Out of the scope
Meeting with representatives of the Pharmaceutical Industry on the shortage of medicines, 12 December 2019

Participants:
SANTE: Martin Seychell, [redacted], [redacted], [redacted]
GROW: [redacted], [redacted], [redacted], [redacted]
Medicines for Europe (Vaccines for Europe) and Medichem, EFPIA

In his introductory speech, Martin Seychell stressed the dependency of the European pharmaceutical industry on the API produced in third countries and underlined the quality shortcomings identified in some of those API. Both issues contribute to the occurrence of the shortages in the EU. The high dependency on third country suppliers of API for essential medicines is also worrying from the public security point of view. The purpose of the meeting is to gain the understanding on the reliance of the European pharmaceutical industry on the third country manufactures of API.

Medicines for Europe, the European association of generic medicines producers, presented their perspective on the issue. Medicines for Europe represent the vertically integrated companies, therefore among them as well API producers. Some of the member companies produce their own API some purchase them from other entities.

Medicines for Europe referred to their letter sent earlier this year to the European Commission on the issue of shortages. It points to the phenomenon of consolidation of production, a cost-containment measure, as one of the reasons of the big reliance on the third country producers of API.

One of the main reasons of that phenomenon are current public procurement practices, based essentially on the criterion of price.

Additionally, pharmaceutical companies are not encouraged to diversify their API supply as any additional API producer generates the important regulatory compliance costs. Due to more and more detailed requirements of the medicinal products dossier, any step of API manufacturing has to be indicated and subject to a variation in case of change. A variation is required even if the API is covered by certificate of conformity (CEP) and the modification of CEP was assessed by EDQM. The changes in the API Master file is assessed as per Marketing Authorisation, what leads to huge administrative burden and additional cost. Medicines for Europe considers that this information should not constitute the part of dossier and be rather assessed and checked in the context of the GMP inspections.

Yet, Europe has a big potential for the API industry of the highest quality, as confirmed by recent FDA report. European producers (EU and Switzerland) supply 30 % of the API for US market and are rated as top quality suppliers. In Europe, the share of the Asian suppliers of the API is important. As regards EDQM data, 62 % of CEP is hold by the Chinese and Indian manufacturers of API.

In the assessment of Medicines for Europe to rebuild the full potential of European API industry 5-10 years would be necessary. The industry would be interested in sourcing from European suppliers if the price is acceptable, the regulatory framework favourable and predictable. Medicines for Europe considers that the efforts should be concentrated on the critical products. It would therefore be necessary to establish list of such products. The measures are required to foster investments in essential API production in Europe. Those could include:

- allowed forms of state aid, balanced procurement rules;
- R&D investments;
- tax deductions;
- fee waivers for introduction of European API manufacturers;
- fee waivers or reductions for companies that invest in the security of supply.
It would be essential to ensure a level playing field for EU manufacturers, bound by high environmental and security, in addition to highest quality standards. Medicines for Europe mentioned in this context the self-regulatory initiative of their members and EFPIA (representing the originator industry) members in the field of antimicrobials. They consider that such initiatives should be rewarded somehow.

Medicines for Europe considers that a dialogue with the US FDA should be pursued to enforce the cooperation on API and secure some advantages for the highest quality API producers in the US under the legal framework for generic medicines (the idea of the producers and the fee waiver resulting from the high position in the ranking).

EFPIA and Vaccines Europe confirmed the impact on the procurement practices on availability issues. EFPIA considers that the issue of the reliance on the API from third countries should be seen in broader context of access to medicines and discussions should involve Member States as well. In the assessment of EFPIA the reliance on the manufacturing capacity in China and India is not as big issue as the insufficient support in Europe of the R&D, what lead to shift of the R&A activities to Asia. EFPIA expressed concerns that any form of promotion of EU manufacturers have to comply with the WTO rules.

Asked by DG SANTE, EFPIA and Medicines for Europe did not perceive the dependency on China and India for raw materials (to produce APIs) as a major issue, while confirming the dependency of API produced there.

DG SANTE agreed that it is important to ensure a level playing field and integrate the costs, including environmental. GROW stressed the importance of that dimension in the context of the New Green Deal and the related Commission documents, among them forthcoming chemical strategy. GROW and SANTE stressed that the momentum is now to address this issue. DG GROW and SANTE proposed to organise the meeting with representatives of the value chain. The representatives of the pharmaceutical organisations confirmed their interest. They consider however that this discussion should involve Member States and payers (insurers) and have as well a political dimension.