ICMRA statement about confidence in vaccine safety and effectiveness (for healthcare professionals)

The benefits of vaccination can be hard to explain to the lay public. People who are not sick might not recognize the role of vaccines in disease prevention and in reducing disease spread as vaccines are preventative for infectious diseases rather than curative or symptom controlling in nature and thus do not have a visible effect on those already ill.

Younger adults also have had little personal experience with family members or friends affected by serious vaccine-preventable diseases, or may feel invincible. There is also a significant amount of incorrect, and potentially deadly, misinformation about the safety and effectiveness of vaccines perpetuated widely through social media. This may lead some to be hesitant or express concerns about vaccination, or even be strongly opposed to it. They sometimes describe themselves euphemistically as “vaccine choice”, “vaccine risk aware” or even “pro-safe vaccine”, which are misleading terms and dangerous for public health.

The World Health Organisation (WHO) has listed vaccine hesitancy as one of the top 10 global public health threats. Vaccination currently prevents 2-3 million deaths per year. That could increase by 1.5 million, if global vaccination rates were increased.

Purpose

This International Coalition of Medicines Regulatory Authorities (ICMRA)* statement aims to provide healthcare professionals with important messages regarding vaccines and vaccination, as well as to reiterate that vaccines undergo robust scientific evaluation by regulators to determine their safety and effectiveness and also continue to be monitored after approval.

Messages that may be used to support dialogue with other healthcare professionals and patients

- Emphasise that vaccines prevent diseases:
    - Vaccines prevent illnesses and deaths due to vaccine preventable diseases
    - Remind that if people are not vaccinated, harmful infectious diseases such as measles, pertussis, polio or influenza will continue to occur or spread. With vaccination, these diseases could be prevented.

    - Vaccines that are available to the public have been assessed extensively for safety and shown to be effective. But for the unvaccinated, diseases such as cervical cancer, measles, pertussis, polio, tetanus or influenza can be fatal or have long-lasting effects on health.

- Emphasise that the benefits of a particular vaccine outweigh potential risks that may be associated with it:
    - Vaccines are usually given to large numbers of healthy people, mostly children, to prevent disease. Rigorous safety standards are in place to ensure that vaccines prevent disease while minimizing the potential risk of harm

- Emphasise that getting vaccinated is part of a wider social responsibility – a decision not to get vaccinated may be seen as a personal choice - but because of herd immunity it can seriously affect others. Low vaccination rates can lead to an epidemic of preventable diseases or to a breakdown of herd immunity because the exposure of the population to the disease increases. When this happens, vulnerable people such as infants who are too young to be vaccinated or immunocompromised people who cannot receive certain vaccines or who respond poorly to vaccination are more readily infected. For herd immunity to be effectively established and maintained, high vaccination coverage, up to 95% of the population for certain diseases such as measles is required.
- Describe your own decision to vaccinate your family - personal stories are powerful.
- Actively call out vaccine misinformation such as the false assertion about the link between the measles-mumps-rubella vaccine and autism. Because of vaccine misinformation, we are now seeing a rise in diseases that were previously almost eradicated, e.g., measles. WHO's Vaccine Safety Net is there to help internet users find reliable vaccine safety information tailored to their needs.

Vaccines and the regulatory process

Vaccines undergo a rigorous scientific evaluation by regulatory authorities. Each vaccine is rigorously assessed for safety, quality and effectiveness to determine whether it can be authorised, using all available scientific evidence from animal data, human clinical trials, and manufacturing information to assess its benefits and risks.

Regulators assess vaccines and their ingredients before they can be placed on the market. Vaccines contain antigens, active ingredients from the virus or bacterium that cause the disease that is being protected against by the vaccine. In some cases, vaccines contain other ingredients such as adjuvants to stimulate the body's immune response to make the vaccine more effective, or stabilisers that keep the vaccine active during storage. When evaluating a vaccine for safety and quality,

regulators take all of the ingredients of a vaccine into account, including the active ingredients as well as other substances.

The decision to approve new vaccines, as well as for medicines for human use, is often informed by independent advice. Regulators may seek independent expert advice from scientific expert committees to inform their decision whether to approve a vaccine. These committees are made up of experts in science, medicine and public health.

Vaccines are of proven pharmaceutical quality. Vaccines are manufactured according to stringent regulatory standards. Vaccines are required to meet manufacturing high quality standards, and batches may undergo laboratory testing by individual national regulatory authorities before they can be supplied.

Vaccines are among the most successful interventions to prevent and control infectious diseases and ensuring their safety is vital. Vaccines are usually given to large numbers of healthy people, mostly children, to prevent disease. Rigorous safety standards are essential to ensure that vaccines bring about their protective effects while minimising the potential risk of harm. Regulators will only approve a vaccine if its benefits outweigh potential risks for the whole lifecycle of the vaccine.

Regulators, often in collaboration with public health authorities, rigorously monitor safety, quality and effectiveness of vaccines after they are approved for use. Safety monitoring includes passive surveillance (receiving and assessing any adverse event reported by consumers, parents or health professionals) as well as active surveillance systems used to investigate potential associations between vaccines and adverse events. Regulatory authorities receive adverse event reports from consumers, health professionals and vaccine manufacturers, and information is shared between regulators internationally such as through discussions with WHO's Global Advisory Committee on Vaccine Safety.

- ➔ **Report any suspected adverse reaction to vaccines and support your patients in reporting, to improve the post-market continuous evaluation of benefit/risk**

If a potential safety issue is identified, an investigation is launched. A strong contribution from health-care professionals to report adverse events following immunisation (AEFIs) is highly appreciated.

Regulators, in collaboration with public health authorities, are able to take decisive action if a safety issue is identified. These actions might include issuing safety communications for patients, healthcare professionals and the community; updating the product information or consumer information for the vaccine; preventing the release of a particular batch of vaccine; and, taking other regulatory actions as necessary.

Many vaccines have been used safely to protect millions of people for many years. High quality studies over many years have compared the health of large numbers of vaccinated and unvaccinated children, and an increasing number of vaccines have been assessed for safety in pregnant women and elders. Some

vaccines have contraindications or precautions for their use to ensure that they are not given to people who have a higher risk of serious adverse events.

Globally, the public can have confidence in the rigour of the process used to scientifically evaluate the safety and effectiveness of vaccines to make a determination whether to approve them for use in the wider population.

* ICMRA brings together 29 medicines' regulatory authorities[1] from every region in the world, with the WHO as an observer. Medicines' regulators recognise their important role in facilitating the provision of access to safe and effective high-quality medicinal products that are essential to human health and well-being. This includes ensuring that the benefits of vaccines outweigh their risks. 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 National Medical Products Administration (NMPA), 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; Central Drugs Standard Control Organisation (CDSCO), India; 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 [HC](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 and the World Health Organization as an observer. Associate members include: Austrian Medicines and Medical Devices Agency (AGES); Danish Medicines Agency; Israel Office of Medical Technology; Health Information and Research (MTHIR); Poland Office of Registration of Medicinal Products and Biocidal Products (URPLWMiPB); Russia Roszdravnadzor; and, Spain Agencia Española de Medicamentos y Productos Sanitarios (AEMPS).

[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