20 January 2020
EMA/689902/2019
Media and Public Relations

Press release

Ten recommendations to unlock the potential of big data for public health in the EU

The joint Big Data Task Force of EMA and the Heads of Medicines Agencies (HMA) proposes ten priority actions for the European medicines regulatory network to evolve its approach to data use and evidence generation, in order to make best use of big data to support innovation and public health, in a report published today.

Big data are extremely large, rapidly accumulating datasets captured across multiple settings and devices, for example through wearable devices, electronic health records, clinical trials or spontaneous adverse reaction reports. Coupled to rapidly developing technology, big data can complement the evidence from clinical trials and fill knowledge gaps on a medicine, and help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems. The rapidly changing data landscape forces regulators to evolve and change the way they access, manage and analyse data and to keep pace with the rapid advances in science and technology.

"I look forward to working with the European Commission and national competent authorities to see how these concrete proposals can be implemented to better harness the potential of big data. This will help to further strengthen the robustness and quality of the evidence upon which we take decisions on medicines," said Guido Rasi, EMA's Executive Director.

"The changes proposed will require investment to build up capacity and skills at national and EU level. This is needed if we want to establish the EU network as a reference for data-driven decision-making," said Thomas Senderovitz, Chair of the HMA Management Group.

The report makes several recommendations out of which ten are viewed as priorities. The most ambitious of these top ten recommendations is the establishment of an EU platform to access and analyse healthcare data from across the European Union (Data Analysis and Real World Interrogation Network, or DARWIN). This platform would create a European network of databases of verified quality and content with the highest levels of data security. It would be used to inform regulatory decision-making with robust evidence from healthcare practice.

Other recommendations are intended to enhance guidance and resources within the EU regulatory network for data quality and data discoverability (choice of key metadata) and to build up computing and analytical capacity. The joint task force advises to develop the skills to process and analyse big

data within the network through training to enhance the capacity of regulators to assess applications for the authorisation of medicines that use big data sources as part of the evidence on benefits and risks. It proposes to establish a learning initiative to track and review outcomes of these types of submissions.

The report also emphasises the need to ensure data are managed and analysed within a secure and ethical governance framework, and in active dialogue with key EU stakeholders including patients, healthcare professionals, industry, Health-Technology Assessment bodies (HTAs), payers, device regulators and technology companies. All these activities should be done in collaboration with international initiatives on big data.

Established in 2017, the HMA - EMA Joint Big Data task force is composed of experienced medicines regulators and data experts appointed by national competent authorities, EMA and the European Commission. The first phase of its work -published in early 2019- reviewed the landscape of big data and identified opportunities for improvements in the operation of medicines regulation. Published today, the practical suggestions made in the second phase of its work aim to inform strategic decision-making and planning by the HMA and EMA and to contribute to the upcoming EU Network Strategy to 2025. The implementation of the recommendations is being considered in full consultation with the European Commission services.

Notes

1. This press release, together with all related documents, is available on the two agencies' websites.
2. More information on big data in medicines' regulation and the HMA/EMA Task force on big data is available here.

Contact our press officers

Heads of Medicines Agencies Permanent Secretariat
c/o Paul-Ehrlich-Institute
Paul-Ehrlich-Straße 51-59
63225 Langen
Germany
E-mail:hma-ps@pei.de

EMA press office
Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu