



Engaging Global Stakeholders to Expand Access to the LNG-IUS

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Medicines360

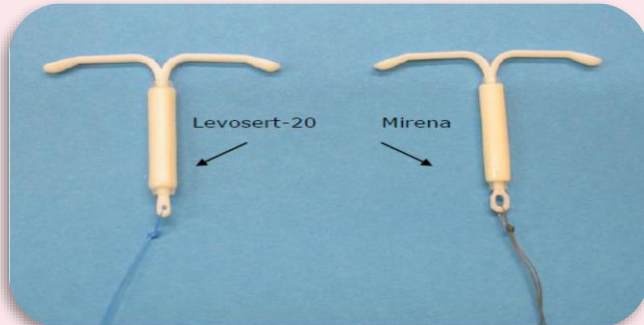
Medicines360 Mission

Medicines360 is a global nonprofit pharmaceutical company with a mission to expand access to high quality medicines for all women, regardless of their socioeconomic status, insurance coverage, or geographic location.



Our First Product: A Hormonal Intrauterine System (LNG-IUS)

T-Shaped, drug loaded IUD



- Total drug load: **52 mg of levonorgestrel (LNG)**
- Designed for **~20 mcg/day** LNG elution rate
- **> 99% effective for up to three years***; high continuation rate at one year
- No scalpel or lidocaine needed for insertion or removal

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Loaded with an insertion device (2 options):

Option 1: Approved by multiple SRA's

- 2-handed inserter



Option 2: In Development

- Medicines360 Proprietary 1-handed inserter



Note: * U.S. study is ongoing; Medicines360 will seek approval for duration of use beyond 3 years

Medicines360's LNG-IUS Has Been Approved in ~20 Countries

- **Approved by the U.S. FDA** in February 2015 for 3 years of contraception*; marketed as Liletta®



- **Approved by the MHRA** for 3 years of contraception and menorrhagia; marketed as Levosert



- M360 creating a global brand name to be used where we have distribution rights

Note: * U.S. study is ongoing; Medicines360 will seek approval for duration of use beyond 3 years

Medicines360 Partners with Allergan to Manufacture and Distribute Its LNG-IUS

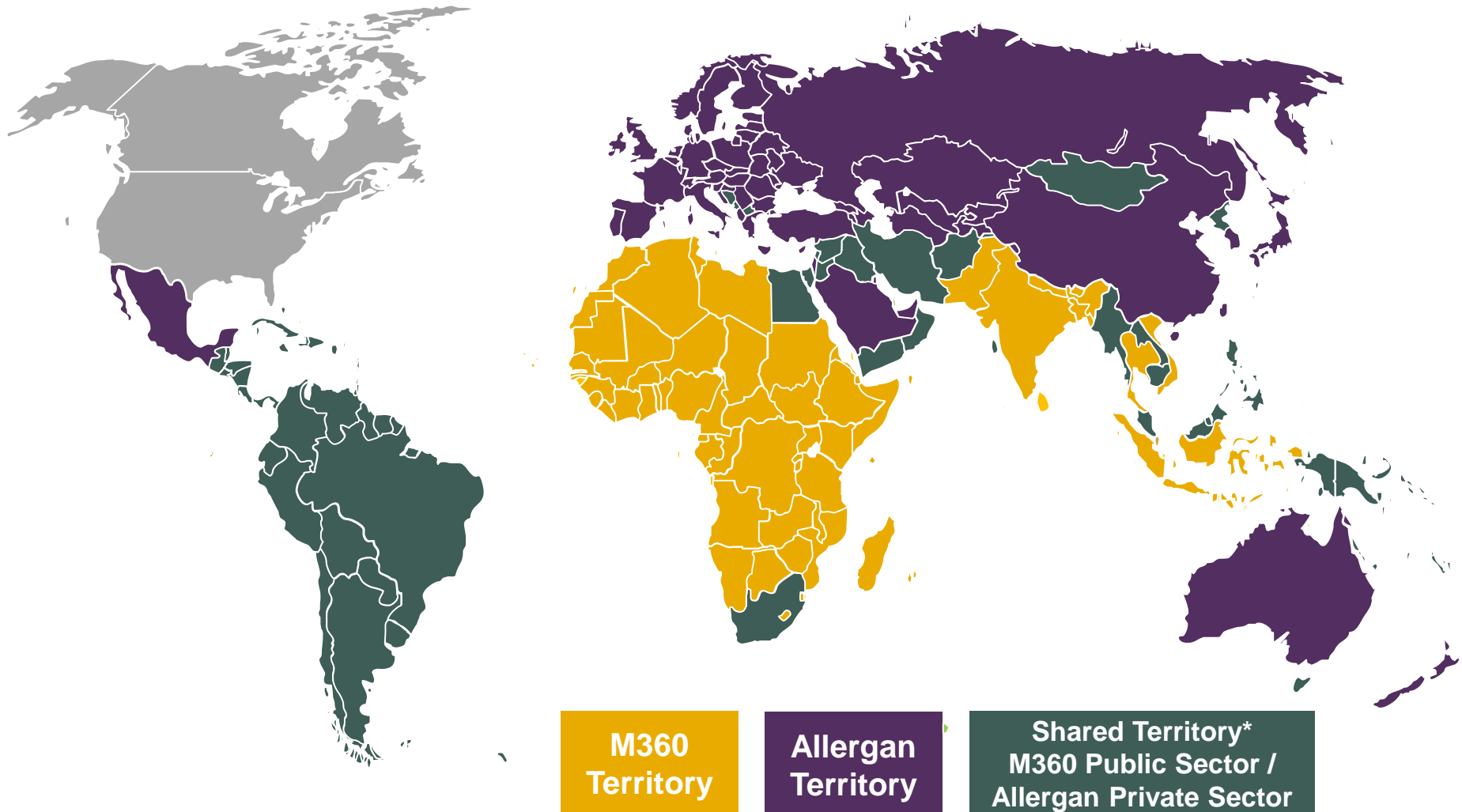
In the U.S.

- Allergan markets the LNG-IUS as Liletta® across the private and public sectors
- Medicines360 provides supplemental training, education and awareness in the U.S. public sector
- Liletta® is available at a commercial price as well as at a lower price of \$50 to health clinics in the public sector

Internationally

- **Medicines360 has exclusive distribution rights in 61 countries (Africa and South/Southeast Asia)**
- Medicines360 and Allergan **share** rights in another 63 countries
- Allergan has exclusive distribution rights in the remaining countries
- M360 negotiated transfer price from Allergan (price varies by order size, ~\$15/unit at an order of 100K units)

Medicines360's LNG-IUS Rights Globally



*Parties to discuss commercialization, expectation that Allergan sells in private sector and M360 sells in public sector

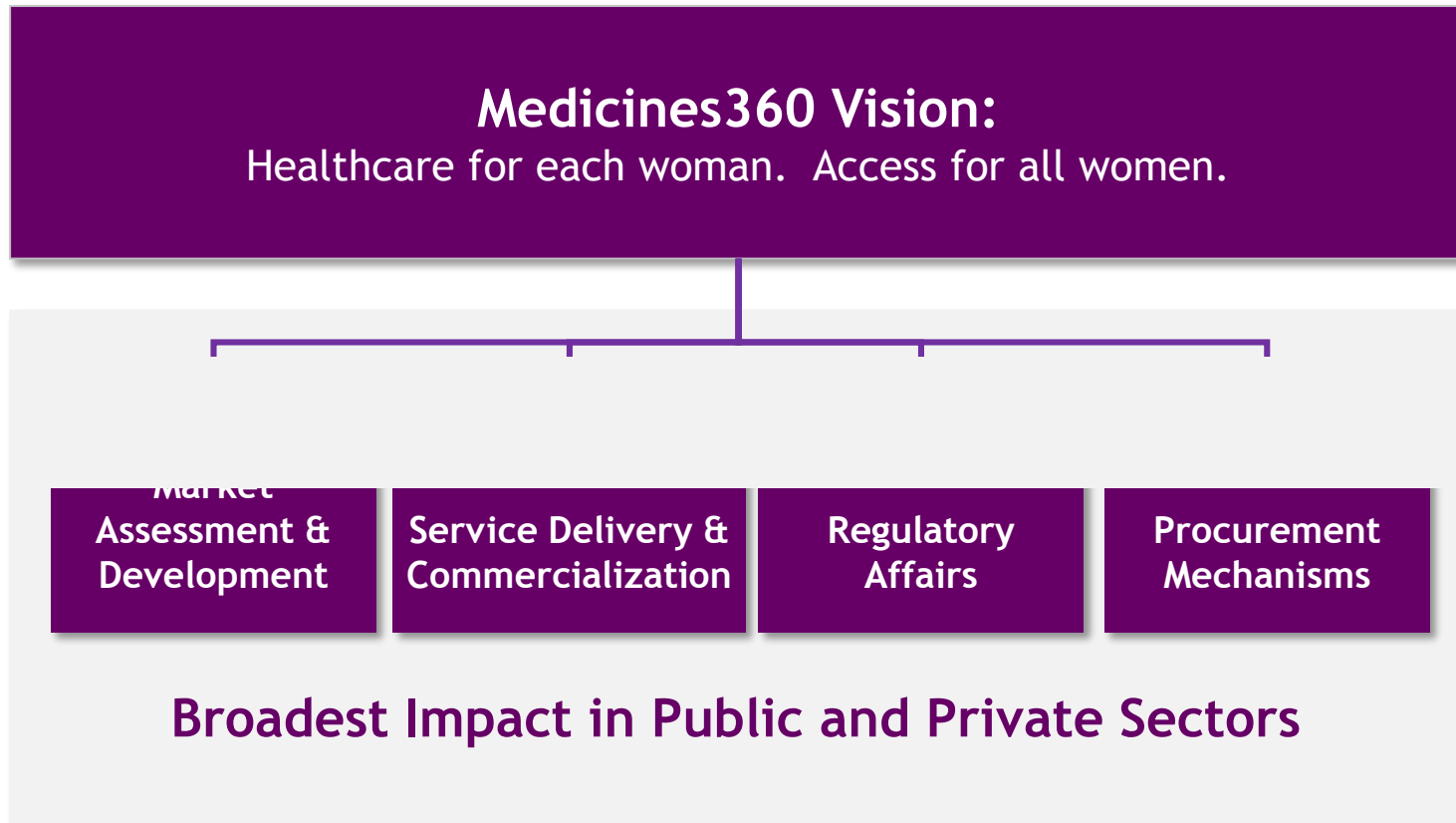
Medicines360 Partnerships for Global Access to the LNG-IUS



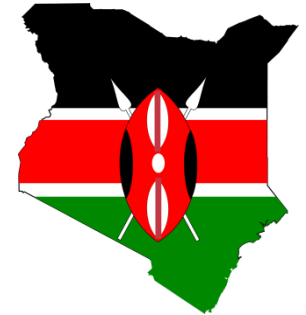
Partnering for R&D

- Medicines360 led the U.S. contraceptive clinical trial for the LNG-IUS
- Allergan created the product and manufactures the product in Belgium
- Medicines360 has negotiated an affordable transfer price for commercialization in developing countries

A Global Stakeholder Engagement Strategy



Market Assessment & Development KENYA



RHSC Innovation Fund

- Preliminary Market Assessment
- Development of a Comprehensive Product Introduction Strategy
- Modification of MSI training materials
- Negotiation of distribution/price ceiling agreement between MSI and Medicines360

Market Assessment INDIA



- Landscape Analysis
 - Evaluate the potential demand for an effective and affordable LNG-IUS through the public, private and social marketing sectors
 - Interviews with Key Informants
- Regulatory Assessment
 - Understand the process for regulatory approval, determine the requirements for in-country clinical trials

Service Delivery & Commercialization

- Engage partners and funders to support LNG-IUS introduction in several countries
 - WCG/PSI for Madagascar (EECO)
 - PSI for Senegal (SIFPO 2)
 - MSI for Kenya (SIFPO 2)

M360 Role

Shared Role

Commercial
Partner Role



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Medicines
360

WCG
WomanCare Global
Sustainable Healthcare



Healthy lives. Measurable results.



**MARIE STOPES
INTERNATIONAL**

Regulatory Affairs

- Use SRA approvals as basis for dossiers, collaborate with commercial partners to determine and execute regulatory strategy
- LNG-IUS on the WHO EML (May, 2015)
- Pursue WHO Prequalification, given SRA approvals
- Pursue global harmonization initiatives to create streamlined and efficient product registration across the region
 - SADC - Southern African Development Community
 - EAC - East African Community



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Organization**

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Sustainable Healthcare



**MARIE STOPES
INTERNATIONAL**

Procurement Mechanisms

- Collaborating with WCG and PSI to procure product through USAID's EECO project
- Initiating discussions with UNFPA for procurement



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Sustainable Healthcare



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“Let us commit to work together to improve access to the best contraceptives. For it is only by working together that we will succeed in achieving universal access to contraception and enable women and men to pursue their dreams and decide their own destiny.”

-- Victoria Hale, Founder, Medicines360

Thank You!

