Meeting between DG SANTE and the representatives of industry, 2 October 2020

Participants:

- *EFPIA:* [redacted]
- *AESGP:* [redacted]
- *DG SANTE:* [redacted]

DG SANTE opened the meeting stressing that preparedness efforts should be stepped up in view of being ready by the end of the transition period and recalled that the industry should make the necessary changes in due to avoid any disruption of the medicines on the EU market and in particular in the smaller markets, like IE, MT, CY.

The industry representatives explained that BREXIT has a significant impact on medicines, despite efforts made (various preparedness actions) it is difficult to say that industry will be ready in due time. The industry appreciated the work from the COM DG SANTE as regards the Brexit notices and the interpretations so far, however there are still unclarities, in particular as the implementation of the IE/NI Protocol and as regards the multi-country packs and the FMD and joint labelling.

DG SANTE raised awareness of the BREXIT readiness in view of the end of the transition period. COM acknowledged the preparedness efforts carried out so far. COM expressed its commitment of also working very hard to ensure that preparedness is achieved and that IE/NI Protocol in implemented correctly and that we have the same common objective that medicines are available and reach patients after the end of transition period in the EU without market disruptions for medicines.

Industry informed that work is ongoing, however there are certain unclarities related to the imports from GB to NI and the supply chains. AESGP said that from their side it would be difficult to comply with the end of the year time line and a derogation of 1 year would facilitate the readiness in NI.

SANTE replied that COM BREXIT Notices on medicines ensured already the needed clarity, flexibility and support in this, including the aspects on joint packs labelling. Industry was reminded that from the COM Notices it was made clear that on the basis of the IE/NI Protocol there will 2 separate systems in GB and NI. On the basis of the IE/NI Protocol, the EU pharmaceuticals acquis will apply as of 01/01/2021 to and in UK in respect to NI. The COM Notice clearly explained what it means for medicines and that are placed on the NI market must comply with the EU pharmaceutical acquis, such as a MA issued either by the COM or by the UK in respect to NI applying the acquis and the procedures should be followed in compliance with the EU pharmaceutical legislation, including for the NAPs. The unclarities were not specified in this meeting just mentioned they were in relation to NI market and the importation. Industry offered to send these issues to further explain them.

As regards the FMD, industry informed that stakeholders are discussing in view of finding a suitable solution under our current FMD framework. An IT system that will be moved from GB to NI. For the moment discussing are ongoing and they will also involve the stakeholder in the UK that will establish the system for the NI.

COM explained the FMD system and requirements due to BREXIT and the issues related to the implementation of the system and the necessary changes need indeed to be made in due time. And

with this meeting we understand that the IT system will be ready with the signature of the contract soon.

As for the unclarities for the IE/NI Protocol and its implementation for medicines, DG Sante explained that depending what they are, EMA might be organising a stakeholders event to reply to implementation issues, if necessary.