Consolidated Joint ICMRA statement Ebola

Medicines regulators to work together internationally to find innovative solutions to facilitate evaluation of and access to potential new medicines to counter Ebola outbreaks

The largest, most severe and most complex outbreak of Ebola virus disease in history is highlighting the absence of authorised medicines to treat or prevent this terrible disease affecting people in a number of countries in West Africa.

In the face of this outbreak, medicines regulators worldwide have committed to enhanced cooperation with the World Health Organization (WHO) and between regulatory agencies to encourage submission of regulatory dossiers and evaluation of the submitted information on potential new medicines. The aim is to accelerate access to investigational treatments for patients most in need during the current outbreak. The enhanced cooperation also aims to ensure that in the future, public health authorities in countries affected by Ebola have safe and efficacious medicines at their disposal, and so strengthen their ability to respond effectively to outbreaks and to save lives.

This pledge was made by members of an interim International Coalition of Medicines Regulatory Authorities (ICMRA) in the margins of the 16th WHO International Conference of Drug Regulatory Authorities (ICDRA) held in Rio de Janeiro from 24-29 August 2014.

Over the past decade, research has been carried out into medicines and vaccines to protect against or to combat Ebola. Some of the investigational medicines or vaccines studied have shown encouraging results in the laboratory and in animal models. However, they have not yet been evaluated for safety and efficacy in humans for the treatment or prevention of Ebola virus disease and may pose risks that have not yet been identified. In addition, these products may be ineffective and it is even possible that some of these investigational medicines might worsen the ultimate outcome of Ebola virus disease.

The role of medicines regulators is to evaluate the detailed evidence generated in clinical studies and to determine that the benefit risk balance of using those medicines is positive for patients in need of prevention or treatment of disease. The countries most affected by the current outbreak of Ebola virus disease often do not have reliable systems for routine data collection. In the current crisis, it is a great challenge to come up with practical solutions to ensure that meaningful data is collected and assessed so that decisions on the benefits and risks of medicines can be taken on the basis of limited scientific evidence, avoiding undue risks to patients.

Regulatory agencies therefore have pledged at their Rio de Janeiro meeting to join their expertise to consider evidence from a wide range of sources to allow for decision-making under a greater degree of scientific uncertainty.

Although the development of medicines against Ebola is ongoing, the majority of patients affected by the virus do not have access to these treatments. Regulators therefore also stress that the search for pharmaceutical interventions must not detract from the need to strengthen basic healthcare measures such as fluids and electrolytes management and to carefully observe the impact and contribution of these measures in the overall response to the disease.

It is important to note that the most effective way to combat the current Ebola outbreak is through basic public health measures, such as good infection control, isolation, contact tracing, and use of personal protective equipment.

These issues will be discussed at a WHO CONSULTATION on potential Ebola therapies and vaccines on 4-5 September in Geneva with regulatory experts from leading agencies worldwide expected to play a key role.

About ICMRA

The ICMRA is a voluntary, high-level, strategic coordinating, advocacy and leadership entity of regulatory authorities that work together to

- address current and emerging human medicine regulatory and safety challenges globally, strategically and in an on-going, transparent, authoritative and institutional manner
- provide direction for areas and activities common to many regulatory authorities' missions
- identify areas for potential synergies
- wherever possible, leverage existing initiatives/enablers and resources

ICMRA Members

Australia (TGA), Brazil (ANVISA), Canada (HPFB-HC), China (CFDA),Europe (EMA and DG-SANCO), France (ANSM), Germany (PEI), Ireland (HPRA), Italy (AIFA), Japan (PMDA and MHLW), Korea (MFDS), Mexico (COFEPRIS), Netherlands (MEB), New Zealand (Medsafe),

Nigeria (NAFDAC), Singapore (HSA), South Africa (MCC),Switzerland (Swissmedic), United Kingdom (MHRA), United States (FDA), WHO

Reference

Introducing the ICMRA (PDF)