



POUR ELLE

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**18TH GENERAL MEMBERSHIP MEETING OF THE
REPRODUCTIVE HEALTH SUPPLIES COALITION**

Regulatory Opportunities and Challenges for New Contraceptives in West Africa

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Regulatory Environment in Africa

- An effective medicines regulatory system promotes and protects public health by ensuring that medicines are of the required **quality, safety and efficacy**.
- Lack of access to essential medicines is a serious global public health issue in Africa.

Source: UN Millennium Project Task Force on HIV/AIDS,

Malaria, TB, and Access to Essential Medicines.



1 in 3

Globally



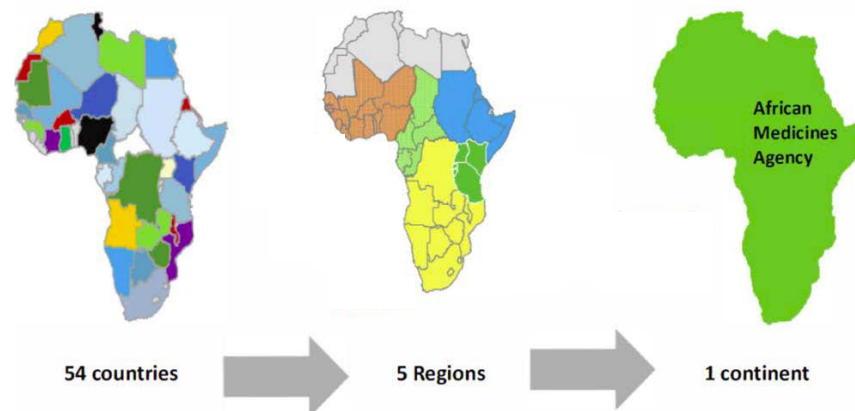
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Sub-Saharan Africa



Regulatory Environment in Africa

- In response, African regulators and the international community mobilized technical and financial resources to create the **African Medicines Regulatory Harmonization (AMRH)** program.
- Various harmonization initiatives have been taken under the AMRH program, and significant progress has been made during the last few years, notably in the EAC. Similar initiatives are now being rolled out in West Africa, SADC, IGAD etc.
- The process for the establishment of the African Medicines Agency (AMA) by 2018 has made tremendous progress with the drafting of the Legal and Institutional Framework and business plan.



Regulatory Environment in West Africa

- Some countries in West Africa have a well-developed regulatory system, e.g., Nigeria (NAFDAC), Ghana (GFDA) and Senegal (DPM).
- The 8 Francophone member states (NMRAs) of the UEMOA agreed on a common technical dossier format and policies.
- February 2015: NEPAD Agency facilitated the launch of the West Africa MRH Project, including
 - Framework of collaboration between WAHO and UEMOA.
 - Harmonization of WAHO and UEMOA CTDs with technical support from WHO.

Upcoming:

- Developing technical guidelines through Technical Working Groups.
- A series of activities between regional agencies have also been undertaken as part of capacity and confidence building among NMRAs.

Regulatory Challenges in West Africa

- Differences among **regulatory standards, expertise and policies**, as well as **lack of mutual recognition** constrain registration activities in West Africa and are significant barriers to better overall health.
- Improvement of communication between member countries will make integration easier.
- In some countries, the **absence of guidance** with clear regulatory procedures and timelines makes it challenging for manufacturers to introduce new medicines.

Registration of the SILCS Diaphragm in Niger

- January 2017: regulatory landscape assessment performed.
- August 2017: application for registration of Caya® contoured diaphragm and Caya® Gel was filed.
- Successfully approved on February 7, 2018, with PSI as the Marketing Authorization Holder.



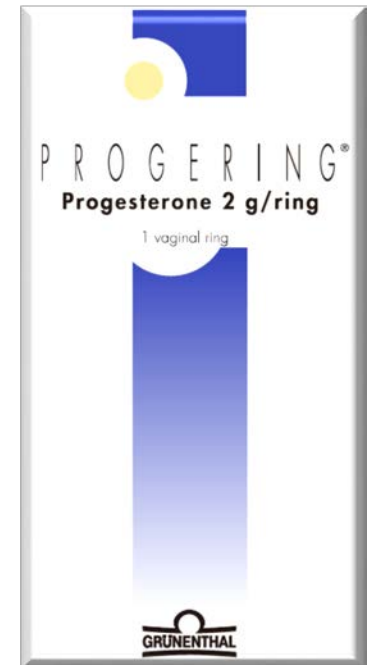
Registration of the Progesterone Vaginal Ring (PVR) in Senegal

- January 2018: Regulatory landscape assessment performed.
- Identification of Marketing Authorization Holders
- Q2 2018: Anticipated CTD Dossier completion.
- Q3 2018: Anticipated application submission.



Registration of the Progesterone Vaginal Ring (PVR) in Nigeria

- June 2015: Regulatory landscape assessment performed.
- June 2016: Progering® trademark accepted.
- January 2017: Trademark approval
- Q2 2018: Anticipated application submission.





QUESTIONS?

*If you want to go
fast, go alone.
If you want to go
far, go together.*

- African Proverb