Recommendations for a path towards understanding the acceptability of evidence derived from 'Big data' in support of the evaluation and supervision of medicines by regulators were published on 15 February as part of a summary report of the Heads of Medicines Agencies (HMA) - EMA Joint Big Data task force .

The recommendations and associated actions set out what needs to be addressed, but the mechanisms by which this may be achieved requires further focused work over the coming year. Stakeholders are invited to submit feedback and observations on the recommendations to inform the upcoming work of the group.

Massive amounts of data are generated on a daily basis through wearable devices, electronic health records, social media, clinical trials or spontaneous adverse reaction reports. There is no doubt that insights derived from this data will increasingly be used by regulators to assess the benefit-risk of medicines across their whole lifecycle. However, in order to benefit from and make prudent use of the data collected, regulators need a deeper understanding of the data landscape.

Stakeholders and members of the public are invited to submit their comments on the core recommendations in the summary report (not to exceed 1,000 words) to bigdatasec@dkma.dk until **15 April 2019**. In particular, views on prioritisation of future actions would be welcomed.

Further information and related documents are available by clicking here.

Please note that EMA may collect and further process some personal data of stakeholders and interested parties who submit contributions to the consultations. For more information, see Specific privacy statement for public consultations.

For more information on the European regulatory system for medicines, please click here (brochure available in all languages).

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With kind regards,

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