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Press Office

**Press release**

# EMA Management Board: highlights of March 2015 meeting

## New Vice-Chair elected and joint strategy to 2020 for European medicines agencies network endorsed

### Election of new Vice-Chair

The European Medicines Agency's (EMA) Management Board elected Dr Christa Wirthumer-Hoche, the Head of the Austrian Medicines and Medical Devices Agency, as its Vice-Chair for a three-year period.

Dr Christa Wirthumer-Hoche succeeds Prof Dr Walter Schwerdtfeger, following his retirement from the German Federal Institute for Drugs and Medical Devices.

### European medicines agencies network strategy to 2020 endorsed

The Board endorsed a draft strategy to 2020 developed together by EMA and national medicines regulatory authorities for both human and veterinary medicines in the Member States of the European Union (EU). The draft strategy will be released for a three-month public consultation shortly. The publication will be announced on the EMA and the Heads of Medicines Agencies (HMA) websites.

EMA and the national medicines regulatory authorities agreed for the first time on a joint high-level strategy for the EU medicines agencies network and key priorities for the next five years. An ever more coordinated approach and a strengthened collaboration are needed to address the multiple challenges and opportunities that the network is facing.

### Review of EMA's 2014 activities

The Board also adopted the Agency's 2014 annual report. The document will be published in April 2015.

The report highlights the high number of new medicines recommended for marketing authorisation in 2014, both for human (82) and animal (20) use.

Pre-authorisation activities increased significantly in 2014 and resulted in 16% more requests for scientific advice for human medicines and 63% more applications for orphan designation compared to

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2013. This continues a trend already observed in 2013 and indicates an improved use of EMA support tools by medicine developers.

The number of suspected side effects reported in EudraVigilance, the EU adverse drug reaction collection and management system, continues to increase (a 6.5% increase compared to 2013 for human medicines and a 27% increase for veterinary medicines). This reflects an increased commitment of stakeholders to report side effects.

**Advanced therapies - achievements and challenges**

Dr Paula Salmikangas, Chair of EMA's Committee for Advanced Therapies (CAT) and senior researcher at the Finnish Medicines Agency, presented the achievements and ongoing challenges in the area of advanced therapies, i.e. medicines that are based either on cells, genes or tissues. Five advanced therapies have been granted an EU-wide marketing authorisation since the creation of the CAT in 2009. This includes the first therapy based on stem cells in 2015. Four advanced therapies are currently under evaluation, including two cell-based, one gene-based and one tissue-based therapy. In 2015, the CAT expects to start evaluating two to three additional medicines.

"While the number of authorised advanced therapies is still limited, the pipeline is large. This is shown by the number of clinical trials being conducted and the increasing volume of requests for scientific advice and classification of medicines as advanced therapy medicinal products. We expect more medicines, including breakthrough therapies for difficult to treat diseases, in the near future", explained Dr Salmikangas.

The CAT Chair stressed the fact that most developers of advanced therapies are very small companies or come from academia. These sponsors often encounter difficulties in fulfilling current good manufacturing practice (GMP) requirements and post authorisation obligations. Companies also face multiple scientific and regulatory challenges during the development of advanced therapies. Therefore, Dr Salmikangas underlined that the European Commission, together with the CAT, are exploring measures to improve the regulatory environment for these therapies and to help translate research into medicines that are safe, effective and of high quality for the benefit of patients.

## Notes

1. All relevant documents adopted at the Management Board meeting will be available on the Agency's website in due course. This press release is available on the Agency's website.
2. Dr Wirthumer-Hoche has been involved in the European medicines regulatory network since 1995, when Austria joined the European Union. She was a member of the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) between 2005 and 2013. She is the co-Chair of the recently created EU network training centre and has been a member of the EMA Management Board since October 2013.
3. Correction: the increase in the number of suspected side effects reported in EudraVigilance for human medicines compared to 2013 is 6.5%.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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