TEN CORE PRINCIPLES TO PROTECT PATIENTS FROM FALSIFIED MEDICINES
EFPIA/PGEU/GIRP Joint Position Paper
March 2011

The Directive on falsified medicines introduces mandatory, harmonised pan-European safety features for medicines at risk of falsification. With counterfeit medicines a clear and growing threat, EFPIA, PGEU and GIRP fully support this move. New technologies can offer significant protection against breaches in the legitimate supply chain. However, this also demands greater clarity on how best to use these features to provide robust protection.

EFPIA, PGEU and GIRP believe any framework for implementing the Directive, in particular the delegated acts and all preparatory work, should reflect the following key principles:

1. Combining tamper-evident packaging with a unique serial number:

- EFPIA, PGEU and GIRP support the requirement in the falsified medicines directive that the safety features should consist of a unique serial number placed on each pack together with packaging that would reveal if a pack has been opened or tampered with.
- Checking a unique, randomised, serial number placed on each pack against a central database at the point of dispensing is currently one of the most secure ways to verify product authenticity. However, a product verification system can only secure the content of the pack if it remains sealed at all times. Using tamper evident packaging makes it clear whether the pack has been opened or tampered with and is therefore an essential complement to a product verification system.
- EFPIA and PGEU consider that safety features should be applied to all prescription medicines to ensure the same level of security. Therefore if a risk-based approach for prescription medicines is pursued, exemptions should be based on therapeutic categories, narrowly defined (e.g. ATC 4 level), rather than individual products to minimise the risk to patient safety.

2. Guaranteeing continuity of protection throughout the entire supply chain:

- As regards the obligations on the repackager to replace mandatory safety features, the original pack serial number should be cancelled in the database by the repackager and a new number provided. The original and new numbers must be linked in the database to enable the product to be tracked in case of recalls or other safety issues.

3. Ensuring a single coding and identification system on each pack across the EU:

- Given the movement of medicines across national borders, any effective coding and identification system must be able to exchange information between Member States. There should therefore be a harmonised standard coding system across the EU.
- In order to ensure that the coding system facilitates other functionalities such as reimbursement, the EU harmonised standards should allow for the incorporation of relevant national codes.

- EFPIA and GIRP propose using a two-dimensional code[12] containing a unique serial number to encode all selected products. This code can be verified against a database. This means that pharmacists can rapidly verify the status of each pack before dispensing it to the patient. As well as the serial number, the code would store the expiry date along with product identification (including national code) and batch numbers, providing additional patient safety enhancements.

4. Ensuring product verification database systems can work together across the EU:

- In addition to using a common standard for pack identification in Europe, all national database systems must also be able to work together and exchange information in order to allow any pharmacist, and wholesaler where deemed necessary, in any Member State to check whether the pack has been dispensed before, irrespective of its country of origin.
- There should be sufficient flexibility to implement national or regional solutions within an overall EU technical framework.
- National database systems should meet equivalent quality assurance requirements.
- Without this interoperability, counterfeiters would be able to exploit gaps between national systems to insert falsified medicines into the legitimate supply chain.

5. Verifying every serialised pack at pharmacy level:

- It is everyone's responsibility in the supply chain to ensure that medicines delivered to patients are safe and genuine.
- Pharmacy level verification at the point of dispensing with an interface for wholesalers is a robust and cost-effective way to improve patient protection.
- However, unless every individual serialised pack is verified at the point of dispensing, patients will not benefit fully from the safety features. The unique serial number can only provide protection against counterfeits if it is routinely checked against a central database and the status changed on the database to 'dispensed' when the product is handed to the patient.
- Systems should be configured so that pharmacists can undertake checks when medicines enter pharmacy stock, as well as at point of dispensing. Since the technical challenges of point of dispensing verification vary across the EU, pharmacists may initially adopt a system of verification when medicines enter the pharmacy, until such time as any technical issues with regard to point of dispensing verification have been resolved.
- The process of verification in the pharmacy should be virtually instantaneous in order to ensure efficient pharmacy workflow and the avoidance of delays. In order to ensure that products are verified in one scanning action, verification software should be integrated with existing pharmacy software. The process of verification at the wholesale level should allow products to be checked during forward logistics as well as for returning medicines and without changing the status on the database.
- Stakeholders shall work together to define standard procedures for exceptional events such as verification failure, system failure etc.

6. Maximising all the potential benefits of mass serialisation:

- Using mass serialisation provides benefits over and above improved counterfeiting prevention. Maximising these should help to encourage widespread use of identification systems and assist all stakeholders.

---

[1] *Data matrix ECC 200*

[2] *PGEU does not endorse a particular technology at this stage*

- The coding system enables the pharmacist to automatically read the batch number, serial number and expiry date, significantly enhancing patient safety and improving product recall procedures.
- The system may also facilitate the provision of additional services to patients by pharmacists.

7. Focusing on securing patient safety and protecting patient privacy:

- Verification systems are for preventing counterfeits, not for accessing individual pharmacy data.
- Manufacturers do not seek, and will not have access to, individual patient/prescribing profile information.
- Transactional data belongs to the pharmacist, or in relation to wholesaler verification, to the wholesaler. However, relevant stakeholders will need to see certain data to help investigate when there is a verification failure, a product recall or a level of unusual activity related to a specific serial number, in accordance with national circumstances.
- Any additional use of transactional data would need to be agreed between the stakeholders in accordance with national circumstances.

8. Using safety features that are simple, robust and cost-effective:

- The product verification solution proposed should meet the criteria of being practical, affordable and accessible. Unnecessarily complex and costly solutions should be avoided.

9. Working Together in the Interests of Patient Safety:

- As key stakeholders in the verification process, we are committed to working together to establish an efficient, viable and effective system to protect patients against the threat of counterfeit medicines.
- The establishment and management of product verification systems should be undertaken by relevant stakeholders. For the governance of product verification systems, EFPIA, PGEU and GIRP favour the setting up of independent non-profit organisations to be jointly managed by relevant stakeholders, building on the current coding environment in the various countries and meeting the needs of patients and all players in the supply chain.
- Each stakeholder will be severally responsible for the system.

10. Involving other stakeholders

- EFPIA, PGEU and GIRP welcome the involvement of other relevant stakeholder organizations which play an active role in the pharmaceutical supply chain in the further elaboration of the product verification system at point of dispensing. Together we can ensure a strong and comprehensive system to take forward the fight against counterfeiters.