# 102nd Heads of Medicines Agencies Meeting

## 26th November 2020

## Highlights of the Meeting

The 102nd meeting of the Heads of Medicines Agencies (HMA) hosted by the Federal Office of Consumer Protection and Food Safety (BVL) and the Paul-Ehrlich-Institut (PEI) within the German Presidency of the Council of the European Union was held virtually on 26 November 2020. The Heads of the European medicines regulatory agencies, representatives from the European Medicines Agency (EMA) and European Commission (EC) exchanged views on the current activities. Significant parts of the meeting focused on the current and future strategic plans and initiatives of the network, the Brexit and the implementation of the new veterinary legislation.

### Benchmarking of Mediciens Agencies (BEMA) - Update

The Heads acknowledged the latest develepments carried out by the BEMA Steering Group, promoting the voluntary benchmarking process that, by annual cycle, co-evaluation of the performance of national medicines regulating authorities.
The Heads supported that the questionnaire has been revised in line with new HMA-EMA joint strategy 2020-2025 and that the revision of Key Performance Indicators was ongoing. The BEMA database was successfully transferred from VMD, United Kingdom to INFARMED, Portugal. Acknowledging the experience of the BEMA SG Members, their ageed support to the WHO was noted.

### Update on Brexit – Perspectives from HMA, EMA, EC, CMDh and CMDv

An in-depth exchange between HMA, EMA, EC, CMDh and CMDv on Brexit-realted topics was carried out. The Commission reportet that the negotiations with UK on an agreement on the terms of the future cooperation were still ongoing. CMDh informed HMA that overall the number of Brexit-affected authorization had further decreased since HMA I in September 2020. However, for some Member States the situation continues to be challenging, as the number of marketing authorisations affected by Brexit is still high. The CMDv reported thaton the veterinary side there were no more products with UK as Reporting Member State. Regarding centralized procedures, EMA reported that most marketing authorization holders

have made the necessary changes and are now ready to be compliant with the legal frame coming into force after 31 December 2020.

### HMA Crisis Management Plan

As inititated during the 100th HMA meeting in May 2020 the HMA Crisis Management Plan (HMA CMP) Task Force, following the agreed principles for a draft HMA CMP in September 2020, the task force presented a draft including the distinct criteria for activating the HMA CMP. HMA thanked the task force for their work resulting in an important instrument to manage future crises.

### Implementation of the Veterinary legislation

The Heads witnessed the progress of the implementation of the veterinaty legislation, as presented in a dedicated session with the HMA Taskforce on Coordination of the Implementation of the Veterainary Regulation (TFCIVR – overall HMA coordination of implementation), EMA (compliance of databases) and EC (legal procedural affairs). In the same context, the CMDv reported the progress of its Legislation working group, consisting of four subgroups: Variations, Marketing authorisation procedures, Packaging/labelling templets, SPC harmonisation. The general principles of the SPC harmonisation were presented and endorsed by HMA.