Vaccine Strategy

Pharmaceutical committee 2 July 2020

Vaccines Strategy – 17 June 2020

The Commission wants to find a vaccine within **12-18 months** without compromising on safety, quality or efficacy

The European Union faces two major challenges:

Early large-scale **investments in production capacities** are needed to reduce the risks for vaccine producers before guarantees exist that these vaccines will pass the clinical trials.

Large quantities of raw materials need to be secured so that production can start as soon as clinical trials are concluded, or even earlier.

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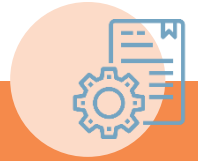
Vaccines Strategy

Two pillars

Securing the production of sufficient quantities of vaccines in the EU through **Advance Purchase Agreements**



Adapt the EU rules to the current urgency to accelerate the development, authorisation and availability of vaccines, while ensuring their safety and efficacy

On-going activities of the regulatory flexibility pillar :

- ✓ framework for **emergency use;**
- ✓ identification of **labelling/packaging flexibilities**

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Regulatory flexibility pillar-Emergency Use

- Proactive effort to coordinate EU approach for possible need of an early use of a vaccine in high risk populations prior to marketing authorisation.
- Coordinated and harmonised scientific assessment at EU level facilitated by EMA, similarly to the compassionate use schemes.
- Hybrid model based on Articles 5(2) of Directive 2001/83 and Article 5 (3) of Regulation (EC) No 726/2004
- Scientific assessment on vaccine's early use at EU level via CHMP opinion, actual implementation is left to Member States

Regulatory flexibility pillar – Labelling/packaging flexibilities

- Flexibility in labelling and packaging requirements to facilitate the rapid deployment of the vaccine once available
- Article 63(3) of Directive 2001/83/EC allows for exemptions from certain labelling and packaging requirements
- Flexibilities under consideration include :
- reduction of language requirements to one (English) – other languages available online, use of multi-vial presentations, possibility of local printing of leaflets to accommodate one patient leaflet per dose, reduction of blue box requirements, dedicated EMA webpage for centrally authorised products

Next steps

- **Emergency use :**

✓A more specific model is currently being developed in collaboration with EMA

✓Presentation and discussion with Member States through appropriate fora.

- **Labelling/packaging flexibilities:**

✓Ongoing reflection with EMA on identifying feasible options for centrally authorised products;

✓Discussion with Member States through appropriate fora (e.g. QRD group).

Thank you

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