



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Press release

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# EMA Management Board: highlights of October 2016 meeting

Board elects Grzegorz Cessak as vice-chair, adopts Agency's mid-year report and signs off reflection paper on European medicines web portal

### **New vice-chair elected**

At its 6 October 2016 meeting in London, the European Medicines Agency's (EMA) Management Board elected Grzegorz Cessak as vice-chair of the Board for a three-year period. [Dr Grzegorz Cessak](#) is President of Poland's Office for registration of Medicinal Products, Medical Devices and Biocidal Products, a post he has held since July 2009. He has served as a member of EMA's Management Board since January 2010. Dr Cessak steps into the role that was vacated by Christa Wirthumer-Hoche following her election as chair at the March 2016 Management Board meeting.

### **Mid-year report: launch of PRIME is a success**

The Management Board heard an update on EMA's activities in the first half of 2016. In human medicine, EMA's new scheme to support the development of promising medicines addressing unmet medical needs (PRIME) has been successful so far; 48 applications were received between its launch on 7 March 2016 and the end of June; to date, 64 applications have been received\*.

Overall, the number of new applications for marketing authorisation received in the first half of 2016 was comparable to that received during the same period in 2015 (42 in the first half 2016 versus 45 in the first half 2015).

In veterinary medicine, there was a steep increase in the number of applications for marketing authorisation received (12 in the first half of 2016 compared to three in the first half of 2015). EMA's Innovation Task Force, which opened to veterinary medicines in November 2013, is increasingly used by medicine developers. Three requests were received in the first half of 2016. The task force offers a forum for early dialogue on innovative therapies and technologies with medicine developers, in particular micro, small and medium-sized enterprises (SMEs) and academics. It helps to identify and address early any scientific, legal and regulatory issues related to the translation of emerging science into medicines.

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



## European medicines web portal is given go-ahead

The Board adopted a [reflection paper](#) on the development of a European medicines web portal, which sets out a vision for the portal and the expected benefits, and how best to achieve this vision. The multilingual website will provide access to free, reliable and unbiased information on all medicines authorised in the European Union (EU) for patients, consumers, carers, healthcare professionals and academia across the EU.

Through the portal, comprehensive information will be provided on a medicine across its lifecycle, from clinical trial information to adverse drug reaction reports. The portal should increase the visibility of information on medicines held by both EMA and the EU Member States.

It will also support high-level European initiatives on data availability by providing downloadable, consumable datasets.

The portal is required by the 2010 pharmacovigilance legislation that came into effect in 2012. EMA, in collaboration with the EU Member States and the European Commission, will now develop a multi-annual delivery plan and start scoping IT solutions to support the project.

## First annual report on independence

The Board also discussed EMA's first annual report on independence which reviews how the Agency's policies on handling competing interests for its scientific committees' members and experts, Management Board members and staff, have been implemented. The 2015 report analysed the declared interests and the resulting restrictions applied, the outcome of compliance checks and adherence to the transparency principles, i.e. the publication of declarations of interest and CVs. The report shows that the principles of the independence policies were complied with.

In line with the Agency's commitment to continuously review its operations, the report also identifies a series of initiatives to be undertaken to strengthen the handling of competing interests whilst maintaining the right balance between impartiality and best expertise. These include a further alignment of the policy for scientific committee members and experts and the policy for Management Board members. The revised policies have been published and the 2015 report will be available on the EMA website in due course.

## Notes

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1. This press release, together with all related documents, is available on the Agency's website.
2. Correction made on 10 October 2016: the number of applications for PRIME received as of 6 October 2016 is 64.
3. 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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