EUROPEAN COMMISSION
DG HEALTH AND FOOD SAFETY
DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth-units

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Topic 4.4.3. Activities on Big Data - EMA

Issue at stake
The increasing volume, complexity and diversity of data now being captured across multiple settings and devices offers opportunities for medicines regulation in terms of a better understanding of diseases, medicines and the performance of products in the healthcare system. However, such data also brings unknowns around data quality and hence the acceptability of such insights as evidence for regulatory decision-making is uncertain. A regulatory strategy is required to understand how and when in the product life cycle the utilisation of such data can bring value.

Summary
Across the Member States of the EU there is rich and diverse healthcare data held in electronic form. This includes electronic health records, immunisations, laboratory diagnostic data, prescribing and dispensing data, disease registries, health determinant data, and datasets of civil registrations including cause of death. Such large data sets may potentially bring a greater degree of precision and accuracy to regulatory decision making, and combining data across Member States provides valuable information for example on national variation, on the effectiveness and impact of different public health interventions and strategies, on larger numbers of patients critical for rare disease/exposures. Increasingly in the future, linkage of clinical data with 'omics data will be critical for delivering novel mechanistic insights and data from wearables and m-health devices may offer a personalisation of the benefit-risk of a medicine and a prediction of an individual's disease trajectory not currently possible. As such, these data hold huge potential as a source of evidence to support decision-making across the Commission and the EU Health Agencies, as well as the Member States and health stakeholders. However, there are significant challenges in its utilisation; healthcare data across Europe is heterogeneous in both standards, content, structure and scope and hence difficult to link and integrate meaningfully. Moreover, understanding if the derived evidence is sufficient robust to support decision making requires knowledge of data sources, their quality and their relevance for the European population. A number of initiatives are ongoing to address these issues from the perspective of the regulatory network including the HMA-EMA Joint Big Data taskforce and a range of national and EMA driven initiatives. The collaboration of all relevant stakeholders will be key in driving successful and sustainable results.

Format of procedure in the eHealth Network meeting
The Commission co-chair introduces the agenda topic. EMA will present activities on big data, followed by a discussion.