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

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PGEU
Pharmaceutical Group of European Union

Members: Professional Bodies & Pharmacists’ Associations

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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 circumstances 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-determined circumstances.
- No monitoring of pharmacy transactions.

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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

1. Subsidiarity,

2. Cost Proportionality,

3. Interoperability,

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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