La strategia europea per il farmaco

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European Commission - DG SANTE

Pharmaceutical Strategy for Europe

- Adopted in November 2020
- Ambitious long-term agenda in the field of pharmaceutical policy
- Objective: creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs

European Commission

Pharmaceutical Strategy in context

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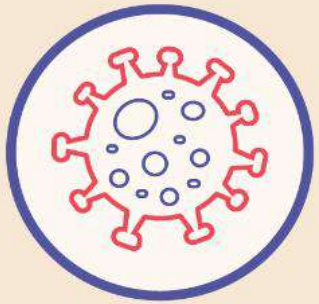
A holistic approach covering the full lifecycle of medicines

- Research & Development
- Innovation
- Clinical Trials
- Digital & data
- Advanced therapies
- IP/incentives
- Pharma legislation
- Health technology assessment
- …

- Market function
- Procurement
- Manufacturing
- Generics, biosimilars, APIs
- Supply chains
- Environment
- Competition policy
- Trade
- …

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

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Flagships of the pharmaceutical strategy

Ensure access and affordability of medicines for patients and health systems sustainability

Unmet needs

- Boost **novel antibiotics**
- Restrict and optimise the **use** of antimicrobial medicines
- Support medicines for **children and rare diseases**
- Collaboration on unmet needs **evidence generation** , **HTA**

Accessibility

- Revise the **system of incentives and obligations** in legislation to support innovation, access and the affordability of medicines
- Improve access to **generic and biosimilar medicines**

Affordability

- Address in legislation the **market effects** impacting on affordability
- Develop **mutual learning and best-practice exchange** on pricing, payment and procurement policies

Revision of the Orphan and Paediatric legislation

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Timeline

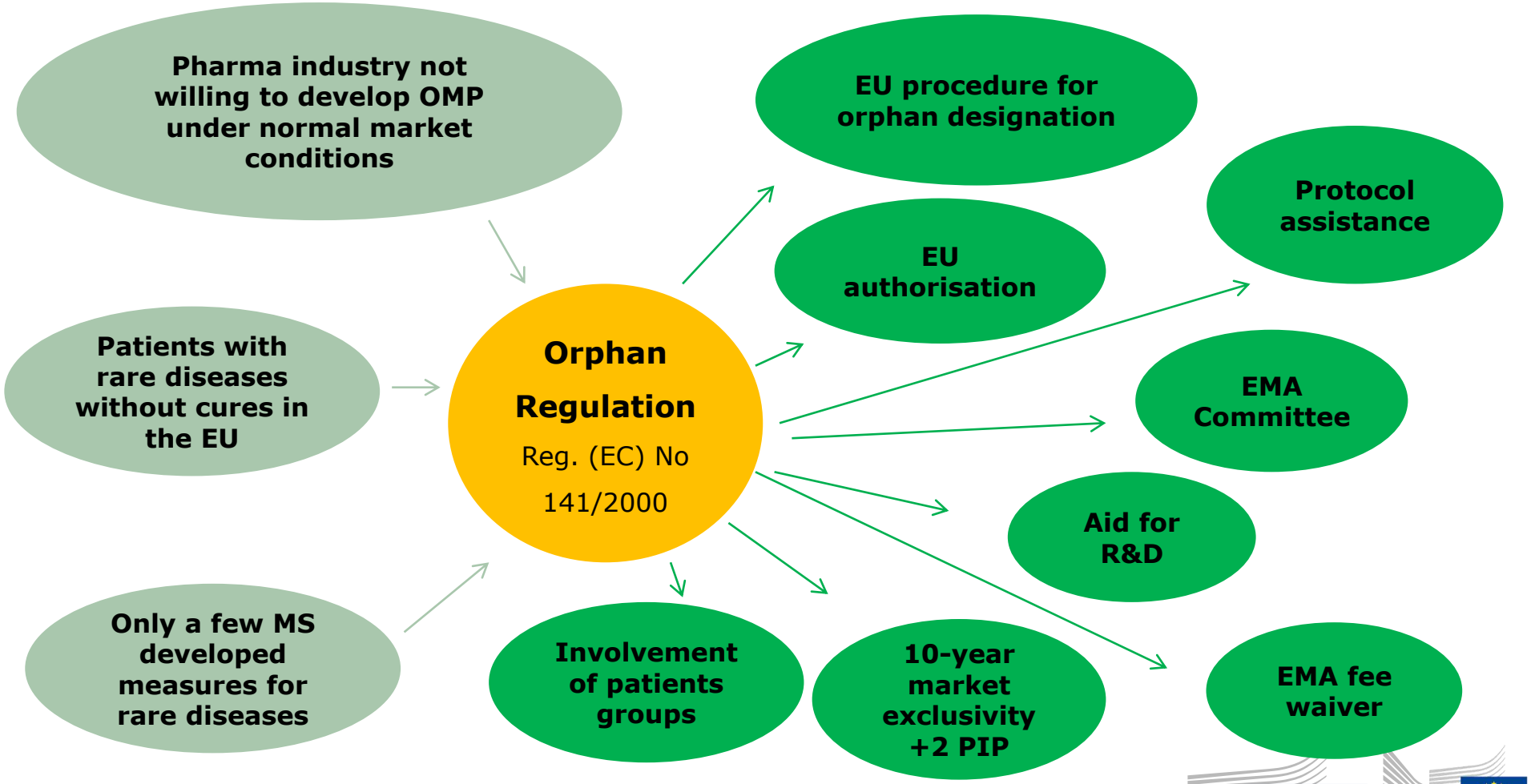
- Evaluation of the orphan and paediatric legislation
- Impact Assessment Roadmap
- Impact Assessment
- Proposal for revision of legislation: end 2022

<u>Important to ensure:</u>

- synergy and coherence between the Orphan and Paediatric Regulations
- complementarity with the revised general pharmaceutical legislation

Problems

Tools



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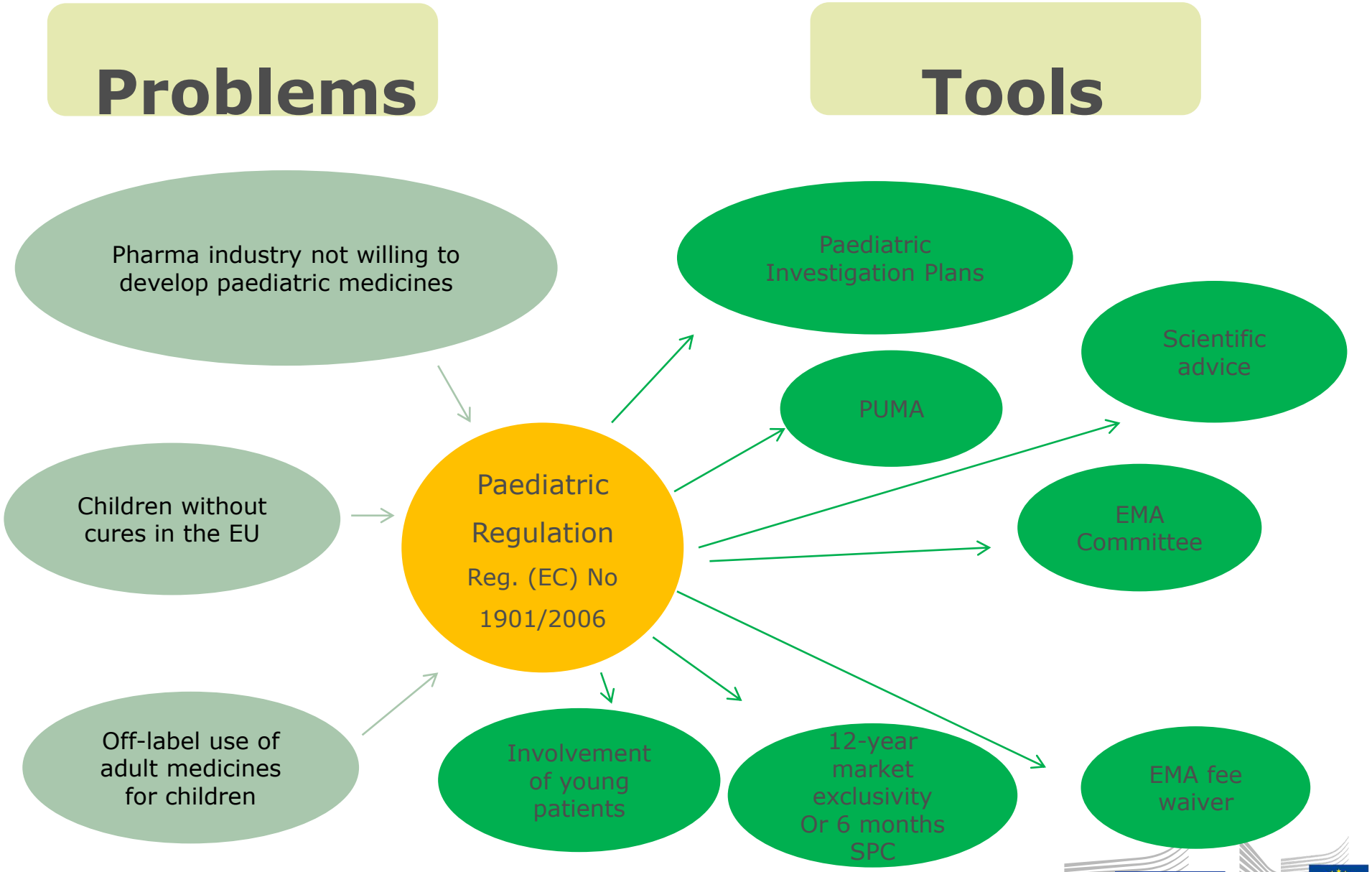
Problems
Tools
Pharma industry not willing to develop paediatric medicines
Children without cures in the EU
Off-label use of adult medicines for children
Paediatric Regulation
Reg. (EC) No 1901/2006
Paediatric Investigation Plans
PUMA
Scientific advice
EMA Committee
Involvement of young patients
12-year market exclusivity Or 6 months SPC
EMA fee waiver

Summary problems found (evaluation)

- Insufficient development in areas of greatest unmet medical needs:
  - 95 % rare diseases no treatment option
  - ‘One-size-fits-all’ incentives and rewards <-> unmet needs
- Availability and *accessibility* varies across MS:
  - No link between incentive and placing on market (orphans)
  - Limited generic competition after expiry of exclusivity periods
- Scientific and technological developments cannot be fully exploited:
  - Instruments not adequate for advances in science:
- Certain procedures inefficient and burdensome.

Objectives of the revision

1. To foster **research and development** of medicines for rare diseases and for children, especially in areas of highest unmet need and in better alignment with patient needs;
2. To contribute to ensuring the **availability and timely access** of patients to orphan and paediatric medicines;
3. To ensure that the legislation is fit to embrace **technological and scientific advances** by adapting the regulatory procedures provided by the legislation;
4. To provide **effective and efficient procedures**, for assessment and authorisation of orphan and paediatric medicinal products.

Possible policy actions

- How the market exclusivity may stimulate development in areas of high UMN;
- Explore possible novel incentives;
- Simplify and modernised PIP procedure.

Thank you

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Public Health information:
http://ec.europa.eu/health/index_en.htm
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https://ec.europa.eu/health/human-use/strategy_en

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