New worldwide regulatory framework proposed for pharmaceuticals

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Professor Sam Salek at the University of Hertfordshire has today (1st June) published a "universal framework" for global regulatory agencies and the pharmaceutical industry to use when weighing up the benefits versus risks of bringing new medicines to market.

In the book *Benefit-Risk Assessment of Medicines* – a collaboration with Professor Stuart Walker, Centre for Innovation in Regulatory Science, London and Dr James Leong, Centre of Regulatory Excellence, Singapore - Professor Salek calls for the framework to be taken up worldwide, to speed up the currently disjointed decision-making process around the commissioning of new drugs.

It is hoped that the framework will globally streamline practices and give all patients worldwide equal access to new, potentially life-saving treatments.

Prof Salek said: "This new universal framework could have a huge global impact on policy. The issue of benefit-risk assessment when deciding whether to bring new medicines to market is a hot topic and for years regulatory bodies have been struggling to find the best model to use, meaning that a huge gap exists between countries when it comes to patients accessing new medicines.

"We have developed a comprehensive system that can be adopted universally, so that the currently non-structured non-transparent decision-making process on new medicines can be streamlined and speeded up.

We hope that this will result in significant and potentially life-saving drugs reaching patients more quickly and ultimately all regions of the world being on a level playing-field."

Over the past decade, pharmaceutical companies and regulatory agencies have been reviewing the benefit-risk assessment of medicines with a view to developing a universally recognised, structured, standardised approach, although until now this has not existed.

The universal framework examines a number of factors, to decide whether or not the benefits of a medicine outweigh the risks, including efficacy, clinical relevance, safety and responsiveness of patients to treatment.

The book also reviews the strategies of major regulatory authorities (US FDA, EMA, Australia and Health Canada) for communicating benefit-risk decisions to stakeholders and how they can be improved using the newly developed template.

Professor Salek together with his collaborators has also published a second book, Pharmaceutical Regulatory Environment:

Challenges and Opportunities in the Gulf Region, which examines the regulatory review practices in the seven Gulf Cooperation Council states, namely Kuwait, Bahrain, Oman, Qatar, Saudi Arabia and the United Arab Emirates.

The Middle East represents the next growth market for the global biopharmaceutical industry but to date there has been limited information about the regulatory review processes employed in these countries. A thorough examination of the strategies currently being implemented by the Gulf States is considered critical to the future regulatory environment in this region.

This book compares national and centralised procedure practices and key performance metrics, including current approval times, review practices and pharmacovigilance standards, in the seven Gulf States. Opportunities for an improved regulatory system are identified, which, if fully implemented, could have a significant impact on patients' access to new medicines.

Provided by University of Hertfordshire