Zika Virus Disease Press Release - *9.2.2016*

Global medicines regulators pledge support to tackle Zika virus disease

The International Coalition of Medicines Regulatory Authorities (ICMRA) has pledged its support to the World Health Organization (WHO) in countering the Zika outbreak. The WHO has declared that Zika constitutes a Public Health Emergency of International Concern.

ICMRA brings together 21 medicines regulators[1] from every region in the world, and its members are working together to fight against Zika virus disease, building on ICMRA's collaborative work on Ebola.

Priorities are to support the rapid development of diagnostic tests, including reference material to assure comparability of results, as well as vaccines and treatments against Zika virus disease. This will be achieved through enhanced international collaboration and by providing scientific advice in the development of such products. Any investigational medical products must be evaluated for quality, safety and efficacy and it is the regulator's role to ensure that the benefits of any new medical product outweigh its risks.

As there is no specific vaccine or treatment currently available, and development of these is at an early stage, ICMRA members are exchanging information on the emerging data about Zika virus infection links to serious health concerns and will work together to review possible investigational vaccine and treatment options, with the goal of expediting their development. They will also ensure the regulatory

[1] ICMRA is an international executive-level coalition of key regulators from every region in the world. It provides a global strategic focus for medicines regulators and gives strategic leadership on shared regulatory issues and challenges. Priorities include coordinated response to crisis situations. Members of the ICMRA include: Therapeutic Goods Administration (TGA), Australia; National Health Surveillance (ANVISA), Brazil; Health Products and Food Branch, Health Canada (HPFB-HC), Canada; China Food and Drug Administration (CFDA), China; European Medicines Agency (EMA) and European Commission - Directorate General for Health and Food Safety (DG - SANTE), European Union; French National Agency for Medicines and Health Products Safety (ANSM), France; Paul-Ehrlich-Institute (PEI), Germany; Health Product Regulatory Authority (HPRA), Ireland; Italian Medicines Agency (AIFA), Italy; Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan; Ministry of Food and Drug Safety (MFDS), Korea; Federal Commission for the Protection against Sanitary Risks (COFEPRIS), Mexico; Medicines Evaluation Board (MEB), Netherlands; Medsafe, Clinical Leadership, Protection & Regulation, Ministry of Health, New Zealand; National Agency for Food Drug Administration and Control (NAFDAC), Nigeria; Health Sciences Authority (HSA), Singapore; Medicines Control Council (MCC), South Africa; Medical Products Agency, Sweden; Swissmedic, Switzerland; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom; Food and Drug Administration (FDA), United States.

processes are as efficient as possible to support the development and delivery of effective and safe medical products to populations in need worldwide.