Review of the Paediatric and Orphan Regulation

4th Nordic Conference on Paediatric Medicines
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57 years of EU pharmaceuticals regulation
SAFETY – EFFICACY - QUALITY

Thalidomide disaster exemplifies the need for EVIDENCE-BASED AUTHORISATION

1965
1st EC legislation: medicines need to be authorised before being placed on the market

1995
Centralised, EU-wide procedure for authorisation – creation of the EMA

2004
Last major revision – extending scope of centralised procedure, simplification

2002
Legislation on medicines for rare diseases

2006
Legislation on medicines for children

2007
Regulation on advanced therapy medicines

2010
New EU Pharmacovigilance rules: better prevention, detection and assessment of adverse reactions, direct patient reporting of adverse events

2011
Legislation against falsified medicines

2020
Pharmaceutical strategy for Europe: addresses long standing challenges, learnings from COVID-19

2022
Revision of general pharmaceutical acts packaged with revision of the O/P legislation

Thalidomide disaster exemplifies the need for EVIDENCE-BASED AUTHORISATION
Responsibilities shared between EU and Member States

- Centralised authorisation procedure
- Inspections of manufacturing sites
- Pharmacovigilance
- Decentralised procedure and mutual recognition procedure to authorise medicines in MS
- Organisation and delivery of health services and medical care
- P&R for medicinal products or their inclusion in the scope of national health insurance schemes

By EU-level standards

EMA and network of National Competent Authorities

Strictly MS competence!
PHARMACEUTICAL STRATEGY FOR EUROPE

Learning from COVID-19, towards a crisis-resistant system

Ensuring accessibility and affordability of medicines

Supporting sustainable innovation, emerging science and digitalisation

Reducing medicines shortages and securing strategic autonomy

#EUPharmaStrategy
Revising the pharmaceutical legislation

A comprehensive review of the pharmaceutical legislation is ongoing:

➢ **Simplification and streamlining** of approval procedures and flexibility for timely adaptation

➢ Adapt legislation to **cutting-edge products, scientific developments** and transformations

➢ Take forward the use of **high performance computing and AI**

➢ **Ensure environmental sustainability** of manufacturing and use of pharmaceuticals
Same objectives of pharmaceutical revision:

• Promote innovation in particular in areas of UMN;

• Balanced system of incentives rewarding innovation and promote affordability and sustainability of health systems;

• Increase access to medicines for EU patients;

• (Reduce environmental footprint);

• Reduce regulatory burden.
Revising the Orphan and Paediatric legislation

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Thank you