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Safe, innovative and accessible medicines: a renewed vision for the pharmaceutical sector

*Focus on:* Legislative proposal on ‘counterfeit’ medicines

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The ‘Pharma package’ of the Commission

- Commission Communication
- Three proposals on
  - Pharmacovigilance
  - Information to patients
  - Counterfeit medicines entering the legal supply chain
Commission communication on a vision for the sector

- A mapping of the perceived challenges and the Commission’s proposals for action
- across a wide range of areas (access to medicines, internal market, competitive EU industry, safety of medicines, globalisation, innovation and research, etc)
- in order to ensure safe, innovative and accessible medicines
‘Counterfeit’ medicines –

- What is the matter at stake?
- What legal changes are proposed?
Risk appraisal

• From lifestyle to life-saving drugs
• From illegal to legal supply chain
The new risk profile has consequences for...

**Public Health**
- Concrete threats
- Loss of confidence

**Economy**
- Negative effects on
- Pharma Industry
- Health care systems

**Internal Market**
Member States start taking action at national level
Strategies…
3 'Pillars' 

1. **Product characteristics** and **Good Manufacturing Practices** (GMP)

2. **Actors in the supply chain** and **Good Distribution Practices** (GDP)

3. **Active Substances** (incl. Inspections)

'1st Pillar':

Product characteristics and 'Good Manufacturing Practices' (GMP)
Placing on the market/manufacturing (1)
– Obligatory safety features

The issue:
No legal basis for harmonisation of safety features

Proposed change (Proposed new Article 54a):
• Legal basis for harmonised approach in Community
• Scope: prescription medicines & risk-based
• Characteristics set out in implementing measures …
Placing on the market/manufacturing (2) – Characteristics obligatory safety features

Shall allow for

- identification check
- authenticity-check
- tracing

To this end, it shall allow to perform verification of

- authenticity
- pack-identification
- pack-tampering

Proposed new Article 54a
Placing on the market/manufacturing (3)

Challenges of obligatory safety features

- Costs
- Restrictions of scope
- Efficiency
- Confidentiality
  - of technique
  - of information
Placing on the market/manufacturing (3) – Information obligation

The issue:
In case of detected counterfeit medicines

⇒ No information obligation to report this

Proposed change in legislation:
Information obligation when suspicion about counterfeit medicines (Proposed new Article 46 (g))
'2nd Pillar':

Actors in the supply chain and 'Good Distribution Practices' (GDP)
Actors in supply chain/GDP (1) – „Traders“

The issue:
- „Wholesaler“ covered by pharmaceutical *acquis*
- Brokers, commercial agents not covered

Proposed change:
- „Positive definition“ of „trader“ (proposed new Article 1(17a))
- Certain wholesaler requirements apply (incl. record-keeping, audit) (proposed new Article 85b)
- Notification obligation (proposed new Article 85b)
- **NB:** No change of definition of wholesaler
Actors in supply chain/GDP (2) – „Introducing“ medicines not intended to be placed on the market

The issue:
Legal uncertainty whether rules on importation apply to products which are ‘introduced’

Proposed change:
• Clarification, that regime for wholesalers apply (proposed new Article 85a, whereas 6 of the proposal)
• Rules for ‘introduction’ (proposed new Article 52b)
Actors in supply chain/GDP (3) – Audit of suppliers by purchasers

The issue:
Audit is a useful tool for self-control
Presently, no requirements for audits – some voluntary initiatives

Proposed changes:
• Audit as additional element of self-control (proposed new sub-§ in Article 80)
• Shared 3rd party audits
• Accreditation by MS (proposed new Article 118a)
The issue:
No transparency about compliant wholesalers

Proposed changes:
• Compliant wholesale distributors are registered in a „EudraGDP“ database (proposed new Article 77(4))
• Same rules as for EudraGMP database apply (proposed new Article 111 (3), (5) - (7))
Actors in supply chain/GDP (5) – Information obligation

The issue:
In case of detected counterfeit medicines ➔ No information obligation to report this

Proposed change:
Information obligation to NCA/MAH when suspicion about counterfeit medicines (Proposed new Article 80(i))


3rd pillar:

Active pharmaceutical ingredients (‘API’) 

- There are recognised international standards
- These apply independently as to where the product is manufactured
- Shortcomings of enforcement mechanisms
API (1) - Enforcement abroad by competent authorities

The issue:
It is not possible to inspect all 3rd country API plants by EU – national competent authorities

Proposed changes:
- Confirmation on GMP compliance from exporting country (proposed new Article 46b (2b))
- Confirmation not required if exporting country has an equivalent control and enforcement mechanism (proposed new Article 46b (3), 111b)
API (2) - Audits by market participants

The issue:
• No legal obligation to audit (only guidelines)

Proposed changes:
• Strengthening responsibility of Manufacturing Authorisation Holder ➔ Obligatory audits (proposed new Article 46(f))
• Cost containment through shared 3rd party audit
• Accreditation by NCA (proposed new Article 118a)
API (3) - strengthened enforcement within the EU

The issue:
Efficient local inspections require some information about activity

Proposed changes:
Notification requirement for manufacturer/importer of API (proposed new Article 52a)
Horizontal enforcement mechanisms

- Inspections guidelines (proposed new Article 111(1), 111a)
- Sanctions (proposed new Article 118b)
- Cooperation with customs (proposed new Article 118c)
Conclusion

Commission proposal is a comprehensive response to health-risks from counterfeit medicines as far as pharmaceutical legislation is concerned

• Multifaceted approach - three 'pillars‘
• No re-vamp of system, but making the existing framework more efficient
• Many measures facilitate enforcement

Thank you!