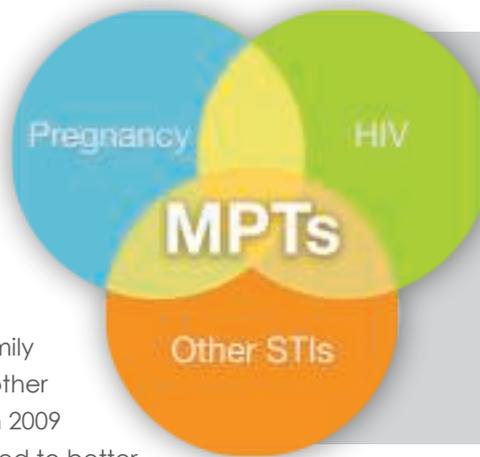




## Background

Products developed with the needs and realities of consumers and the systems where they will be distributed have a greater likelihood of uptake and acceptability. While simple on its face, this principle has not always been included in development of consumer health products or interventions.

When international experts involved in family planning and the prevention of HIV and other sexually transmitted infections (STIs) met in 2009 and discussed how solutions could be linked to better address women's sexual and reproductive health (SRH) needs, the field of multipurpose prevention technologies (MPTs) was born. Building upon decades of contraceptive and microbicide research, MPTs are growing into an exciting strategy for improving SRH, with close to two dozen products in development, nearly a dozen in clinical studies, and partners from 15 countries. At the heart of the Initiative for Multipurpose Prevention Technologies (IMPT) is a commitment to improve the health of women and adolescent girls, who continue to experience the significant health and economic impact from unintended pregnancies and HIV/STI infections. However, it is not sufficient for an MPT product to be effective, it must also be desirable – or at least acceptable – to the intended audience and fit within the realities and constraints of the health systems where they will be delivered.



Multipurpose Prevention Technologies (MPTs) – products designed to deliver protection against HIV, other STIs, and unintended pregnancy in varied combinations – have evolved into an exciting field of research that holds great promise for improving SRH. Developing and evaluating MPTs is complex, and raises questions and challenges in the areas of product development, research and testing, and regulatory approval.

Since the launch of the IMPT, the IMPT Secretariat has served as the central backbone of the IMPT, and works to advance the scientific and technical agenda to support MPTs **by creating working groups, advisory committees, and task forces** comprised of product developers, social science and biomedical researchers, regulatory experts, supporting agencies, and SRH advocates to catalyze this new field and build capacity for MPT development and introduction. Through a collaborative and iterative process, the IMPT and its partners have surveyed the product pipeline, highlighted research gaps, identified regulatory requirements, and recommended strategies for accelerating MPT development.

## Tracking and Prioritizing the MPT Pipeline

In 2010, the IMPT Secretariat began tracking the growing number of MPT candidate products and created a [searchable database, available at the IMPT website](#). In 2012 the IMPT's Scientific Agenda Working Group (SAWG) and Secretariat characterized MPT product attributes, such as product indication and dosage forms, to identify and prioritize those with highest potential for health impact based on input from SRH researchers and other experts from across the globe.

The SAWG recommendations for **priority MPT attributes** are intended to help donors and funding agencies advance MPT product candidates that are most likely to be effective and acceptable to key populations. These SAWG recommendations were reviewed by experts for technical feasibility; regulatory considerations; acceptability, use, and potential for uptake; and potential for product delivery to the target populations. This **prioritization process** – which identified lead candidate types for different MPT delivery systems and product categories – pooled technical expertise between MPT development groups and helped funding agencies and developers focus on product candidates that make best use of limited resources. In 2013, this information was then used to develop [target product profiles for MPT](#) products to guide future development. The IMPT and its partners shared results from these consultations through working group reports, presentations at international conferences, and publications.

## Facilitating Critical Conversations

The IMPT and its coalition of partners have convened **consultations on scientific and technical questions** related to MPT product development. For example, through [meetings with hormonal contraceptive \(HC\) and HIV experts](#), the IMPT has explored the potential impact of MPTs that contain both HCs and anti-retroviral (ARV) drugs, and have identified potential challenges and research gaps, including HC and HIV susceptibility; dosing of HC in combination with anti-retroviral therapy; topical effects and drug-drug-interactions; and biological and social-behavioral aspects of MPT development. Reports from these consultations are available on the [IMPT website](#).

## Exploring Regulatory Considerations for MPT Development

At the same time, the Population Council, an IMPT partner, explored regulatory considerations for MPT product development. Since **regulatory considerations shape product development** and clinical validation of new products, an early step of the IMPT was to outline pathways, challenges, and potential constraints for these various MPT product categories. MPTs that contain a *drug + drug*, or a *drug + device* are "combination products" from a regulatory perspective. These MPTs incorporate different modes of action and different active ingredients requiring multiple strategies to assess safety and effectiveness. The Population Council and regulatory experts shared this information through presentations at international consultations and conferences, as well as journal articles. [These resources are posted at the IMPT website](#).

## Guiding Best Practices for Uptake and Impact

In 2015, the IMPT developed a [Market Access Framework for MPT Development and Introduction](#) to provide a high-level roadmap for organizing activities along the product development timeline as well as detailed descriptions of activities tailored to MPT development and introduction. This Market Access Framework is a tool for both developers, researchers, and the funding community to ensure that MPTs are being developed according to best practices to ensure eventual uptake and health impact.

IMPT partners and other research experts also are considering **ethical questions related to MPT clinical studies** that will be required to build evidence of the safety and effectiveness of MPT products. Clinical research experts also are **discussing questions around study design issues for MPT clinical studies** in the context of roll-out and scale-up of PrEP products in many countries. These discussions are intended to address the challenges that have faced previous microbicide studies, and prepare for the day when MPT products are ready for effectiveness studies.

The scientific and technical topics in the MPT field are evolving. As more products enter the pipeline and move from pre-clinical toward clinical studies, additional information gaps and research areas will be identified.

*This brief highlights some accomplishments from the IMPT and its partners, who have raised **awareness and advocacy** to help the MPT field grow. Separate briefs highlight accomplishments in the areas of **technical and research issues to strengthen MPT product development**, and **incorporating social-behavioral and market research into product development**.*

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