Specialized technical assistance for vaccines

Local Production and Assistance Unit (LPA)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)
World Health Organization (WHO)

Local Production and Assistance (LPA) Unit

What type of assistance?

- Strategy, Policy and Partnership
- Situational Analysis and Readiness
- Technology Transfer Facilitation
- Capacity Building and Technical Assistance
- Technical Assistance for WHO Prequalification
- Country Support

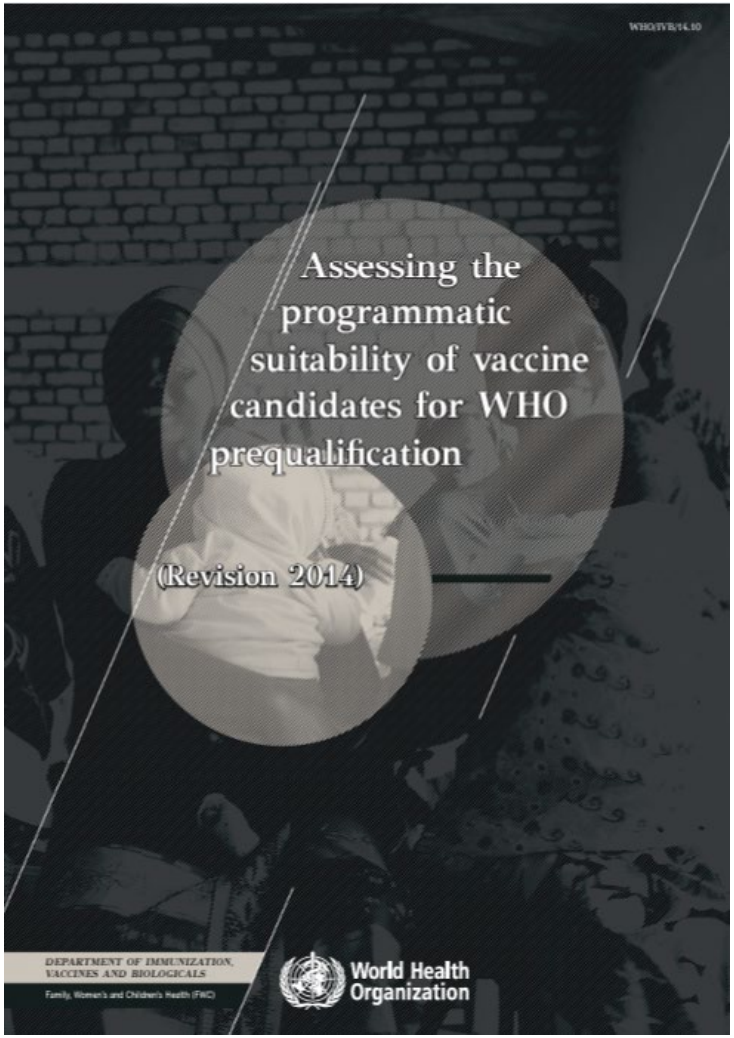
Specialized technical assistance

WHO provides Specialized Technical Assistance to help recipients achieve compliance with international regulatory norms and standards, so that they can attain WHO prequalification (PQ) for priority products or services, or emergency use listing (EUL) for unlicensed products to be used in the context of a public health emergency

- Medicines
- In Vitro Diagnostics
- Vaccines

Where LPA can make a difference

- Assessing the programmatic suitability of vaccines candidates for WHO prequalification (PSPQ)



- WHO PSPQ

Where LPA can make a difference

- Pfizer/ BioNTech COVID-19 mRNA vaccine *Comirnaty*

- EMA: Comirnaty SmPC
- Picture from EPR

Comirnaty

1. NAME OF THE MEDICINAL PRODUCT

Comirnaty 30 micrograms/dose concentrate for dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a multidose vial with a purple cap and must be diluted before use.

One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution, see sections 4.2 and 6.6.

One dose (0.3 mL) contains 30 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Tozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dispersion for injection (sterile concentrate).
The vaccine is a white to off-white frozen dispersion (pH: 6.9 - 7.9).

Comirnaty

6.3 Shelf life

Unopened vial

Frozen vial

2 years when stored at -90 °C to -60 °C.
Within the 2-year shelf life unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C.

When stored frozen at -90 °C to -60 °C, 195-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 3 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed vial

1 month at 2 °C to 8 °C within the 2-year shelf life.
Within the 1-month shelf life at 2 °C to 8 °C, up to 48 hours may be used for transportation.
Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C.
Thawed vials can be handled in room light conditions.

Once thawed, the vaccine should not be re-frozen.

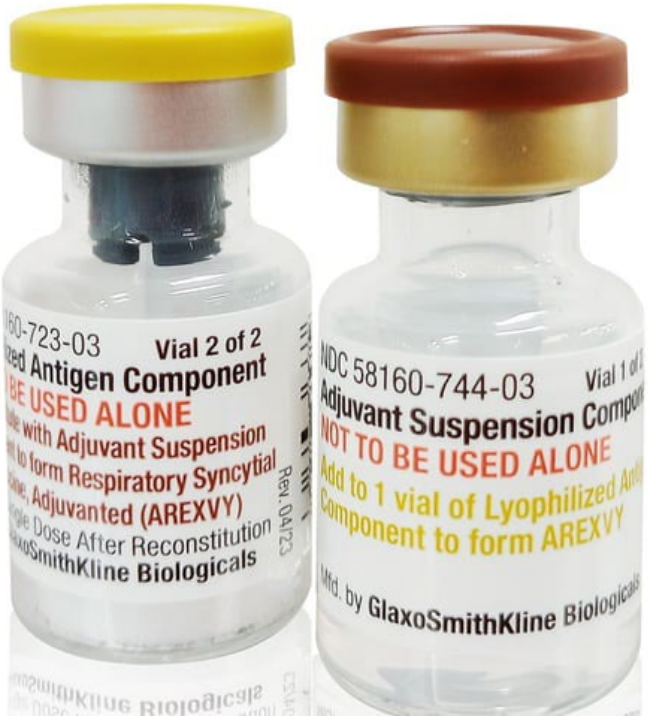
Handling of temperature excursions once removed from the freezer

Stability data indicate that the unopened vial is stable for up to:

- 24 hours when stored at temperatures from -3 °C to 2 °C
- a total of 4 hours when stored at temperatures from 8 °C to 30 °C; this includes the 2 hours at up to 30 °C detailed above

Where LPA can make a difference

- GSK Respiratory Syncytial Virus vaccine *Arexvy*



- EMA: Arexvy SmPC
- Picture from Fierce Pharma

Arexvy

1. NAME OF THE MEDICINAL PRODUCT

Arexvy powder and suspension for suspension for injection
Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

After reconstitution, one dose (0.5 mL) contains:
RSVPreF3[1] antigen[2,3] 120 micrograms

[1] Respiratory Syncytial Virus recombinant glycoprotein F stabilised in the pre-fusion conformation = RSVPreF3
[2] RSVPreF3 produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology
[3] adjuvanted with $AS01_E$ containing:
plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) 25 micrograms
3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* 25 micrograms

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and suspension for suspension for injection.

The powder is white.
The suspension is an opalescent, colourless to pale brownish liquid.

Arexvy

6.3 Shelf life

2 years

After reconstitution

Chemical and physical in-use stability has been demonstrated for 4 hours at 2 °C – 8 °C or at room temperature up to 25 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 4 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Store in the original package in order to protect from light.
For storage conditions after reconstitution of the medicinal product, see section 6.3

Take home message

- Licensing by a regulatory authority operating at high level of performance is not guarantee that the prequalification of a vaccine will be granted.
- LPA-provided specialized technical assistance for WHO PQ can help manufacturers avoid problems that are difficult to resolve when the pharmaceutical development is completed.
- This turned out to be particularly beneficial for the specific requirements of WHO (e.g. programmatic suitability).
- For further information please:
  - ✓ visit Local Production & Assistance webpages
  - ✓ email to localproduction@who.int

Thank you for your attention.