U.S. Food and Drug Administration European Commission **European Medicines Agency**

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PUBLIC STATEMENT
EU (European Commission and EMEA) and FDA agree on guiding principles for joint FDA EMEA voluntary genomic data submission briefing meetings

The European Commission (EC), the European Medicines Agency (EMEA) and the U.S. Food and Drug Administration (FDA) have agreed to a procedure for joint FDA EMEA briefing meetings with sponsors following voluntary submission of genomic data. The procedure has been agreed to within the scope of the confidentiality arrangements between the EC/EMEA and the FDA and is based on prior experience with joint briefings.

Much of pharmacogenomic data are of an exploratory nature and not required to be submitted to health authorities in most cases. However, voluntary submissions of such data is encouraged as a means to ensure that regulatory authorities are familiar with the issues arising from the integration of pharmacogenomics in drug development and to ensure that industry has an opportunity to hear scientific perspectives from the regulatory authorities. These joint voluntary submissions are important for regulatory agencies to ensure that evolving policies are based on the best science, to help in the development of common approaches to genomics in drug development, and to facilitate the use of pharmacogenomic tests during global drug development.

Voluntary genomic data submission packages will be reviewed by the FDA's Interdisciplinary Pharmacogenomic Review Group (IPRG) and the EMEA Pharmacogenetics Working Party (PGWP). Contact information for submitting a request for a joint voluntary genomic data submission meeting can be found in the guiding principles document.

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NOTES:

1. The 'guiding principles – processing joint FDA EMEA voluntary genomic data submissions (VGDSs) within the framework of the confidentiality arrangements' can be found here.
2. Information about the EMEA Pharmacogenetics Working Party can be found here.
3. Information about the FDA Interdisciplinary Pharmacogenomic Review Group can be found here.
4. The confidentiality arrangements allow the EC/EMEA and the FDA to exchange information as part of their regulatory processes. The types of information covered by the arrangements include legal and regulatory issues, scientific advice, orphan drug designation, inspection reports, marketing authorisation procedures and post-marketing surveillance. The arrangements cover medicinal products that are subject to evaluation or authorised under the centralised procedure as well as medicinal products that are authorised at national level by the EU Member States and that are subject to official European Community arbitrations and referrals.
5. More information on the work of the three bodies can be found on the Internet. For the European Commission's pharmaceutical unit click here; for the U.S. Food and Drug Administration click here; for the European Medicines Agency click here

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