SESSION 4
PRESENTATIONS FROM APPLICANTS

Experiences and needs of MERIAL for Registration Procedures
EXPERIENCES AND NEEDS OF MERIAL FOR REGISTRATION PROCEDURES

Merial is now part of Boehringer Ingelheim
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)
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


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

EAEU = Eurasian Economic Union

ASEAN = Association of Southeast Asian Nations
## Comparison of Harmonized Regulatory Systems

<table>
<thead>
<tr>
<th>Countries</th>
<th>EU</th>
<th>UEMOA</th>
<th>EAC</th>
<th>EEU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting date</td>
<td>1995</td>
<td>2009</td>
<td>2016</td>
<td>2017?</td>
</tr>
<tr>
<td>Type of procedures</td>
<td>Centralized Mutual Recognition</td>
<td>Centralized</td>
<td>Mutual Recognition</td>
<td>Mutual and Decentralized, to be confirmed</td>
</tr>
<tr>
<td></td>
<td>Decentralized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Output</td>
<td>1967 Market authorizations since 2006</td>
<td>60 market authorizations</td>
<td>2 countries without registration procedures (Burundi &amp; Rwanda)</td>
<td>All countries with national registration procedures (very diverse)</td>
</tr>
<tr>
<td>Starting ground</td>
<td>All countries with national registration procedures</td>
<td>2 countries without registration procedures</td>
<td></td>
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<tr>
<td>Key issues</td>
<td>Administrative burden; As no leadership in decision, duplication of question-quick decision but painful</td>
<td>Very slow starting process 60 market authorization since 2010… but improving since 2015</td>
<td>Only address vaccines Starting in 2017</td>
<td>Starting date unclear National registration will be cancelled in 2025</td>
</tr>
</tbody>
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- **EU**: 28 countries of the European Union, but started with 17 countries
- **UEMOA**: 8 countries Benin, Burkina Faso, Guinea, Ivory Coast, Mali, Niger, Senegal, Togo
- **EAC**: 5 countries Burundi, Kenya, Tanzania, Uganda, Rwanda
- **EEU**: 5 countries Russia, Belarus, Kazakhstan, Armenia, Kirghizstan
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
NEEDS

SADC  Southern Africa Development Community

EAC  East African Community
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
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.
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!
CONCLUSIONS

- Regional organisations including Mutual Recognition has been shown to bring value
- Merial is in favour and strongly supporting Regional initiative for harmonization / convergence
- Science based decisions, and predictability are key

- Don’t work alone
THANK YOU!