Communication of the President of the Office of 05.07.2023 on the approval by the EMA of the joint statement on the safety of COVID-19 vaccines by the International Coalition of Medicines Regulatory Authorities (ICMRA)

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PREZES
Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

Grzegorz Cessak

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EMA has just endorsed a joint statement on the safety of COVID-19 vaccines issued by the International Coalition of Medicines Regulatory Authorities (ICMRA).

Evidence from more than 13 billion doses of COVID-19 vaccines administered worldwide shows that these vaccines aimed at protecting people from severe outcomes of COVID-19 have a very good safety profile in all age groups, including children and people with underlying medical conditions, immunocompromised patients and pregnant women. The vaccines have saved millions of lives worldwide by significantly reducing the risk of severe disease, hospitalisation and death from infection with SARS-CoV-2.

The statement also highlights that vaccines reduce the impact of long COVID based on several real-world data studies and that there is no safety signal from the very large data set held by international regulators suggesting that this condition is a possible side effect of COVID-19 vaccination.

While the vast majority of side effects of COVID-19 vaccines are mild and temporary, safety monitoring systems have identified some very rare (occurring in less than 1 in 10,000 people) but serious side effects. The statement emphasises that ICMRA countries have very solid safety monitoring systems that continuously collect and analyse reports of suspected side effects, and also robust measures in place to reduce the risk of harm from these side effects.

The statement draws attention to the devastating impact of false and misleading information about the safety of COVID-19 vaccines on public health, as it can result in deaths or severe disease if people avoid getting the vaccines they need. As there have been false claims on social media that COVID-19 vaccines are to blame for the excess deaths during the pandemic, the statement underlines the lack of any evidence to show that COVID-19 vaccines are causing excess mortality. Global regulators encourage people to get information from trusted sources, such as healthcare professionals, scientific sources and national medicines regulators.

ICMRA brings together 38 medicines regulatory authorities from every region in the world, with the World Health Organization (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 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.

More information available on the website: https://www.ema.europa.eu/en/news/global-regulators-confirm-good-safety-profile-covid-19-vaccines [1]

Grzegorz Cessak

President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Źródłowy URL: https://archiwum.urpl.gov.pl/pl/node/7690

Odnośniki
[1] https://www.ema.europa.eu/en/news/global-regulators-confirm-good-safety-profile-covid-19-vaccines