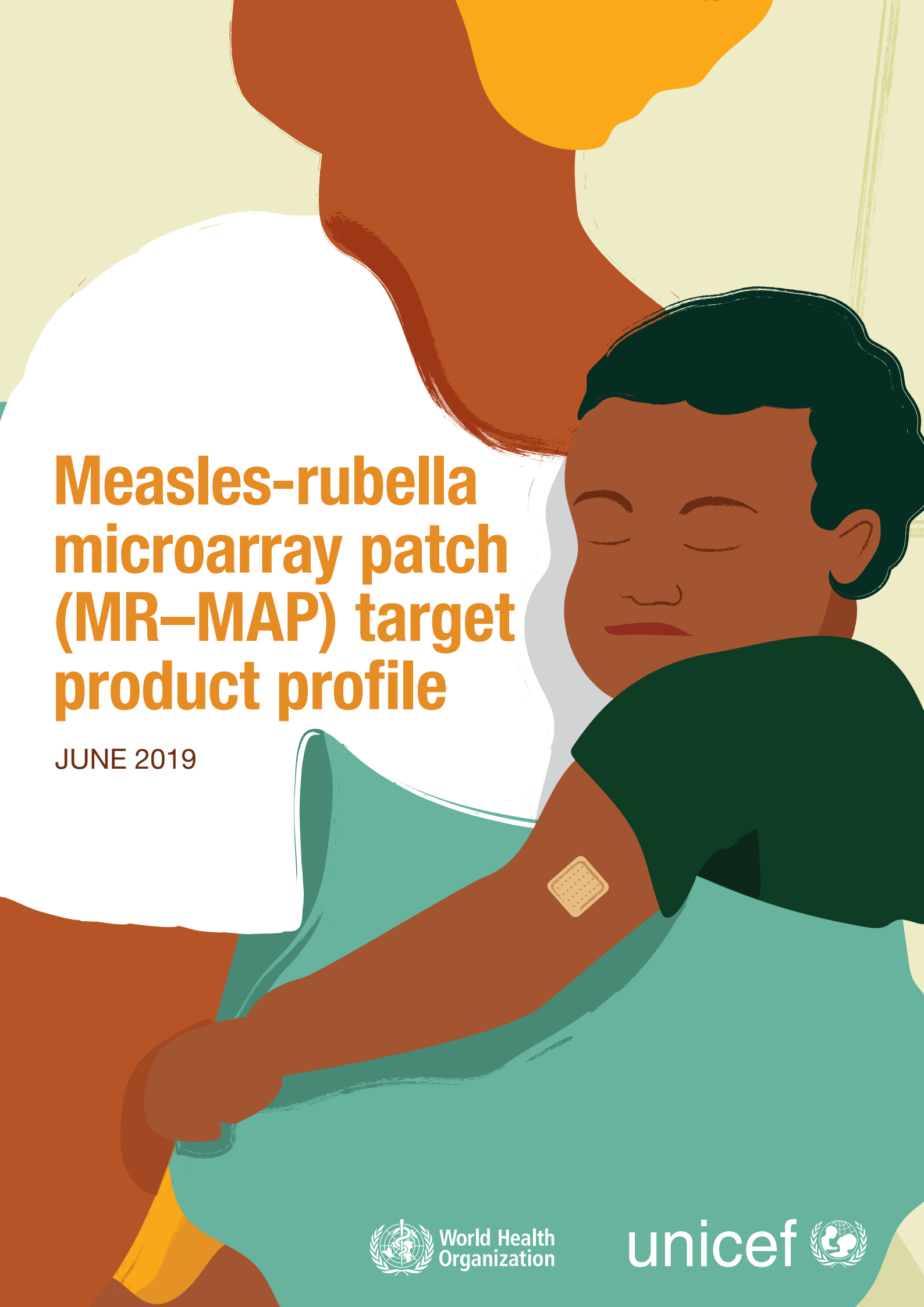

Measles-rubella microarray patch (MR–MAP) target product profile

JUNE 2019

World Health Organization

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Contents

Preface

This target product profile (TPP) describes the minimal and optimal product characteristics for a measles and rubella (MR) microarray patch (MAP) vaccine, with a particular focus on delivery considerations for low- and middle-income countries (LMICs). It is intended to inform MAP developers, vaccine developers, procurement agencies and funders on MR–MAP research and public health priorities, and to facilitate the most expeditious development of MR–MAP candidates that would address the greatest and most urgent public health need in LMICs.

The document is based on an initial MR–MAP TPP developed by PATH and the World Health Organization (WHO) in 2016. It has been updated following input from a WHO working group of independent subject matter experts from diverse areas of expertise, including epidemiology, immunology, manufacturing and clinical development, regulatory affairs, health economics and policy. Specific aspects of the TPP were refined through consultations with various immunization stakeholders including the Immunization Practices Advisory Committee (IPAC) and the TechNet-21 community.

A draft was disseminated widely for public consultation in December 2018 among relevant stakeholders including MAP developers and vaccine manufacturers. The comments received were reviewed by the WHO MR–MAP working group and, where appropriate, incorporated into the TPP. This updated version is endorsed by the United Nations Children's Fund (UNICEF) and co-published with WHO.

While this document contains assumptions concerning regulatory considerations to help frame the rationale for the proposed characteristics, this TPP should not be considered as a regulatory document. The TPP will be updated as product development of MAP technology evolves, or as other changes in the identified need or research and development landscape emerge.

The document is divided into three major sections:

1. General considerations comparing the attributes of an MR vaccine delivered by MAP with those of the current, lyophilized MR vaccine;

2. Generic product characteristics for an MR vaccine on solid coated or dissolvable MAPs; and

3. Generic product characteristics for MAPs for delivery of MR vaccines.

Sections 2 and 3 describe the minimally acceptable and optimal targets for MR–MAP product attributes. However, these attributes are not currently listed in order of priority or importance; should an MR–MAP profile be sufficiently superior to the minimal characteristics under one or more categories, this may outweigh deficiencies in meeting a specific minimal characteristic in the suitability of product procurement.

The primary target audience for this TPP is any entity intending to develop a vaccine for national immunization programme use, including in low resource settings, and eventually to seek WHO prequalification and UNICEF procurement following licensure of its product. However, it is important to note that while this TPP defines aspirational goals for MR–MAP vaccine attributes, it does not supersede the evidence-based assessment by WHO's Strategic Advisory Group of Experts on Immunization (SAGE) for policy recommendation on use; other existing WHO guidance on vaccine development or prequalification; or assessments conducted by national regulatory authorities (NRAs), the European Medicines Agency (EMA), or the United States Food & Drug Administration (FDA).

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Abbreviations

$CCID_{50}$	50% cell culture infectious dose
COGS	cost of goods sold
CTC	controlled temperature chain
EMA	European Medicines Agency
gPPP	generic Preferred Product Profile
HCW	health care worker
HF	human factors
ID	intradermal
IPAC	Immunization Practices Advisory Committee
IQR	inter-quartile range
LMIC	low- and middle-income countries
MAP	microarray patch
MCV1	measles-containing vaccine first dose
MCV2	measles-containing vaccine second dose
MMR	measles–mumps–rubella
MMRV	measles–mumps–rubella-varicella
MR	measles–rubella
NRA	national regulatory authority
NS	needle and syringe
ORI	outbreak response immunization
PDVAC	Product Development for Vaccines Advisory Committee
PQ	prequalified
PSPQ	Programmatic Suitability for Prequalification
PTTI	peak temperature threshold indicator
RI	routine immunization
SAGE	Strategic Advisory Group of Experts on Immunization
SC	subcutaneous
SIAs	supplementary immunization activities
$TCID_{50}$	50% tissue culture infective dose
TPP	target product profile
UNICEF	United Nations Children's Fund
VPPAG	Vaccine Presentation and Packaging Advisory Group
VVM	vaccine vial monitor
VVM–TI	vaccine vial monitor with an integrated threshold indicator
WHO	World Health Organization