EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 802

PHARMACEUTICAL COMMITTEE
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Subject: **Updates on Vaccine Strategy**[1]

Agenda item 5c

On 17 June, the Commission published its vaccine strategy for COVID 19 vaccines. It is a comprehensive document on how the EU aims to accelerate the development, manufacturing and deployment of vaccines against COVID-19. It summarises work, efforts already made, and elements of further work. It also expresses the ambition to deliver a successful vaccine within a timeframe of 12 - 18 months, while acknowledging that millions (possibly billions) of doses may be needed to cover global needs. The core objectives are therefore to secure timely access to vaccines for Member States (MS) while respecting global commitments, to ensure equitable access for all in the EU to an affordable vaccine but also ensure its quality, safety and efficacy. The actions outlined in the Strategy rest on two pillars. The first relates to securing the production of vaccines and sufficient supplies for MS through Advance Purchase Agreements; the second to adapting the EU's regulatory framework to the current urgency and making use of existing regulatory flexibility to accelerate the development, authorisation and availability of vaccines while maintaining standards for vaccine quality, safety and efficacy.

Main initiatives under the regulatory pillar currently on going concern the possible early access of a vaccine to certain parts of the population prior to a marketing authorisation and the alleviation of certain labelling and packaging requirements to enable its rapid deployment once authorised.

With regard to the possible use of a vaccine before an authorisation, this should not be seen as an encouragement for such use. It is rather a proactive effort to ensure a coordinated EU approach to be prepared for a situation where questions about the early use of a vaccine in high risk populations may arise.

Building on existing national emergency use schemes, the Commission sees the possibility for a coordinated and harmonised scientific assessment at EU level facilitated by EMA, similarly to the compassionate use schemes. A more specific model is currently being developed in collaboration with EMA and will then be presented to Member States.

[1] This document has not been adopted by the European Commission and, therefore, it does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.

For future centrally authorised vaccines the Commission is currently engaging with EMA on identifying flexibilities for labelling and packaging requirements such as reduction of language requirements, multi-dose vials to facilitate the deployment of any authorised vaccine. Also on this issue, further exchanges with Member States will follow in due course through appropriate fora.