



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Press release

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# EMA Management Board: highlights of October 2019 meeting

At its 3 October 2019 meeting in Amsterdam, the European Medicines Agency's Management Board elected Lorraine Nolan as vice-chair of the Board for a three-year period. Dr Nolan is Chief Executive of the Health Products Regulatory Agency (HPRA) in Ireland, a post she has held since January 2016. She has served as a member of EMA's Management Board since March 2016. Dr Nolan replaces Grzegorz Cessak of Poland as vice-chair.

The Chair welcomed two new civil society representatives to the Board. Marco Greco, president of the European Patient Forum (EPF) and Ioannis Natsis, policy manager for universal access and affordable medicines at the European Public Health Alliance (EPHA) will represent patient organisations. They will both serve a three-year term that can be renewed once. Marco Greco and Ioannis Natsis join the two representatives of doctors' and veterinarians' organisations who were re-appointed as civil society members to the Board.

## Brexit update

The Board was updated on the Agency's ongoing preparations for the withdrawal of the United Kingdom from the European Union. Interim arrangements allowing staff to telework from London have now largely come to an end. The total available workforce is roughly 730 - a further 6% reduction compared to the last update to the Board in June.

Due to these ongoing resource constraints, delivery of EMA's work programme for Q4 2019 will be challenging for the Agency, particularly in view of the need to implement new legislation for veterinary medicines and medical devices, which will bring additional workload.

In order to be best prepared to address future challenges with the existing workforce, Executive Director Guido Rasi announced that the Agency is reviewing its organisational structure and looking to set up task forces that will focus on areas that are also key priorities for the network such as digital business transformation, data analytics and methods, regulatory science and innovation, and clinical trials and manufacturing strategy.



Operations in the area of human medicines will be integrated to strengthen the therapeutic focus all along a medicine's lifecycle, with the ultimate aim of assuring the quality of scientific opinions and further improving support to EMA's scientific committees.

Overall, this will ensure that the Agency is geared up for the future with more efficient processes firmly rooted in digital technology to keep pace with rapid advances in science. More information will be shared with stakeholders in due course.

The Board also heard that in accordance with current planning, the construction of the new EMA building in Amsterdam Zuid will be finalised in November 2019 and the building will then be handed over to EMA on 15 November. Between mid-November and January, moving of equipment, IT configuration and testing will take place so that staff can move in during the week starting 13 January 2020.

### **Mid-year report 2019 adopted**

The Management Board heard an update on the Agency's activities in the first half of 2019. The number of new initial evaluation applications for human medicines received in the first half of 2019 was 34% higher than that received during the same period in 2018 (63 in the first half of 2019 versus 47 in the first half of 2018).

In veterinary medicine, initial evaluation applications also increased compared to the first half of 2019 (13 applications received in the first half of the year vs seven in the same period in 2018). The number of requests for scientific advice for veterinary medicines decreased slightly compared to the previous year - 12 in the first half of 2019 compared to 16 during the same period in 2018.

The number of transfers of marketing authorisation applications dropped significantly compared to 2018, returning to 2017 levels. This is because most of the Brexit-related transfers had been submitted by the end of 2018.

EMA's mid-year report will be published on the EMA website shortly.

### **EU IT systems required by the Clinical Trial Regulation**

The Management Board endorsed the six-monthly monitoring report on the development of the Clinical Trial Information System (CTIS), which assesses the performance of the IT supplier against agreed key performance indicators.

The Board agreed that actions proposed in the report should be further developed, e.g. improving the quality of the work delivered by the supplier and selecting the critical items needed for audit, as well as extending the monitoring period for at least three releases.

The first release developed in the agile, iterative delivery model was validated in September 2019 by the nominated product owners of EU Member States, sponsors and the European Commission. It was confirmed that all 79 items had been delivered. This release enhanced CTIS functionalities concerning submission of clinical trials and their assessment process, user management and included other general improvements.

In the coming months, the product owners will carry out an operational assessment of the system to identify critical business blockers to be developed for the auditable version, to enable the Board to consider the timing of the audit.

### **Ongoing access-to-documents cases**

The Board took note of the recent opinions of Advocate General Hogan in the context of two ongoing access-to-documents cases that are currently pending before the Court of Justice. If the Court of

Justice were to follow the recommendations set out in these opinions, EMA's existing transparency policies would be impaired and have to be revised.

Whilst waiting for the decisions of the Court of Justice, EMA Management Board members reiterate that making available to the public most data submitted to the Agency for the purpose of marketing authorisations and variations, generates trust in the EU regulatory network, broadens the scientific knowledge base, fosters the development of medicines and ultimately benefits public health.

## Notes

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1. This press release, together with related documents, will be published on the Agency's website shortly;
2. More information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

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