

### What is a TPP?

A **Target Product Profile (TPP)** outlines the intended product attributes and other critical details for a specific product in development and describes them in terms of the desired label claims for the product. In this way, a development program for a given product may begin with the desired final product attributes in mind. The general structure of a TPP itself resembles a product label, or product insert, that would be found associated with a regulatory licensed commercial product or device, and it provides information on that product's *indications, dosage, mechanism of action, target populations, efficacy, storage/shelf life, preclinical and clinical safety, pharmacokinetics, contraindications*, and relevant data pertaining to each of these attributes.

### The Role of a Generalized TPP

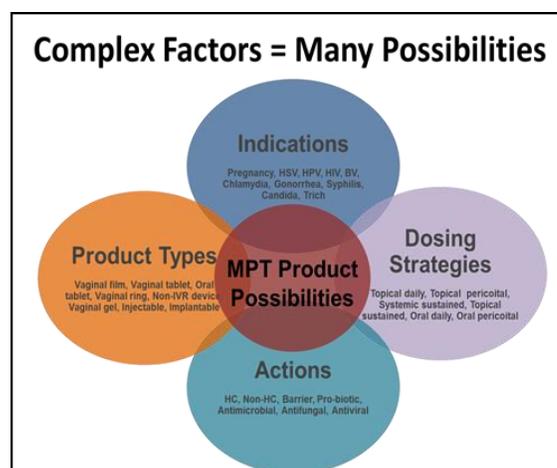
Conventionally, a TPP is produced to serve as a communication mechanism between product developers and the FDA, providing a [detailed framework](#) of targeted achievements for the product development process in order to result in the specific label claims for the desired product. Recently, the TPP concept has been generalized and expanded, particularly in the area of public-private partnership (PPP) product development efforts. A more general TPP designed to broadly define a desired product type (as opposed to a specific product) may serve as a guidance tool for funders and product developers, assuring that product development efforts and goals are aligned and focused on products with the highest potential for public health impact.

A TPP serves as the standard through the course of a specific product development effort. Defining the appropriate product design elements and performance requirements at the beginning of the effort serves as the basis for continued product-based investments according to GO/NO GO development decisions. In other words, **a TPP for a particular product concept can be used to help align investors and product developers around specific product attributes necessary for addressing unmet medical needs in targeted at risk populations.**

### Why do we need TPPs for MPTs?

Multipurpose prevention technology (MPTs) development is a complex and likely expensive process. The inherent complexities of MPTs lead to a wide array of potential MPT configurations.

The development of MPT dosage-form specific TPPs will help the MPT field by providing a framework for product developers and supporting agencies to use in the development of specific product TPPs, providing benchmarks for evaluation of the development process. Robust TPPs for MPTs that are rooted in the objectively defined attribute requirements for these products is critical, particularly in the context of a more limited resource environment which cannot accommodate more tangential product development efforts or investments.



## Purpose

In 2012, [Initiative for Multipurpose Prevention Technologies \(IMPT\)](#) managed an exercise to define general target attributes for MPT products. While prioritizing specific MPT product dosage forms (i.e., long acting injectables, intravaginal rings, and on-demand products), it became clear that it was necessary to move beyond a listing of general MPT product attributes and to develop more specific TPPs focused on each type of prioritized product dosage form. These dosage-form specific TPPs focused on defining the necessary attributes and required supporting data for the successful development of impactful MPT products. The main objectives for developing these TPP guidance documents were to:

- 1) Provide design and development guidance to MPT product developers regarding the specific product attributes necessary for an impactful MPT product, and
- 2) Provide a tool that could inform decision making by funding organizations with regard to evaluation of product development investment options.

The availability of specific TPPs for the individual MPT dosage forms would therefore provide a useful means of developing a particular *product specific* TPP that is appropriately populated with target attributes. This could then serve as a standard for GO/NO GO decision making by the funders and product developers engaged in the product development.

## Methodology

Initial drafts of the TPPs were produced in collaboration between the IMPT and the Bill & Melinda Gates Foundation. The product attribute categories are consistent with those defined in the [FDA guidance for TPPs](#), and were intended to address the necessary label claims for a high impact TPP. Importantly, it was recognized that individual product development organizations would need to produce their own product specific TPPs for their particular MPT candidates. However, a goal was for these dosage-form specific TPPs derived by the IMPT to serve as guidance to developers by reflecting the product attributes that were consistent with funder goals for MPT product design. Therefore, review of these draft product TPPs involved both funder and product developer input.

The TPPs were initially reviewed and revised by members of the IMPT [Scientific Agenda Working Group \(SAWG\)](#), which is comprised of technical experts from the major MPT supporting agencies. The drafts were then circulated more widely to include MPT product development organizations, other relevant experts in product development and clinical evaluation, and IMPT regional experts.

## Results

Although the total response to the opportunity for these groups to review the TPPs has been limited, the collective feedback was comprehensive and aligned. Specific input from these reviewers was incorporated into each TPP. Importantly, it is recognized that proper MPT TPPs will continue to be informed by new data as it becomes available to the field. Consequently, it is anticipated that better informed TPPs will become available through regular review in the context of new information. MPT Dosage-Form Specific TPPs are available for Long Acting Injectables and Intravaginal Rings (IVR) and can be found on the CAMI Health website.