


Dear all,
Please find below, for your information, the minutes of the bilateral of the Commissioner with Medicines for Europe on the Pharma strategy.
Kind regards,


Participants

Commission:
Commissioner Kyriakides, Giorgos Rossides, Karolina Herbout-Borczak, Chrystalla Papanastasiou, (CAB Kyriakides).

COVID-19

MfE: Thanked to Commission for the good cooperation during the pandemic on avoiding shortages and the possibility of green lanes to keep supply chains open. MfE mentioned that EU pharmaceutical production has proven to be robust as production was maintained and scaled up massively to quickly

increase supply (up to 800% increase over the same period in 2019). This was partly due to a strong manufacturing footprint in EU.

Pharmaceutical Strategy

MfE: Stressed that even though EU manufacturing of medicines still exists, increases in manufacturing cost (average cost in off patent sector in Germany is 17 cents today compared to 6 cents 10 years ago) causes a move of manufacturing from west to east. EU MS must introduce **MEAT** (most economically advantageous) criteria for **pharmaceuticals procurement** in off patent medicines with a combination of other factors like quality and guarantee of supply. Multi-winner procurement should be the rule. Regulatory dialogue through regular calls should be kept. y. The public procurement directive already recommends the use of MEAT criteria, this should be followed by all MS.

MfE mentioned that generics, biosimilars and added value medicines are part of solution as their impact on budget is minimal. However, in some MS (especially in eastern Europe) there are still severe **access restrictions** - especially for biosimilars. **Clawbacks** and other funding techniques make off patent manufacturing non sustainable and redirect funds to finance the high cost of innovative medicines. For example in the area of antibiotics some of which are extremely cheap production is not sustainable which may lead to withdrawals which in turn decrease therapeutic options. Regulatory cost and maintenance costs of such products are driving these withdrawals. The strategy should include actions to improve regulatory processes to help the maintenance of well-established products. The **variations procedure** should be simplified by reducing the administrative burden for reporting. The nature of 50% of variations today is purely administrative. We can use digital tools to turn this paper process into a digital one. The goal should be to **reduce by at least 50%** this administrative waste. Also the Commission should create a **tailored pathway to develop follow-on products** which will bring affordable options to the market. Other bottlenecks include **patent ever greening**, **patent linkage** (a generic company cannot register a generic if a patent is still valid), the **harmonised implementation of the Bolar exemption**, **uptake of biosimilars** (in eastern Europe mostly). The last can be tackled by providing incentives for prescription.

The Commission should look into the root causes of **shortages** (Covid related shortages were mostly about demand spikes and only 3% were quality related). MfE supports the provision of obligation to supply (already included in legislation). MfE stressed that the current **API manufacturing** base is strong (400 production sites in EU). The EU should promote investment in critical manufacturing infrastructure. The creation of a European medicines supply committee could help. Also, as part of the Green deal, it should promote investments in green manufacturing in the EU. Overall financial support should be combined with market incentives.

The EU should work with international partners to avoid export restrictions and enforce GMP rules. Finally, MfE reiterated its call for a multi stakeholder forum which would facilitate discussion on access.

DG SANTE: Recognised the importance of the generics industry in the strategy. Off patent innovation and access are priorities in the roadmap which is only an outline there point will be reinforced in the strategy communication. Patents, the Bolar exemption, procurement are all issues the Commission services are working on (together with DG Grow). Variations is an area we are committed to look at as part of evaluation and possible review of legislation.

Commissioner Kyriakides: The role of generics will strengthen the strategy which will be as inclusive as possible. We recognise the issue of dependence on APIs and MfE's data would be useful.

Access/affordability/digitalisation will be addressed in the strategy. An open channel of communication and ongoing engagement is crucial.