COVID-19 Vaccines Monitoring Preparedness
From: EMA
Sender: 5.1.2e
Date: 09/09/2020
Deadline for responses (if applicable): 24/09/2020
EPITT Reference: 19609
EPITT PhV Topic Title:
NUI on COVID-19 Vaccines Monitoring Preparedness
Type of NUI
General request for information

Reason

As part of the ongoing work on vaccines monitoring preparedness, the Agency is currently developing a document that gives an overview of the enhanced monitoring activities to be carried out in the EU for COVID-19 vaccines. The document describes the roles, responsibilities and interactions of the stakeholders involved and the activities planned. It also takes into account the lessons learned from the 2009 H1N1 flu pandemic, adapted to the current public health emergency.

With this NUI we would like to collect information about any existing plans or initiatives at national level that are currently being made for the monitoring of COVID-19 vaccines. This information may be of interest not only to inform the strategy, but also to know which MS will be in a position of providing additional data in case of specific safety issues.

Information Requested

1. National competent authorities may play a role in the tracking of vaccine distribution by brand and batch number. Examples of such systems may range from the new 2-dimensional barcode system to inclusion of vaccination registries and traceability systems for vaccines. Are you aware of any of these system in place in your member state?
2. Are you aware of any systems in place to collect vaccination coverage for the whole country? Would you receive these data and make it available to EMA? If so, would these data be stratified by age, dose, gender and other important variables? What other kind of post-marketing data could be collected and shared (besides coverage data and ADRs) at national level? E.g. follow up data on vaccines effectiveness and immunogenicity, etc.
3. What preparedness activities have you put in place so far, or are you planning to have? E.g. teams dedicated to the pandemic, vaccination information web-sites, etc.
4. Are there plans in your member state to vaccinate specific patient groups as a priority? If so, please explain which patient populations these would be.

Response NL

1. In general it is currently too early to provide detailed answers. Although considered crucial from regulatory and scientific perspective, practical implementation of vaccination registration and traceability infrastructure in the context of a planned national COVID immunization is currently still subject of discussions with the Dutch Department of Health. Especially issues related to privacy requirements present both legal and political challenges.
2. Routine Systems in place to collect vaccination coverage are in place. Also see 1.

   These data would be made available to EMA, but at this moment it is premature to provide details, *i.e.* regarding stratification.

   Follow-up data on vaccines effectiveness and immunogenicity will be collected in the context of the ACCESS project. Lareb will collect data and follow up information according to the ICH-e2b (R3) legislation and GVP guidelines. Reports on AEFI related to immunogenicity will be captured by the spontaneous reporting system (SRS). In addition reports on lack of efficacy can also be reported to the SRS. Both subjects will be closely monitored and information shared with other stakeholders.
3. Preparedness activities: A dedicated national operational team consisting of experts from Medicines Evaluation Board (CBG-MEB), Pharmacovigilance Centre Lareb, Public Health

Authority (RIVM) and Department of Health (VWS) has two-weekly meetings to discuss preparedness and national implementation of national immunisation.

Regarding vaccination information web-sites (in Dutch, selection):

https://www.cbg-meb.nl/onderwerpen/medicijninformatie-het-nieuwe-coronavirus/vaccins-tegen-covid-19

https://www.rivm.nl/coronavirus-covid-19/vaccins

https://www.lareb.nl/news/voorbereidingen-gestart-voor-bewaken-veiligheid-en-werkzaamheid-coronavaccins

4. Yes, but this is still pending discussions in the Dutch Health Council (Gezondheidsraad). A recommendation regarding target groups is expected in November 2020.