PharmacyVoice
Speaking up for community pharmacy

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Pharmaceutical Society of Northern Ireland

Professional Forum

Consultation response

European Commission consultation – "Delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification"

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As the health care professional who sees the patient most, and with a focus on the use of medicines, pharmacists have been very concerned by the cases of counterfeit medicines entering the legitimate supply chain and in some cases reaching the end-user. We therefore welcome the European Union's decision to legislate to increase security measures within the medicines supply chain and reduce the risk of patient harm as a result of the illegal and dangerous activities of counterfeiters.

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
- The system should be cost effective and not overly bureaucratic
- New regulation imposed on community pharmacy should be proportionate to the risks identified
- 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

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

Community pharmacies handle medicinal products made by hundreds of different manufacturers. In the UK alone, we dispense well over 1 billion packs of medicine per year. Any variance in technical standards between manufacturers will introduce inefficiencies into the dispensing process. In the UK there are eight different pharmacy computer systems, and integrating this software with multiple technical standards will create significant costs in terms of IT development. Policy option 1/1 would add cost and considerable complexity to the system. Policy option 1/2, with harmonisation of technical standards, would deliver a consistent and cost effective process.

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

The approach set out in point 2.1.1 seems reasonable, and we offer no alternative.

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

Community pharmacies already receive information alerts when a product recall is issued, so that any units of 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.

Community pharmacies should 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.

Additional functionality should only be approved when the value of the benefit outweighs the cost. On balance, we believe that incorporating the expiry date and batch number is justifiable in the interests of patient safety and supporting efficient working processes within pharmacies.

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? Please comment.

We are continually looking for ways to deliver a more efficient and patient-focused service from pharmacies. If we identify new ways to enhance efficiency within pharmacy practices through the use of the authentication system, then we should look for opportunities to add appropriate new functionality to the system. There is currently no use for a reimbursement number within the UK. We see no reason, however, for a field for the reimbursement number not to be included within the barcode. This will provide the opportunity to insert a reimbursement code at some point in the future, if a reason for its inclusion presents itself.

Q5. Please comment on the three concepts describer 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.

We set out four over-arching principles at the start of the document. Radio-frequency identification would represent an expensive and over-engineered response to the challenge of eradicating counterfeit medicines. On these grounds, it is unsuitable.

The challenge of adopting linear barcodes will be including all the technical information (product code, serial number, batch number, expiry date and possibly reimbursement code) in the available space. Linear barcodes will not fit into the available space on many smaller products such as eye drops. 2D barcodes make more effective use of the space available on medicinal products. 2D barcodes therefore seem to best meet the requirements of the Directive.

While in UK terms, a change required as a result of regulation would result in reimbursement of costs to pharmacy through the normal contract mechanisms, we would flag this up as a cost to be picked up in any impact assessment.

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, most GP surgeries procure and administer medicines within the 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 will be necessary to apply the same authentication obligations to medical practices.

The Commission should be aware that in the UK there are a range of other settings from which medicines are supplied directly to patients. 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 and others for onward supply or administration to patients. Consideration needs to be given to how these products can be authenticated. Pharmacies could authenticate products at the point they are supplied to these end-users, who are generally health care professionals and effectively acting as proxies for the patient. But it should be recognized that in these situations authentication is not technically taking place at the point of supply to the patient.

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 Directive did not explicitly require pharmacies to complete systematic authentication of products in community pharmacy. The consultation overlooks this point and makes the assumption that pharmacies will authenticate products. The Commission should be aware that this is highly likely to create additional workload within pharmacies, which will introduce new costs to the funders of health services.

Nevertheless, on the basis that the authentication process must be virtually instantaneous and not impact unduly on pharmacy processes, we believe pharmacy authentication is the only practical option. Other considerations, including a role for wholesalers to complete systematic authentication, would be suboptimal and wouldn't provide the end-to-end assurance of authenticity that would be achieved through pharmacy authentication.

Random verification of products by wholesalers could be a proposition, allowing for the capture of counterfeit or sub-standard products earlier in the supply chain. However, success would depend on the number of random checks being carried out at wholesale and would not address the need for a robust system of authentication at the point of dispensing.

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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 the industry stakeholders could take responsibility for delivering the repository system. The stakeholders, 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 cost-effectively.

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.

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 income. Indeed all

pharmacy owners should expect that information on the volume of their business remains confidential. We agree strongly with the position established by the cross sector EFPIA/GIRP/PGEU/EAEPC group that data belongs to its creator, and would like the Commission to explicitly recognize this.

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 support an explicit statement that a patient's personal data cannot be sent to the repository.

As we have highlighted above, 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 income. Indeed all pharmacy owners should expect that information on the volume of their business remains confidential. There should be an explicit recognition that the pharmacy owns the data that it adds to the repository.

We support the proposal that re-packaged products should have an equivalent safety feature 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?

Anatomical Therapeutic Chemical Codes (ATCs) are broad and will contain a range of medicines at higher and lower risk of counterfeiting. If this approach is chosen, then the highest risk product within the group should be selected for the risk assessment. However, it does not seem appropriate to risk assess by ATC.

An unfair commercial situation will occur if certain versions of a molecule require serialisation, whilst others do not. For this reason, we do not support risk assessment by brand.

Therefore we believe that active pharmaceutical ingredient is the most appropriate level for the risk assessment to operate at.

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

The criminals involved in counterfeiting medicines will apply sophisticated tools to the process of highlighting products to target. The proposed classification criteria are simplistic and unlikely to accurately highlight those products that should be provided with the protection of serialisation and authentication.

The Directive stated that prescription only medicines would require security features, and over the counter medicines would not, unless a risk assessment determined otherwise. The risk assessment should closer reflect the direction in the Directive.

We find the decision to determine that products valued at more than 2 Euros are "high priced" to be highly arbitrary and unrealistic. According to these risk assessment therefore, products costing less than 2 Euros are much less likely to require security features. Evidence suggests that low value items can also be targeted by counterfeiters if they are manufactured in high volume. We have analysed prescription data to try and establish how many products dispensed in the UK have a value above 2 Euros. We believe that only around 50% of products dispensed (i.e., around 500m) cost more than 2 Euros. We would be very concerned if low-value high volume products are excluded from the requirement to have security features, as this would appear to introduce a flaw into the system.

The Commission also needs to consider how decisions made using the risk assessment will influence practice within community pharmacies. Pharmacies in the UK dispense well over 1 billion packs per year, with a typical dispensary handling 250-300 medicines per day. A decision to include some prescription only medicines, and exclude a large number of others, will be difficult to implement in busy community pharmacies. The Directive has the greatest chance of successful implementation if all prescription only medicines require authentication. This will allow a single working process within pharmacies.

In light of the above points, we recommend that all prescription only medicines should be subject to the requirements of security features. No prescription only medicines should therefore be listed in the Delegated Acts. We do not see any reasonable argument for including over the counter medicines, other than in a few exceptional cases, within the scope of the security feature requirements. We recommend that a sophisticated assessment tool is developed to highlight those few OTC medicines that may be targeted by counterfeiters, and provide a mechanism for ongoing risk-based assessment by regulatory authorities.

The Commission should also give consideration to a small group of medicines that are classified as OTC, yet are supplied from the dispensary on prescription. To facilitate efficient pharmacy workflows, these medicines should be required to have a barcode.

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

1. Monitored Dosage Systems

There is an established practice in the UK of providing certain patients, for whom medicines adherence can be a problem, with a "Monitored Dosage System" (MDS). 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). 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 problem by simply requiring an authentication at some point prior to dispensing when medicines are dispensed within an MDS pack. It is vital that the bulk packs that are often used in MDS packs are still available on the market.

2. 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 should be required, as a point of supply authentication for each patient would be impossible.

3. 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. It is inconceivable that an authentication system could be introduced without the UK Government first introducing original pack dispensing. It is therefore necessary for the UK Government to immediately start work to end the unhelpful and wasteful practice of part pack dispensing, to ensure that we are in a position to introduce authentication in time for when this part of the Directive must be implemented. As stated above, it is crucial that the bulk packs used in MDS dispensing are not removed from the market.

4. Costs of implementation

We suggest that the Commission undertakes an assessment of the costs associated with implementation of the Directive.

5. Barcode quality

Pharmacies in England 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 potentially disuse. 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.

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. But pharmacists should have the professional discretion to undertake retrospective authentication or temporarily suspend authentication altogether, in response to circumstances.

Information on pharmacy organisations

Pharmacy Voice

Pharmacy Voice (PV) represents community pharmacy owners in the UK. Its founder members are the Association of Independent Multiple pharmacies (AIMp), the Company Chemists' Association (CCA) and the National Pharmacy Association (NPA). The principal aim of Pharmacy Voice is to enable community pharmacy to fulfil its potential and play an expanded role as a healthcare provider of choice in the new NHS, offering unrivalled accessibility, value and quality for patients and driving forward the medicines optimisation, public health and long term conditions agendas.

Pharmacy Voice creates a stronger, unified voice for community pharmacy to influence the policy and commissioning agenda for its members. We are pleased to have the opportunity to respond to this consultation.

Independent Pharmacy Federation

The voice of Independent pharmacists
www.theipf.co.uk

The Pharmaceutical Society of Northern Ireland Professional Forum

The Professional Forum is the responsible body of pharmacists in Northern Ireland

Confidentiality

We agree that our comments within this response may be shared and published as being representative of the views of Pharmacy Voice, the Independent Pharmacist Federation and the Pharmaceutical Society of Northern Ireland Professional Forum.

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