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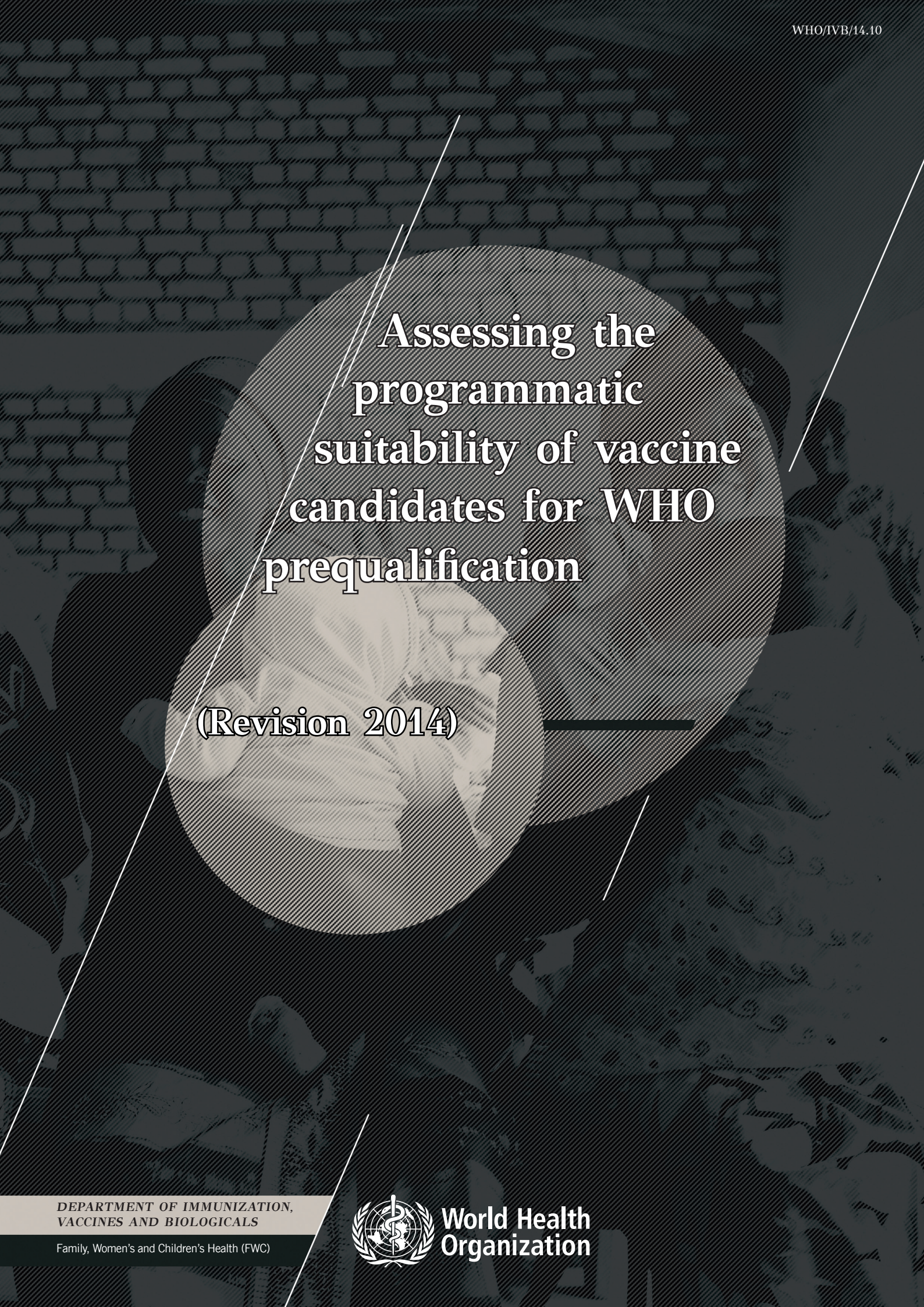

Assessing the programmatic suitability of vaccine candidates for WHO prequalification

(Revision 2014)

DEPARTMENT OF IMMUNIZATION, VACCINES AND BIOLOGICALS

Family, Women's and Children's Health (FWC)

World Health Organization

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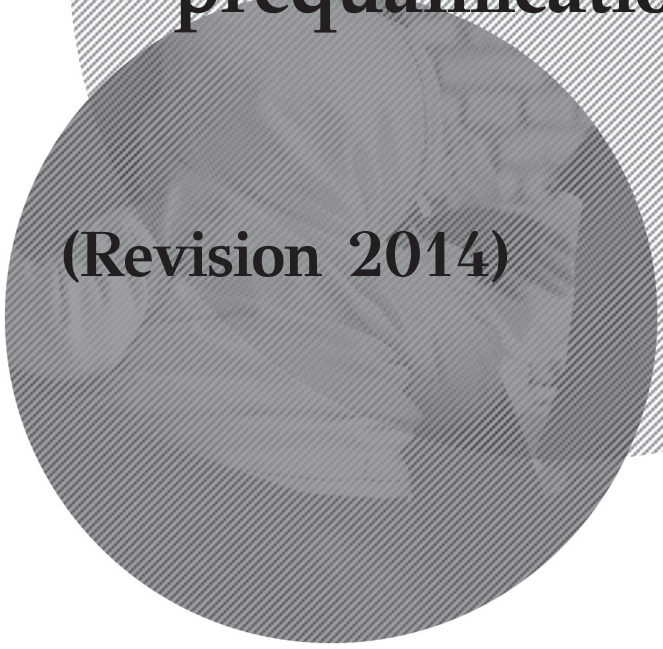

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1. Foreword

The aspiration of an ideal vaccine - one that is low cost, high efficacy, heat stable, freeze tolerant, multi-antigen, user friendly and environmentally friendly - is currently a hopeful dream. Yet, it is critical to uphold its attainment as the driving force for the development of new and innovative vaccines.

In recent years, the drive towards accelerated new vaccine introduction in developing countries has tended to emphasize the important social benefits of reduced morbidity and mortality, in some cases accepting product presentations lacking many of the highly desirable product characteristics mentioned above.

As a result, new vaccines have emerged that, although generally safe and effective in the prevention of major diseases, often incorporate characteristics that are undesirable in a developing country setting — complex handling, high cold-chain capacity requirements, complex waste-disposal requirements and very high cost.

Experience has shown that, once a new vaccine product reaches the clinical trial stage, it is extremely costly and time-consuming to reformulate the product in order to incorporate additional characteristics that were not contemplated in the original experimental design. It is therefore crucial to consider packaging and presentation characteristics from the earliest stages of pre-clinical development both in developed and developing countries for vaccines of global usage. This is often done through reference to target product profiles.

It is important to disseminate guidance for industry, to assist product development teams and pre-clinical scientists, to identify characteristics and innovations that are highly valued in terms of future vaccine products intended for use in developing countries, and to vigorously encourage them to include those characteristics from the earliest stages of pre-clinical study. Previous work to develop such guidance includes that of the Malaria Vaccine Initiative[1], the Target Product Profile (TPP) for the Advance Market Commitment (AMC) for pneumococcal conjugate vaccines[2] and the Vaccine Presentation and Packaging Advisory Group, which more recently developed a Generic Preferred Product Profile (gPPP)[3] for new vaccines. The World Health Organization (WHO) prequalification (PQ) process is the mechanism available to the international community to assess whether new vaccine products adequately feature mandatory, critical and preferred characteristics, and are suitable for use in developing countries. A manufacturer may contact the PQ Secretariat to discuss the compliance with mandatory, critical or any innovative characteristics during pre-clinical or clinical development stage, although no final, binding decision can be made until the dossier is submitted for prequalification.

To achieve standardization and uniformity of the programmatic suitability requirement for prequalification, vaccines that are already prequalified, or were in the process of prequalification at the time of the implementation of this process and which are not compliant with its requirements will follow a transition process, which is described later in the document.

A time-limited Programmatic Suitability of Vaccine Candidates for WHO Prequalification (PSPQ) Working Group was formed and charged with drafting an initial version of this document early in 2010. The PSPQ Working Group was made up of representatives from national ministries of health, international organizations (WHO, UNICEF, PAHO), vaccine industry and others with experience in the procurement of vaccines and the management of national immunization programmes.

2. Background

As part of WHO's vaccine prequalification (PQ) process, product summary files (PSFs) are assessed by the WHO PQ Secretariat to determine *'the suitability of the vaccine for the immunization services where it is intended to be used'* (p.6, WHO/IVB/05.19[4]). Assessed characteristics include *'... presentations offered ... labelling, information provided on package inserts ... , and packaging ...'*. This is part of the broader process intended *'to ensure that vaccines used in national immunization services in different countries ... meet particular operational specifications for packaging and presentation'* (p.1, WHO/IVB/05.19[4]). Also, WHO published a new *Technical Report Series* (TRS) 978 Annex 6 *"Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies"*[5] in Feb 2013, replacing the earlier document (WHO/BS/2155.10).

The PQ process is focussed on the use of vaccines as outlined by the vaccine manufacturer. Any use of vaccine not outlined by the manufacturer is not taken into consideration in the PQ process, even though WHO may recommend "off-label" use of vaccines in certain circumstances.

Although the assessment of the suitability of vaccines for the immunization services where they are intended to be used has always been part of PQ, historically, the assessment of the PSFs to determine programmatic suitability had not been formally structured, with the outcome based on individual expert inputs and WHO PQ Secretariat consensus.

In recent years, the emergence of novel or unique vaccine presentations, such as relatively large packed volume pre-filled syringes that do not include an auto-disable feature, injection device materials that require non-standard disposal methods and fully liquid low multi-dose vials without preservative, has driven the need to explicitly define the characteristics that determine programmatic suitability and the process for assessing