

Considerations for the Regulatory Approval of Multipurpose Prevention Technologies (MPTs)

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~and~

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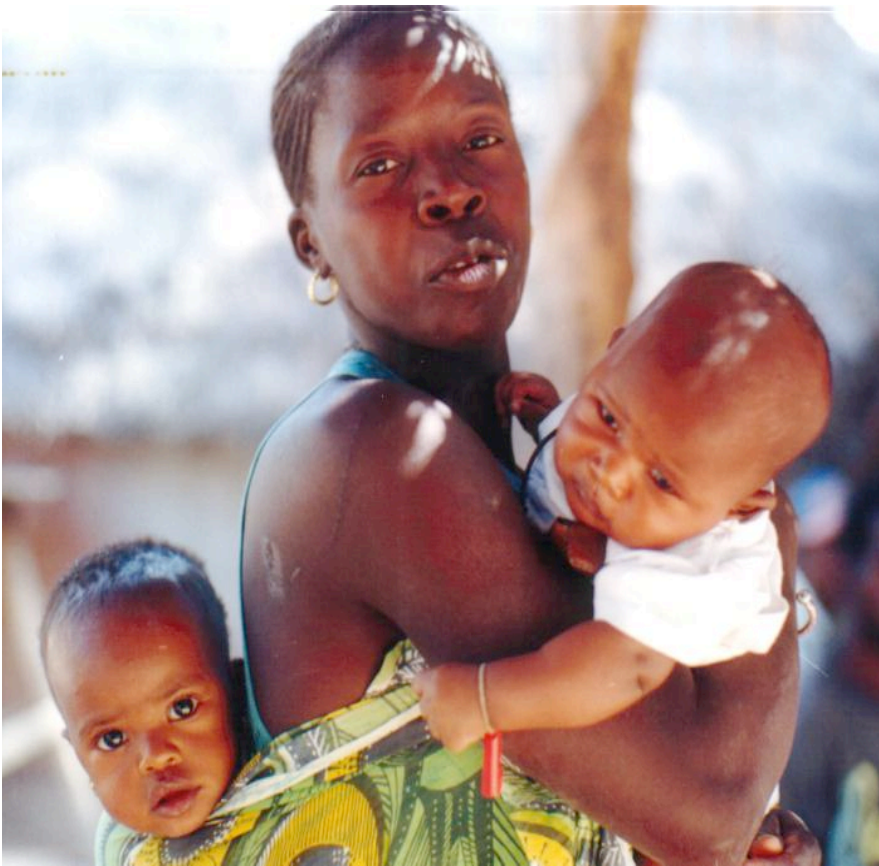


11-12 December, 2012
India Habitat Centre - New
Delhi, India

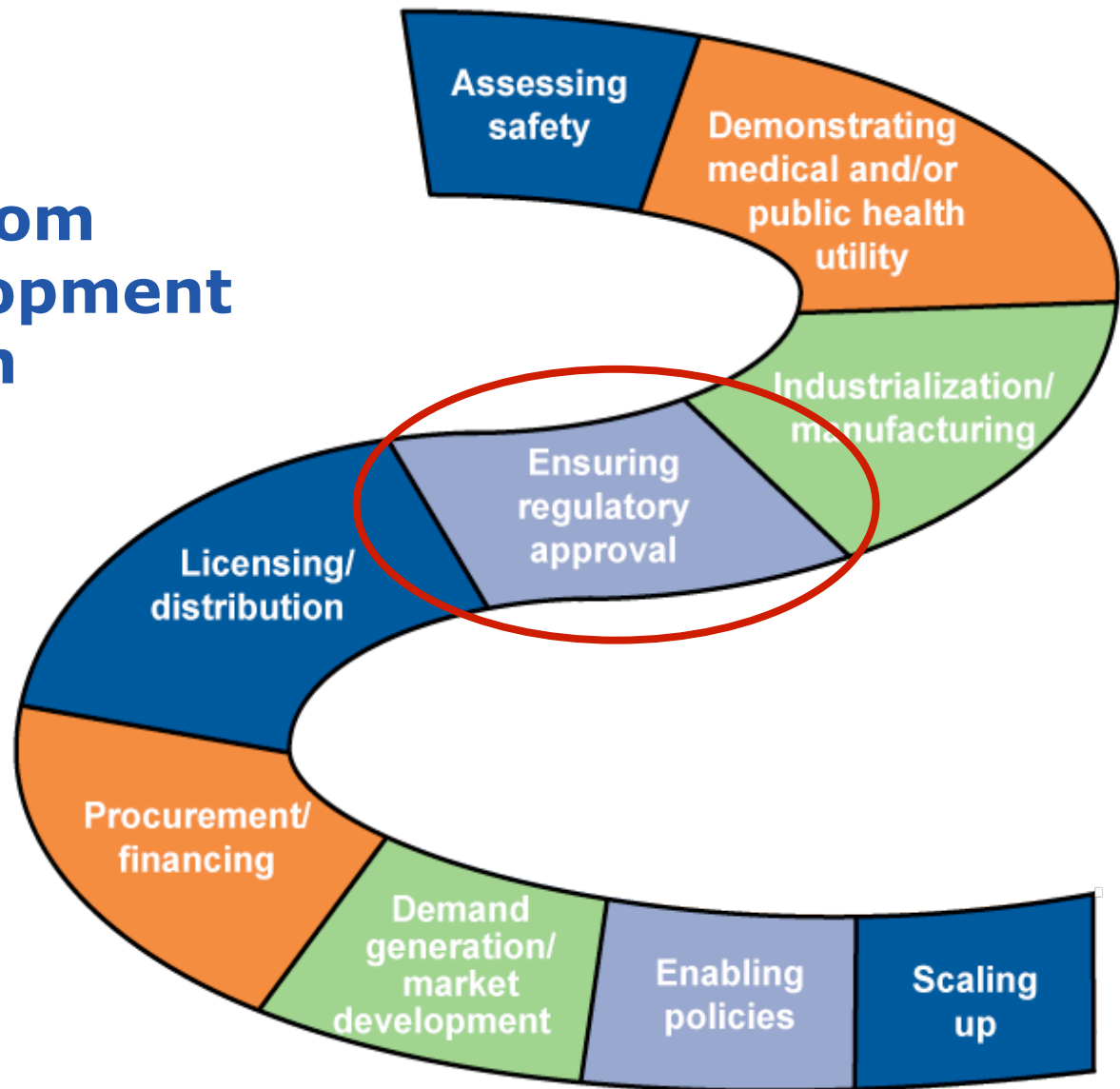


Who Needs MPTs?

Diverse groups of women across geographies, ages, cultures



Constructing a Critical Path from Product Development to Introduction





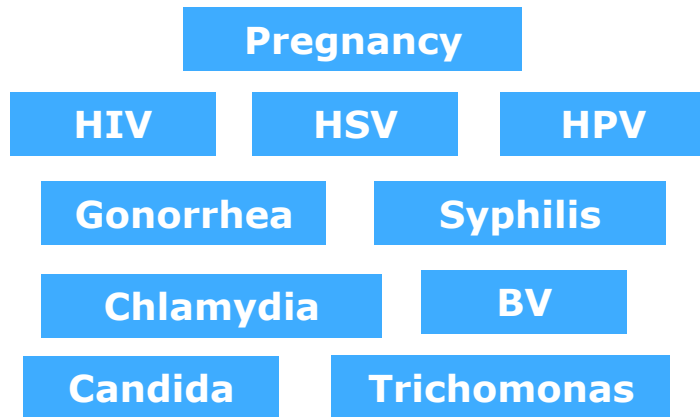
Ensuring
regulatory
approval

CRITICAL ACTIVITIES

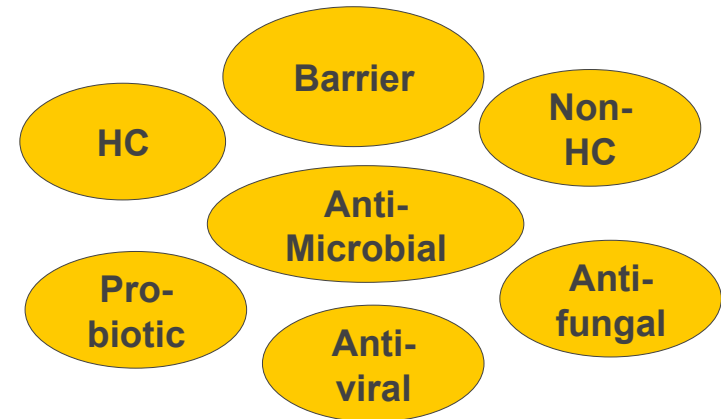
- **Clarify regulatory pathway(s) for MPTs**
- **Engage regulatory bodies at global and local levels**
- **Work with product developers and/or manufacturers to submit dossiers**

Complexities of developing MPTs:

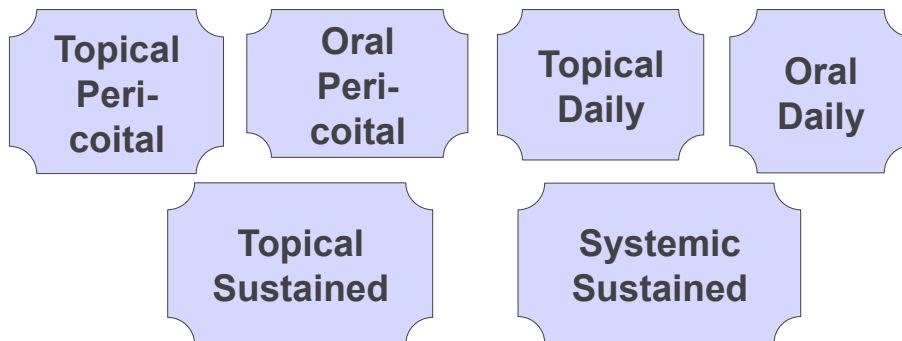
INDICATION



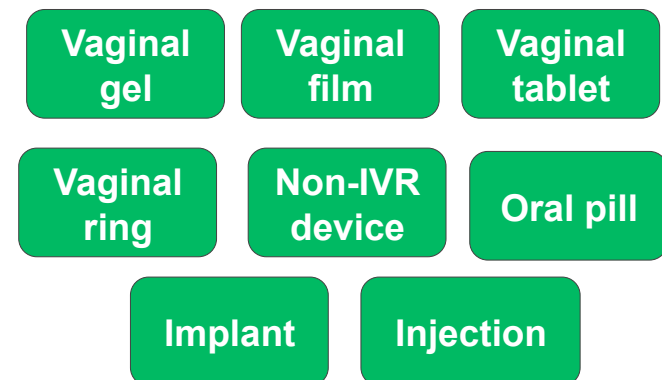
MECHANISM OF ACTION



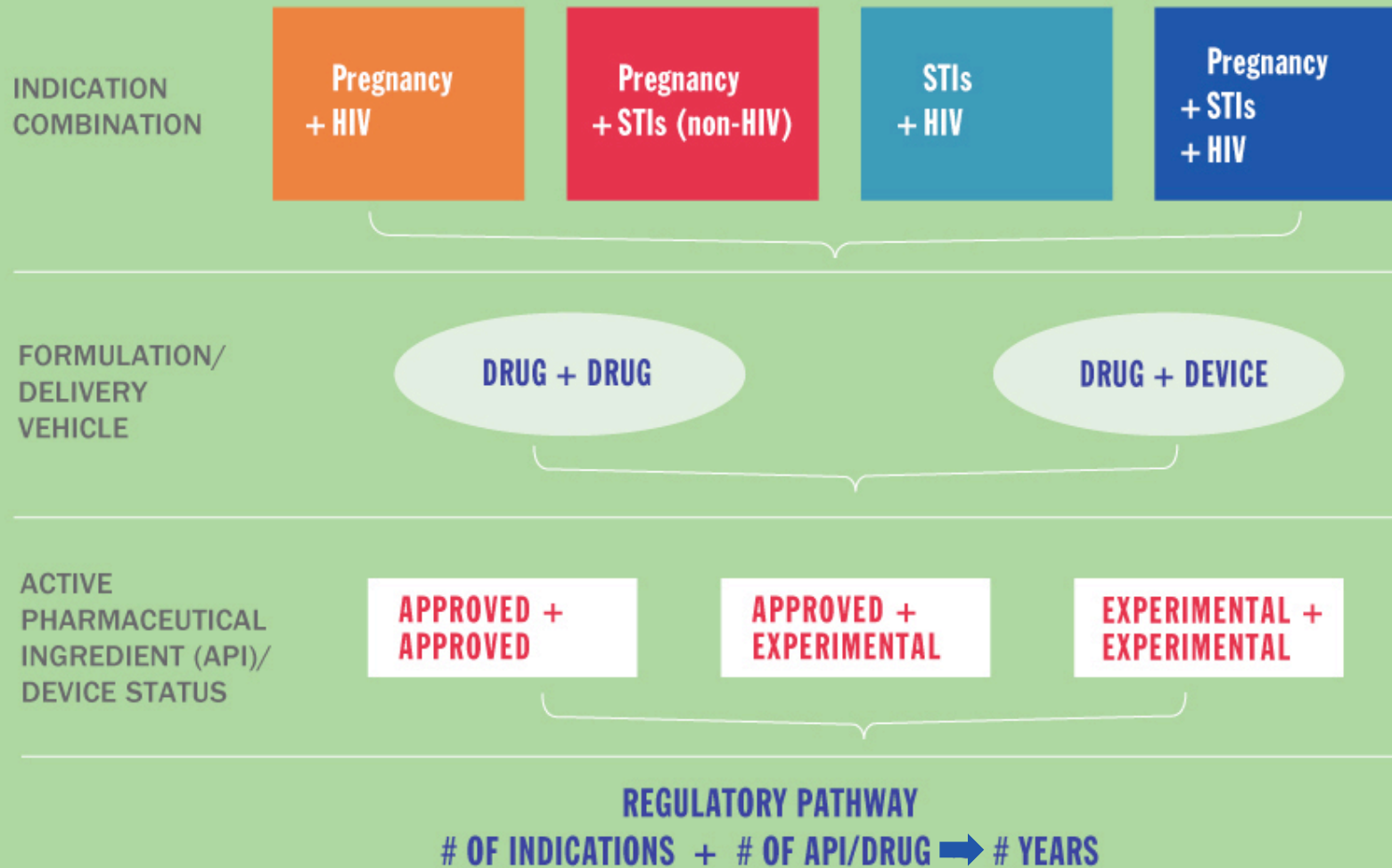
DOSAGE & ADMINISTRATION



FORMULATION & DELIVERY



MPT Pathway: A Typology



Martha Brady
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MPT Regulatory Puzzle



Specific regulations will vary with each MPT,
however

the following perspectives provide a basis:

- ✓ Experimental versus approved
- ✓ Drug versus device
- ✓ Systemic versus topical delivery

Thank you!