

To: TOKARSKI Slawomir (GROW); [REDACTED]

Subject: Flash: Meeting with the new President of Medicines for Europe, Mr Christoph STOLLER, 16 December 2020

Meeting with the new President of Medicines for Europe (MfE), Mr Christoph STOLLER (General Manager Germany-Austria for TEVA Pharmaceuticals

[https://www.tevapharm.com/featuredstories/Christoph Stoller Appointed as new President of Medicines for Europe.aspx](https://www.tevapharm.com/featuredstories/Christoph%20Stoller%20Appointed%20as%20new%20President%20of%20Medicines%20for%20Europe.aspx)), **Monday, 16 December**

Background: Medicines for Europe (MfE) is the association representing manufacturers of generics and biosimilars (G/Bs) medicines in Europe. MfE called for the meeting to introduce its new President and to discuss MfE's priorities for the next Commission cycle.

Participants:

- DG GROW: Slawomir TOKARSKI (Director F), [REDACTED]
- Medicines for Europe: Christoph STOLLER (President), Adrian VAN DEN HOVEN (General Director), [REDACTED]

Discussions:

- An EU high level forum of pharma stakeholders would be helpful to discuss the challenges of the EU pharmaceutical sector.
- Shortages of supply of medicines in the EU
 - o Need to tackle root-causes.
 - o One of the causes of these shortages relates to the way public procurement (PP) is conducted in many EU MS where "lowest price" seems to be the only award criterion. This price-only criterion pushes manufacturers to reduce production cost as much as possible by outsourcing production to only one supplier of APIs, namely from India or China (EU manufacturers import 67% of their APIs from these two countries). Chinese API manufacturing sector has undergone a consolidation process with closures of many factories (sometimes due to environmental reasons). This makes that the 'supply chain' has become vulnerable. Also the lack of transparency of variability of the market is a major cause. Although to better ensure the supply, a second

supplier of APIs is very helpful but very costly as an additional regulatory dossier is needed. This is generally not taken into account in the evaluation of tenders. MfE advocates for additional award criteria such as quality, environmental aspects and security of the supply. Germany is considering a proposal of law to improve PP of medicines.

- Supply of antibiotics is a especial concern.
- Need to have more manufacturing of active pharmaceutical ingredients (APIs) and medicines in the EU
- Some Eastern EU MS have scarce access to biosimilars, leaving patients in those EU MS without access to certain treatments (MfE considers this as a competition issue mostly).
- The implementation of the falsified medicines rules has been costly for G/Bs manufacturers, slowing down production.
- DG SANTE will launch a study on shortages of medicines in the EU.
- On intellectual property rights (IPRs):
 - Evergreening: patents on indications will be increasingly relevant in a context of personalised medicines and other scientific developments. MfE and EFPIA (the European association representing innovative medicines companies) are discussing how to deal with off-label use aspects (in the context of enforcement of secondary medical use patents).
 - Implementation of the SPC waiver(**): MfE's member companies are satisfied with new Regulation 2019/933 on the 'SPC waiver'. Major investments in biosimilars are taking place in the EU (being the waiver one of the factors that positively influenced those investment decisions).
 - European-SPC: MfE favour the ideas of both a single grant mechanism and a unitary-SPC.
 - Bolar: MfE informed that Poland has aligned its Bolar provision with the German practice. MfE sees the inconsistency of the Bolar provision in the UPC Agreement with the updates of the Bolar legislation in many EU MS.

Next steps:

- DG SANTE to launch a study on shortages of medicines in the EU.
- DG GROW to conclude the evaluation of the SPC and Bolar legislations.

Best,

*(**) SPC waiver: Regulation 2019/933 has just introduced it in the EU. A SPC title confers the same rights as a patent does. SPC holders are typically pharmaceutical innovators. The EU 'SPC waiver' consists on a 'export wavier' and a '6-month stockpiling waiver'. An "export waiver" (or exemption) allows generic and biosimilar manufacturers to produce in the EU during the EU SPC term of protection of the reference medicine but only for export purposes to third-countries. A "stockpiling waiver" (or exemption) allows generic and biosimilar manufacturers to produce in the EU during the las 6-months of the EU SPC*

term of protection of the reference medicine for stockpiling in the EU for the purpose of [faster] day-1 entry in the EU market.

