PGEU GPUE Groupement Pharmaceutique de l'Union Européenne

Pharmaceutical Group of the European Union

Representing European community pharmacists

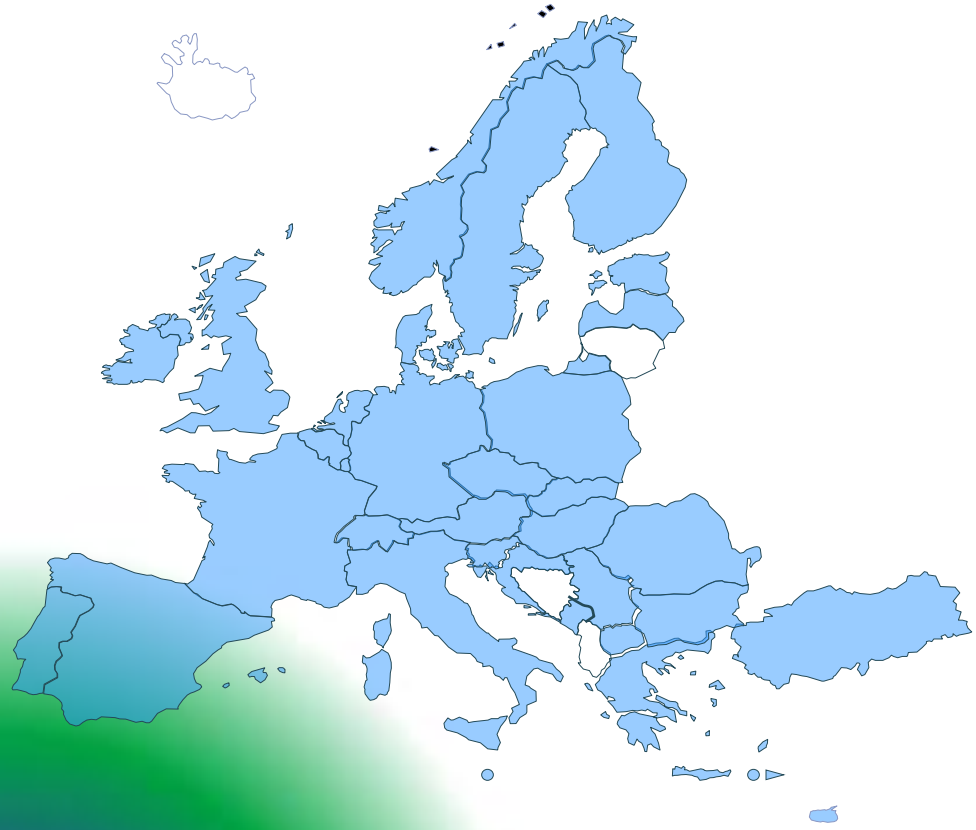
Pharma security and the new European legislation to prevent counterfeiting: PGEU

JURATE SVARCAITE

PGEU

Pharmaceutical Group of European Union

Members: Professional Bodies & Pharmacists' Associations



2011: 32 Countries

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APB
Association Pharmaceutique Belge
Algemene Pharmaceutische Bond
hfd
HRVATSKO FARMACEUTSKO DRUŠTVO
CROATIAN FARMACEUTICAL SOCIETY
Παγκύπριος Φαρμακευτικός Σύλλογος
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APTEEK
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apotek
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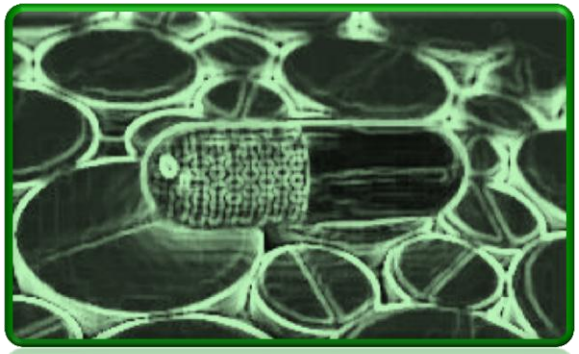
MAGYAR GYÓGYSZERÉSZ KAMARA
1989
LFB
LATVIJAS FARMACEITU BIEDRĪBA
PHARMACISTS' SOCIETY OF LATVIA
KMP
founded 1900
Apotekforeningen
anf
Associação Nacional das Farmácias
FdS
Farmaceutsko društvo Srbije
CONSEJO GENERAL DE COLEGIOS OFICIALES DE FARMACÉUTICOS
Royal Pharmaceutical Society of Great Britain
Schweizerischer Apothekerverband
Société Suisse des Pharmaciens
Società Svizzera dei Farmacisti
NPA
National Pharmacy Association

Content



- Key Background Principles
- What the Directive does and **does not** say
- Why Pharmacy?
- The Issues from a Pharmacy Perspective
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- The Known Unknowns
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Key Background Principles

- Addressing counterfeit medicines through serialisation is a justified *precautionary* strategy.

- As a sector we cannot afford to be seen to be passive on this issue – we need to adopt best practice and the highest possible standards.

- There is a strong case for a European solution – fragmentation is only going to increase costs, and the problem by its nature does not respect borders.

What the Directive does and does not say

- The Directive does not explicitly call for serialisation,
- The Directive does not limit the application of safety features to medicines at risk of falsification,
- The Directive does not explicitly oblige member states to implement an authentication system,
- The Directive does not allow firm conclusions about the scope,
- The Directive does not necessarily assume pharmacists participation in authentication,
- The Directive only defines the scope of Commission action in very general terms – it is not clear how much harmonisation the Commission is required to adopt.

Why Pharmacy?

- ✓ Safest approach is to secure patient interface,
- ✓ Authentication systems have significant ancillary advantages for patient safety,
- ✓ Strong ‘trust’ profile reinforces confidence in the system,
- ✓ Experience to date suggests technological feasibility and professional acceptance.

The Issues from a Pharmacy Perspective (1)

- Authentication should not dramatically change daily pharmacy practice:
  - Scanning time needs to be split second – this means full integration into existing pharmacy software,
  - Pharmacists should be allowed to reintroduce packs,
  - Right to overrule system in exceptional circusmtances has to be secured.
- System should be relatively manageable for re-packers,
- Scanning at entry to pharmacy should be a possibility.

The Issues from a Pharmacy Perspective (2)

- Personal data is sacrosanct.
- Transactional data belongs to the party undertaking the transaction – n.b. this is not just about confidentiality, it is about commercial property rights.
- Data could be disclosed during investigation in pre-deretmined circumstances.
- No monitoring of pharmacy transactions.

The Issues from a Pharmacy Perspective (3)

The system needs to be proportionate in terms of cost and Pharmacy costs are underestimated:

- EFPIA's Pilot estimated pharmacy costs based on Swedish Pilot,
  - In Sweden there was one software provider and 100% of broadband coverage,
  - In Austria there are 7 pharmacy software providers and 80% of pharmacies having a broadband connection.
- Average cost for a scanner 250 €.
- Portuguese Pharmacy Association (ANF) estimated country wide costs for pharmacies to be € 6,800,000.

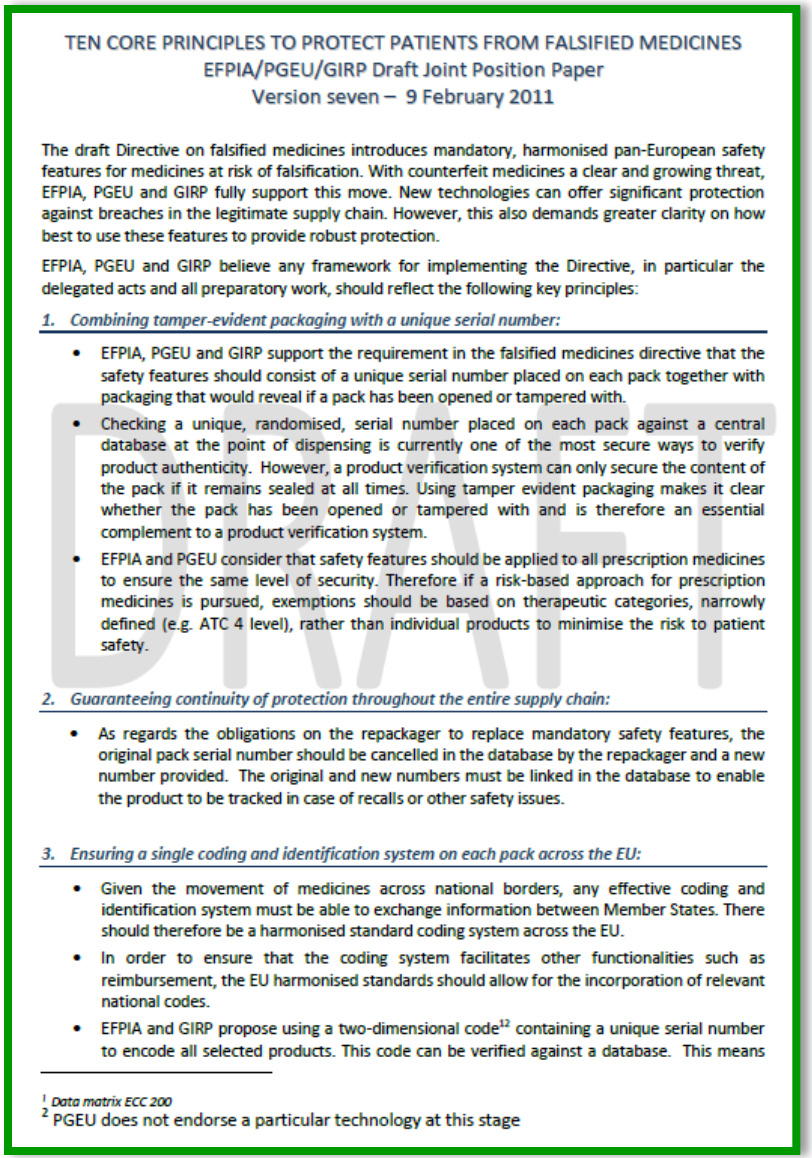
4 Key Principles for an EU authentication system

❶ Subsidiarity,

❷ Cost Proportionality,

❸ Interoperability,

❹ Stakeholder Autonomy and Co-operation.



TEN CORE PRINCIPLES TO PROTECT PATIENTS FROM FALSIFIED MEDICINES
EFPIA/PGEU/GIRP Draft Joint Position Paper
Version seven – 9 February 2011

The draft 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[1][2] containing a unique serial number to encode all selected products. This code can be verified against a database. This means

[1] *Data matrix ECC 200*
[2] PGEU does not endorse a particular technology at this stage

The Known Unknowns

- Delegated Acts process is new territory for everyone – no-one really knows it will work;
- No-one understands how the EDQM project is supposed to fit into this;
- The Directive is widely misunderstood at 'ground level', and its full implications underestimated;
- There are wildly differing interpretations of the impact of the Risk Assessment – it presents serious difficulties for the European Commission.

Some Predictions

Within **10** years:

- ✓ The Risk Assessment will have been forgotten and all prescription medicines will be serialised,
- ✓ The majority of EU states will have an authentication system in place,
- ✓ Authentication will take place at pharmacy level,
- ✓ The threat of counterfeit penetrations of the legal supply chain will have been substantially eradicated.

THANK YOU

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