiation between white and black list medicines. The unacceptable alternative would be several different processes for medicines that change definition and therefore the way in which pharmacy staff are required to manage them. Such a series of systems would impose an unacceptable burden upon pharmacy personnel.

In light of the above points, we recommend that all prescription only medicines should be subject to the requirements of security features. The RPS suggests that the model used to determine on which list medicines should be placed, should be further refined as a greater understanding of counterfeiter behaviour is developed.

Q13. Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

Monitored Dosage Systems

UK law suggests that sufficient measures should be taken to amend practice to enable patients to receive their medicine. Current practice allows for the redispensing of products into a Monitored Dosage System (MDS) where the patient may benefit for the advantages in adherence that such systems may provide. This is a system in which all the medicines due at a particular time are packaged together in a blister or box. Typically the weekly medicine requirement would be separated into 28 such blisters or boxes (four per day for seven days). This system is also used for patients who display poor medicines adherence. Good medicine adherence is vitally important in ensuring that patients derive the greatest possible therapeutic effect from medicines. In the UK, MDS plays a significant role in promoting adherence.

The consultation envisages authentication at the point of dispensing. The preparation of MDS packs requires the splitting of dispensing packs, making authentication at the point of dispensing impossible in all cases. The delegated acts should recognise this issue by simply

requiring an authentication at some point prior to dispensing, or during the assembly process when medicines are dispensed into an MDS pack

Dispensing from bulk packs

Whilst this activity is now less prevalent, there are still many cases when pharmacists dispense medicines from bulk packs containing up to one thousand tablets. The delegated acts should acknowledge that in these circumstances only a pre-supply authentication would fulfill the requirements of the Directive, as a point of supply authentication for each patient would be impossible. It is impractical for lists of patients to be kept in instances where very many patients receive medicine from the same bulk container.

Original Pack Dispensing

In the UK, established practice results in patients receiving single or multiple part-packs of medicines in many cases, rather than original dispensing packs. The end result of such practice can be that two tablets are separated from the original pack, with little chance for the batch number or expiry date being evident. Under the delegated acts, it is likely that patients in England will receive packs with the tamper-proof seal broken by the pharmacist. An efficient authentication system will rely on patients generally receiving complete packs which can be scanned at the point of dispensing. A change of practice is required within the UK to ensure that the anti-counterfeiting system can be introduced.

Costs of implementation

The costs of implementing this system could be substantial. These costs must, wherever possible, be minimised. This can be done by fitting in system changes in line with regular hardware or software upgrades. However, costs should not reduce the potential to enhance patient safety

Barcode quality

The Commission must ensure that standards are put in place to ensure that the printing of the barcode on packs by marketing authorisation holders is of adequate quality. Pharmacies in Great Britain have experienced problems scanning linear barcodes as part of the Electronic Transfer of Prescription system. This has created inconvenience for pharmacy staff and wasted time which could be better directed to clinical care. If the quality of barcodes used for the authentication check is substandard leading to problems scanning, the serialisation and authentication system will fall into disrepute and potential disuse.

6. Temporary system failure

It would seem probable that from time to time access to the repository will become temporarily unavailable to pharmacies as a result of a range of international, national and local technical problems. It is not feasible to suspend the pharmacy service simply because authentication is not possible, nor is this necessary to maintain the overall integrity of the system. The specification for the system should of course include adequate assurances of service levels and response times, with the potential for offline scanning to facilitate retrospective verification when the system reverts to normality. Pharmacists should also have the professional discretion to undertake retrospective authentication or temporarily suspend authentication altogether, in response to circumstances. The use of GTIN information in number format in addition to a 2-D barcode could facilitate a form of scanning should scanning equipment fail within any particular pharmacy.

Please contact Charles Willis at: charles.willis@rpharms.com or 0207 572 2670 for any further information.