IFRC guidance for involvement in COVID-19 vaccine introduction

Guidance for NS support to COVID 19 vaccination programs

As the COVID-19 pandemic continues to spread, a number of manufacturers have developed COVID-19 vaccines, some of which are licensed and/or approved for Expanded Use Listing (EUL) by National Regulatory Authorities (NRAs). In response to the pandemic, many countries are planning vaccination activities, and Red Cross and Red Crescent National Societies are being asked to support these initiatives. The decision to support vaccination activities should take into account whether the candidate vaccine has been shown to be safe, effective, and approved by WHO or by an NRA meeting WHO standards (1).

IFRC recommends NS support COVID-19 vaccination programs if these conditions are met:

1. The vaccine is WHO prequalified or has been approved for Expanded Use Listing (EUL) by WHO
   or…
2. The vaccine is approved for licensure or EUL by a National Regulatory Authority (NRA) that is fully functioning according to WHO standards (1).

If these conditions are met, IFRC funding can be used to support vaccine introduction and related activities (e.g. social mobilisation, demand creation).

NS run a reputational risk supporting introduction of vaccines that are not WHO-prequalified or EUL listed or approved by an NRA that does not meet WHO standards. In countries introducing vaccines in these settings, NS need to manage expectations about what they can do and what should be expected of them.

Rationale for IFRC policy:

WHO prequalification ensures vaccines used in immunization programmes are safe and effective, and provides Member States and procurement agencies (such as Gavi, the Vaccine Alliance and the Global Fund) and UN organizations (such as UNICEF) with the information required to purchase vaccines matching the specific needs of the programme. WHO also surveys and shares vaccine data on efficacy, potency, thermostability, presentation, labelling and shipping conditions. For a vaccine to enter the prequalification process, the NRA must be determined "functional" according to WHO indicators (2).

Currently, WHO reports that regulatory capacity and enforcement is insufficient in many countries and that only 30 percent of regulatory authorities globally function according to acceptable standards (3). In addition, manufacturing of vaccines has become increasingly globalized, with products and the materials that go into them crossing several borders before they reach patients. This requires even greater global vigilance.

How are new vaccines approved and licenced?

WHO prequalification

WHO, through its Department of Regulation and Prequalification (RPQ), provides advice to UN agencies on the acceptability of vaccines considered for purchase by such agencies. The purpose of the WHO prequalification assessment is to provide assurance that candidate vaccines meet:

a. WHO recommendations on quality, safety and efficacy, including compliance with WHO-recommended Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) standards; and
b. Operational specifications for packaging and presentation of the relevant UN agency.

This is to ensure that vaccines provided through the UN for use in national immunization services in different countries are safe and effective, and are suitable for the target populations, at the recommended immunization schedules, and with appropriate concomitant products.

Several conditions apply for prequalification evaluation:

a. vaccine is considered a priority for UN supply,
b. complies with mandatory characteristic for programmatic suitability
c. NRA responsible for the regulatory oversight of the product has been assessed by WHO as "functional", and
d. a marketing authorization (MA) or EUA (or equivalent) has been granted by the relevant NRA.

The prequalification process takes into account needs from WHO programmes (e.g. Immunization, Vaccines and Biologicals Department) and the International Health Regulations to comply with eradication, elimination or control initiatives, as well as recommendations of WHO's Strategic Advisory Group of Experts (SAGE) on immunization.

Emergency Use Listing

WHO RPQ has also developed the Emergency Use Listing (EUL) process to expedite the availability of unlicensed medical products needed in public health emergency situations. The process assists interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a public health emergency (PHE), based on an essential set of quality, safety, and efficacy/immunogenicity data.

The EUL procedure defines (a) the steps that WHO will follow to establish eligibility of unlicensed products for assessment under this procedure; (b) the essential information required; and (c) the process to be used in conducting the assessment to determine whether an unlicensed product can be listed on a time limited basis, while further data are being gathered and evaluated. Draft points to consider for the assessment of COVID-19 vaccines have been developed and published (2,3,4).

The WHO EUL is not equivalent or an alternative to WHO prequalification, and should not be thought of as such. The EUL is a special procedure for unlicensed vaccines in the event of a PHE,

when the community and public health authorities may be "willing to consider the use of vaccines that have had critical information on efficacy and safety available". EUL is intended to provide a time-limited listing for unlicensed products in an emergency context when available evidence of quality, safety and efficacy outweighs the risk. As part of the EUL, it is expected that the manufacturer will complete the development of the product and submit for licensure and WHO prequalification.

Based on the status of development of candidate COVID-19 vaccines and the extent of the available quality, safety and efficacy data and regulatory approvals by relevant NRAs, WHO will determine whether to follow either the EUL process or prequalification.

What is IFRC's recommendation for National Society participation in clinical trials?

Participation in clinical trials:
IFRC recommends a very cautious approach that carefully weighs the risks and benefits associated with clinical trials of new vaccines, including and an in-depth risk analysis that addresses potential negative health and humanitarian impact, along with reputational risk.

For NS considering support for clinical trials, IFRC recommends participation only in the following settings:

- Trial has been reviewed and approved by a fully functioning National Regulatory Authority (according to WHO standards). This could include a multi-centre trial where the protocol has been established in a country with a fully functioning National Regulatory Authority. However, the study would still need to be approved by: (1) the National Regulatory Authority in country; and (2) the entity that reviews protocols around research that involves human subjects.

IFRC funding cannot be used to support clinical trials.

NS run a reputational risk when becoming involved in trials and vaccine introduction without a fully functioning National Regulatory Authority. In countries with fully functioning National Regulatory Authorities, NS need to manage expectations about what they can do and what should be expected of them.

References and Resources:

1. www.who.int/medicines/regulation/wla_introduction/en/: list of "stringent" NRAs
2. www.who.int/medicines/regulation/prequalification/prequal-vaccines/WHO_Evaluation_Covid_Vaccine.pdf?ua=1
3. https://www.who.int/news/item/01-07-2019-why-we-need-strong-regulatory-systems-to-reach-universal-health-coverage
4. An unofficial tracker for vaccine licensing is available here: www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker