EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

PHARM 795

PHARMACEUTICAL COMMITTEE
12 March 2020

Subject: **Dependency of the EU pharmaceutical industry on active pharmaceutical ingredients and chemical raw materials imported from third countries**[1]

Agenda item 7

The purpose of this agenda item is to discuss the EU's dependency on active pharmaceutical ingredients (APIs) and chemical raw materials imported from third countries and on its possible links with the issue of the medicine shortages in Europe.

According to the 2008 impact assessment for Falsified Medicines Directive[2] (SEC(2008)2674), 90% of APIs for generic medicines are sourced from India and China. For innovative medicines, many APIs are produced in Europe. According to the FDA, 31 % of the US supplies of APIs comes from Europe.[3] Yet even when APIs are produced locally, we know that most of the raw materials, for both generics and innovative medicines, are sourced from China.

This dependency has been discussed in meetings between the Commission and representatives of the European chemical and pharmaceutical industries. We are concerned that our dependency on imports of APIs and chemical raw materials will put increasingly at risk the supply of certain essential medicines and threaten the EU's strategic autonomy. The recent outbreak of COVID-19 shows that a disruption of supply from India and China in the pharmaceutical value chain could present a major health security issue.

The European Commission services have started collecting information to better understand the problem in order to identify and assess potential solutions. At this stage in particular, we would like to better understand the scale of our dependency, establish links with shortages of medicinal products in case supply of APIs/raw materials is disrupted and establish a list of critical medicinal products. For that reason, we would like to ask the representatives of the Member States in the Pharmaceutical Committee the following questions:

[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.
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008SC2674&from=EN
[3] FDA report on Drug shortages: root causes and potential solutions. 2019.

1) What are the medicines currently in shortage in your Member State due to manufacturing issues? How many can you link to problems with APIs or raw materials supplied from outside the EU?
2) Which 10 medicines, out of the list established in the reply to above, would you consider most critical?
3) Are there any other critical medicinal products where the APIs/chemical raw materials are sourced from third countries and for which you believe production capacity in Europe should increase?
4) What was/is the capacity of APIs/chemical raw materials production in your Member State? Do you have information on the APIs or chemical raw materials that are produced in your Member State? Are you aware of production in another EU Member State?
5) What could be done at European, as well as Member State level, to decrease the dependency on imports of APIs and chemical raw materials? Do you believe that this would help to address the issue of medicine shortages you are facing? Is your Member State planning or considering any specific initiative to address this issue?

We will ask the Pharmaceutical Committee to present their responses orally at the next meeting on 12 March, in particular to question 5. We would also ask that written responses to the questions are sent to sante-pharmaceuticals-b4@ec.europa.eu by 31 March 2020.