New journal series provides insights on European medication-related guidelines

May 30 2018

A new series published in the *British Journal of Clinical Pharmacology (BJCP)* aims to help clinicians, researchers, and patients access and understand recent guidelines and regulatory documents issued by the European Medicines Agency (EMA), which oversees the scientific evaluation and safety monitoring of medicines in the European Union.

"We felt that the rich information available at the EMA with regard to drug development deserved a wider audience than drug companies involved in registering their products," said Professor Adam Cohen, Editor-in-Chief of the journal and the Director of the Centre for Human Drug Research, in The Netherlands. "Every treatment of a patient is also a small clinical trial, and clinical pharmacologists need to know about the EMA guidelines," added Professor Cohen, who co-authored an editorial introducing the series. "Reading our commentary series, which provides immediate hyperlinks to the guidelines, is an efficient way of disseminating the existing knowledge about drug development in a certain therapeutic area. This will be useful for practicing clinicians, patients, and researchers."

The new series, which was developed in collaboration with the EMA, aims to provide an annotated version of some relevant EMA guidelines and regulatory documents, thereby helping them to reach a wider audience and opening a forum for discussion.

The first commentary in the series focuses on the First in Human guideline that was revised, taking into account the lessons learnt from the

recent tragic events in a trial in France. "The revised guideline aims to ensure the safety and wellbeing of trial participants going forward, taking into account the increasing complexity of early clinical trials," said co-author Milton Bonelli, MD, Head of Clinical Pharmacology and Non-Clinical Support at the EMA. "We hope that this publication will provide further understanding of the provisions included to all professionals involved in this key part of medicines development."

All future commentaries in the series will share the same format: starting with a summary of the main points covered in the guideline, followed by experts' opinions on relevant and controversial issues in the guideline and where it may change current practice. Throughout the commentary, hyperlinks will guide readers to the relevant sections of the guideline.

"We at the EMA recognise that many of our regulations, guidances, and evidentiary standards have direct relevance to the scientific community," said Hans-Georg Eichler, MD, MSc, who is the EMA's Senior Medical Officer. "We are therefore grateful to have this platform with BJCP, which will help us better explain our scientific positions and policies, thereby supporting clinical investigators and academic developers of new medicines."

More information: "Annotated guidance to the European Medicines Agency (EMA) guidelines and regulatory documents. A new series of the BJCP." Adam Cohen and Sergio Bonini. *British Journal of Clinical Pharmacology*. Published Online: 31 May 2018, DOI: 10.1111/bcp.13599

"Commentary on the EMA Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products." Joop van Gerven and Milton Bonelli. *British Journal of Clinical Pharmacology*. Published Online: 31 May 2018, DOI: 10.1111/bcp.13550

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