WHO Target Product Profiles (TPP) Process and Implications for WHO NTDs

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WHO Target Product Profile

- Intends to facilitate the most expeditious development of missing health products **addressing the greatest and most urgent public health need**
- Recognizes that **access, equity and affordability** are integral parts of the innovation process and need to be **considered at all stages**, not just after a product is developed
- Serves as a strategic reference document for comparison and transparency on alignment between **WHO's preferences** and that of industry or funding entity.

WHO TPP Core Process

1. Determine if a WHO TPP is needed and clarify the unmet public health need

   A. Is the public health issue a priority? What is the use case for the missing health product?

   B. Are existing products or products in the pipeline able to meet the critical public health needs in settings where the need is greatest?

WHO TPP Core Process

2. Define the scope and purpose of the TPP and obtain approval from the WHO Science Department
3. Determine whether there is an audience for such a TPP outside WHO through external consultations with relevant audiences

WHO TPP Core Process

4. Constitute a scientific group* to develop the TPP
   - leading scientists and experts
   - public health officials
   - regulators
   - in-country end-user representatives
5. Develop a version zero draft of the TPP document with the TPP development group and produce a version 0.1

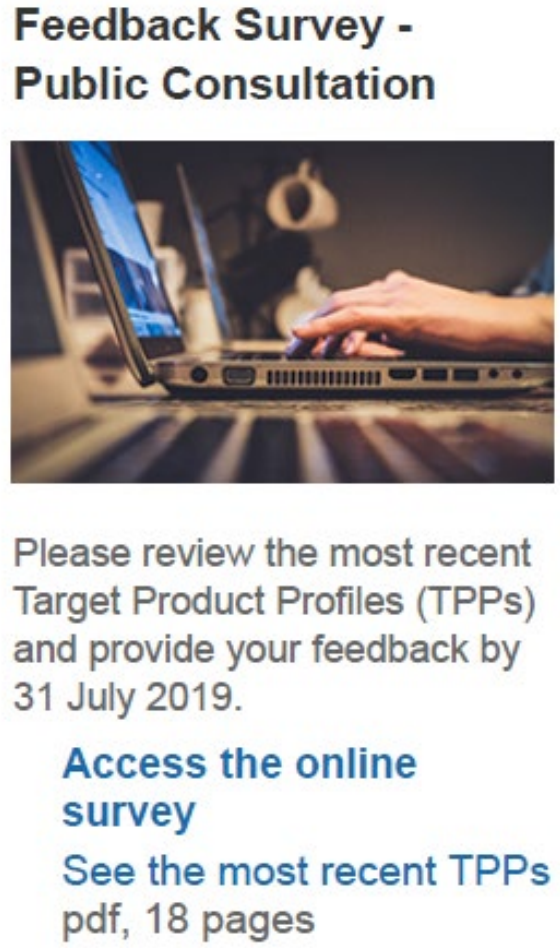
WHO TPP Core Process

6. Post version 0.1 for public consultation for 28 days.

   - Standard feedback form

   - Disseminate news of consultation widely

   - Specifically seek comments from industry, relevant product development partnerships, funders, scientists, and end-users.



WHO TPP Core Process

7. Share comments received with TPP development group, together with a proposed next version of the TPP and decide:

   a. further consultation and revision

   b. endorsed as version 1.0, dated and posted on WHO's website

WHO TPP Core Process

8. Upload to the (WHO) Global Observatory for Health R&D and Product Profile Directory.

http://origin.who.int/research-observatory/resources/databases/processes/en/index4.html

Implications for WHO NTD Diagnostic Development

- DTAG subgroups will support WHO to
  - clarify the unmet public health needs
  - determine whether existing TPPs, available or pipeline products address the needs
  - define the scope of new TPPs and ensure that they are aligned with the public health need
  - serve as the scientific group to develop new TPPs

So – where are we now with respect to NTD TPPs?

- More than 20 TPPs have been developed
  - BU, GW, HAT, Leishmaniasis, Leprosy, LF, Mycetoma, Oncho, Scabies, SCH, STH, and yaws (and others under development)
  - See WHO website here: https://cdn.who.int/media/docs/default-source/ntds/neglected-tropical-diseases-non-disease-specific/status-target-product-profiles-for-ntds.pdf?sfvrsn=74b6c3d_7
- Donors have invested in new diagnostic tests based on the availability of TPPs

Published TPPs

	Disease	Subject	Web link to publication
1.	Buruli ulcer	TPP for a rapid test for diagnosis of Buruli ulcer at primary health-care level	https://iris.who.int/handle/10665/353982
2.	Dracunculiasis (Guinea-worm disease)	TPP to detect prepatent Dracunculus medinensis infections in animals	https://iris.who.int/handle/10665/376398
3.	Dracunculiasis (Guinea-worm disease)	TPP to detect Dracunculus medinensis presence in environmental samples	https://iris.who.int/handle/10665/376399
4.	Human African trypanosomiasis	TPP for a gambiense HAT test to identify individuals to receive widened treatment	https://iris.who.int/handle/10665/352579
5.	Human African trypanosomiasis	TPP for a test for rhodesiense HAT diagnosis usable in peripheral health facilities	https://iris.who.int/handle/10665/344165
6.	Human African trypanosomiasis	TPP for an individual test to assess gambiense HAT infection in low prevalence settings	https://iris.who.int/handle/10665/365383
7.	Human African trypanosomiasis	TPP for a high-throughput test for verification of elimination of gambiense HAT	https://iris.who.int/handle/10665/365384
8.	Leishmaniases (dermal)	TPP for a point-of-care test for dermal leishmaniases	https://iris.who.int/handle/10665/353980
9.	Leishmaniasis (visceral)	TPP for a diagnostic test to confirm cure of VL	https://iris.who.int/handle/10665/378031
10.	Leishmaniasis (visceral)	TPP for a diagnostic test to confirm VL	https://iris.who.int/handle/10665/378703
11.	Leprosy	TPP for a diagnostic test to confirm leprosy in individuals with clinical signs and symptoms	https://iris.who.int/handle/10665/371647
12.	Leprosy	TPP for a diagnostic test to detect Mycobacteriun leprae infection among asymptomatic contacts of leprosy patients	https://iris.who.int/handle/10665/371646

Published TPPs (cont.)

13.	Lymphatic filariasis	TPP for LF to support decisions for stopping triple-therapy NDA	https://iris.who.int/handle/10665/340080
14.	Lymphatic filariasis	TPP for surveillance of LF	https://iris.who.int/handle/10665/340081
15.	Mycetoma	TPP for a rapid test for diagnosis of mycetoma at primary health-care level	https://iris.who.int/handle/10665/353979
16.	Onchocerciasis	TPP for mapping onchocerciasis	https://iris.who.int/handle/10665/341719
17.	Onchocerciasis	TPP for stopping MDA	https://iris.who.int/handle/10665/341719
18.	Scabies	TPP for starting MDA	https://iris.who.int/handle/10665/353981
19.	Scabies	TPP for stopping MDA	https://iris.who.int/handle/10665/353981
20.	Schistosomiasis	TPP for monitoring and evaluation	https://iris.who.int/handle/10665/344813
21.	Schistosomiasis	TPP for transmission interruption and subsequent surveillance	https://iris.who.int/handle/10665/344813
22.	Snakebite envenoming	TPPs for animal plasma-derived antivenoms: antivenoms for treatment of snakebite in sub-Saharan Africa	https://iris.who.int/handle/10665/369786
23.	Snakebite envenoming	TPPs for animal plasma-derived antivenoms: antivenoms for treatment of snakebite in south Asia	https://iris.who.int/handle/10665/378302
24.	Soil-transmitted helminthiases	TPP for monitoring and evaluation of soil-transmitted helminth control programmes	https://iris.who.int/handle/10665/342539
25.	Yaws	TPP for identifying a single case of yaws	https://iris.who.int/handle/10665/353978
26.	Yaws	TPP for detecting azithromycin resistance	https://iris.who.int/handle/10665/353978

Key Considerations

- Effective interventions are being delivered for many NTDs and prevalence is declining
- The need for highly specific tests increases as prevalence declines
- Multiple tests may be required for a given disease to address different use cases
- Independent test evaluation helps ensure test performance and the acceptability of tests by the end user
- WHO is opening new pathways to recommend new tests for use by country programs