

Collaborative procedure for licensing Prequalified vaccines

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World Health
Organization

WHO PREQUALIFICATION PROGRAMME



Strategic priorities

**Secure the supply
base for priority
medicines**

**Facilitate access to
quality products
for developing
countries**

**Improve efficiency
of the
prequalification
procedure**

**Expand portfolio
according to needs
and options for
introduction**

Supply Security

Monitor closely the performance of prequalified vaccines including FU audits and conducting production capacity assessments

Actively seek for additional sources for priority vaccines

Secure the supply base for priority vaccines for developing countries

Establish risk mitigation strategies in case of failure of NRA



Access

Facilitate access
to quality
products for
developing
countries

**Single standard of quality
(WHO recommended requirements)**

**Consolidated investigation, reporting
and communication in response
to quality or safety concerns**

**Implementation of an
expedited/facilitated registration
procedure for prequalified vaccines
in receiving countries**

**Mechanisms to minimize wastage of
vaccines, facilitate outreach
(VVMs, MDVP, CTC)**

Accelerated registration of WHO prequalified vaccines

Objective

Assist countries to adopt a facilitated, expedited procedure for the national registration of prequalified vaccines.

Who can benefit

Countries procuring through UN agencies

and/or

Countries procuring directly but requiring WHO prequalification as a tender condition

where the national regulations include provisions to shorten the normal regulatory approval process.



Implementation of Procedure for expedited review of imported prequalified vaccines for use in national immunization programmes (WHO/IVB/07.08)

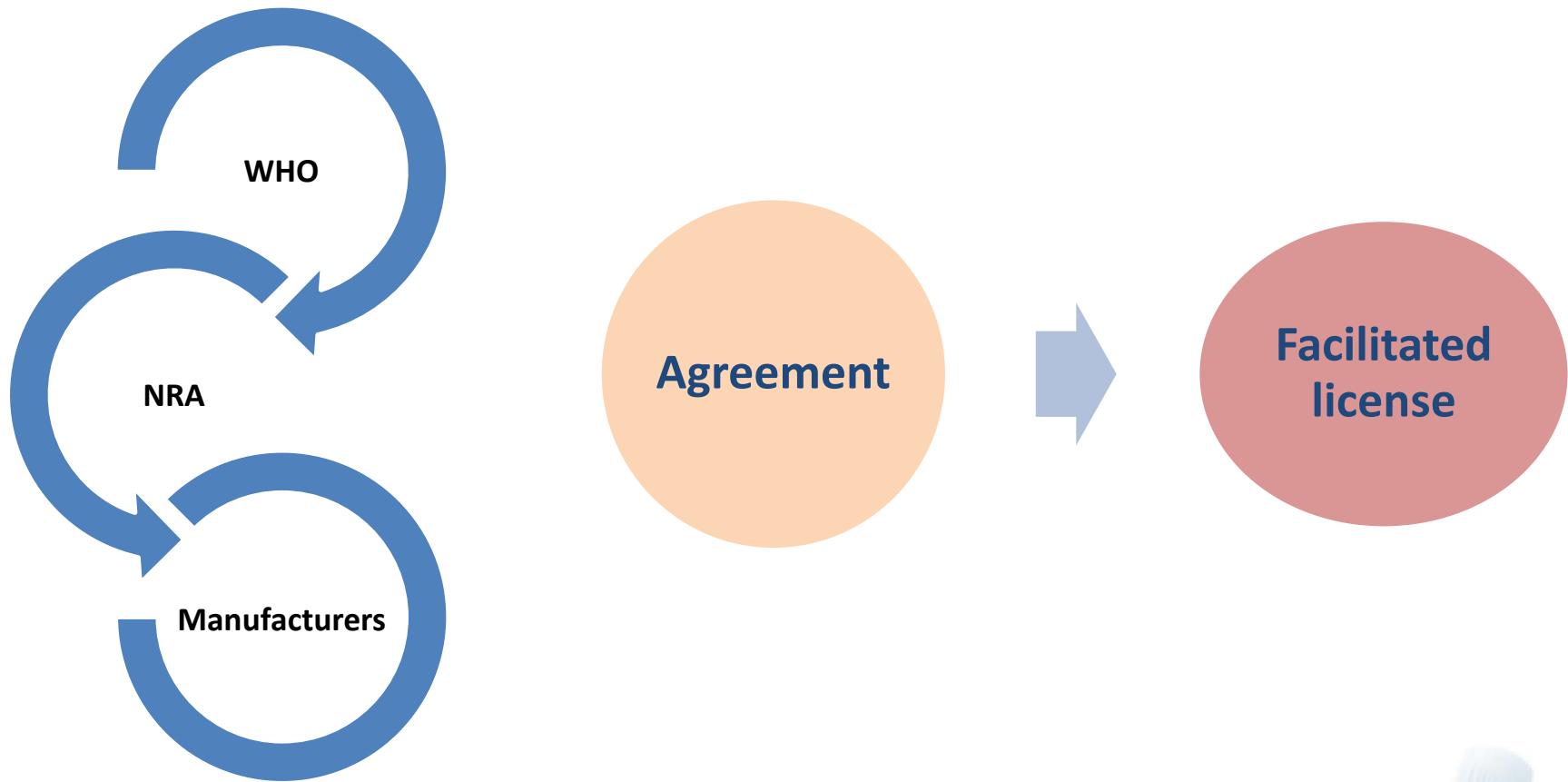
Firstly used for registration of MenAfriVac in 26 countries of the belt



Accelerated national registration of WHO-prequalified pharmaceutical products and vaccines.

Vaccines	Pharmaceuticals
<p>Procedure for expedited review of imported prequalified vaccines for use in national immunization programmes (WHO/IVB/07.08)</p>	<p>Collaborative procedure between the World Health Organization Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products.</p>
<p>Expert Committee on Biological standardization</p>	<p>Expert Committee on Specifications for Pharmaceutical Preparations</p>
<p>Firstly used for registration of MenAfriVac in 26 countries of the meningitis belt</p>	<p>Procedure in place since 2012 Collaborative agreements signed with 20 National Regulatory authorities 33 procedures finalized Details on www.who.int/prequal</p>

Revision of procedure



Principles of collaborative registration (1)

- 1. Interested National Regulatory Authorities (NRAs) agree to respect principles of the Collaboration as regards sharing of complete confidential assessment and inspection outcomes and acceleration of regulatory approvals.**
- 2. The company submits to the NRA the dossier with same technical data in CTD/PSF format, and provides agreement to share information among NRA and PQT. Fees to NRA follow national requirements.**
- 3. WHO/PQT shares the confidential assessment reports, inspection reports, and laboratory results via a secured website to designated NRA focal persons. Advice and consultations provided if necessary.**

Principles of collaborative registration (2)

4. The NRA uses shared information at its discretion – e.g. for acceptance, verification, quality assurance, training. NRA is committed to decide within 90 days. NRA informs WHO/PQT about its decision and justifies, if deviating in its decision from WHO/PQT.

5. The procedure includes provisions for variations and for notification of suspensions and withdrawals of prequalified product both ways (NRAs and WHO/PQT).

Joint collaborative procedure for pharmaceuticals and vaccines: Path forward

- **Revised procedure published on the web**

http://www.who.int/immunization_standards/vaccine_quality/expedited_review/en/

- **Discussion with stakeholders started**

- **Pilot for vaccines is under preparation**

- **Endorsement by relevant expert committees expected in 2015**

- **Extension of current agreements with NMRAs to vaccines (potentially also Diagnostics)**

- **Based on collaboration agreements, full reliance on PQ as potential mechanism for accelerated registration of products for emergency use.**

- **Newcomers are welcome to participate!**



POLIO ERADICATION AND ENDGAME STRATEGIC PLAN 2013-2018

The Strategic Advisory Group of Experts on Immunization (SAGE), recommended in 2012 the withdrawal of the type 2 component of oral polio vaccine (OPV) from routine immunization programmes in all countries, facilitated by the introduction of at least one dose of IPV

Weekly epidemiological record wer 8901

The last case of wild poliovirus type 2 (WPV2) was seen in 1999

88% of the total of the circulating vaccine derived poliovirus (cVDPV) cases in recent years were caused by the vaccine derived type 2 strain

Introduction of IPV by 2015 and bOPV by 2016 in all countries

www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/en/
www.polioeradication.org



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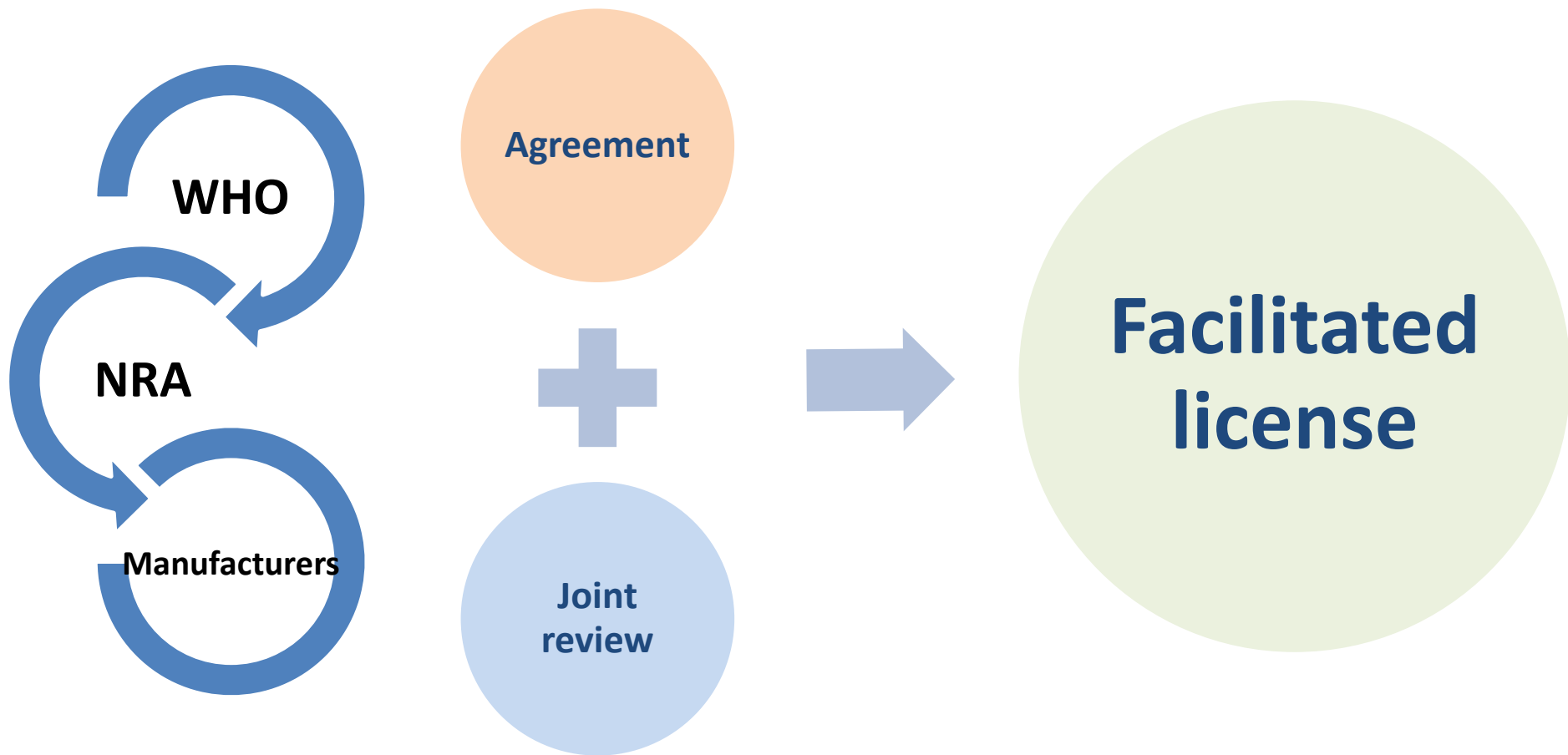


Facilitating license of IPV

- Mapping the current status of licensing of IPV vaccines in all regions and the potential regulatory pathways for licensing.
- Three pathways have been identified:
 - Pathway 1: Reliance on PQ: Waiver
 - Pathway 2: Standard licensing procedure for those countries where national regulatory procedures do not allow a facilitated license and there is adequate NRA capacity.
 - Pathway 3: Expedited procedure for licensing for those countries without the capacity for the standard procedure and where national regulatory procedures allow a facilitated licensing of PQd vaccines.



Facilitating license of IPV: PQ pathway



Path forward facilitating license of IPV

Joint review

AFRO countries
20-24 October 2014 Turkey

SEARO countries
10-14 November
Thailand

Francophone countries:
Benin, Burkina Faso,
Cameroon, Cote
d'Ivoire, Mali, Senegal,
Togo

Anglophone countries:
Botswana, Ethiopia,
Ghana, Sierra Leone,
Tanzania, Uganda, Zambia,
Zimbabwe : ENGLISH

Bhutan, Myanmar and
Sri Lanka

Path forward: IPV and bOPV

- Ensuring license of IPV vaccine
- Ensuring approval of variations (IPV).
- WHA resolution to facilitate bOPV introduction
- Facilitating license of bOPV:
 - Discussion of Collaborative agreement concept.
 - AFRO and SEARO countries: October-November 2014
 - Extension of collaborative agreements to vaccines
 - New agreements (pharmaceuticals and vaccines)
 - Advocacy workshop: EURO and PAHO (December 2014, Q1 2015)
 - Other regions: 2015



Path forward: Other vaccines

- **Ensuring licensing of emergency vaccines:**
 - **Development of criteria for facilitating license of pandemic flu vaccines in an emergency situation. Pandemic influenza preparedness (PIP)**
 - **Mock procedure: seasonal flu vaccine**



Summary

- Prequalification system ensures the quality, efficacy and safety of medicines, vaccines and immunization devices and diagnostics for global use.
- Facilitate access to quality products for developing countries
- The collaborative registration of PQed medicines is a work-sharing and confidential information sharing mechanism, which already produces results: in 80% of 33 application registration was granted in less than 90 days.
- Multiple benefits are seen for participating NMRAs, manufacturers and WHO (e.g, facilitated decision making, learning, harmonization of dossiers, assurance about the same product, faster access, life cycle management).
- Based on collaboration agreements, full reliance on PQ as potential mechanism for accelerated registration of products for emergency use.

