Medicines & Healthcare products Regulatory Agency

Research and analysis

Report of the Commission on Human Medicines Expert Working Group on COVID-19 vaccine safety surveillance

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Summary

In May 2020, the Commission on Human Medicines established an Expert Working Group (EWG) to advise the Medicines and Healthcare products Regulatory Agency (MHRA) on its safety monitoring strategy for COVID-19 vaccine(s).

The EWG held four meetings from May to October 2020, during which it considered proposals and methodologies for MHRA-led vigilance activities. Based on this advice, the MHRA has developed, and now has in place, a four-stranded approach to vigilance, which is summarised in this report

Background

Since the emergence of the COVID-19 pandemic, research and development of candidate vaccines to protect against the SARS-CoV-2 virus has gathered pace at global level. In the UK, a Government Vaccine Task Force (VTF) has been established to expedite and co-ordinate efforts to research, produce and supply a COVID 19 vaccine (https://www.gov.uk/government/news/government-launches-vaccine-taskforce-to-combat-coronavirus).

Several vaccines have now been authorised for use, and many more are at an advanced stage of development, at global level (https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines). These are based on a range of technology, some of which is very well-established in other authorised vaccines (such as inactivated virus or purified protein subunits, with or without an adjuvant), some are based on viral vector platforms, including those used in recently-authorised vaccines (such as Ebola vaccine) and others are based on emerging mRNA technology.

In the UK, as of 14 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) has authorised the supply of the Pfizer/BioNTech (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19), the Oxford University/AstraZeneca (https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) and Moderna (https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna) vaccines, following a thorough review of the safety, quality and efficacy. These are now being deployed in the UK in accordance with the recommendations of the UK Joint Committee on Vaccination and Immunisation (JCVI).

The need for post-authorisation vigilance

The intense focus, rapid funding, recruitment and prioritised regulatory oversight of trials at global level has allowed clinical trials for COVID-19 vaccines to proceed at pace, without compromising any of the usual, high standards of scientific rigour. In accordance with the usual requirements to support an authorisation of a new