EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 810

V.2

PHARMACEUTICAL COMMITTEE 21 October 2020

Subject: Vulnerability of the global supply chain (endorsement of a draft mandate)

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Agenda item 4

The issue of EU dependency on the active pharmaceutical ingredients (APIs) sourced in third countries, in the context of the broader discussions on supply issues, is being present on the agenda of the Pharmaceutical Committee since its 86th meeting. On its 88th meeting, the Pharmaceutical Committee agreed to establish an ad hoc working group to look closer to this issue. The representatives of DE, PL, NL, CZ, IE, MT, DK and ES declared interest in joining the group. The work of the group is also of high interest to EMA.

On 16 September 2020 the first meeting of ad hoc group took place. The meeting was attended not only by Member states representatives that volunteered to take part in the work of the group and EMA, but also by majority of other Member States.

The purpose of this meeting was to discuss the problem definition as well as data gathered by the Commission so far on the basis of initial input from the Member States. The group discussed as well its name and mandate. The group concluded that its focus should be to identify the vulnerabilities of supply chain, rather than only dependencies on APIs. In the light of this conclusion, the group considers that its formal title should be **ad hoc group on vulnerabilities of the global supply chains**.

Post meeting note: the title agreed is 'Ad hoc group on vulnerabilities, including dependencies, of the global supply chains'

The group seeks endorsement of the Pharmaceutical Committee of its mandate to provide opportunity for an exchange of information between Member States and coordinate EU level actions and initiatives to address the problem of vulnerabilities of global supply chains of medicinal products destined for the EU, as part of the implementation of the Pharmaceutical Strategy.

The group is open to the participation of representatives from all Member States interested, including from national departments and agencies that are involved in the issue of supply chain security from complementary points of views (including industrial, research, procurement, trade, competition).

Action:

Seek endorsement of the Pharmaceutical Committee of the name and mandate, as described above.

Ask for providing input to the questions shared as a follow up of the meeting of 16 September 2020.