



GALVmed / OIE
stakeholder workshop on the harmonisation
of the registration of veterinary medicinal products

**Atelier régional GALVmed / OIE sur l'harmonisation
des autorisations de mise-sur-le-marché des
produits vétérinaires**

JOHANNESBURG/ JOHANNESBOURG
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SESSION 4

P R E S E N T A T I O N S F R O M A P P L I C A N T S

Experiences and needs of MERIAL for Registration Procedures



EXPERIENCES AND NEEDS OF MERIAL FOR REGISTRATION PROCEDURES

Merial is now part of Boehringer Ingelheim

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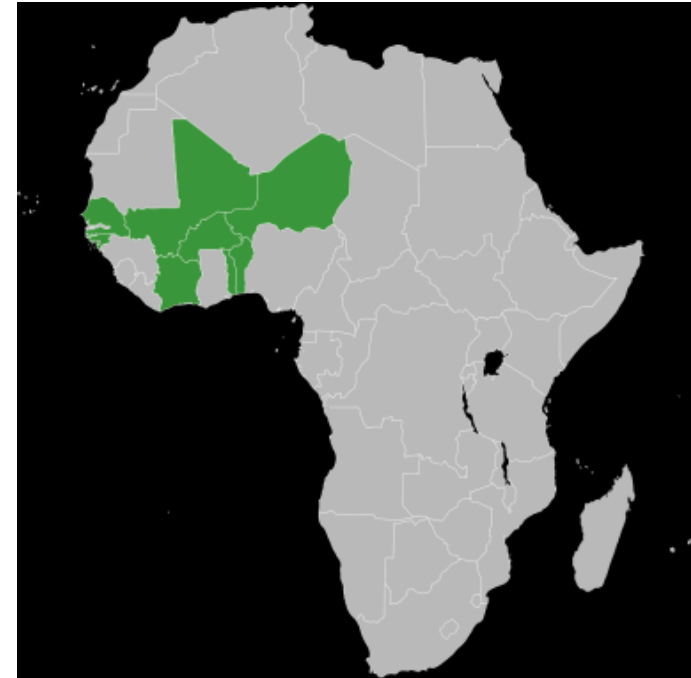


EXPERIENCES - FOCUS ON AFRICA

MERIAL operates in more than **29** countries in Africa

And Holds **693** market Authorizations

Including **16** centralized procedures with West African Economic & Monetary Union - WAEMO (Union Economique et Monétaire de l'Ouest Africain – UEMOA)



Union Economique et Monétaire de l'Ouest Africain (UEMOA)

EXPERIENCES

Registering is time consuming and a **road block to market access**

→ An harmonized regulatory system allows for :

- Simplification of the regulatory workload
- Improves predictability
- Enhance compliance
- Allow access to smaller markets where regulatory hurdles exceeds market value
- Reduce average time to market for a block of countries

EXPERIENCES - THE HARMONIZED REGULATORY SYSTEMS EXPERIENCE

- ❑ Mutual Recognition Procedures – MRP - Exist in European Union (1995), & East African Community (2016)
- ❑ Other **harmonised** procedures exist : Centralised Procedure exists in E.U.(1995), in West African Countries - WAEMU (2009)
- ❑ **Other regions** are interested in and /or starting to use harmonised process.

→ EAEU, ASEAN, ZAZIBONA, SADC

EAEU = Eurasian Economic Union / **ASEAN** = Association of Southeast Asian Nations / **SADC** = Southern Africa Development Community / **ZAZIBONA** = Zambia, Zimbabwe, Botswana, Namibia)

EXPERIENCES - EAEU & ASEAN

MAP 1



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EAEU = Eurasian Economic Union



ASEAN =
Association of Southeast Asian Nations



Comparison of Harmonized Regulatory systems

Comparison of Harmonized regulatory systems	EU	UEMOA	EAC	EEU
Countries	28 countries of the European Union , but started with 17 countries	8 countries Benin, Burkina Faso, Guinea, Ivory Coast, Mali, Niger, Senegal, Togo	5 countries Burundi, Kenya, Tanzania, Uganda, Rwanda	5 countries Russia, Belarus, Kazakhstan, Armenia, Kirghizstan
Starting date	1995	2009	2016	2017?
Type of proceddures	Centralized Mutual Recognition Decentralized	Centralized	Mutual Recognition	Mutual and Decentralized, to be confirmed
Output	1967 Market authorizations since 2006	60 market authorizations	Not started	Not started
Starting ground	All countries with national registration procedures	2 countries without registration procedures	2 countries without registration procedures (Burundi & Rwanda)	All countries with national registration procedures (very diverse)
Key issues	Administrative burden; As no leadership in decision, duplication of question-quick decision but painful	Very slow starting process 60 market authorization since 2010... but improving since 2015	Only address vaccines Starting in 2017	Starting date unclear National registration will be cancelled in 2025

EXPERIENCES - HARMONIZED REGULATORY SYSTEMS: LESSONS LEARNED

What systems and tools are needed to enable mutual recognition?

→ The 4 pillars approach

- ❑ Pillar 1: **Common** set of technical registration requirements
- ❑ Pillar 2: Registration **Procedure**: MRP, define the how
- ❑ Pillar 3: **Political Will & Legal framework** to operate: existing supranational body/organization/forum & national laws to be adapted
- ❑ Pillar 4: **Implementation**: need for a coordinated, practical, hands-on and step-by-step guidance



SADC Southern Africa Development Community



EAC East African Community

NEEDS



NEEDS : THE INDUSTRY VISION *

Efficient regulatory systems that result in
harmonized,
science-based decisions
in predictable timeframes,

resulting in the wide availability of safe and effective
Veterinary Medicines.

** HealthforAnimals Board Meeting – 9 March 2016*



NEEDS : FOR REGULATORY SYSTEMS ...

- ❑ Science based decisions (no differentiation for local/global companies)
- ❑ Predictable timeframes – max 24 months new products, max 12 months significant changes, and accelerated pathways for needed products
- ❑ Efficient Regulation – reduced administrative burden
- ❑ More co-operation/recognition of assessments of other country Authorities
- ❑ Innovation – fair returns on investment

NEEDS : REGULATORY SYSTEMS ...

- Enabling for highly innovative products
- Global developments support all registrations
- Manufacture possible anywhere in world to same set of standards
- Companies able to operate a single **pharmacovigilance** system
- Rules on use of medicines require veterinary **registered products** to be considered first

NEEDS : FOR REGULATORY CONVERGENCE / HARMONIZATION

- ❑ Regulatory convergence is not simply “all Authorities accepting VICH guidelines” for study conduct
- ❑ It is the **convergence** of all regulatory aspects e.g. the Initial registration, how variations, pharmacovigilance etc. are managed in all countries where registration of veterinary medicines is necessary
- ❑ “Ultimate” general goal being a single package of studies, single dossier format, common approval outcome (species, indications, warnings etc.) & common management following authorisation
- ❑ “Realistic” goal required a **stepwise** approach in the direction of the ultimate goal

NEEDS : REGULATORY CONVERGENCE / HARMONIZATION - LESSONS LEARNED

Pillar 4 - Implement: a coordinated, practical, hands-on and step-by-step guidance

- ❑ Implementation: Start to **reflect as early as possible**.
One of the first blocking points in EAC recent experience was to get the MRP form recognized/ available at each Member states level. (The current main issue to translation of MRP into each country regulations)
- ❑ Seek **help** from other authorities to guide during the learning curve (bilateral cooperation programs exist)
- ❑ Plan a first application evaluation with the industry (**pilot**)
- ❑ Organize **training** with support from consultant / other authorities
- ❑ **Deliver!** The industry and the customers are waiting!

C O N C L U S I O N S

- ❑ Regional organisations including Mutual Recognition has been shown to bring value
 - ❑ Merit is in favour and strongly supporting Regional initiative for harmonization / convergence
 - ❑ Science based decisions, and predictability are key
- ❑ Don't work alone**

THANK YOU!



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BACK UP SLIDES

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