Review of the Paediatric and Orphan Regulation

4th Nordic Conference on Paediatric Medicines

13 September 2022

Fabio D'Atri

DG SANTE

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

2007
Regulation on advanced therapy medicines

2006
Legislation on medicines for children

2002
Legislation on medicines for rare diseases

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

European Commission

Responsibilities shared between EU and Member States

- Centralised authorisation procedure
- Inspections of manufacturing sites
- Pharmacovigiliance
- …..

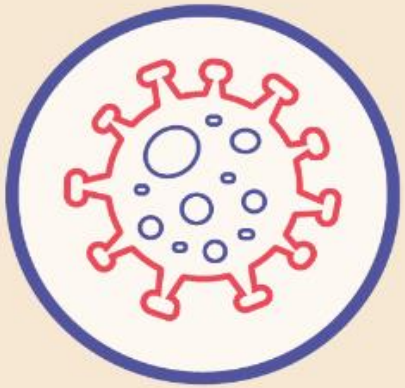
EMA and network of National Competent Authorities

By EU-level standards

- 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

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

European Commission

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

Revising the Orphan and Paediatric legislation

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

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

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

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

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.

Thank you

European Commission