swissmedic

Efficacy of COVID-19 vaccination

As with all medicines, the efficacy, quality and safety of a vaccine must be demonstrated on the basis of results from clinical trials before it can be authorised. Swissmedic requires results from trials with animals and humans. The principal efficacy criteria to be assessed for vaccines include the formation of antibodies against the pathogen and the degree of protection against an illness in those who are vaccinated compared to non-vaccinated individuals.

Double-blinded clinical trials

For the COVID-19 vaccines, over 30,000 people in large-scale clinical trials were randomly assigned to groups and given either the vaccine or a placebo. Neither the study participants nor the investigators knew who had received what. Next, the risk reduction in the vaccinated individuals was compared with that in the non-vaccinated participants. The main criterion for authorisation was an efficacy level whereby the vaccine prevented COVID-19 in at least 50% of the vaccinated subjects. This goal was exceeded since symptomatic cases were prevented in far more than the specified target of 50% of cases (end of 2020 / start of 2021: reduction in relative risk of more than 90%). Therefore, the criteria for efficacy were satisfied. As regards safety, the side effects and their severity were compared between the placebo group and the vaccination group. The safety analysis after administration showed a distinctly higher reactogenicity (e.g. fever, pain) in the vaccine group compared to the placebo group. Following authorisation, the reports of serious and non-serious side effects and their incidence in vaccinated individuals were compared with the known incidence in a non-vaccinated population (e.g. for myocarditis, which was not observed in the clinical trials with the mRNA vaccines). If the incidence is higher in vaccinated individuals, even rare side effects can be identified, as was the case for myocarditis or urticaria. Swissmedic usually grants an authorisation if the expected benefit of the medicinal product outweighs its risks.

The authorisation process

The submitted authorisation applications for the COVID-19 vaccines were approved step by step (rolling submission). The authorisation process is fast-tracked in this rolling submission although, as with a standard process, all the steps of the review must be completed and all the data checked. The safety of patients is paramount, and the three most important requirements of safety, efficacy and quality were fully taken into account. For their part, the external experts of the independent scientific Swissmedic consultation committee (Human Medicines Expert Committee / HMEC) undertook a thorough review. They agreed with the internal assessment and recommended authorisation of the COVID-19 vaccines.

Market surveillance after launch

Demonstrating effective protection against adverse drug reactions requires a longer observation period and was confirmed by studies conducted by public institutions and in various population groups. The authorisation decisions included conditions that required the companies to submit documentation on long-term efficacy and safety after authorisation. These conditions were satisfied.

International cooperation

The criteria described above were the result of international cooperation with foreign regulatory authorities. Guidelines were jointly drawn up by, specifically, the International Coalition of Medicines Regulatory Authorities (ICMRA), the Access Consortium (Australian Therapeutic Goods Administration (TGA), Health Canada, Health Sciences Authority (HSA) Singapore, the UK Medicines and Healthcare products Regulatory Agency (MHRA), the World Health Organization (WHO), the Federal Drug Administration (FDA) and the European Medicines Agency (EMA). All newly obtained findings are constantly fed into the benefit-risk assessment, both for vaccines that have already been authorised and for the granting of new authorisations. Since over 13 billion doses of vaccines against COVID-19 had been administered worldwide by January 2023, an extensive database on the safety of these vaccines now exists. Based on the latest information, the vaccines have proved

to be effective against the existing variants, especially as they prevent serious cases of the disease, hospitalisations and fatalities. The benefit-risk profile continues to be extremely positive.