ICMRA statement about confidence in vaccines (for the general public)

Globally, vaccination prevents 2-3 million deaths per year, according to the World Health Organisation's (WHO) calculations. As the world anxiously awaits a vaccine to combat the COVID-19 pandemic, there is perhaps no more appropriate time for the International Coalition of Medicines Regulatory Authorities (ICMRA) to highlight the importance of vaccines.

ICMRA presents this statement on vaccines to:

- highlight the benefits and safety of vaccines for you and your family
- call attention to the fact that it is everyone's responsibility to get vaccinated. We vaccinate not only to protect our family, friends and community but also to protect future generations
- explain that global regulators have robust, scientific, independent processes in place to determine the safety, quality and effectiveness of vaccines, and vaccines continue to be monitored once administered to the public.

Vaccines save lives. Vaccines protect you and the people around you from serious and life-threatening infectious diseases that used to kill millions of people every year. Diseases like the measles, whooping cough, polio, tetanus and influenza (the seasonal flu), are still killing many thousands of people in vulnerable populations every year and causing long lasting health problems in many more, where vaccines are not available. Although we do not yet have a vaccine to prevent COVID-19, the development of such a vaccine is one of the highest public health priorities today, because it can help protect everyone against this major threat.

Getting vaccinated is an act of responsibility. There are some people in the community who cannot be vaccinated because they are too young, too sick or their immune systems are weakened. They may be family members or people you know – your grandparent, your neighbour's newborn, a colleague with a chronic disease. If we are not vaccinated, diseases will spread to these people with potentially fatal outcomes. In many countries, the Ministry of Health, in collaboration with the World Health Organization, decide which vaccines are added to the national immunisation program, taking into consideration multiple factors, including safety, quality, suitability, affordability and cost-effectiveness.

Vaccines undergo rigorous scientific evaluation by regulatory authorities. Vaccines are rigorously reviewed and tested to make sure there is evidence that they are safe, effective and high quality before they are approved for use and administered to the public. Regulators use the best available scientific evidence from clinical trials and manufacturing information to assess the benefits of each vaccine. Regulators may decide to solicit independent expert advice from vaccine scientific committees. The decision of whether or not to approve each vaccine for use is made by the government regulator and is independent of the pharmaceutical industry.

Vaccines are medicines of continuously proven pharmaceutical quality. Vaccines are manufactured according to the same high standards as other medicines. Vaccine manufacturers are required to meet manufacturing quality standards, and as a further check, batches may undergo laboratory testing by individual national regulatory authorities before they can be supplied to the public.

Assuring vaccine safety is an extremely important part of their regulation. Regulators will only allow the use of a vaccine if its benefits outweigh potential risks, monitoring them for the whole lifecycle of vaccines. Vaccines are given to large numbers of people (including children and pregnant women), most of whom are healthy. Very high safety standards are essential to minimise any potential risk of harm.

Regulators assess all ingredients in a vaccine before it can be supplied. Beside the active ingredient(s) deriving from the target virus(es) or bacterium(a), vaccines may contain, other substances used to make the vaccine more effective or to stabilise it during storage. When evaluating a vaccine for safety and effectiveness, regulators take all of the ingredients of a vaccine into account, including the active ingredients as well as other substances.

Each vaccine lot is individually tested by the National Control Laboratory. In addition to the quality tests performed by each manufacturer, vaccines belong to a special category of medicines which are also subjected to analytical testing by a governmental control laboratory before their use with the public.

Regulators and health authorities continue to rigorously monitor the safety, effectiveness and quality of vaccines after they are approved and released for use.

Regulators receive and follow up on adverse event reports from consumers, health professionals, and vaccine manufacturers. There are robust systems in place to monitor the safety of marketed vaccines to ensure adverse reactions are detected. Problems suspected with vaccines are thoroughly investigated. Regulators notify health professionals and the public if there is a safety concern for a particular vaccine.

Background

About vaccines

Vaccines are medicines that protect you and those around you against specific infectious diseases, such as measles, whooping cough, polio, tetanus, influenza and many others. Vaccination is the act of receiving a vaccine, which in most cases involves having the vaccine injected with a needle.

Vaccines can contain:

- inactivated viruses or bacteria
- severely weakened forms of viruses or bacteria
- small, purified components of viruses or bacteria.

After receiving a vaccine, your body's immune system can remember the virus or bacterium and fight off an infection much more effectively than if it was encountering the virus or bacterium for the first time. This will usually stop you from becoming infected with the disease, or if infected, significantly reduce the severity of your symptoms.

Some people experience minor side effects following vaccination, such as a mild fever and pain or swelling at the injection site that are usually short-lived. Serious side effects, like allergic reactions, are very rare. Countries have systems to collect reports of these adverse events following immunisation. Some vaccines have contraindications or precautions for their use. This helps ensure that particular vaccines are not given to people who may have a higher risk of serious adverse events.

About ICMRA

ICMRA brings together 29 medicines regulatory authorities from every region in the world, with the WHO as an observer. Medicines regulators recognise the importance of facilitating access to safe, effective, high-quality products that are essential to human health and well-being. This includes keeping the pace with advances in science needed to set standards and drive the decision-making process, as well as maintaining efficient regulatory processes that support the development and delivery of innovative medicinal products while ensuring that benefits of these products outweigh any associated risk.