European Industrial Pharmacists Group response to the consultation on a unique identifier for medicinal products

A. CONSULTATION TOPIC N°1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Introduction

EIPG appreciates that a number of pharmaceutical companies may already have invested in the development of systems that satisfy the requirements of the Directive with regards to the introduction of the obligatory safety features, and that therefore, leaving the choice of the technical specifications to the manufacturer may be the least costly option for these companies. Nevertheless, the EIPG feels that cost savings at the manufacturing level will not account for the increased expenditure at wholesale distribution and points of dispensing in order to implement the necessary capital investment in hardware and software needed to cope with the diversity of features that would result from individual manufacturers establishing their own technical specifications. The impact would be most severely felt in countries which rely heavily on wholesale distribution of medicinal products, rather than local manufacturing, to ensure supply of medicinal products in their health care systems. Moreover, having manufacturing companies establishing their own technical specifications will place undue pressure on professionals at all levels of the manufacturing and supply chains of medicinal products, since qualified persons, responsible persons and dispensing pharmacists will need to be familiar with a variety of safety features in order to fulfill their professional obligations; the possibility of counterfeit products going undetected due to lack of familiarity with all the safety features in an unregulated market would therefore increase.

Consequently, EIPG is feels that the Commission should opt for **Policy Option n°1/2: Harmonisation through regulation**.

Regulation of the composition of the serialization number

EIPG is of the opinion that the serialization number should contain the manufacturer product code, unique identification number of the pack, batch number and expiry date. The first two items are, indeed, the minimum items needed for the identification of the pack. However, EIPG feels it is also recommendable to include the batch number and expiry date in the serialization number, as these items of information are key elements of current systems operated by both manufacturers and wholesale distributors in ensuring traceability and stock control, product recalls, and control of stock on a FEFO (first expired, first out) basis. The inclusion of the batch number and expiry date in the serialization number would make it feasible to extend current stock control software systems to include the serialization number, and therefore facilitate traceability of individual packs throughout the pharmaceutical supply chain.

With regards to the reimbursement number, however, although the inclusion of this element in the serialization number might have some advantages, EIPG **does not feel that it is advisable to include the reimbursement number in the serialization number**. Reimbursement numbers and their format already differ from one country to another in order to suit the needs of the individual Member States, so harmonization of criteria in order to include the reimbursement number within the serialization number would prove challenging. Moreover, not all Member States operate a reimbursement list, whilst in those that do, there are some Member States where not all medicinal products are on a reimbursement list. This will lead to difficulties in establishing serialization numbers for those medicinal products that are not on a reimbursement list, particularly when a manufacturer is producing batches for countries with similar languages, but different reimbursement systems.

EIPG therefore recommends that the format of the serialization number should be:

Manufacturer Product code	Unique identification number of the pack	Expiry date	Batch number
XXXXXXXXXXXXXX	XXXXXXXXX	XXXXXX	XXXXX

Regulation of the technical characteristics of the carrier

The linear barcode carrier is widely used and therefore linear barcode readers are already present in most distribution and point of dispensing systems. However, the model being proposed by EIPG above contains more data than will probably fit in the linear barcode. Furthermore, although the linear barcode is already in use in Belgium, Greece and Italy as a carrier for the serialization number, an increasing number of countries are already contemplating the use of the 2D datamatrix, and commercial software and hardware for the use of the 2D datamatrix is already widely available, and although capital outlay would probably be required in the process of the implementation of this project, it is quite likely that the fact that datamatrices are also being used for other industrial and consumer goods will mean that wholesale distributors and points of dispensing will see additional benefits in the implementation of this technology. RFID probably constitutes what would be the state of the art in terms of serialization technology, but the costs for the implementation of this technology would probably be prohibitive.

EIPG therefore recommends the use of the 2D-Barcode as the carrier for the serialization number. However, in keeping with the concept that harmonization of the unique identifier should occur through regulation, the pharmaceutical industry and the European health authorities need to find common ground on this issue.

B. CONSULTATION TOPIC N° 2 - MODALITIES FOR VERIFYING THE SAFETY FEATURES

EIPG is of the opinion that penetration of the pharmaceutical supply chain by counterfeit medicinal products can occur at any point throughout the chain, from manufacturer, through wholesale distributors, to points of dispensing. EIPG is of the opinion that a policy that only involves systematic check-out of the serialization number at the dispensing point will place

undue pressure on dispensing pharmacists as they will be uniquely responsible for detecting counterfeit medication. Moreover, such a policy would not take into account the reality that Good Distribution Practices require wholesale distributors and Responsible Persons to be alert for counterfeit penetration and to report any such incidence. Thus, whilst implementation of systematic verification of the serialization number at wholesale distributor level is unfeasible, as it would vastly increase both wholesale distribution costs and the workload of quality systems at wholesale distributor levels, possibly resulting in delays in the timeframes of delivery of medicinal products through the supply chain, the reality is that quality assurance systems at wholesale distributor level will probably implement random verification of the serialization numbers as part of their control systems on incoming medicinal products, prior to release for distribution. Consequently any cost increases inherent in such a policy would probably, irrespective of the provisions regarding the verification of the serialization number, be incurred as part of the new Good Distribution Practices.

EIPG is therefore of the opinion that the best policy to pursue is **Policy Option N° 2/2: Systematic check-out of the serialization number at the dispensing point, but with additional random verifications at the level of wholesale distributors.**

C. CONSULTATION TOPIC N°3 - PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

EIPG does not feel that EU governance is an appropriate model for the management of the repositories system, primarily due to the costs that would be involved in setting up such a system at a pan-European level. At the other end of the spectrum, the option of a stakeholder governed repository, whilst possibility providing the greatest flexibility, may suffer from a disadvantage common to an EU-governed system, namely, that it will not adequately address the specificities of the wholesale distribution mechanisms of the individual Member States. Consequently, in view of the foregoing, EIPG believes that the most feasible option is that of a **national governance** controlled system.

With regards to the repackaging of medicinal products, the EIPG recommends that the repositories system should provide for a system of linking of the serialization number of the repackaged product to the serialization number of the original product, thereby enabling traceability all the way back to the original manufacturer.

D. CONSULTATION TOPIC N°4 - LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES

With regards to the proposed classification system, whilst the system appropriately takes into account the risk of falsification of a medicinal product and the severity of the conditions that the medicinal product is intended to treat, there does not seem to be any scientific rationale in the manner in which the various parameters are quantified into a points system, and therefore

the EIPG feels that the propose quantification should be justified scientifically, possibly through an identification based on the ATC code.