Health Product Profile Directory: for smarter, more efficient R&D to tackle global health priorities

Frequently Asked Questions

What is the Health Product Profile Directory?
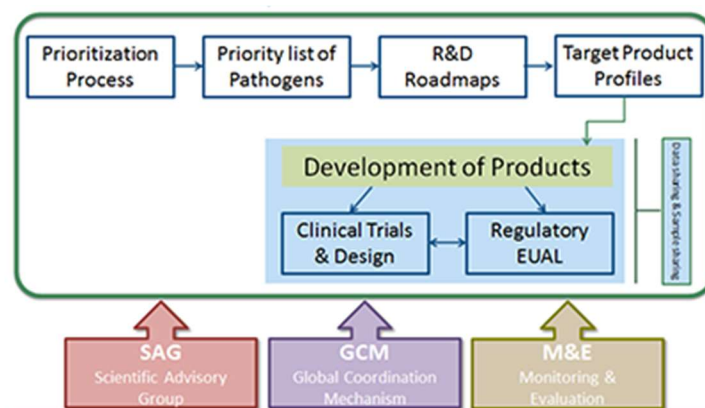
The Health Product Profile Directory is a free-to-use online resource created and developed by TDR on behalf of WHO as a global public good to improve the efficiency of efforts to develop new products for neglected diseases and populations as well as threats to global health. It provides a searchable database of the 8-10 key characteristics used to describe desired health products, including medicines, vaccines, diagnostics and medical equipment. Links are provided to access the full Product Profile document where this is publicly available. The Directory was launched in May 2019 and will be regularly updated.

Why was the Product Profile Directory created?

The Ebola outbreak of 2014-15 and other recent pandemics have highlighted the urgent need for centralized information at global level to guide and improve coordination of efforts to develop new health products for neglected diseases and populations. The initial concept for this resource is contained in the TDR report, *Health Product Research and Development Fund: a Proposal for Financing and Operation* (2016). Specifically, the Directory:

- Provides a repository for existing health product profiles.
- Introduces harmonization and standardization in the description of health product profiles.
- Enables a high-level landscape analysis of R&D activity related to these product profiles.
- Emphasizes access, equity and affordability as integral parts of the innovation process that need to be considered at all stages, not just after a product is developed.

Figure 1: An example of product profiles in the R&D process

What is a Health Product Profile?

A product profile is a written document describing the characteristics of a health product. They are used in planning research and development and can also frame the description of a product for regulatory purposes. There are two broad categories (without standard nomenclature) that have be defined following a review of more than 200 published documents:

- **Preferred Product Characteristics (PPCs)** are prospective, strategic documents describing an ideal product class often at the early stage of development or seeking to stimulate innovation in a new area. For WHO the preferred term here is Preferred Product Characteristics (PPC) but other agencies use similar terms including Ideal Product Profile, Intervention Product Profile or Target Candidate Profile (among others).
- **Target Product Profiles (TPPs)** are used when a pipeline develops, and more specific targets and minimum performance characteristics are able to be described with a much narrower specific description.

All variations of product profile are captured in the Health Product Directory.

What is the significance of WHO authored product profiles?

Where WHO has identified a priority need for a product class, but the stage of development is early, some documents will use the term Preferred Product Characteristics (PPCs) focusing on providing strategic guidance and higher-level considerations (for example 2nd generation malaria vaccines).

WHO Preferred Product Characteristics (PPCs) describe WHO preferences for parameters. In particular, these include its indications, target groups, possible intervention strategies, and features of clinical data desired related to safety and efficacy. These preferences are shaped by the unmet public health need in a priority disease area for which WHO encourages new research and development. In keeping with its mandate, WHO preferences reflect its desire to promote the development of products with high public health impact and suitable for use in low to middle-income countries.

WHO Target Product Profiles (TPPs) are intended to support the development of missing health products and are needs based and focused on public health priorities. WHO TPPs emphasize access, equity and affordability as integral parts of the innovation process that need to be considered at all stages, not just after a product is developed.

A WHO TPP is intended as a strategic reference document for comparison and transparency on alignment between 1) WHO's preferences for product development in a given area and 2) the product or development programme specific TPP used by the industry or funding entity. The WHO TPP document should inform product developers, regulatory agencies, procurement agencies and funders on R&D and public health priorities. It is intended to facilitate the most expeditious development of products addressing the greatest and most urgent public health need.

What are the inclusion criteria for a health product profile to be listed in the Directory?

The Directory does NOT aim to cover all health products. Instead it describes profiles of health products for which there is currently no market or limited incentive for research and development. These include: poverty-related neglected diseases, diseases identified as having the potential to cause pandemics (e.g. Ebola), new products to combat anti-microbial resistance, products with a focus on addressing health issues in low- and middle-income countries, and products prioritized for global action by the World Health Organization and are clearly marked as authored by WHO.

The Directory also lists those product profiles authored by Product Development Partnerships, commercial companies and other organizations that share the same inclusion criteria listed above. These are labelled non-WHO profiles.

When launched the Directory contained 196 profiles developed by 24 different agencies (WHO, UNICEF, R&D funding agencies, PDPs and pharmaceutical companies). 191 profiles have a target of an infectious disease. 5 profiles describe a vaccine to combat breast cancer and 4 contraceptive products.

The HPPD will be regularly updated and maintained.

What can I use the Health Product Directory for?

The Directory allows a user to search by disease, product type, date of creation, author (who produced the profile) and status (whether the profile is still active or has been archived as a historical record.) The Directory provides a url or contact email to enable the user to access, where available, the full document with more detailed information on the profile. The user can compare up to three product profiles directly on screen or download their search results directly into a Microsoft Excel spreadsheet for further analysis. The WHO Global Health R&D Observatory provides graphics showing an analysis of the data in the Health Product Directory.

How do I submit a new profile?

Any organization that meets the inclusion criteria can submit a summary of their product profile via the online form. Please note this must include a url linking to the publicly accessible full document of the product profile or a contact email where requests for further information can be sent. Where a collaboration has generated a product profile a lead author of the profile must be selected.

The **inclusion criteria** are: health product profiles for which there is no market or limited incentive for research and development. This includes: the poverty related neglected diseases, the diseases identified as having the potential to cause pandemics (e.g. Ebola), new products to combat anti-microbial resistance and those products with a focus on addressing health issues in low- and middle-income countries.

Submission Process

There are two ways to enter text into the form. Either choose an item from the drop-down menu, options will be displayed as you type, or enter text free style where no drop-down option is available. If an item is not available in a drop-down list (for example your organization is not listed) please add that information as free text.

Table 1. below provides a brief description of the health product characteristics required to list your profile in the Directory. **Please note not all characteristics apply to all types of product profile.**

Table 1:   Description of the health product profile characteristics contained in the Health Product Profile Directory.

Profile Characteristic	Example descriptions
Document title	A description of the health product profile including product type target disease and/or health condition for a target population or geographic location.
Author	The lead organization that developed and published the health profile. When a profile was published in a journal the main institutional affiliation of the corresponding author was chosen.
WHO	A check box to enable quick separation of WHO-authored health product profiles from those authored by others.
Diseases	One or more disease and/or health condition (e.g. reproductive health) targeted by the product.
Product type	Short-description of the product type: diagnostic; drug; vaccine; digital health; drug regimen; injectable/implant; not defined. As the directory content grows these definitions will expand.
Year published	The year the profile document was published
Status	Active: the profile is still considered relevant Archive: the profile is no longer relevant. In the Health Product Directory profiles older than5 years from the current date are considered archive.
Indication	The purpose of the product e.g. to provide immunization against disease A. To identify presence of bacteria B in drinking water.
Intended use	Primarily used for diagnostics to separate triage, screening and more precise diagnosis.
Target population	Age group or other specific sub-population groups
Sample type and volume	Primarily for diagnostics describing the medium that is tested e.g. blood, stool, saliva, drinking water.
Use setting	Who would use the product and under what conditions, infrastructure requirements e.g. trained nurse in a low resource setting primary health care facility, no cold chain. Shelf life.
Performance	Describes for diagnostics: specificity, sensitivity, reproducibility, robustness, time to result. Nature of result qualitative or quantitative.

Profile Characteristic	Example descriptions
Efficacy	For drugs and drug regimens: the clinical characteristics, dosing, pharmaco-dynamics, rate of onset of action, interaction with other therapeutics etc. For vaccines: expected efficacy, duration, reversibility, strain coverage, interaction with other vaccines etc.
Safety	For drugs, drug regimens and vaccines: clinical safety and tolerability, safety monitoring requirements, contra-indications and relation to specific populations types e.g. infants, pregnant women, during breast-feeding.
Comments	Additional comments not able to be categorized above.
Document url	Ideally an archive providing a permanent url where the full document is published openly online.
Contact email	A contact email for further information on the product profile

Please note the Directory is moderated so when your profile is submitted it will not be immediately live in the Directory. The content will be reviewed to ensure the data in the fields correspond with the definition above. Following review, it will be published within 3-4 working days. No profile will be published without containing either contact details as an email or a url to the public document.

Please note the Disclaimer statement below that inclusion in the directory of non-WHO authored profiles does NOT imply any endorsement or recommendation of that product profile by the World Health Organization.

How do I update an existing profile?

It is important that the product profiles are correctly labelled as either Active – the information is still considered up to date or Archived – the product profile is no longer active.
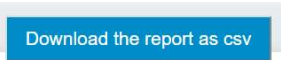If a product profile you have responsibility for is updated submit the new profile via the submission form and clearly indicate which product profile that exists in the Directory this replaces. During review the original profile that has now been updated will have its status changed to Archive.

The Product Profile Directory will automatically default the status of a profile to Archive after 5 years from its publication date.

The content will be reviewed to ensure the data in the fields correspond with the definition above. Following review, it will be published within 3-4 working days. No profile will be published without containing either contact details as an email or a url to the public document.

How do I use the Health Product Profile Directory?

There are two search functions for the Health Product Directory.

1. Enter a key word in the [Type a new search] box and press

2. For a Filtered search use the drop-down menus for the following categories: [Disease] [Product Type] [Author] [Status] and/or [Year]. These can be used in any combination and the filters can be added or deleted. If no filter is used the whole database is produced in the search output.

3. To launch a Filtered search use the BLUE search button

4. NB **do not** use the button for Filtered searches.

How do I view my search results?

There are three options to view the outputs of a search:

1. View the results as a basic list on screen. Please note this list might extend over several pages

2. Use the tick box next to the basic list items to highlight up to 3 profile and press to view and compare the 3 profile summaries side by side.

3. All the data in the Health Product Directory is free to download. After a search press the button to download the output as a csv file into Microsoft Excel for further analysis.

To return to the Home screen use the [<-back] button at the top left of the screen. To return to the TDR site press

Contact details

For any queries regarding the Product Profile Directory please email: pp-directory@who.int

Disclaimer – inclusion in the directory of non-WHO authored profiles does NOT imply any endorsement by the World Health Organization.

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