NHS European Office

NHS European Office Concept Paper Response

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

Background

The National Health Service (NHS) is one of the largest publicly funded health care systems in the world providing the majority of healthcare in England. The NHS is committed to the principle of universal access to healthcare which is free at the point of use. Every 36 hours the NHS sees over one million patients who make use of a wide range of health services ranging from primary care, in-patient care, long term health care, ophthalmology and dentistry. The NHS is a major employer in Europe with 1.3 million people on its payroll.

This response has been coordinated by the NHS European Office[1] in consultation with NHS organisations including NHS hospital pharmacies and pharmacists. The views presented reflect the role of the NHS as a provider of services and a dispenser of medicines; particular consideration is given to the role of hospital pharmacies.

General comments

The NHS European Office welcomes the opportunity to respond to the Concept paper, particularly as the European Commission is not required by law to consult on issues assigned to the Delegated Acts of a Directive. We are however concerned that while the details relating to the construction of the unique identifier of a medicinal product may be considered 'non-essential' elements of the broader Directive, and may therefore be assigned to the Delegated Acts, we believe that the content of the Concept Paper goes beyond the non-essential aspects of the Directive, particularly in terms of regulating the technical characteristics of the unique identifier and the modalities for verification of the safety features. The proposed content of the Delegated Acts threatens to interfere and impede the way that medicines are dispensed in Member States, particularly with regards hospital pharmacies.

While we strongly advocate measures to guarantee the safety of medicinal products within the supply chain, we are opposed to any form of regulation which stipulates processes for dispensing medicines and the point at which a medicine should be considered 'checked out' or 'dispensed', particularly if such processes have not been open to parliamentary scrutiny. This is critical to the way hospital pharmacies operate and would incur significant administrative and financial implications, as well as increase the likelihood of medicinal product waste across the hospital pharmacy system.

[1] The NHS European Office represents the English National Health Service. Its role is to inform the NHS of EU issues and to ensure that the NHS makes a positive contribution to EU developments.

Consultation point 1

Leaving the choice of technical specification to the individual manufacturer

The choice of technical specification for the unique identifier should not be left to each individual manufacturer. The technical specification should be standardized after further consultation with stakeholders. We do not support the proposal to allow each company to produce its own technical specification, as this would require pharmacies having to implement a number of different systems to verify the various unique identifiers used. This approach would be impractical, time-consuming and would no doubt incur substantial cost, as pharmacies would need to have the technical support to read the various different types of identifiers.

Harmonisation through regulation

While harmonization would be the preferred approach, we do not support the need for regulation in this area. Consideration first needs to be given to the design and procurement of equipment required. Ensuring consistency is the major issue. Multiple presentations of serialisation codes would not be practical.

Consultation point 2

Manufacturer product code and pack number

We are in favour of including the manufacturer's product code and pack number embedded in the bar code, as this will aid traceability.

Consultation point 3

Additional product information

Any additional information, such as batch numbers and expiry dates which can aid stock management, is to be commended and would assist the efficient handling of drug recalls.

Consultation point 4

National reimbursement numbers

We support measures to promote a unified approach.

Consultation point 5

Regulation of the technical characteristics of the carrier

In the main, UK hospitals do not have the technology to read or the IT systems to process or utilise 2D or RFID. While most do have linear barcode readers, feedback from NHS hospital pharmacists suggests that even these are not as widespread in the hospital sector as the Concept Paper suggests. It is possible that hospitals using a robotic dispensing system may be better placed to read the newer systems, however these too would likely require hardware and software upgrades. The impact on electronic prescribing systems also needs to be taken into

account, as these would require software changes to allow the use of 2D data matrix reading. Furthermore, we question whether the equipment would be available and successfully working with existing software programmes by the intended implementation date in 2014.

Whichever system were to be introduced would have some financial impact, as pharmacy computer systems would require software changes (re-writing), and this in turn may also require additional human resources or skills training, the costs of which would also need to be taken into account. At any rate the level of costs incurred will clearly be dependant on the code preferred, but this must be uniform to avoid the need to have different types of equipment to deal with different codes.

Consultation points 6 and 7

Points of dispensation and verification of safety features

While the Commission acknowledges the particular characteristics of the supply chain within Member States in relation to consultation points 6 and 7, the NHS European Office considers that the Commission has over-stepped its mandate in this area. We support the tightening-up of safety features for medicinal products and general measures for the verification of such features, but we do not support requirements which stipulate the way a medicinal product should be dispensed and which threaten to interfere with the way hospital pharmacies operate. There is no evidence in the UK that a counterfeit medicine has entered the UK supply chain in between the point of entry into the hospital pharmacy system and it being checked out again. To force a major operational change in this area when there is no evidence to suggest this is necessary would be costly, administratively burdensome and disproportionate to the intended purpose of the Delegated Act. We do not believe there is a need to change the status quo as regards the checking in and checking out of medicines from the hospital pharmacy. The potential impact on hospital pharmacies of the proposals put forward in the Concept Paper are so significant that it is inappropriate to consider them non-essential elements of Directive 2011/62/EU, and in this respect they should not be dealt with via the Delegated Acts.

In practical terms the Commission would need to develop a greater understanding of hospital pharmacies and their practices to ensure that any new requirements support as opposed to hinder current ways of working. For example, in the UK a medicinal product is not dispensed at the patient's bedside but may be dispensed to a hospital ward. In this situation, medicinal products can often be returned to the hospital pharmacy if they haven't been used. However if, as the concept paper suggests, a medicine has been dispensed from a hospital pharmacy for patient use and thereby checked out from the repository, the medicine cannot then be re-introduced into the supply chain (i.e. checked back into the hospital pharmacy for later use). As a result, a medicine issued within the hospital, even if it does not leave the hospital, will not be able to be reused. This would lead to increased waste of medicinal products and increased cost due to additional purchasing of products. In the same way there is currently a tendency for certain hospital dispensing activities not to issue original packs, where only part packs are needed to complete a course of treatment for a specific clinical need. If a new pack is required

for a patient treatment, but the quantity dispensed is not the full pack, then a dispensation check on the serialisation number is carried out. The remainder of the pack will then be returned to the pharmacy. If, as suggested under these new rules, the serialisation number check cannot take place again since the “pack” has been checked out, are we to assume that the remainder of the pack would go to waste?

In addition, we have concerns about potential delays in the supply of medicines required for patient care as a result of additional requirements on hospital pharmacies. Naturally we support the concept of dispensing systems which guarantee the safety of products throughout the supply chain. However this requires further thought and additional consultation with stakeholders, including manufacturers, wholesalers and pharmacies. Consideration should be given to the volume of products processed and additional workload, as well as to the amount of time which may be required to adhere to new quality management processes and technological specifications.

Consultation point 8

Repositories system and governance structures

While we see the value in the introduction and use of repositories systems and while theoretically a pan-european governance system may initially be perceived as a worthwhile option due to the level of movement of products throughout the EU, we believe that such a model is over-ambitious and consequently unworkable. In the UK currently there is no harmonized system to which all actors supplying medicines are connected. Indeed between individual hospitals different types of databases exist.

The proposal to introduce a national, let alone a pan-european system, would present huge challenges, would require the interaction of multiple technologies, and would incur significant cost. The costs of introducing such systems would ultimately divert resources away from frontline patient care, which in turn would impact on healthcare delivery.

We believe the points made under “stakeholder governance” should be recognized and recommended as good practice and that voluntary self-regulation in association with the National Competent Authority should be the preferred approach.

A further point of note is the prevention of hacking which is mentioned in this section when considering repositories. This is the first time this is mentioned, but we would see this as vitally important to the feasibility of the entire proposal and as such should be given increased consideration.

Consultation point 9

It is agreed that security is very important to the success of this initiative.

Consultation point 10

Protection of personal data

There would be no need for patient details and therefore we do not support provisions relating to personal data to be included within the Delegated Act.

Re-packaging of medicinal products

Provisions relating to the re-packaging of medicinal products, including overlabelling are already included within the scope of the Directive and should therefore not be included in the Delegated Act.

Consultation point 11

Identification criteria

We strongly believe that scope of the safety features and the identification criteria for identifying medicinal products is an essential element of Directive 2011/62/EC and should therefore not be assigned to the Delegated Act. Furthermore points 77 and 78 fail to acknowledge that while a medicinal product may be subject to prescription in one Member State, it may be considered an-over-the-counter product in another.

At any rate, the multiple parameters put forward by the Commission under Consultation point 11 to define whether the unique identifier is used or not presents cause for confusion. If there were two lists and the safety measures were only used in one and not the other, would this not encourage counterfeit activities of those products without the safety feature?

In addition it could be just as critical if a hazardous substance entered the supply chain under the guises of a low price, low volume item.

Consultation point 12

See above.

Consultation Point 13

Other issues

Whilst we applaud the sentiment of this Concept Paper, and recognise the need to improve controls within the supply chain to prevent the introduction of counterfeit medicines, the gravity of a number of issues raised and their potential impact on the way hospital pharmacies currently operate are so great that they go beyond the ‘non-essential’ elements of Directive 2011/62/EC and as such should not be dealt with via the Delegated Acts.