TARGET PRODUCT PROFILES FOR NEEDED ANTIBACTERIAL AGENTS:

enteric fever, gonorrhoea, neonatal sepsis, urinary tract infections and meeting report

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World Health Organization

Expert meeting on target product profiles for needed antibacterial agents

3–4 October 2019, Geneva, Switzerland

Meeting report

Introduction

This is the report of the scientific advisory group meeting on the development of target product profiles (TPPs) for needed antibacterial agents for enteric fever (typhoid fever), gonorrhoea, neonatal sepsis and urinary tract infections, that took place in Geneva, Switzerland, on 3–4 October 2019.

Antimicrobial resistance (AMR) has increased worldwide in recent decades, limiting treatment options for many bacterial infections. In 2015, AMR was recognized as a global public health challenge with the adoption of the Global Action Plan (GAP) by the sixty-eighth World Health Assembly, providing countries with a blueprint for action to combat AMR both nationally and internationally.[1]

In response to GAP objective 5, WHO developed the *Global priority list of antibiotic-resistant bacteria* and the report *Antibacterial agents in clinical development* in 2017, and the report *Antibacterial agents in preclinical development* in 2019, to provide evidence-based guidance and a public health perspective in developing new antibacterial therapies.[2,3]

WHO has subsequently formulated TPPs to meet the need for specific antibacterial agents. TPPs are used by drug developers to provide strategic guidance for product development programmes, and to specify the intended use, target populations and desired attributes of potential new products. In the regulatory context, TPPs help to frame development in relation to submission of product dossiers. In the context of public health, WHO TPPs set R&D targets for funders and developers by outlining the desired performance and operational characteristics of potential new products.

1 Global action plan on antimicrobial resistance. Geneva: World Health Organization; 2015 (https://www.who.int/antimicrobial-resistance/global-action-plan/en/, accessed 23 January 2020).

2 Prioritization of pathogens to guide discovery, research and development of new antibiotics for drug-resistant bacterial infections, including tuberculosis. Geneva: World Health Organization; 2017 (WHO/EMP/IAU/2017.12; https://www.who.int/medicines/areas/rational_use/prioritization-of-pathogens/en/, accessed 23 January 2020).

3 Antibacterial agents in clinical development: an analysis of the antibacterial clinical development pipeline, including tuberculosis. Geneva: World Health Organization; 2017 (WHO/EMP/IAU/2017.12; https://www.who.int/medicines/areas/rational_use/antibacterial_agents_clinical_development/en/, accessed 23 January 2020).

The TPP development process

The TPPs for new antibacterial agents were developed in line with the standard WHO procedure for TPPs (Fig. 1). In January 2019, an interdepartmental meeting of WHO experts was held, identifying five clinical syndromes for which new antibacterial therapies are urgently needed due to increased resistance to existing therapies. These five clinical syndromes are neonatal sepsis, gonorrhoea, typhoid fever, urinary tract infections (UTIs) and intensive care unit (ICU) patient-focused indications.

WHO then developed scoping documents for each of these five clinical syndromes, followed by an internal consultation with the WHO departments – Health Products, Policy and Standards; Immunization, Vaccines and Biologicals; Global HIV, Hepatitis and STI Programmes; and Maternal, Newborn, Child & Adolescent health and Ageing. This was followed by an external consultation process involving a broad set of clinical and drug-development experts. The proposed ICU patient-focused indication TPP was thereafter removed, as the scope was considered too broad. WHO prepared draft TPP documents for the remaining four clinical syndromes, reflecting the written comments received from the internal WHO experts.

A scientific advisory group of senior scientists, clinical and product development experts, public health officials and regulators was established following the WHO standard procedure for TPPs regarding geographical and gender balance, diversity in expertise and management of conflict of interest (see Annex 1). This group provided written feedback on the draft TPP documents, which, together with the feedback from the internal WHO consultation, informed subsequent amendments of the draft TPPs. From 1 to 29 September 2019, WHO published the following draft TPP documents for public consultation:

- empirical therapy of neonatal sepsis in high-resistance settings/targeted therapy for multidrug-resistant (MDR) Gram-negative neonatal sepsis;
- therapy of diagnosed uncomplicated gonorrhoea;
- therapy of uncomplicated typhoid fever; and
- oral therapy of acute uncomplicated UTI.

Following the public consultation period, WHO convened a face-to-face meeting of the scientific advisory group and the relevant internal WHO experts on 3–4 October 2019 in Geneva, Switzerland, to discuss the draft TPPs, validate the feedback received from the public consultation and update the TPP documents accordingly (Fig. 2). The list of participants is detailed in Annex 1.

Fig. 1. TPP development process