



**To:** ROSSIDES Giorgos (CAB-KYRIAKIDES); [REDACTED] (CAB-KYRIAKIDES); [REDACTED] (SG); [REDACTED] (SG); [REDACTED] (SG); [REDACTED] (SG); [REDACTED] (SG); [REDACTED] (SG); GALLINA Sandra (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (GROW)

**Subject:** Discussion with EFPIA

Dear colleagues,

**Please find the Summary discussion with representatives of the European Federation of Pharmaceutical Industries and Associations (EFPIA) on 23 September 2020**

The virtual meeting was requested by EFPIA indicating that the main topics would be the upcoming initiative on the European pharmaceutical strategy and the more general issue of dealing with intellectual property. The discussion also touched on the health related initiatives announced in the address on the State of the Union delivered by President von der Leyen.

The key issues discussed are presented below:

**Role of European industry in the context of the Covid-19 crisis**

EFPIA praised the good coordination by the Commission that allowed the industry to react appropriately and ensure the medical needs during the crisis. However, at this point there is a clear need for more precise data on patients' needs at national level in Member States. The existing ECDC data, last updated on 10 August, is not appropriate and EFPIA is using its own projections which is not ideal. So far the industry was very responsive to Commission's requests to meet production and supply needs but currently the situation is different as some Member States already made stocks; industry would not be able to produce appropriately for a second wave if it is left in the dark on stocks and needs. There is a clear need for a structured exchange of information on forecasting demand data.

Commission acknowledged a risk of complacency after the first wave and the importance to have reliable data on needs. It will continue to strongly advocate this vis-à-vis Member States. Commissioner Breton is continuing the dialogue with relevant countries and the Clearing House established by the Commission continues to work. In the short term Commission will continue to raise awareness on these issues. For the mid- term (November 2020), Commission is preparing a number of initiatives, including the revision of the ECDC and EMA mandates, to address identified shortcomings and improve preparedness and health crisis response. This push is also supported by the DE Presidency.

**More EU in the health area (Health Union)**

EFPIA inquired about the foreseen initiatives and whether the announced European BARDA will be limited to pandemics.

Commission explained that a first step will be a package of proposals in November, based on current provisions of the Treaties, aiming at improving the European response, especially for health emergency. The Conference on the Future of Europe is expected to address increased citizens' expectations in the health area at European level which could also lead to discussions on competence. As for the European BARDA, which would not necessarily be limited to pandemics preparedness and response only, the idea is to start discussing with all stakeholders, industry and Member States. The idea has been welcomed but there is a need for a debate on scope and functions that add value before choosing options for

financing and structure. Lessons learned from the Covid-19 are the starting point and the discussion may be launched in November as part of the same package of initiatives.

### **European Pharmaceutical Strategy/Intellectual Property/Competition**

EFPIA stressed the geographical diversity of the companies that they represent which is key to ensure a good match with demands on the European market. The industry is a bit concerned about the re-shoring message from the EU which could hurt EU competitiveness and affect the leading position as largest exporter of medicines in the world and the strong European position in the international value chains. The discussion at European level seems to focus exclusively on production and less on innovation (R&D). EFPIA sees a need for re-balancing the two strands.

Commission stressed that the debate has just started and the upcoming European Council, postponed for 1 October, will also address the issue of strategic autonomy. Commission argues for “open strategic autonomy”, in order to make it clear that we are not talking about autarchy but about strategic sovereignty, not producing everything in the EU but also not depending on very few supply sources. We need to diversify supply chains. This approach goes hand in hand with the industrial eco-system and the green and digital transitions. Given the strong political emphasis on this issue in Member States, which expect credible proposals, it would be useful if EFPIA could provide concrete examples of how sovereignty over supply chains can work in practice in order to make it more tangible for decision makers (NB – point agreed by EFPIA);

In terms of initiatives to be announced in the pharma strategy, EFPIA raised a concern about changing existing basic legislation, e.g. paediatric medicines acquis, which would send the wrong signal to industry as opening a period of uncertainty. EFPIA also made the point that work on safety and greening of pharmaceuticals continues and inquired about their idea to set up a platform on innovative medicines.

Commission took note on the EFPIA position on the revision of pharma basic legislation and stressed that many improvements can still be made via non-legislative actions. The idea is not to propose heavy rules but to improve the current situation without a complete overhaul of the acquis. However, there is an increased pressure for more transparency and affordable access. On the platform on innovative medicines, the approach supported by the Commission is to bring together all relevant stakeholders from various sectors, not only industry, and avoid mere talking shops. The upcoming European pharma strategy may also address this issue.

EFPIA also touched on the issues of intellectual property (IP) and the upcoming IP action plan, which it considered very important for the development of the pharma industry and its international competitiveness. EFPIA also questioned the idea of compulsory licensing and inquired about changes in the competition rules that will affect the pharma industry. Commission stated that the IP importance is well acknowledged and there is no hidden agenda with the upcoming action plan. At the same time, there needs to make sure that there is no monopoly on knowledge. A good example is the recent approach in the ACT-Accelerator where, although no obligation is put on companies to share IP, companies benefitting from public funding are expected to contribute to facilitating universal and fair access to new solutions. Compulsory licensing is already a legal possibility but it is seen as a last resort not an instrument to be used upfront. On competition, there is a need to review various state aid guidelines, e.g. on energy, and the idea is to see if current rules are fit for purpose in a post-Covid 19 context.

### **Brexit**

Commission inquired about preparedness industry plans in the Brexit context. EFPIA mentioned that discussions already started in 2019. However, the Covid-19 crisis led to the use by Member States of stockpiles made for Brexit purpose. There is also an issue with supply for IE. EFPIA will send more information on all these issues.

#### **EU4Health programme**

EFPIA inquired about on-going discussions and the financial envelope for the programme. Commission explained the latest proposal agreed at the European Council, with a sizeable financial envelope as compared to current programme. Commission will continue to support an ambitious programme. The European Parliament indicated that EU4Health programme is part of the programmes for which they would like to see an increase but there is the reality of negotiations and inter-play with other important financing programmes.

#### **Attendance:**

**EFPIA:** [REDACTED] (General Director), [REDACTED] (Executive Director) and other EFPIA representatives

**Commission:** Kurt Vandenberghe (Cabinet of the President), [REDACTED] (Cabinet of Commissioner Kyriakides), [REDACTED] (General Secretariat of the Commission)



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