IFPMA statement

Our take on Zika virus

Geneva, 3 March 2016 − The International Federation of Pharmaceutical Manufacturers and Associations, IFPMA, which includes some of the world's leading manufacturers of vaccines, confirms that there is currently no approved vaccine or treatment for Zika virus (ZIKV) available.

On 1 February 2016, the World Health Organization (WHO) declared the ZIKV outbreak. Over recent weeks, increasing evidence is emerging of a link between ZIKV infection and microcephaly, as well as Guillain-Barré syndrome. In light of these announcements, our vaccines manufacturers are actively assessing the situation together with their partners in this area.

Our vaccines manufacturers along with other members have mobilized resources and are making their utmost effort to develop a variety of potential diagnostics, therapeutic, and vaccines to respond to the ZIKV public health emergency.

Several member companies have indicated that they are considering the potential of pursuing ZIKV vaccine candidates based on work previously carried out against other flaviviruses, such as West Nile and dengue fever, including:

- one company that has started working on a vaccine research and development project targeting the prevention of ZIKV infection;
- one company that has confirmed deploying their teams on-site to investigate the set-up of such research and development project; and has stated the need for a consortium of organizations to take on Zika;
- Other member companies that are looking at how their established R&D and industrial infrastructure can be rapidly leveraged to help understand the spread of ZIKV and contribute to speeding up the identification of a vaccine candidate for further clinical development .

Our vaccines manufacturers emphasize that vaccine development is a lengthy and laborious process, typically taking 10-15 years. However, those companies that are able to leverage existing experience, network and infrastructure gained from R&D for the same family of viruses may be able to halve the time needed to develop a vaccine for ZIKV. Even with an available vaccine candidate for ZIKV, their safety in humans is to be tested with extraordinary measures deployed by regulators and manufacturers to fast-track the process with continued ethical oversight. It remains therefore premature to say how long development might take or speculate on the outcome.

We will follow closely the WHO Emergency Committee and regional meetings planned over the coming months, which will further define the priority areas for research. Where our member companies have competencies, they will join governments and academia in the coordinated global effort to quickly develop diagnostics, therapeutics, and vaccines for ZIKV.

IFPMA holds that ZIKV, along with other recent public health emergencies such as Ebola, shows it is essential that the world is better prepared and takes a proactive approach to identify and respond to outbreaks. Resilient health systems are critical to preventing future crises, which otherwise result in devastating consequences for human health, economies, and global security. Investing in human resources

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and general infrastructure and increasing per-capita spending on health, will lay the foundation for control of similar epidemics. It is also fundamental that countries refrain from imposing measures making difficult and burdensome for researchers across the globe to get access to pathogens' biologic materials.

IFPMA supports the ongoing constructive working relations between WHO and external stakeholders, including industry. These are necessary interactions to ensure the global community can effectively respond to pandemic emergencies and for effective and timely coordination of tools to fight dangerous pathogens. This has been critical in the efforts to develop an Ebola vaccine and the actions taken should be reviewed to identify the successes and remaining gaps, as well as lessons learned, for all global health community stakeholders.

Our biopharma industry is actively involved in the fight against diseases affecting vulnerable populations. In 2015, it counted 186 compounds in development for neglected tropical diseases (NTDs). The industry's R&D programs and pipelines show commitment to addressing these pressing health challenges. Most of these R&D projects are carried out through innovative collaborations with non-industry partners.

Background

Until recently, Zika virus (ZIKV) was considered very rare and seemingly benign. However, in May 2015, the Pan American Health Organization (PAHO) issued an alert regarding the first confirmed ZIKV infection in Brazil. Since then it has spread across Latin American and the Caribbean.

For many, the ZIKV is harmless; an estimated 80 percent of people do not develop any symptoms after being infected. For those who do develop symptoms, they are usually mild — a rash, headaches, pain in the joints and bones, and fever.

However, over the past year, public health officials believe there is growing evidence to suggest that ZIKV may be linked to birth defects in newborns and neurological conditions in adults. At the moment, epidemiological data is scarce, and if there is an association of infection with birth malformations and neurological syndromes, it is not known what the level of risk is for pregnant women. Concern among public health bodies is high since there are currently no effective interventions to control vector mosquitoes.

On 1 February 2016, the first meeting of the Emergency Committee was convened by the World Health Organization (WHO) regarding clusters of microcephaly cases and other neurologic disorders in some areas affected by ZIKV. The Committee advised that the recent clusters of cases in Brazil, following a similar cluster in French Polynesia in 2014, constitute a Public Health Emergency of International Concern (PHEIC). World Health Organization (WHO) believes that by declaring a "public health emergency of international concern (PHEIC)" for the ongoing outbreak of the ZIKV and its "strongly suspected" link to microcephaly in Latin America, governments, researchers and industry would make a coordinated global effort to quickly develop diagnostics, therapeutics and vaccines.

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