First meeting of the WHO Strategic and Technical Advisory Group working group on access to safe, efficacious and quality-assured health products for neglected tropical diseases

Virtual meeting, 15–16 September 2022
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This publication contains the report of the first meeting of the Strategic and Technical Advisory Group working group on access to safe, efficacious and quality-assured health products for neglected tropical diseases and does not necessarily represent the decisions or policies of WHO.
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Abbreviations and acronyms

GAP-f  Global accelerator for paediatric formulations
GAT    GAP assessment tool
NTD    neglected tropical disease
PADO   paediatric drug optimization
WHO    World Health Organization
1. Introduction

The WHO Department of Control of Neglected Tropical Diseases (WHO/NTD) manages a diverse portfolio of 20 diseases and disease groups, each with its own unique epidemiology and implementation challenges. These programmes aim to achieve set goals for disease control, elimination as a public health problem, elimination of transmission, or eradication, as determined through expert consultations in collaboration with countries. This requires consistent emphasis on the availability, accessibility, acceptability and affordability of medicines and other health products for NTDs.

The STAG Working Group on access to safe, efficacious and quality-assured health products for NTDs ("the Working Group") was established in 2021 to facilitate alignment of stakeholders on strategies and best practices for improving access to medicines and other health products for NTDs. Following its introductory meeting in January 2022, the Working Group held its first technical meeting virtually on 15–16 September 2022. The agenda is reproduced in Annex 1 and the participants are listed in Annex 2.

1.1 Opening remarks

Dr Gautam Biswas, Director ad interim, WHO/NTD, welcomed participants to the meeting. He mentioned that access to NTD health products had been impacted during the coronavirus disease (COVID-19) pandemic and that measures were taken to adapt to challenges globally. He summarized the key achievements made in 2021–2022 including the delivery of 1.9 billion tablets of NTD medicines; the prequalification by WHO of four new medicines; the submission of five new dossiers for prequalification; and the webinar on improving access to NTD health products (7 December 2021). He recognized the critical role of a revitalized Working Group in achieving the 2030 targets of the NTD road map for 2021–2030 ("the road map) and in ensuring access to NTD health products in all populations in need. Finally, he wished the participants a productive meeting.

1.2 Purpose of the meeting, expected outcomes and appointment of rapporteurs

Sarah Andersson, Chair of the Working Group, said that the purpose of the meeting was to review and highlight the priority areas of work in improving access to NTD health products and recommend the establishment of subgroups (if needed) or areas of active participation to actively engage in the identified priority issues. Hye Lynn Choi, Technical Officer/WHO Prequalification, and Perrer Tosso, Senior Manager, United States Pharmacopeia, were appointed rapporteurs. Participants were then invited to introduce themselves and indicate their areas of expertise and experience.
2. Technical sessions and discussion

2.1 NTD diagnostics evaluation

Camilla Ducker, Consultant, WHO/NTD, provided background on the critical need of NTD diagnostics to support the achievement of the road map targets. The WHO Diagnostics Technical Advisory Group for Neglected Tropical Diseases and its subgroup on manufacturing and regulatory pathways had advised WHO to establish a regulatory pathway to evaluate the quality, safety and performance of NTD diagnostics. Currently, there is no established mechanism. WHO/NTD is discussing with WHO Prequalification options for evaluation, particularly for diagnostics with lower risk (Class A and B) levels. NTD diagnostics are unique, as those used for mass drug administration programmes, for instance, have a lower risk classification (Class B); yet there is very little interest from manufacturers due to an unprofitable market and the unknown or uncertain quality of many NTD diagnostics. An expert review panel for diagnostics, an interim risk-assessment mechanism providing time-limited recommendations, or similar process, will be established for NTD diagnostics to provide reasonable assurance of product safety and effectiveness. Priorities could be for lymphatic filariasis, onchocerciasis, schistosomiasis and yaws (pending regular updates). The ways in which members of the Working Group can contribute to the evaluation process would be discussed, pending a decision by WHO senior management on the appropriate mechanism for the panel.

2.2 GAP-f and paediatric drug optimization for NTDs

Martina Penazzato, GAP-f lead, WHO Research for Health/Science Division, described the GAP-f and its activities. Recognizing the challenges with limited availability of child-friendly paediatric formulations for public health programmes, GAP-f, a WHO network, was created to address the gap in paediatric treatment by coordinating a concerted response across the product life cycle, from prioritization to evaluating, developing and delivering products. GAP-f works on several diseases, including HIV, TB, hepatitis, antibiotics, childhood cancer and now NTDs. She presented the GAP-f strategy to stimulate accelerated access to paediatric formulations together with its various partners.

Tiziana Masini, GAP-f prioritization consultant, WHO Research for Health/Science Division, provided further details on the prioritization process, known as paediatric drug optimization (PADO). Given the challenges in developing paediatric formulations, including lengthy and expensive clinical research, small and fragmented market for medicines for children, and uncoordinated research and development efforts, PADO seeks to identify priority medicines and formulations to be investigated and developed. In addition, it aims to identify promising candidates that require accelerated investigation plans, provide guidance to research and development, define a clear research agenda and enable alignment among funders, procurers, researchers, manufacturers and regulators.

The list of PADO priorities contains priority formulations to be investigated and developed with a time horizon of 3–5 years, and a watch list of promising candidates for investigation and development in children aged 5–10 years. The process will include background assessment, review of gaps and opportunities and prioritization of research and development. PADO for NTDs will require a disease-specific approach due to specific issues and involve diverse groups of experts and networks. The proposed priority NTDs include schistosomiasis, visceral leishmaniasis, human African trypanosomiasis, strongyloidiasis, onchocerciasis and scabies. The specific objectives for each disease were presented to the group. The first PADO
meeting (17 October 2022) would be on schistosomiasis, with other PADO meetings during Q4 2022 and Q2 2023. Interested Working Group members can participate in each meeting to provide their expertise and help with potential, next rounds of prioritization.

2.3 Gap assessment tool on access and logistics

Ashley Souza, Associate Director of Programs, NTD Support Center, The Task Force for Global Health, presented the background and status of the NTD GAP Assessment Tool (GAT). GAT is a periodic, global-level assessment tool introduced in the road map. It analyzes all 20 NTDs against 11 dimensions to provide a systematic, collective understanding of gaps globally and of bottlenecks in NTD programmes that are impeding progress towards achieving the road map targets; it is a call for collective action to accelerate progress. One of four dimensions prioritized is access and logistics. The working group on monitoring, evaluation and research of the WHO Strategic and Technical Advisory Group for Neglected Tropical Diseases is tasked with developing the GAT. The GAT defines the dimension assessment criteria for access and logistics, separately. This dimension will be assessed at national and global levels. Questionnaires for the national and global level assessments are now completed and expected to be launched within the next month.

Pamela Mbabazi, WHO/NTD, clarified that the GAT will not be an annual exercise; rather, it will be implemented three times by 2030. Responding to a question on specific issues at country level, Dr Mbabazi indicated that those will not be highlighted in the global assessment but can be addressed by required actions in the qualitative part of the exercise.

Members of the Working Group will have an opportunity to review the GAT and contribute to its planned implementation. Xiaoxian Huang, WHO/NTD, highlighted the possibility of developing an investment proposal for access and logistics and invited interested members of the Working Group to participate and contribute to it.

2.4 Leishmaniasis procurement steering committee

Fabienne Jouberton, Médecins Sans Frontières International, and Chair of the steering committee on leishmaniasis procurement, described the challenges to accessing leishmaniasis products. These include the limited number of manufacturers with acceptable standards of quality, high prices, the small and fragile market, uncoordinated procurement practices, lack of visibility on demands and insufficient funding. For the five leishmaniasis products currently used, potential solutions were discussed to address specific, identified issues. To facilitate coordinated procurement, engagement with manufacturers and market shaping, WHO/NTD established the procurement steering committee for leishmaniasis in 2020. The committee developed an annual forecast for 2021 and 2022 and shared it with manufacturers. It also coordinated with partners and manufacturers to ensure adequate production and supply for miltefosine and diagnostics. A market shaping strategy is yet to be developed, and strong and effective procurement coordination is required. The committee will continue to develop forecasting models and scenarios, explore mechanisms and other initiatives to create a healthy market, and advocate for more funding.

A member of the Working Group asked if technology transfer was being considered to expand the manufacturer base and respond to the discontinuation of certain products. Fabienne Jouberton replied by giving an example of technology transfer for IT-Leish (a diagnostic tool for leishmaniasis) from Bio-Rad to Mologic. The group discussed whether this procurement coordination mechanism should include other diseases.
3. Drug efficacy monitoring

Antonio Montresor, WHO/NTD, gave an overview of the need to monitor drug efficacy and the role of the working group on drug efficacy. Monitoring of drug efficacy is required because helminths can develop resistance under high drug pressure from use of single medicines. Soil-transmitted helminthiases and schistosomiasis have long-term control programmes and no new drugs are in the development pipeline. The working group on drug efficacy is responsible for developing standard methods to assess anthelmintic drug efficacy, supporting endemic countries to assess and test new medicines or combinations of medicines for use in second-level treatment with preventive chemotherapy. Revision of the manual to estimate therapeutic efficacy is planned in early 2023.

The Working Group suggested to continue testing combinations of already registered medicines (for example, albendazole + ivermectin, pyrantel + oxantel, tribendimidine) as second-line interventions. Responding to a question on the egg per gram level, Dr Montresor mentioned that the new limit for re-intervention can be reflected in the revised manual. Dr Mbabazi also addressed the need to expand drug efficacy monitoring beyond helminths. A member of the Working Group suggested building on the increased capacity of countries to conduct genome sequencing of organisms. Dr Montresor also pointed out that albendazole and mebendazole are rarely absorbed; they act directly on worms in the intestine. Therefore, dosing based on the pharmacokinetics study is ineffective in increasing efficacy.
4. Conclusions and recommendations to STAG

The Working Group deliberated on the various topics presented to its members. The recommendations are based on the scope of the Working Group, recognizing that increasing access requires more leadership, coordination, financial support and other mechanisms such as volume guarantees or any other initiatives that need to be explored.

Recognizing that its members do not have the complete background on all the initiatives that were presented, the Working Group concludes and recommends as follows:

4.1 On coordination of procurement: establish a subgroup to support market shaping and procurement coordination mechanisms, including supply and demand forecasting.

Given the experience of the leishmaniasis procurement steering committee, it will be critical that this subgroup has strong leadership (a secretariat) and resources to ensure it meets regularly and can be effective. An option would be to extend the scope of the existing steering committee on leishmaniasis procurement to other diseases and medicines (as needed) by reinforcing its governance and capacity to fulfill its objectives.

4.2 On evaluation of NTD diagnostics: establish a subgroup to support this activity.

The Working Group is particularly interested in the classification of in vitro diagnostics and the recommended review processes and recommends establishing a subgroup to support this activity (as required, pending the decision on prequalification of medicines for NTDs).

4.3 On the GAT assessment tool on access and logistics: involve the Working Group in any additional reviews to ensure that intended impact is achieved.

The Working Group foresees that the GAT assessment tool is essential to provide a baseline for the demand and supply issues for NTD diagnostics and medicines and will significantly inform its work. Recognizing that the tool is at an advanced stage, the Working Group must be involved in any additional reviews to ensure that it produces the intended impact and welcomes being part of the review of the findings.

4.4 On the GAP-f: share additional information on disease prioritization with the Working Group.

This is a technical area of interest to the Working Group that requires significant attention and investment. Additional information on how medicines or diseases are prioritized would be helpful. The Working Group understands that its members may be involved in this depending on which medicines are being addressed at the time (or which expertise is needed).
4.5 On drug efficacy monitoring: expand the scope of the initiative to include diseases and medicines other than those currently monitored, and secure appropriate resources.

The Working Group considers this a priority. It is essential to closely monitor the development of resistance to medicines across the NTD landscape and to expand this initiative to diseases and medicines other than those currently monitored, especially in cases where only one medicine is available to treat a particular disease. It will be helpful to know the decision process in choosing the current medicines being studied and design a strategy to expand its current scope. This is an area that requires resources (both financial and technical) to be able to expand the scope.
5. Wrap-up and closure

In wrapping up the meeting, the Chair of the Working Group commended its members and requested that they meet in a week’s time to discuss the topics further and formulate the recommendations. The above recommendations were shared with the WHO secretariat after that meeting. In closing, discussions around creating or reviving subgroups were held and it was noted that they should be streamlined to avoid any duplication.

In his closing remarks, Afework Tekle, WHO/NTD, thanked everybody for their interesting and candid discussions and participation. WHO remains committed to engaging with stakeholders and moving to the next steps to ensure access to NTD health products. Finally, he said that if the situation allowed the next meeting of the Working Group would be held in person in 2023.
Annex 1. Agenda

### DAY 1 – 15 September 2022, Thursday

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<td>14h10–14h20</td>
<td>Introduction</td>
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<td>14h20–14h40</td>
<td>NTD diagnostics evaluation</td>
<td>Camilla Ducker</td>
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<td>14h40–15h10</td>
<td>GAP-f and PADO for NTD</td>
<td>Martina Penazzato</td>
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<td>Tiziana Masini</td>
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<td>15h10–15h30</td>
<td>GAT on Access and Logistics</td>
<td>Ashley Souza</td>
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<td>15h30–16h00</td>
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### DAY 2 – 16 September 2022, Friday

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<td>Leishmaniasis procurement</td>
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<td>Drug efficacy monitoring</td>
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<td>15h50–16h00</td>
<td>Closing</td>
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Annex 2. List of participants

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Invited speaker

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