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Directorate

## EMA-EUnetHTA three-year work plan 2013–2015

### Introduction

In October 2008, the Pharmaceutical Forum<sup>1</sup> — a high-level ministerial platform set up as a three-year process (2005–2008) for discussion between European Union (EU) Member States, EU institutions, industry, healthcare professionals, patients and insurance funds — agreed on conclusions and recommendations in order to find relevant solutions to public-health considerations regarding pharmaceuticals, while ensuring the competitiveness of the industry and the sustainability of the national healthcare systems<sup>2</sup>. One of these recommendations provided a political mandate to initiate collaboration between the European Medicines Agency (EMA) and the European network for Health Technology Assessment (EUnetHTA), with the aim of improving the availability and best use of data relevant to health technology assessment (HTA).

The ensuing collaboration<sup>3</sup>, focusing as a first step on the improvement of European public assessment reports (EPARs), has demonstrated the opportunity to engage in discussions and collaboration on better exchange of data and information in a number of areas.

### **Objective of EMA-EUnetHTA collaboration**

The objective of the EMA-EUnetHTA collaboration is to identify opportunities for, and undertake specific steps to implement, improvements to the efficiency of the process and conditions for patients' timely access to an effective medicine.

The following sections present the areas for EMA-EUnetHTA collaboration identified as the focus of European regulatory-HTA interaction during 2013-2015. The EMA-EUnetHTA collaboration will continuously explore future directions and areas for cooperation. Both organisations observe and adhere to the respective remits and obligations of [the EMA](#) and [EUnetHTA](#).

The EMA-EUnetHTA three-year work plan will be reviewed and updated when deemed necessary by both parties, and at least once a year.

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<sup>1</sup> [http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pharmaceutical-forum/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pharmaceutical-forum/index_en.htm)

<sup>2</sup> [http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/pharmaforum\\_final\\_conclusions\\_en.pdf](http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/pharmaforum_final_conclusions_en.pdf)

<sup>3</sup> Six joint meetings have been held to-date. [Meetings minutes](#)

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See websites for contact details

**European Medicines Agency** [www.ema.europa.eu](http://www.ema.europa.eu)  
**EUnetHTA** [www.eunethta.eu](http://www.eunethta.eu)



## ***Areas of collaboration***

- Scientific advice/early dialogue involving regulators and HTAs.
- Scientific and methodological guideline development.
- Post-licensing (post-authorisation) data generation.
- Availability of clinical study data.
- Orphan medicinal products.
- Cooperation in pilot projects.
- Cooperation in specific pilot projects of EUnetHTA JA2.
- Conferences, workshops and seminars/meetings.

## **Activities in each of the areas of collaboration**

### ***Scientific advice/early dialogue involving regulators and HTAs***

- Regular (half-year; at the joint meetings) mutual updates on the developments in this activity area at the EMA and within EUnetHTA.
- Explore and implement, if/when relevant, mutual participation in specific scientific advice/early dialogue, as observers.
- Responding to the evaluation surveys on a specific scientific advice/early dialogue by way of individual organisations of EUnetHTA or the EMA providing such a response, if requested.
- The EMA organises and EUnetHTA contributes to the workshop (November 2013) on parallel scientific advice in drug development.

### ***Scientific and methodological guideline development***

- Regular (half-year; at the joint meetings) mutual updates on the developments in this activity area at the EMA and within EUnetHTA.
- The EMA to continue providing EUnetHTA an overview of EMA guidelines under public consultation, on a regular basis.
- Individual EUnetHTA members to explore possibilities for providing their input to the public consultations on EMA guidelines.
- Explore ways of the EMA contributing to the development of disease-specific guidelines to be undertaken by EUnetHTA.

### ***Post-licensing (post-authorisation) data generation***

- Regular (half-year; at the joint meetings) mutual updates on the developments in this activity area at the EMA and within EUnetHTA.
- Explore coordinated approaches on post-authorisation data collection, such as possible parallel advice, and explore the possibility of developing or testing methodologies for post-authorisation data collection that are relevant to support regulatory and HTA activities.

- Develop involvement of the EUnetHTA partners in the EMA's ENCePP Working Group on Health Technology Assessment, with the aims of avoiding duplication of activities and of creating synergies.

### ***Availability of clinical study data***

- EUnetHTA to support the EMA's efforts in ensuring transparency of clinical trials, and to comment on the draft EMA clinical trials publication and access policy.

### ***Orphan medicinal products***

- The EMA to provide updates on transparency proposals for orphan medicinal products at future meetings.
- Promote dialogue on coordinated approaches to address issues specific to orphan medicinal products with regard to post-authorisation activities relevant to supporting regulatory decisions and HTA recommendations.

### ***Cooperation in pilot projects***

- Explore and implement, if/when relevant, joint participation in pilot projects of mutual interest to both parties and/or joint participation in pilot projects initiated by third parties (e.g. IMI).

### ***Cooperation in specific pilot projects of EUnetHTA JA2***

- EUnetHTA to update on the developments in and experiences from the pilot projects of rapid and full HTAs on medicinal products.
- EMA and EUnetHTA to explore to which extent information before and directly after the CHMP opinion can be exchanged for the timely use in the pilot projects of rapid and full HTA on medicinal products, and to further optimise presentation of information in regulatory documents for later use in HTA.

### ***Conferences, workshops, and seminars/meetings***

- Cooperation in developing a programme of, and participation in, events relevant and appropriate for contribution by both parties.

## **Regular EMA-EUnetHTA joint meetings**

EMA-EUnetHTA meetings will be held on a half-year basis and hosted interchangeably by the EMA and EUnetHTA. Minutes of the meetings will be made publicly available on the websites of the EMA and EUnetHTA.