The EU Pharmaceutical Reform

EU support to SMEs

Olga Solomon, DG SANTE,
European Commission

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European Commission

Topics

Simplification

Acceleration of authorisations

Digital by default

Cutting-edge technologies

SMEs support scheme

Key advantages

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Simplification

How do we simplify procedures and reduce administrative burden?

Simplification of procedures and structures

- **Simplify procedures** for all medicines: e-PL, abolish renewal and sunset clause, among other
- **Optimise EMA's structure** and simplify regulatory procedures
- Allow **EMA to review data in phases**, as they become available ("rolling" or "phased" review)
- **Establish active substance master file** to avoid duplication of assessment of chemical active substances (and additional quality master file)
- **Simplified rules for GM medicines**
- Stronger **interactions with downstream decision-makers** (HTA, P&R)
- **Also at national level there a specific adjustments: simplify 'repeat use procedure'** → if MSs do not request the update of assessment report, RMS shall provide the AR within 30 days (instead of 90 updated AR)

Acceleration of authorisation

How do we speed up the access to markets?

Acceleration of authorisation

- **Reduce assessment and approval time** from 277 days to 226 days
  - EMA scientific assessment: 210 → 180 days
  - Commission authorization: 67 → 46 days
- **Accelerate assessment** for medicines which are of **major interest** from the point of view of public health to 150 days.
- These are visible reductions that are supported by other changes such as
  - **Restructuring of EMA structure**
  - **Strengthen the early regulatory support** by EMA, particularly for promising medicines under development for unmet medical needs (PRIME)
  - Possibility for regulators to **reject immature applications** to **limit clock stops** that delay the decision

Digital by default

How do we enhance efficiency with digital processes?

The “digital by default” approach

- **Regularize electronic submission** of applications and other procedures
- **Facilitate the use of electronic product information and multi-language packages**
- **Support and allow use of AI** through the lifecycle of medicines
- **Facilitate use of real-world evidence**, and of **health data** for regulatory purposes

Cutting-edge technologies

How do we consider the developing science?

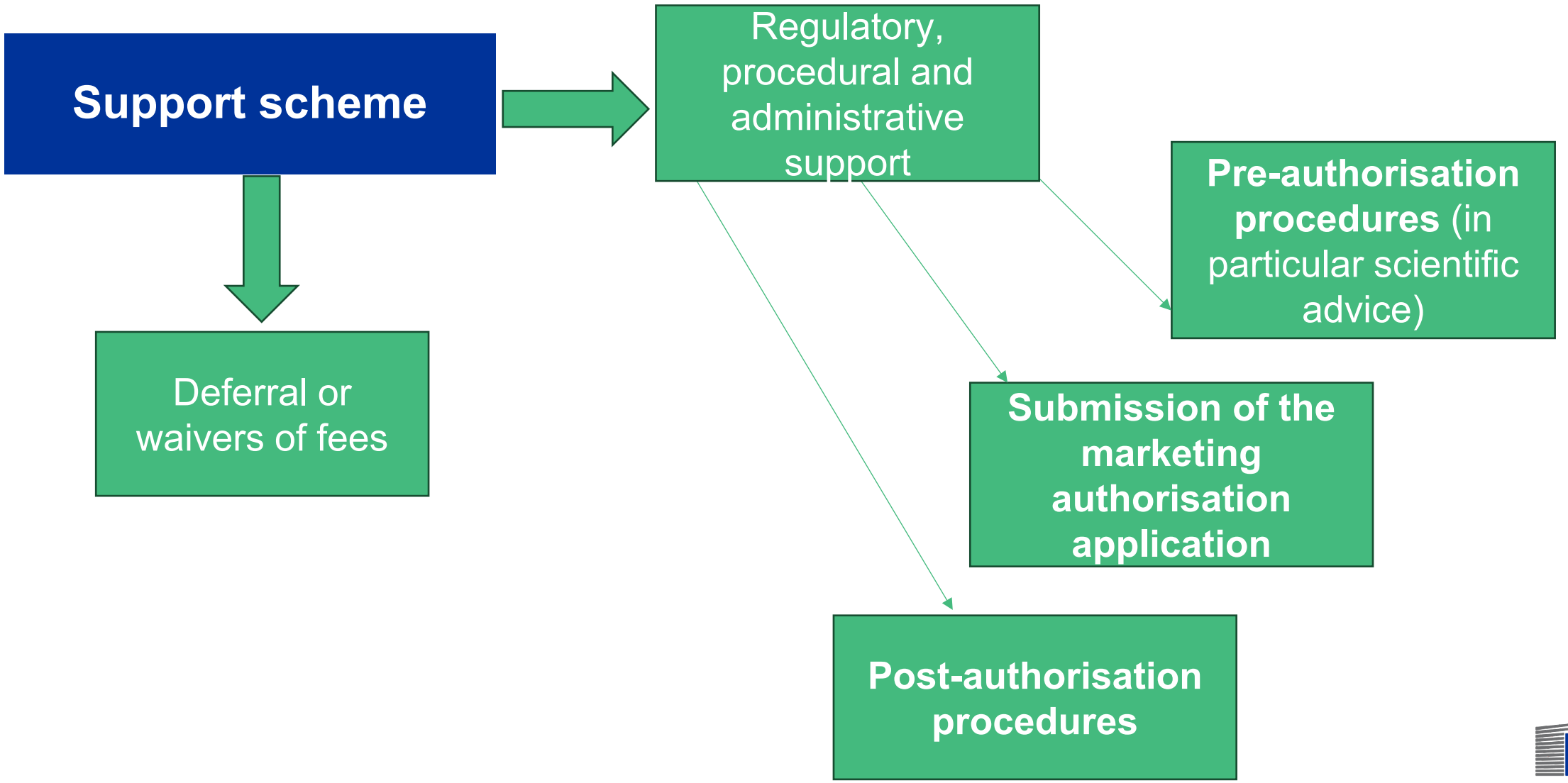
Cutting-edge and novel technologies

- **Future-proof regulation with regulatory sandboxes** by allowing the testing of new and innovative therapies
- **Adapted frameworks** with specific regulatory requirements tailored to the characteristics of certain **novel medicines**
- **Improve clarity** on the **interplay between EU legislative frameworks** for medicines and other health technologies (e.g. medical devices, substances of human origin)
- **Recognise platform technologies**
  - i.e. adjustments to the medicine are made based on the characteristics of the patient or the causing pathogen

SMEs support scheme

How do we dedicate support specifically to SMEs?

Special support for SMEs



Key advantages

What aspects of the general legislation are of great interest to SMEs?

Key advantages of interest

Wider use of electronic processes and reduction of administrative burden

Regulatory sandboxes to support the development of innovative products

Scientific support from EMA (especially for PRIME)

Incentive schemes for unmet medical needs, orphan medicines, AMR in the form of data protection and vouchers

Beyond the pharma reform

What is happening besides the pharmaceutical reform?

Beyond the pharma reform

- **The Critical Medicines Act** takes a preventive approach in the form of industrial policy measures to support, i.e., investment in EU manufacturing capacity.
- **The Biotech Act** proposal promotes innovation and competitiveness of the biotech sector in the EU by., i.e., alleviating regulatory and administrative complexities.
- **The Life Sciences Strategy** puts forward an EU investment plan to facilitate funding for clinical research and a matchmaking interface to connect startups, industry and investors.

Thank you