Health for Animals
global animal medicines association

Industry perspective and experience of registration / authorization system of drugs and vaccines in the Middle East

Regional Seminar for OIE National Focal Points for Veterinary Products

Beirut, Lebanon, 7-9 November 2017

Philippe Sabot on behalf of HealthforAnimals.

www.AnimalHealthMatters.org
www.healthforanimals.org

HealthforAnimals

- global representative body of companies and associations
- R&D, manufacturing, commercialisation
- veterinary medicines, vaccines, parasiticides and other products

Top 9 global companies

Bayer HealthCare

zoetis

Virbac

Elanco

MERCK Animal Health

Boehringer Ingelheim

Vétoquinol Signe de Passion

Phibro Animal Health Corporation

ceva

HealthforAnimals represents 85% of the global animal health sector.

29 Regional associations

NORTH AMERICA
Canada
Mexico
United States

EUROPE and AFRICA
Europe
Belgium
Denmark
France
Germany
Ireland
Italy
Netherlands
Portugal
Spain
Sweden
Switzerland
United Kingdom
South Africa

CENTRAL/SOUTH AMERICA
Argentina
Brazil
Chile
Paraguay

ASIA/PACIFIC
India
Australia
Indonesia
Japan
Korea
New Zealand
South-East Asia
Thailand

The associations represent 200+ medium-sized and smaller companies.

Industry Current experiences In middle-east countries

Very diverse way for market access :

→Import permit, Special license

→Tenders

→Full market authorization

With an on-going and steady increase of regulatory technical requirements:

→Dossier’s content

→GMP requirements, sites accreditations

Industry Current experiences In middle-east countries

Harmonization

→ No active Regional Organization, neither an harmonized approach,

→ Although The Cooperation Council for the Arab States of the Gulf (GCC)

Has established an harmonized process for Human Health products, with GCC Drug Registration (GCC-DR)

And could serve as a basis for Veterinary medicines

- The GCC-DR committee consists of two members nominated by each state.

GCC members: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates and Yemen as member in Health Council.

Needs : 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 : For 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

Harmonized regulatory systems experience

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

Harmonized regulatory systems experience

- Mutual Recognition Procedure – MRP - Exist in European Union (1995), & East African Community (2016)

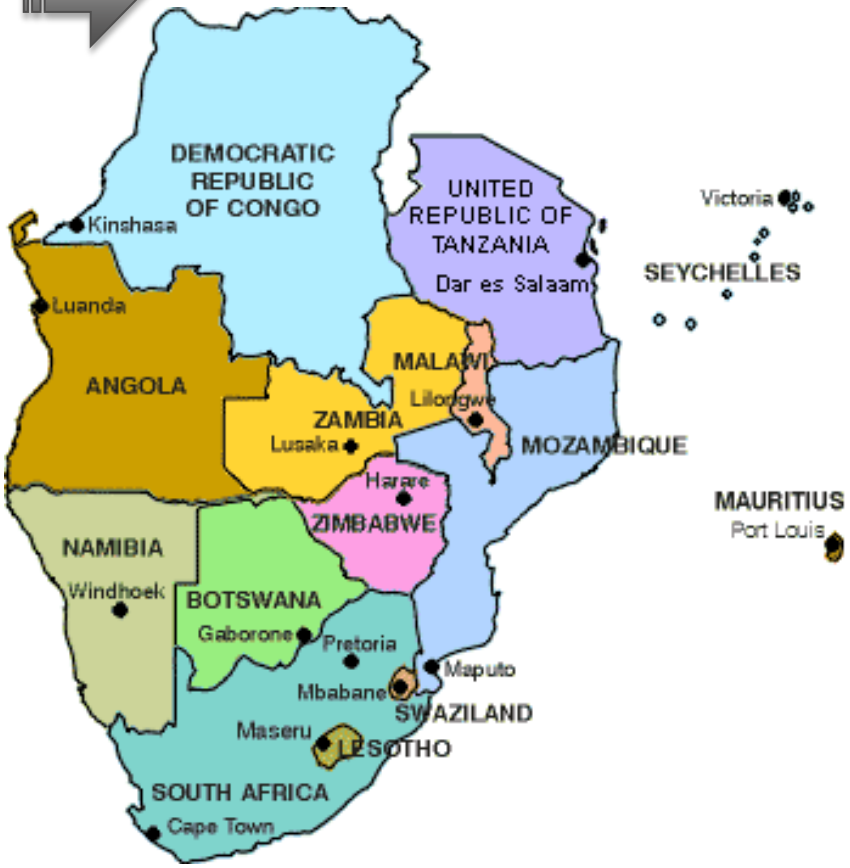
- Other **harmonised** procedures exist : Centralised Procedure exists in E.U.(1995), in West African Countries - WAEMU (2009)

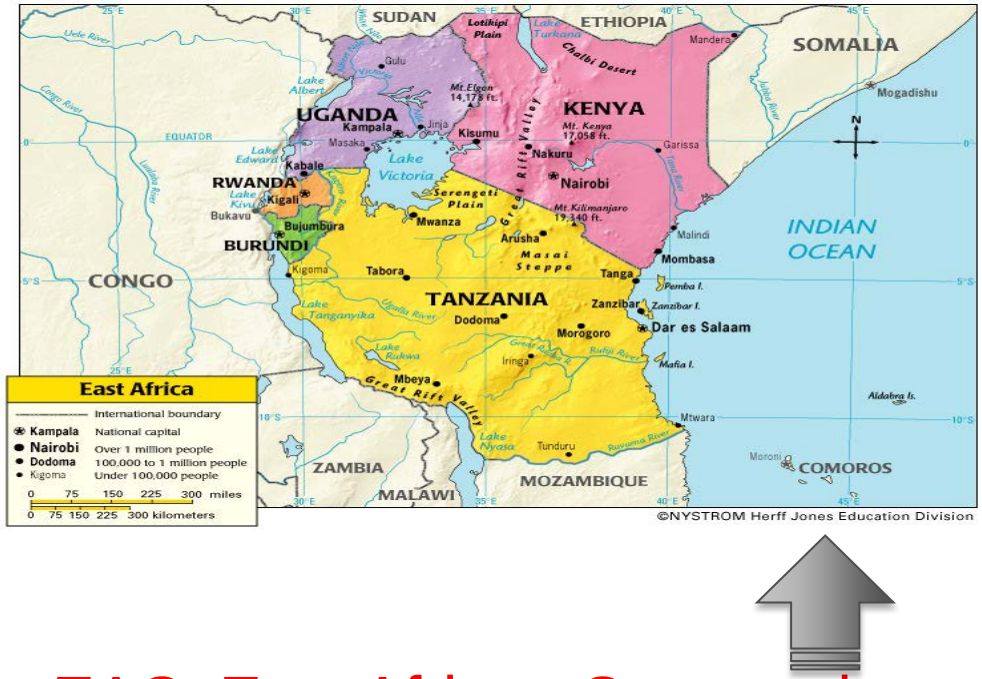
- **Other regions** are interested in and /or starting to use harmonised process.
  → EAEU, ASEAN, ZAZIBONA, SADC

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

Existing regional harmonization initiatives

SADC Southern Africa Development Community

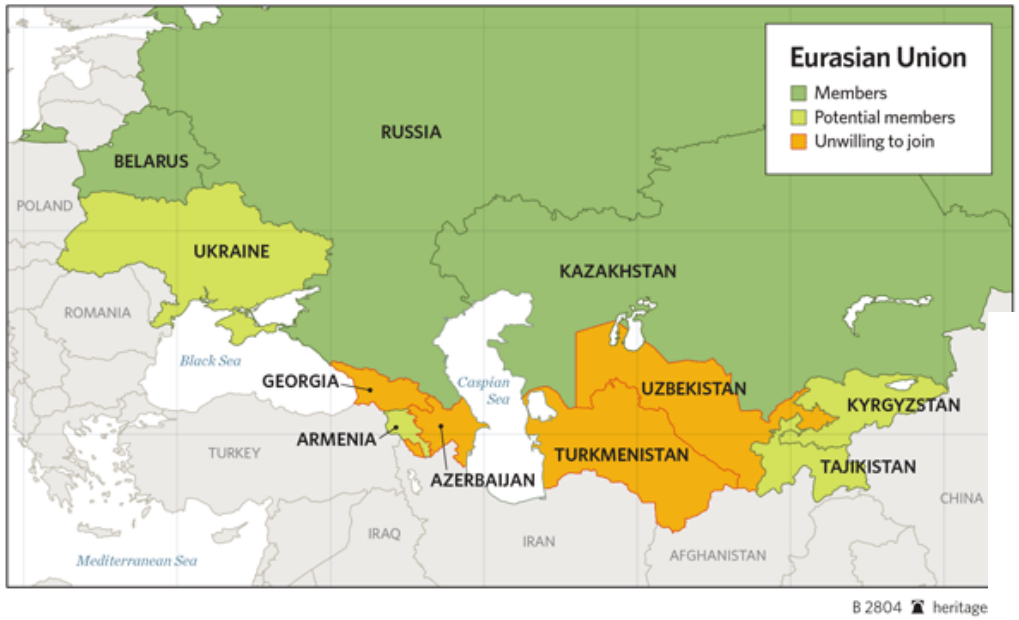




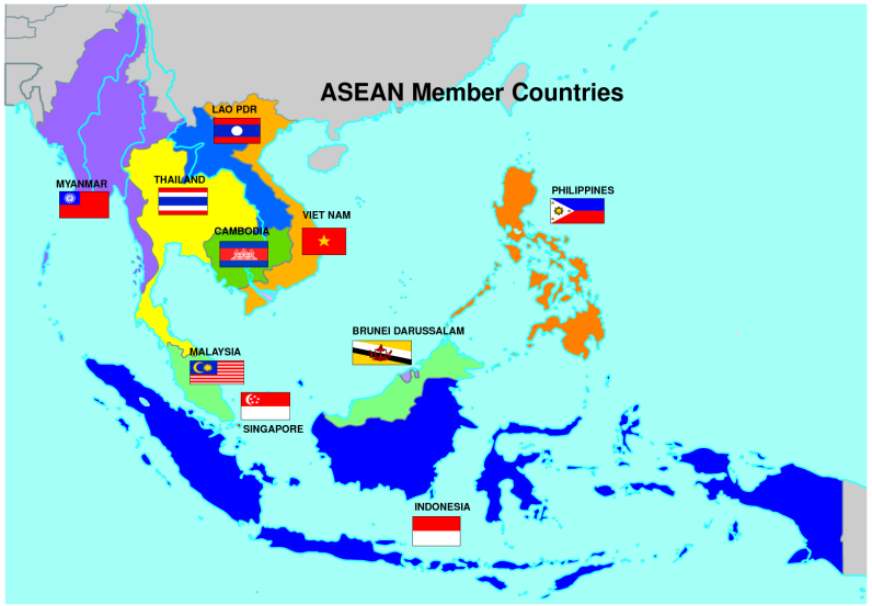
EAC East African Community

Existing regional harmonization initiatives

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? 2018
Type of proceddures	Centralized Mutual Recognition Decentralized	Centralized	Mutual Recognition	Mutual and Decentralized, to be confirmed
Output	1967 Market authorizations since 2006	~70 market authorizations	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 Tanzania needs to get onboard	Starting date unclear National registration will be cancelled in 2025

Regulatory harmonization– 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

Regulatory harmonization– Lessons learned

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

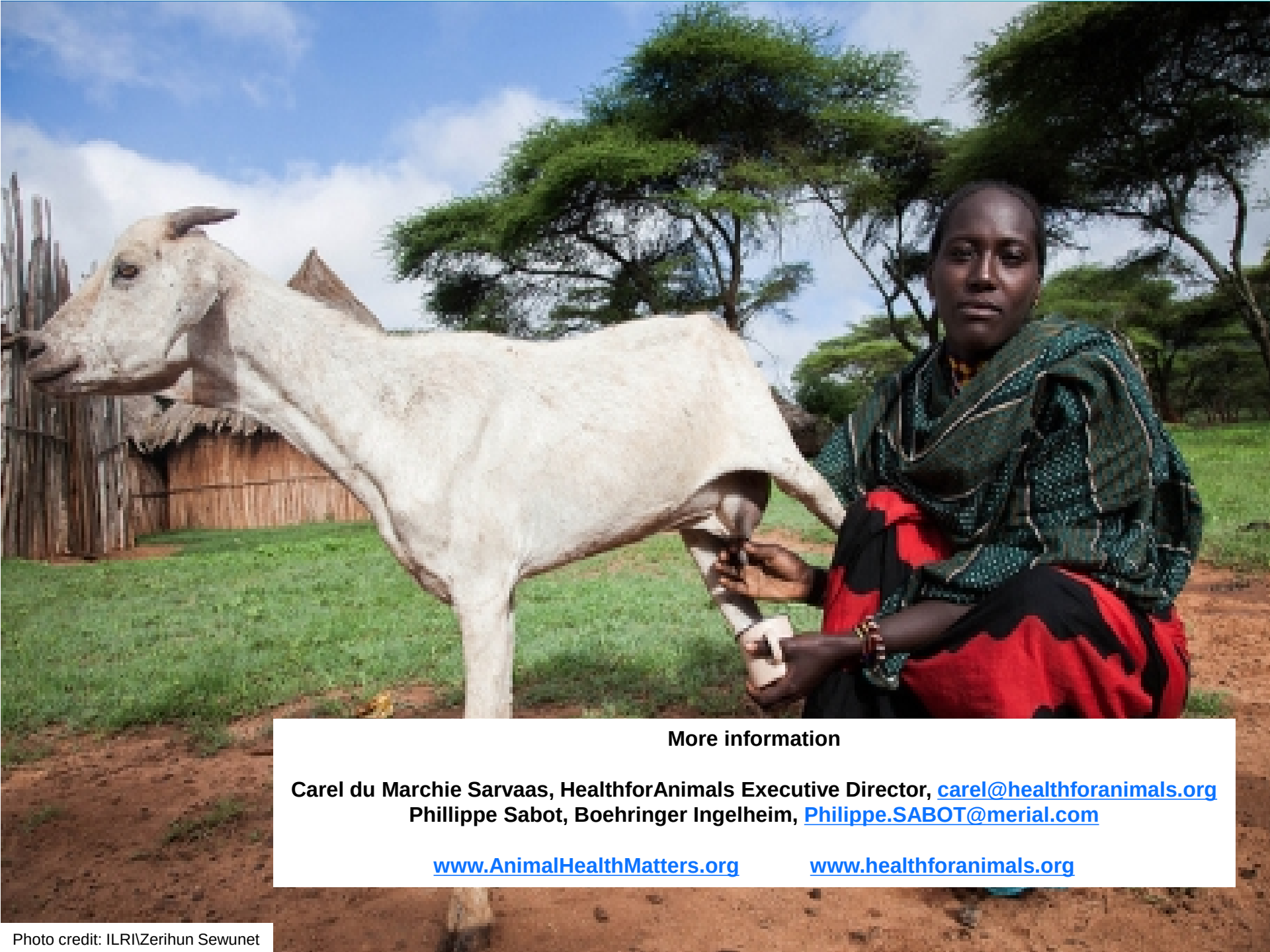
- Implementation: Start to **reflect as early as possible**. One of the first blocking points in EAC recent experience was to get the MRP form recognized/ available at each Member states level.

- 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 common registration procedure has been shown to bring value
- The industry is in favor and strongly support Regional initiative for harmonization / convergence
- Science based decisions, and predictability are key
- **Don’t work alone**



More information

Carel du Marchie Sarvaas, HealthforAnimals Executive Director, carel@healthforanimals.org
Phillippe Sabot, Boehringer Ingelheim, Philippe.SABOT@merial.com

www.AnimalHealthMatters.org **www.healthforanimals.org**

Photo credit: ILRI\Zerihun Sewunet