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Contents

1. Background and rationale

One of the key World Health Organization (WHO) missions is to enable access to high quality, safe and efficacious/well performing health products (in vitro diagnostics (IVDs), medicines, vaccines, vector control products, medical devices and other products and services) that are suitable for use in populations in greatest need. Two essential elements to achieve this goal are the generation of policy recommendations for health interventions and the WHO Prequalification (PQ) assessment[1] that rely on evidence from well-designed and well-conducted trials with appropriate endpoints, to demonstrate their public health value as well as efficacy/performance and safety of the products. However, limited horizon scanning or interactions with product developers, either in the public or private sector may not allow, at times, appropriate anticipation or systematic planning of relevant policy recommendations and/or timely prequalification assessment and listing for certain products/classes.

In addition, interactions between WHO and developers may depend on individual technical department strategies and modalities and the interaction between technical departments (TDs), product developers and the Prequalification Team (PQT) is not standardized. As a result, some policy recommendations are being issued without any immediate prospects for prequalified products or there may be unnecessary intervals between policy recommendation and availability of prequalified products. Moreover, developers may not be aware of the type of data that are critically needed to enable WHO to make scientifically sound, evidence-based policy recommendations and/or to fulfill PQ requirements, leading to delays in the development of guidelines and issuing of recommendations as well as delays in prequalification assessments and subsequent listings of novel health products.

Some processes for joint TD(s)/PQ activities have been established within WHO (for example, for vector control products, to determine the appropriate assessment pathway for individual products[2]), but there is no such process in place specifically for joint TD(s)/PQ interactions with product developers. A standardized corporate process for interactions between TD(s), PQT and product developers would assist in addressing these issues.

In this context, WHO's science division (SCI) has developed **optimized corporate processes** to better link research and product development with access (Box 1)**.** One of these processes is the **WHO Coordinated Scientific Advice (CSA) procedure for health product research and development (R&D)** whereby product developers may approach WHO and obtain joint advice from the relevant TD(s) and PQT, coordinated by the Science Division (SCI), if the product is likely to meet criteria for public health value (as evidenced by alignment with WHO TPPs or other criteria where no TPPs are available). The present document outlines the basic principles, contents, procedures and outputs of this CSA.

[1] https://extranet.who.int/pqweb/ accessed 29 April 2021

[2] https://extranet.who.int/pqweb/vector-control-products/determination-pathway accessed 29 April 2021

The revised WHO process for research and development (R&D) and health product assessment:

1. **Better anticipate** to trigger the policy development process, including horizon scanning and developing or endorsing preferred product characteristics (PPCs)/target product profiles (TPPs), in order to stimulate innovation, guide product development and provide predictability to manufacturers with respect to the evaluation process anticipated for these new tools.
2. **Develop WHO policy recommendations** based on the generation of evidence by manufacturers and/or research groups to demonstrate that an intervention has public health value.
3. **Ensure timely prequalification assessment outcomes** through appropriate generation of evidence needed to fulfil prequalification requirements.
4. **Optimize uptake:** Policy guidance is disseminated and its use supported and monitored.

Box 1. Revised WHO process for optimization of R&D and health product assessment

2. Scope of the CSA procedure

The scope of the CSA procedure is based on a series of key principles that are outlined below.

The scope of the WHO Coordinated Scientific Advice procedure is to provide advice to product developers on the generation of robust data for future evaluation towards WHO policy recommendation and product prequalification in areas of unmet public health needs.

This includes discussion on pros and cons of various clinical development methods and trial options so as to maximize the relevance of trial outputs. In turn, it is expected that the CSA procedure will allow product developers to understand better the WHO perspective.

On this basis, advice will be provided on product development questions concerning the following aspects of new products or updated forms of known products:

- quality
- non-clinical aspects
- clinical/epidemiological aspects.

Throughout this document, it is important to bear in mind that the procedure is not a route for WHO