



Protecting Livestock – Improving Human Lives

Review of requirements and processes for registration of veterinary products in selected African and Asian countries

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Executive Summary

The present document provides a summarised overview of requirements and processes for the registration of veterinary products in a limited number of African and Asian countries.

A number of salient points can be made:

- Although the majority of African countries have registration systems or related legislation in place, many of them do not effectively regulate the use of veterinary products in the country.
- Registration systems and procedures are constantly being put into place and/or evolving in African countries (and many other countries). The information provided here is thought to be accurate as of late 2015 but changes will certainly take place over the next few years. Precise details on the numbers of copies of dossiers, samples, documents such as Free Sales Certificates, etc. need to be checked with the relevant authorities when a submission is made.
- Sadly, centralised systems such as the one for UEMOA (the West African Economic and Monetary Union) are not operating effectively, and on the contrary are encouraging the introduction of unregulated products. UEMOA's system is operating for the registration of products, but it is slow, with very rigorous requirements similar to those for registration in the European Union. It is hoped that it will evolve toward greater effectiveness¹.
- Regional approaches could constitute a good basis for improving the situation in Africa.
- The information required in a dossier varies from country to country. Some countries will accept a basic dossier that contains mainly summary information, while others require a dossier containing extensive information and details similar to those required for a registration in the EU.

- All countries require additional documents to the dossier, e.g.:
 - Good Manufacturing Practice (GMP) Certificate
 - Certificate of Free Sale
 - Certificate of Pharmaceutical Product (CPP)
 - Certificate of Analysis
 - Information about the Qualified Person
 - Power of Attorney
 - Copies of Marketing Authorisations from other countries where the product is registered

In addition, these documents may need to be notarised and/or certified in the country of origin.

- Countries increasingly have specific packaging requirements, such as:
 - Batch number
 - Date of manufacture
 - Expiry date
 - Local registration number
 - Manufacturer's address

¹ UEMOA Member States are Benin, Burkina Faso, Guinea-Bissau, Ivory Coast, Mali, Niger, Senegal and Togo.

Africa

Photo: GALVmed/Karel Prinsloo



Review of requirements and processes for registration of veterinary products in **Benin**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Benin relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation. UEMOA has also decried the poor quality of many of the dossiers it has received in the past.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

Websites: www.uemoa.int www.izf.net

APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA; Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

- > **Applicant:** The Company of the product responsible for manufacturing and marketing.
- > **Local Responsible Person(s):** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

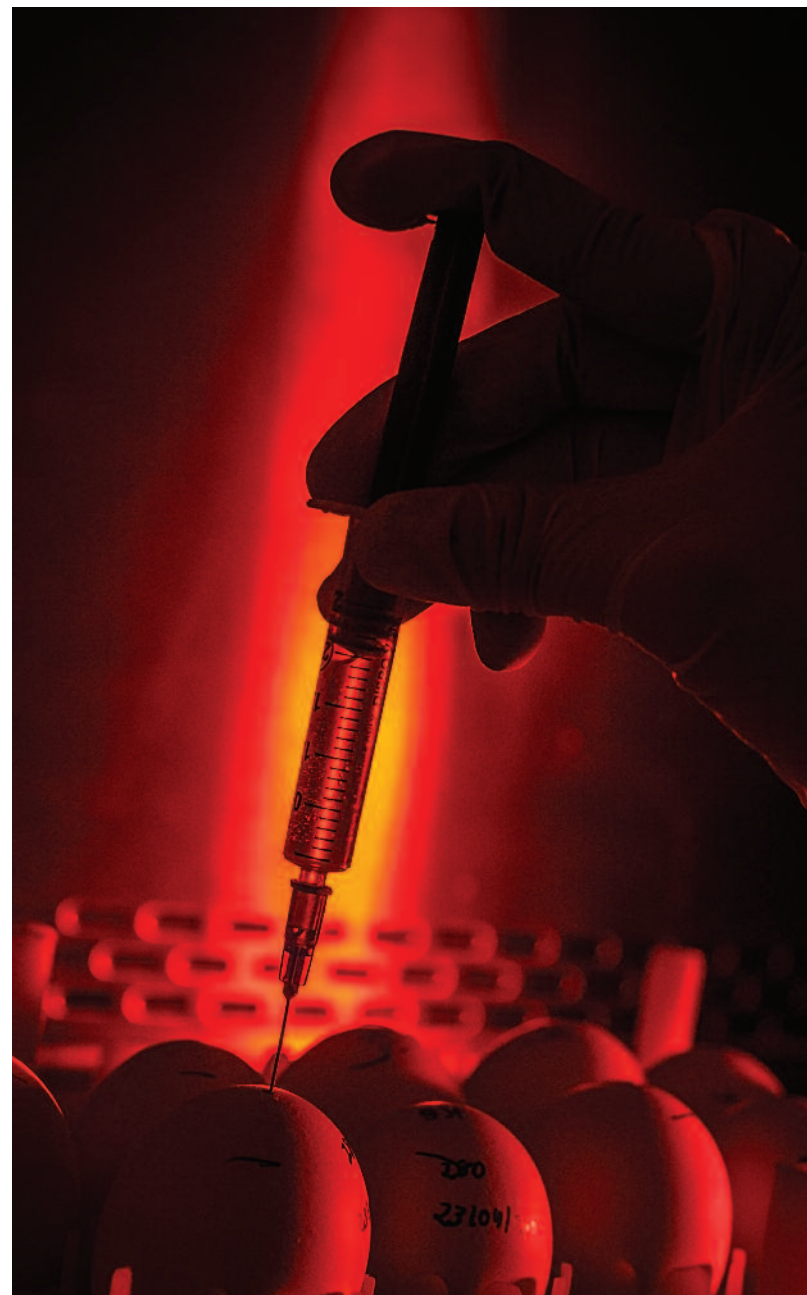
Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Part I: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in French but some reports can be supplied in English.
- > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
- > Expert reports must be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer – except for different pack sizes of same injectable products.
- > Numbers of registration dossiers to be sent:
 - > Paper version: one original and three copies for Parts I, II and V; one original and two copies for Parts III, IV, VII, VIII and IX.
 - > Electronic version: 13 CD-ROMs containing all parts.
- > Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.



PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal. The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> First time application

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing Plant Master File
Inspection fees	Five pack samples and copies of package inserts & labels

> Application for variation of a registered product

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	

➤ **Address for submission of applications**

Commission de l'UEMOA
380 Avenue du Professeur Joseph Ki-Zerbo
BP 543 Ouagadougou 01
Burkina Faso
Tel: 226 50318873
E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form or Dosage Form, send at the same time: 344 USD Generic per pharmaceutical form: 1,720 USD	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees : 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12–18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years.

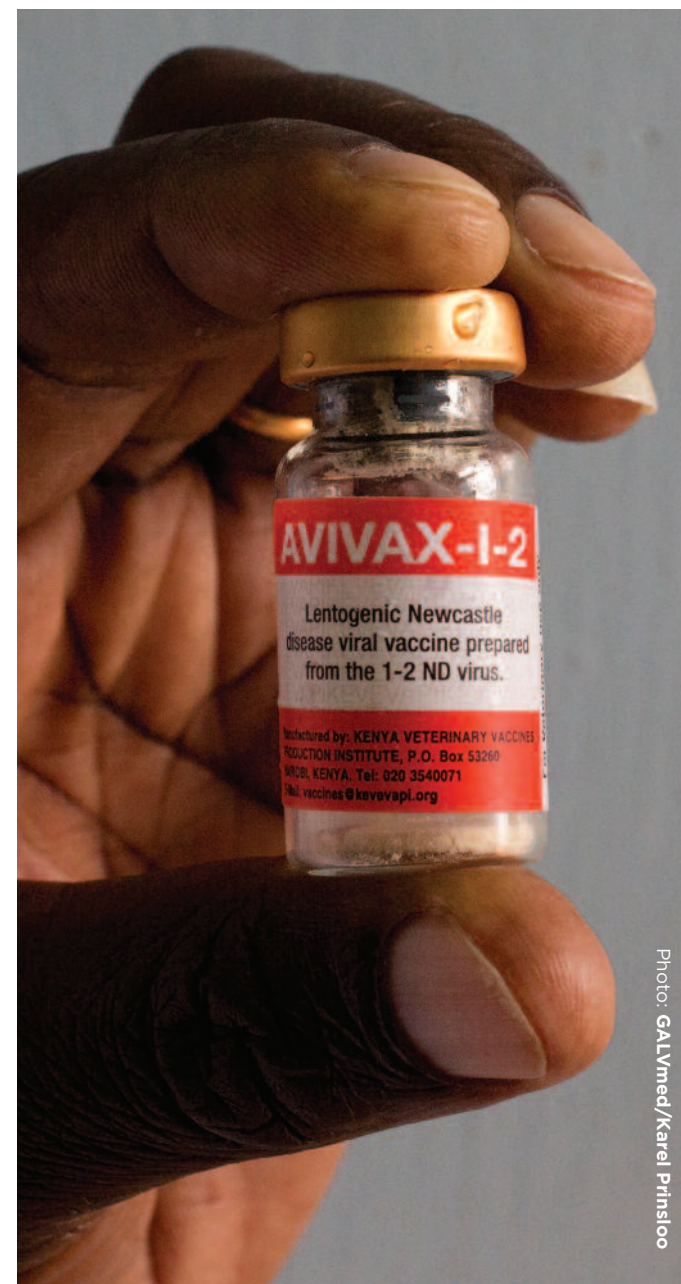


Photo: GALVmed/Karel Prinsloo

PRACTICES

- A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
 - When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
 - Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
 - A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
 - Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
 - Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
 - Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
-
- The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
 - The Director of Veterinary Services (DVS) can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
 - Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import Permit which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.

Review of requirements and processes for registration of veterinary products in **Burkina Faso**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Burkina Faso relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

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APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA; Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

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- > **Local Responsible Person(s):** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Part I: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in French but some reports can be supplied in English.
- > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
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PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal. The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> First time application

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing Plant Master File
Inspection fees	Five pack samples and copies of package inserts & labels

> Application for variation of a registered product

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	



Photo: GALVmed/Karel Prinsloo

➤ **Address for submission of applications**

Commission de l'UEMOA
 380 Avenue du Professeur Joseph Ki-Zerbo
 BP 543 Ouagadougou 01
 Burkina Faso
 Tel: 226 50318873
 E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form or Dosage Form, send at the same time: 344 USD Generic per pharmaceutical form: 1,720 USD	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees : 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12-18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years.

PRACTICES

- A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
 - When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
 - Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
 - A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
 - Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
 - Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
 - Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
- The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
 - The Director of Veterinary Services (DVS) can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
 - Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import Permit which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.

Review of requirements and processes for registration of veterinary products in **Burundi**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Officially the regulatory authority for veterinary products is the Directorate of Veterinary Services. However, there is no registration process in place for all veterinary products. Discussions have started with senior executives in the office of the Ministry of Agriculture and Livestock on the elaboration of a Ministerial order establishing an authority for the regulation of veterinary immunologicals in Burundi.

Burundi is part of the regional process for mutual recognition of veterinary biologicals initiated by the East African Community (EAC), but this process has not yet been put in practice in the country.

APPLICABLE LEGISLATION

None.

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

Not yet implemented, despite being part of the EAC. Therefore, not applicable.

PHARMACEUTICALS

Not applicable.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

Not applicable.

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Not applicable.

PRACTICES

- > All sorts of products are found on the market.
- > It is expected that if an Applicant applies for Marketing Authorisation (MA) through the EAC Mutual Recognition Procedure (MRP), an MA obtained in Kenya, Tanzania or Uganda for a biological product will be recognised in Burundi, although this process has not yet been put in place in Burundi and it will certainly still take several years to be put in practice in the EAC.

Review of requirements and processes for registration of veterinary products in **Cameroon**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Cameroon has a National Registration System for veterinary medicinal products.

The Ministry in Charge of Veterinary Services, Department of Veterinary Pharmacy has the mandate to approve and to register all veterinary medicinal products (biologicals, pharmaceuticals, pesticides), to appoint inspectors and to order inspections of premises.

This department is not functioning at all, due to lack of structure and human resources.

Website: www.spm.gov.cm/en/documentation/laws-and-statutory-instruments.html

APPLICABLE LEGISLATION

Law 90/033 (1990); Law 2000/017 (2000); Law 2000/018 (2000); Law 2001/006 (2001)

Decree 178/CAB/PM

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** Owner responsible for manufacturing of the product or licence holder.
- > **Local Responsible Person(s):** An applicant not resident in Cameroon shall nominate an authorised person (veterinarian, pharmacist, or licensed as a pharmaceutical importer and wholesaler) who resides in Cameroon to be the Local Responsible Person for communication with authorities, monitoring the product on the market and handling eventual product recalls.

> Documentation

- > Part I: Application Form and Summary of Product Characteristics
- > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product
- > Part III: Safety
- > Part IV: Efficacy
- > Part V: Bibliographical References

> Facts on the submission

- > Application should be made in French or English.
- > One printed copy should be submitted in which each Part or Section is bound separately.
- > Expert reports may be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Part I: Application Form and Summary of Product Information
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	Commercial samples
Registration Certificate from country of origin	Index
Application fees	Five samples and copies of package inserts & labels

> Application for variation of a registered product

Alteration application form	Samples of the altered product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Commercial samples of each pack size being submitted for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	

> Commercial samples needed for registration and renewal of registration

- > Solid forms (bolus, powder): 50
- > Liquid forms (oral solution, soluble powder, antiparasitic lotion): 20
- > Creams (gel, paste): 20
- > Injectable forms: 30
- > Ocular products: 30

> Address for submission of applications

Minister in Charge of Veterinary Services
Department of Veterinary Pharmacy
Yaounde, Cameroon

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees Trypanocidal drugs, oral avian products: 2.5 million XOF (4,235 USD) Antibiotics: 1.5 million XOF (2,540 USD) Antiparasitics, internal: 1 million XOF (1,693 USD) Antiparasitics, external: 500,000 XOF (847 USD) + 10% for each dosage form and pharmaceutical form	Dossier alteration fees: 30% of registration fees
Application renewal fees: 50% of registration fees	

$$1 \text{ XOF (FCFA)} = 0.00169 \text{ USD}$$

Officially, registration is obtained six months after having transmitted the registration dossier to the Department of Veterinary Pharmacy.

There is no need for renewal and/or to deposit a registration dossier for alteration of a product.

PRACTICES

- **IMPORTANT:** In actuality, an applicant only has to deposit the registration dossier and to pay the registration fees at the Department of Veterinary Pharmacy. Once they have received the certificate of payment they can start immediately importing and marketing the veterinary medicinal product in Cameroon. Due to lack of structure and human resources the Department of Veterinary Pharmacy is not functioning at all.
- Veterinary medicinal products coming from several veterinary pharmaceutical companies are widely available in the country without having transmitted registration dossiers to the registration authorities. They are very often of poor quality and/or counterfeit.
- Some ethical veterinary companies have deposited the registration dossiers of their products with the registration authorities and started at the same time importing and marketing their products in Cameroon.
- Animal owners have access to all medicines, and either treat their own animals or get paraprofessionals to do it.
- Sale of pesticides for tick control is uncontrolled, with products being sold in all types of shops.



Review of requirements and processes for registration of veterinary products in **Comores Union**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

The Comores Union has no registration authority for the registration of human and veterinary medicinal products (pharmaceutical and biological).

APPLICABLE LEGISLATION

No legislation actually in place.

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

No legislation in place; can be imported freely.

PHARMACEUTICALS

No legislation in place; can be imported freely.

PROCESS FOR REGISTRATION

- **Useful address when importing veterinary medicines**
Direction des Laboratoires et des Pharmacies
Union des Comores

PRACTICES

- Many poor quality and counterfeit drugs are available on the market (many of Chinese and Indian origin).
- The Comores Union has no veterinary services and no practising veterinarians.
- The best way to sell veterinary drugs in the Comores Union is to go directly and find a local importer/distributor/wholesaler of veterinary medicinal products.

Review of requirements and processes for registration of veterinary products in Democratic Republic Of The Congo (DRC)

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Officially the regulatory authority for veterinary products is the Directorate of Veterinary Services. But there is no registration process in place for any veterinary products.

APPLICABLE LEGISLATION

Registration of veterinary drugs including vaccines is provided for under the Pharmacy Act.

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

Not applicable.

PHARMACEUTICALS

Not applicable.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

Not applicable.

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Not applicable.

- > All sorts of products can be found on the market. There is no registration system in place for veterinary drugs and vaccines, although the Pharmacy Act provides for registration of veterinary drugs.
- > The Director of Veterinary Services under the Animal Diseases Act issues permits for importation of vaccines and authorises their use in the country.

Review of requirements and processes for registration of veterinary products in **Ethiopia**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Ethiopia has a National Registration System. The Ethiopian Veterinary Drug and Feed Administration and Control (EVDFAC) is under the Ministry of Agriculture. EVDFAC has the mandate to approve and to register all veterinary medicinal products (biologicals, pharmaceuticals, pesticides), to appoint inspectors and to order inspection of premises.

EVDFAC uses the guidelines developed by International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and the World Health Organization.

APPLICABLE LEGISLATION

Ethiopian Food, Medicine and Health Care Administration and Control Authority Regulation 189/2010

Proclamation 728/2011: established a veterinary drug authority. This newly established veterinary drug authority has been part of the East African Community (EAC) biological products review process, and is using the documentation developed for the EAC for biological products. Ethiopia wants to set up a Memorandum of Understanding with the EAC to take part in Mutual Recognition Procedures once these are in place.

BIOLOGICALS

- > **Regulated by:** www.fmhaca.gov.et/documents/Guidevetregi.pdf
- > **Applicant:** The owner of the product, responsible for manufacturing.

- > **Authorised Local Agent (Representative):** An applicant not resident in Ethiopia shall appoint a Technical Person who resides in Ethiopia to communicate with authorities and assessors. The Authorised Local Agent is any company or legal person established in the country who has received a mandate from the manufacturer to act on their behalf for specific tasks with regard to the manufacturer's obligations under legislation of the medicine and other regulatory guidance issued by the Authority.
- > **Documentation**
 - > Module I: Application Form, Agency Agreement and Summary of Product Characteristics
 - > Module II: Dossier Overall Summary and Product Dossier (DOS-PD)
 - > Module III: Quality
 - > Module IV: Non-clinical Studies
 - > Module V: Clinical Studies
- > **Facts on the submission**
 - > Applications should be made in English.
 - > One electronic version on CD-ROM and one paper copy, with each Module bound separately, to be submitted.
 - > Expert reports must be included.
 - > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Part I: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	Five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Product master file
GMP inspection fees	Pack samples and copies of package inserts & labels

> Application for variation of a registered product

Alteration application form	Samples of the altered product
Detailed description of the alteration with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 45 days before expiry of registration	Five commercial samples of each pack size being submitted for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee
Current site master file	

> Address for submission of applications

Veterinary Drugs and Feed Administration and Control
 Authority of Ethiopia
 P.O. Box 5681
 Addis Ababa
 Ethiopia

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 1,000 USD	Dossier alteration fees, foreign product: 500 USD
GMP inspection, foreign country: 4,000 USD	Application renewal fees, foreign product: 500 USD

Processing time is officially between 180 and 360 days; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection is required before finalising the registration. The Local Agent can speed up the registration process when well introduced in EVDFAC. In general, registration of veterinary medicinal products is a very long and difficult process because priority is given to the registration of human medicinal products.

Once issued a registration is valid for five years.

PRACTICES

- › In Ethiopia the registration of veterinary medicinal products very often changes ministry. In the past it has been under the Ministry of Health.
 - › A lot of tender business still exists in Ethiopia, which is in the hands of the federal and/or regional governments. For tender business there is no official need for the veterinary drug to be already registered in Ethiopia. Tenders are always given to the lowest bidder, so very often to counterfeit or very poor quality products.
 - › For pesticides a field trial must be carried out in Ethiopia, paid for by the applicant.
 - › Many unregistered products, usually of low quality and cheap, are available on the market. They are directly imported or come into the country from neighbouring countries.
 - › The animal health market in Ethiopia is very price- and not quality-orientated.
-
- › In the pastoralist areas drugs are sold in drug shops that are not under the control of veterinary pharmacists.
 - › Animal owners have access to all medicines and either treat their own animals or get paraprofessionals to do it.
 - › The EVDFAC lacks adequate human, financial and physical capacity to ensure that only registered veterinary drugs are imported and marketed in the country.
 - › Sale of pesticides for tick control is mostly uncontrolled, with products being sold in all types of shops.
 - › Ethiopia has the largest livestock population in Africa. More than 95% is owned by small and very small poor pastoralist livestock keepers.

Review of requirements and processes for registration of veterinary products in **Ghana**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Ghana has a National Registration System.

The Food and Drugs Authority (FDA) is under the Ministry of Health. It has the mandate to regulate food, human drugs, veterinary drugs and medical devices and to ensure adequate and effective standards.

Websites: www.fdaghana.gov.gh

All information about registration of human and veterinary allopathic drugs can be found in the FDA's Guidelines for the Registration of Human and Veterinary Allopathic Drugs; and for biologicals in the Guidelines for the Registration of Human and Veterinary Biologicals.

APPLICABLE LEGISLATION

Public Health Act, 2012 (Act 851)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** The product owner or licence holder.
- > **Authorised Local Representative (Local Agent):** Applicants not resident in Ghana shall appoint a person who resides in Ghana to be a responsible person and the contact person between the FDA and the product owner or licence holder. The application should be submitted by the Local Agent. The Local Agent shall be a registered pharmaceutical wholesale company or an accredited manufacturer's representative in Ghana.

> Documentation

- > Part I: Application Form and Summary of Product Characteristics
- > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product
- > Part III: Safety
- > Part IV: Efficacy
- > Part V: Bibliographical References

> Facts on the submission

- > Applications should be made in English.
- > Two electronic copies on CD-ROM and one printed version, where each Part or Section is bound separately, should be submitted.
- > Expert reports can be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Authorised Local Representative.

> Documentation

- > Part I: Application Form and Summary of Product Information
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

Note: It is possible that documentation should follow the Common Technical Document (CTD) format. This is not the same dossier structure as Parts I-IV. This is stated on the Ghana FDA website – applicants should confirm if it is required for veterinary products.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	At least 5 commercial samples
Registration Certificate from country of origin	Index of Registration File
Application fees	Drug master file
GMP inspection fees	Four samples and copies of package inserts & labels

> Application for variation of a registered product

Variation application form	Samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	At least five commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee
Current drug master file	

> Address for submission of applications

The Chief Executive Food and Drugs Board
 PO Box CT 2783
 Cantonments – Accra
 Ghana

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 1,800 USD	Application renewal fees, foreign product: 1,800 USD to be paid every three years
GMP inspection fees, foreign company: 20,000 USD	

Processing time is officially six to nine months; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection is required before finalising the registration. The Authorised Local Representative can speed up the process when well introduced in the FDA.

Once issued, a registration is valid for three years.

PRACTICES

- Many unregistered products, mainly of poor quality and/or counterfeit, are available on the market (many of Chinese and Indian origin); they are coming illegally into Ghana from the neighbouring countries, mostly via Nigeria.
- Inspectors appointed by the FDA monitor the importation, distribution and sale of human drugs, but they do not control veterinary drug importation, distribution or sale.
- There is a perception in the livestock sector that the FDA, being under the Ministry of Health, does not give priority to registration of veterinary medicines.
- Sale of pesticides for tick control is uncontrolled, with products being sold in all types of shops.
- The Authorised Local Representative (Local Agent) plays a very important role and can speed up the registration process when well introduced in the FDA. He is also responsible for forwarding samples and printed matters to the Board.
- The applicant is in all instances responsible for customs duty and clearance of the samples.
- The Director of Veterinary Services (DVS) can issue permits for importation and sales of all categories of veterinary drugs.
- Sales and distribution of veterinary products (pharmaceuticals, vaccines and diagnostics) are conducted by the private sector. However, vaccine distribution and sales are still controlled by the DVS.
- Private veterinarians can import registered products and vaccines, except live vaccines which are part of the DVS mandate.



Photo: GALVmed/Karel Prinsloo

Review of requirements and processes for registration of veterinary products in **Guinea-Bissau**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Guinea-Bissau relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

Websites: www.uemoa.int www.izf.net

APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA; Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

- > **Applicant:** The Company of the product responsible for manufacturing and marketing.
- > **Local Responsible Person(s):** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in French but some reports can be supplied in English.
- > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
- > Expert reports must be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer – except for different pack sizes of same injectable products.
- > Numbers of registration dossiers to be sent:
 - > Paper version: one original and three copies for Parts I, II and V; one original and two copies for Parts III, IV, VII, VIII and IX.
 - > Electronic version: 13 CD-ROMs containing all parts.
- > Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal.

The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> First time application

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing Plant Master File
Inspection fees	Five package samples and copies of package inserts & labels

> **Application for variation of a registered product**

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> **Application for renewal of registration**

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Currentsite master file	

> **Address for submission of applications**

Commission de l'UEMOA
 380 Avenue du Professeur Joseph Ki-Zerbo
 BP 543 Ouagadougou 01
 Burkina Faso
 Tel: 226 50318873
 E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees : 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12 – 18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years.

PRACTICES

- A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
 - When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
 - Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
 - A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
 - Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
 - Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
- Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
 - The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
 - The Director of Veterinary Services (DVS) can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
 - Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import Permit which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.

Review of requirements and processes for registration of veterinary products in Ivory Coast

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Ivory Coast relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

Websites: www.uemoa.int www.izf.net

APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA; Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

- > **Applicant:** The Company of the product responsible for manufacturing and marketing.
- > **Local Responsible Person(s):** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in French but some reports can be supplied in English.
- > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
- > Expert reports must be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer – except for different pack sizes of same injectable products.
- > Numbers of registration dossiers to be sent:
 - > Paper version: one original and three copies for Parts I, II and V; one original and two copies for Parts III, IV, VII, VIII and IX.
 - > Electronic version: 13 CD-ROMs containing all parts.
- > Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal.

The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> First time application

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing Plant Master File
Inspection fees	Five pack samples and copies of package inserts & labels

➤ **Application for variation of a registered product**

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

➤ **Application for renewal of registration**

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	

➤ **Address for submission of applications**

Commission de l'UEMOA
 380 Avenue du Professeur Joseph Ki-Zerbo
 BP 543 Ouagadougou 01
 Burkina Faso
 Tel: 226 50318873
 E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form or Dosage Form, send at the same time: 344 USD Generic per pharmaceutical form: 1,720 USD	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees : 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12 - 18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years.

PRACTICES

- A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
 - When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
 - Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
 - A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
 - Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
 - Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
- Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
 - The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
 - The Director of Veterinary Services (DVS) can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
 - Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import Permit which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.

Review of requirements and processes for registration of veterinary products in Kenya

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Kenya has a National Registration System.

Kenya is a Member State of the East African Community (EAC), whose current members also include Uganda, Tanzania, Rwanda and Burundi. Through GALVmed, EAC has developed a harmonised registration system for veterinary biological products and has adopted the concept of Mutual Recognition Procedures (MRP) in the region. It is expected that if an applicant applies for a Marketing Authorisation (MA) through the EAC Mutual Recognition Procedure (MRP), a dossier assessed by Tanzania or Uganda for a biological product could be authorised in Kenya after progressing through the MRP, although this process has not yet been put into practice in the EAC.

The Pharmacy and Poison Board (PPB), under the Ministry of Medical Services, holds the mandate to approve and register medicinal products (biological and pharmaceutical); appoint inspectors and order inspection of premises; as well as promote rational use of drugs and medical devices.

Pesticides are regulated by the Pest Control Products Board (PCPB), under the Ministry of Agriculture. It has a mission to provide an efficient and effective regulatory service for importation, exportation, manufacture, distribution, transportation, sale, disposal and safe use of pest control products and mitigate potential harmful effects to the environment.

APPLICABLE LEGISLATION

For veterinary drugs and biologicals: Pharmacy and Poisons Act (CAP 244)

For pesticides: Pest Control Products Act (CAP 346)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** The application for the registration of a drug shall be made only by:
 - > The licence/patent holder
 - > The manufacturer
- > **Local Technical Representative:** If an applicant is not a resident in Kenya, they shall nominate an Authorised Person (licensed as a pharmaceutical importer and wholesaler) who resides in Kenya to be a Local Technical Representative for communication with authorities, monitoring the product on the market and handling eventual product recalls.
- > **Documentation**
 - > Part I: Product Information
 - > Part II: Quality, Manufacturing and Control
 - > Part III: Safety
 - > Part IV: Efficacy
 - > Part V: Bibliographical References
- > **Facts on the submission**
 - > Although PPB is the regulatory authority for veterinary biologicals, the Director of Veterinary Services (DVS), under the Animal Diseases Act, has to authorise their use in the country. The DVS issues permits for importation of vaccines. Vaccine importers have to get permits from the DVS and PPB.
 - > Applications should be made in English.
 - > One electronic copy on CD-ROM and one printed copy, in which each Part or Section is bound separately, should be submitted.
 - > Expert reports have to be included.
 - > Separate applications must be made for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

- > **Applicant:** The application for the registration of a drug shall be made only by:
 - > The licence/patent holder
 - > The manufacturer
 - > Local Technical Representative (see Biologicals)
- > **Documentation**
 - > Part I: Application Form
 - > Part II: Pre-clinical and Clinical Data

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Two duly filled application forms (Original and Duplicate) and an electronic copy (MS Word on a CD-ROM) including their supporting documents	Three samples of the smallest commercial pack(s) from one batch with batch certificates of analysis
Registration certificate from country of origin	Manufacturing site master file
Non-refundable application fee for registration of a pharmaceutical product	Pack samples and copies of package inserts & labels
GMP inspection fees for facilities not yet inspected by PPB	

> Application for alteration of a registered product

Alteration application form	Samples of the altered product
Detailed description of the alteration with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Three samples of the smallest commercial pack(s) from the same batch along with batch certificates of analysis
Duly filled in application form for renewal of registration	Non-refundable application fee for registration of pharmaceutical product
Batch Manufacturing Record (BMR) of a real batch manufactured within at most six months before the submission of the application	GMP inspection fees for facilities not inspected and approved by PPB within the last 3-5 years
A site master file in case the product is manufactured at a plant(s) not inspected and approved by PPB	

> Address for submission of applications

The Registrar, Pharmacy and Poisons Board
 Lenana Road
 P. O. Box 27663-00506
 Nairobi
 Kenya

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration of a pharmaceutical product: Imported into Kenya: 1,000 USD Fully manufactured in Kenya: 500 USD	Renewal of registration of a pharmaceutical product: Imported into Kenya: 500 USD Fully manufactured in Kenya: 300 USD
GMP inspection fees: 4,000 USD	

The registration process is officially 180 days. Once a query is raised, the process is halted. Good Manufacturing Practices (GMP) inspection may be required before finalising the registration. However, registration will often take much longer because the PPB gives a much higher priority to the registration of human medicinal products. The Local Technical Representative can, if well introduced in PPB, speed up the registration.

Once issued, a registration is valid for five years.

OUTLINE OF PROCESS

Receiving of new applications	Documentation in hard copies and electronic form; samples and fees
Evaluation process	
Laboratory analyses of product sample	
Verification of compliance to current current Good Manufacturing Practices (cGMP)	Site inspection
Consideration by Committee on Drug Registration	A summary of recommendations of evaluation, laboratory analysis and GMP status reports presented to the committee for assessment

PRACTICES

- There is a very strong perception in the livestock sector that the PPB, being under the Ministry of Health, does not give priority to registration of veterinary medicines.
- Several unregistered products, usually of poor quality and/or counterfeit, are available in the market.
- The Ministry of Livestock and the veterinary profession have been working on having a separate act and agency for the registration of veterinary medicines, outside of PPB, which is more focused on human medicines. An act, the VSVPP Act of 2011, has been in discussion.
- In the pastoralist areas, drugs are sold in drug shops that are not under the control of pharmacists.
- Animal owners have access to all medicines and treat their animals or get paraprofessionals do it.
- Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
- Sale of pesticides for tick control is uncontrolled, with products being sold in all types of shops.

Review of requirements and processes for registration of veterinary products in **Malawi**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Malawi has a National Registration System, which is not very operational. Currently, every registered (and unregistered) importer/distributor can import and market veterinary drugs in Malawi.

The Pharmacy, Medicines and Poisons Board (PMPB) is under the Ministry of Health. It has the official mandate to regulate food, human drugs, veterinary drugs and medical devices and to ensure adequate and effective standards, but at least for the registration and control of veterinary medicines, this organisation is not currently functional.

Malawi is a member of the Southern African Development Community (SADC). The SADC has been working on a regional harmonisation system for the registration of veterinary products, starting with veterinary drugs, but this system is not yet in place.

APPLICABLE LEGISLATION

Pharmacy, Medicines and Poisons Act (1988)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

Because there is no real registration in Malawi, it is recommended to submit a minimum registration dossier to the PMPB.

- > **Applicant:** The product owner or licence holder.

- > **Local Importer/Distributor with registered business in Malawi:**
An applicant not resident in Malawi must appoint an Authorised Person who resides in Malawi to be responsible as a contact person between PMPB and the product owner or licence holder. The application should be submitted by the Authorised Person. However, for Variations to Marketing Authorisations, PMPB say that they follow EU requirements.
- > **Documentation**
 - > Part I: Application Form and Summary of Product Characteristics
 - > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product
 - > Part III: Safety
 - > Part IV: Efficacy
 - > Part V: Bibliographical References
- > **Facts on the submission**
 - > Applications should be made in English.
 - > One printed version should be submitted in which each Part or Section is bound separately.
 - > Expert reports can be included.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Authorised Local Importer/Distributor. Submit a minimum registration dossier.

> Documentation

- > Part I: Application Form and Summary of Product Information
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

There is no real registration authority for veterinary medicines but it is recommended to submit a minimum registration dossier to the PMPB which will allow the Registered Local Importer/Distributor to import veterinary medicines without any difficulty.

> Address for submission of applications

Pharmacy, Medicines and Poisons Board
PMPB Building
Chilambula Road
Lilongwe
Malawi

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Officially there are no registration fees to be paid.

PRACTICES

- > Most of the veterinary drugs available in Malawi are unregistered products, usually of substandard quality and/or counterfeit, which arrive in Malawi from the neighbouring countries or through direct import.
- > Drugs are sold through veterinary pharmacists and drug shops.
- > Pesticides are registered officially through the Pest Control Products Act.
- > Sale of pesticides for tick control is uncontrolled, with products being sold in many types of shops.
- > Veterinary assistants sell pesticides through drug shops in rural areas.
- > Officially it is an offense to sell pesticides and veterinary medicines that are not registered, but there is no regulatory system in place to control the presence of non-registered drugs and vaccines.
- > There is no adequate capacity to monitor legal and illegal import of veterinary drugs and vaccines.
- > The Director of Veterinary Services (DVS) maintains an inventory of vaccines that are in use in the country.
- > The DVS decides which vaccines are to be used in animals. Veterinarians should give a prescription for purchase of vaccines.
- > Sales and distribution of veterinary products (pharmaceuticals, vaccines and diagnostics) are conducted by the private sector, through local importers/distributors with registered businesses in Malawi.
- > Livestock production and disease control is not a high priority in the country, which has predominantly only subsistence farming.

Review of requirements and processes for registration of veterinary products in **Mali**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Mali relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

Websites: www.uemoa.int www.izf.net

APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA; Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

- > **Applicant:** The Company of the product responsible for manufacturing and marketing.
- > **Local Responsible Person(s):** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in French but some reports can be supplied in English.
- > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
- > Expert reports must be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer – except for different pack sizes of same injectable products.
- > Numbers of registration dossiers to be sent:
 - > Paper version: one original and three copies for Parts I, II and V; one original and two copies for Parts III, IV, VII, VIII and IX.
 - > Electronic version: 13 CD-ROMs containing all parts.
- > Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal. The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> First time application

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing Plant Master File
Inspection fees	Five pack samples and copies of package inserts & labels

➤ **Application for variation of a registered product**

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

➤ **Application for renewal of registration**

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	

➤ **Address for submission of applications**

Commission de l'UEMOA
 380 Avenue du Professeur Joseph Ki-Zerbo
 BP 543 Ouagadougou 01
 Burkina Faso
 Tel: 226 50318873
 E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form or Dosage Form, send at the same time: 344 USD Generic per pharmaceutical form: 1,720 USD	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees : 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12 - 18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years.

PRACTICES

- A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
- When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
- Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
- A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
- Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
- Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
- Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
- The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
- The Director of Veterinary Services (DVS) can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
- Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import License which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.



Review of requirements and processes for registration of veterinary products in **Morocco**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Morocco has a fully-functioning National Registration System for veterinary medicinal products.

The National Office for Food Hygiene and Safety (ONSSA) is the legal authority, and its unit responsible for registration of veterinary product is the National Laboratory for the Control of Veterinary Medicinal Products (LNCMV). ONSSA and LNCMV are under the Ministry of Agriculture and Fishery.

LNCMV has the mandate to approve and to register all veterinary medicinal products (biologicals and pharmaceuticals), appoint inspectors and order inspection of premises.

Website: www.onssa.gov.ma

APPLICABLE LEGISLATION

Law 21-80 with Application Decree 2-82-541; Food Law, Regulation 178/2002

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** The owner, responsible for manufacturing of the product.
- > **Local Representative:** An applicant not resident in Morocco shall nominate an authorised Moroccan company (licensed as a veterinary pharmaceutical importer and wholesaler) resident in Morocco to be the Local Representative for communication with authorities, monitoring the product on the market and handling eventual product recalls.

> Documentation

- > Part I: Administrative Documentation: Application Form and Summary of Product Characteristics
- > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product Documentation
- > Part III: Safety Documentation
- > Part IV: Efficacy Documentation
- > Part V: Expert Reports for Quality, Safety, Stability and Efficacy (compulsory)

> Facts on the submission

- > Applications should be made in French, but sections of the dossier may be in English. There is a specific format in French for the application.
- > One printed dossier should be submitted in which each Part or Section is bound separately. The Administrative part can also be given as an electronic version (CD-ROM).
- > Expert reports must be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products. Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the authorities.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Representative.

> Documentation

- > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies Documentation
- > Part IV: Pre-clinical and Clinical Data Documentation
- > Part V: Expert Reports for Quality, Safety, Stability and Efficacy (compulsory)

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	Seven commercial samples
Registration Certificate from country of origin	Index of complete registration file
Application fees	Manufacturing plant master file
GMP inspection fees	Seven pack samples and copies of package inserts & labels

> Application for variation of a registered product

Variation application form	Seven samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days, but preferably six months before expiry of registration	Seven commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee
Current plant master file	

> Address for submission of applications

Directeur LNCMV
Rue Ikhlass
Coté Yacoub el Mansour
BP 4509, Akkari Rabat, Maroc
Tel: +212 37690477

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 1,400 €	Dossier variation fees, foreign product: 400 €
GMP inspection fees, local product: 500 DHS/person/day (40 €/person/day) GMP inspection fees, foreign product: 900 €/person/day	Application renewal feeds, foreign product: 400 €

Processing time is officially 180 days, typically 6-12 months; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. The Local Representative can speed up the process when well introduced in LNCMV.

Once issued a registration is valid for five years.

A variation is equivalent to the renewal of a product and results in a licence that is valid for five years from the date of approval of the variation.

PRACTICES

- > The Local Representative can speed up in a significant way the whole registration process, when well introduced in LNCMV.
- > Registration approval is given by a Commission that meets 2-4 times per year. The dates of the meetings are not fixed and submissions are generally dealt with in chronological order. It is often the case that there are too many submissions for the Commission and those at the bottom of the list are postponed until the following meeting.



Photo: GALVmed/Karel Prinsloo

Review of requirements and processes for registration of veterinary products in Niger

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Niger relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

Websites: www.uemoa.int www.izf.net

APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA; Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

- > **Applicant:** The Company of the product responsible for manufacturing and marketing.
- > **Local Representative:** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Representative.

- > **Documentation**
 - > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
 - > Part II: Chemistry, Manufacturing and Quality Data
 - > Part III: Safety and Residue Studies
 - > Part IV: Pre-clinical and Clinical Data

- > **Facts on the submission of Pharmaceuticals and Biologicals**
 - > Applications should be made in French but some reports can be supplied in English.
 - > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
 - > Expert reports must be included.
 - > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer – except for different pack sizes of same injectable products.
 - > Numbers of registration dossiers to be sent:
 - > Paper version: one original and three copies for Parts I, II and V; one original and two copies for Parts III, IV, VII, VIII and IX.
 - > Electronic version: 13 CD-ROMs containing all parts.
 - > Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal. The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> **First time application**

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing Plant Master File
Inspection fees	Five pack samples and copies of package inserts & labels

> **Application for variation of a registered product**

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> **Application for renewal of registration**

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	

> Address for submission of applications

Commission de l'UEMOA
380 Avenue du Professeur Joseph Ki-Zerbo
BP 543 Ouagadougou 01
Burkina Faso
Tel: 226 50318873
E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form or Dosage Form, send at the same time: 344 USD Generic per pharmaceutical form: 1,720 USD	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees: 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12-18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years

PRACTICES

- > A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
- > When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
- > Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
- > A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
- > Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
- > Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
- > Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
- > The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
- > The Director of Veterinary Services (DVS) can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
- > Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import License which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.

Review of requirements and processes for registration of veterinary products in **Nigeria**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Nigeria has a National Registration System. The National Agency for Food and Drug Administration and Control (NAFDAC) is under the Regulatory and Registration Directorate of the Ministry of Health. NAFDAC has the mandate to approve and to register all medicinal products (biologicals, pharmaceuticals and pesticides), appoint inspectors and order inspection of premises as well as promote rational use of drugs and medical devices.

Websites: www.nafdac.gov.ng

APPLICABLE LEGISLATION

Food and Drugs Act (1999)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** The owner responsible for manufacturing of the product.
- > **Local Responsible Person(s):** An applicant not resident in Nigeria must nominate an authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in Nigeria to be a Local Representative for communication with authorities, monitoring the product on the market and handling product recalls.

> Documentation

- > Part I: Application Form and Summary of Product Characteristics
- > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product
- > Part III: Safety
- > Part IV: Efficacy
- > Part V: Bibliographical References

> Facts on the submission

- > Applications should be made in English.
- > The electronic copies (CD-ROM) should be submitted; no paper copies.
- > Expert reports should be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Representative.

> Documentation

- > Part I: Application Form and Summary of Product Information
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

IMPORTANT:

A three-step process is used.

- (i) Registration of the brand name (trademark registration), required before product registration can proceed. This is carried out locally and should take 1-2 months. Once trademark registration is issued, it is valid for 7 years.
- (ii) E-submission of the dossier.
- (iii) Laboratory analysis of finished product samples. A Product Certificate is then issued by the registration approval committee.

Complete documentation as per guidelines	Three commercial samples
Registration Certificate from country of origin	Index of complete registration file
Application fees	Manufacturing plant master file
GMP inspection fees	Three pack samples and copies of package inserts & labels

> Application for variation of a registered product

Variation application form	Three samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Three commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee
Current plant master file	

> Address for submission of applications

Office of the Director, Regulatory and Registration Directorate
44 Herbert Macaulay Way
Yaba, Lagos
Nigeria

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign pharmaceutical product: 1,700 USD Registration fees, foreign biological product: 1,000 USD	Dossier alteration fees, foreign product: 500 USD
GMP inspection fees, foreign country: 4,000 USD	Application renewal fees, foreign pharmaceutical product: 1,700 USD Application renewal fees, foreign biological product: 1,000 USD

Processing time is officially 180 days; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection is required before finalising the registration. Registration of a veterinary product is a very long and slow process – it may take several years – because NAFDAC gives priority to human medicinal products. However, the Local Representative can speed up the process when well introduced in NAFDAC.

Once issued a registration is valid for five years.

PRACTICES

- > Many unregistered products, usually of poor quality and/or counterfeit, are widely available on the market, which are produced in Nigeria or are coming into Nigeria from neighbouring countries.
- > Inspectors appointed by NAFDAC have the mandate to monitor the importation, distribution and sale of all medicinal products; this is true for human medicinal products but not at all for veterinary medicinal products.
- > In the pastoralist areas drugs are sold in drug shops that are not at all under the control of NAFDAC inspectors.
- > NAFDAC lacks adequate human, financial and physical capacity to ensure that only registered veterinary drugs are imported and marketed in the country.
- > NAFDAC, being under the Ministry of Health, gives enormous priority to the registration of human medicinal products and none at all to veterinary medicines.
- > Once the registration dossier is submitted to NAFDAC, it is possible to ask for a special import licence which allows starting marketing the medicinal product in Nigeria. A very motivated and very well introduced Local Representative in NAFDAC can easily arrange this special import licence and can also speed up the whole registration process.



Photo: GALVmed/Karel Prinsloo

Review of requirements and processes for registration of veterinary products in **Rwanda**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Officially the regulatory authority for veterinary products is the Directorate of Veterinary Services. However, there is no registration process in place for all veterinary products.

Rwanda is part of the regional process initiated in the East African Community (EAC) for mutual recognition of veterinary biologicals. But this process has not been in practice in the country.

Importation of veterinary products is on the basis of Import Permits issued by veterinary authorities.

APPLICABLE LEGISLATION

Loi 12/99 du 02/07/1999 relative to «L'art Pharmaceutique»

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

Not implemented, despite being part of the EAC. Therefore, not applicable.

PHARMACEUTICALS

Not applicable.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

Not applicable.

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Not applicable.

PRACTICES

- Rwanda is a bit more organised than other countries in the region, but despite that there are a few illegal products found on the market.
- It is expected that through the mutual recognition process of the EAC, a Marketing Authorisation obtained in Kenya, Tanzania or Uganda would allow biological products to be authorised in Rwanda, but this is not yet in place.

Review of requirements and processes for registration of veterinary products in **Senegal**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Senegal relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

Websites: www.uemoa.in www.izf.net

APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA;
Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

- > **Applicant:** The Company of the product responsible for manufacturing and marketing.
- > **Local Responsible Person(s):** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person

> Documentation

- > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in French but some reports can be supplied in English.
- > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
- > Expert reports must be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer – except for different pack sizes of same injectable products.
- > Numbers of registration dossiers to be sent:
 - > Paper version: one original and three copies for Parts I, II and V; one original and two copies for Parts III, IV, VII, VIII and IX.
 - > Electronic version: 13 CD-ROMs containing all parts.
- > Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal. The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> First time application

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing Plant Master File
Inspection fees	Five pack samples and copies of package inserts & labels

> **Application for variation of a registered product**

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> **Application for renewal of registration**

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	

> **Address for submission of applications**

Commission de l'UEMOA
 380 Avenue du Professeur Joseph Ki-Zerbo
 BP 543 Ouagadougou 01
 Burkina Faso
 Tel: 226 50318873
 E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form or Dosage Form, send at the same time: 344 USD Generic per pharmaceutical form: 1,720 USD	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees : 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12 - 18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years.

PRACTICES

- > A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
 - > When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
 - > Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
 - > A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
 - > Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
 - > Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
-
- > Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
 - > The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
 - > The Director of Veterinary Services (DVS) can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
 - > Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import License which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.

Review of requirements and processes for registration of veterinary products in **Sierra Leone**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Sierra Leone has no real registration system in place. It has a law, the National Drugs Control Act (2008), which seeks to regulate pharmacists and pharmacist technicians and provides the rules for importation, storage and transportation of human drugs. But this law is not implemented. There is therefore no regulatory authority in place for the registration, importation, manufacturing or sale of human and veterinary products.

Sierra Leone is part of the Economic Community of West African States (ECOWAS). There are indications that ECOWAS is looking to put in place the same system as that used in UEMOA. This will be a very long process and a similar system is not likely to be fully functional for at least another ten years.

APPLICABLE LEGISLATION

National Drugs Control Act (2008)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

No regulatory authority and no registration procedures exist for the registration of human or veterinary products.

PHARMACEUTICALS

No regulatory authority and no registration procedures exist for the registration of human or veterinary products.

PRACTICES

- > Sierra Leone is a country which is still experiencing civil war.
- > Some human drugs are imported through the government and through NGOs.
- > Most essential human drugs are missing.
- > The market has a lot of substandard and counterfeit human and veterinary products with only very few quality human drugs available sporadically.
- > With regard to veterinary products, Sierra Leone has virtually no veterinary drugs of quality; veterinary products that exist are typically substandard or counterfeit. These are prevalent on the market and mostly are from neighbouring countries.

Review of requirements and processes for registration of veterinary products in **South Africa**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

South Africa has two National Registration Systems for veterinary products: Act 36 of 1947 under the Department of Agriculture, Forestry and Fisheries; and Act 101 of 1965, as amended, under the Ministry of Health.

APPLICABLE LEGISLATION

Act 101 of 1965 – Medicines and Related Substances Control Act

Act 36 of 1947 – Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act: also regulates pesticides and over-the-counter medicines. For the purpose of this review, Act 36 will be used, as it is the one which is mostly used for the registration of veterinary products.

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS AND PHARMACEUTICALS

- > **Applicant:** Defined as the person in whose name an application for the registration of a stock remedy has been filed.
- > **Registration Holder:** Defined as the person to whom a certificate of registration in respect of a particular stock remedy has been issued.
- > **Local Responsible Person:** A Registration Holder has to be a South African entity. An applicant not resident in South Africa shall nominate an authorised person or institution who is established in South Africa, to submit the application and to be the local entity responsible for communication with authorities, monitoring the product on the market and handling eventual product recalls.

> Documentation

The dossier format is CTD (Common Technical Document). This is essentially the same information that is included in an EU registration dossier, but the presentation of the data is not the same. All dossiers should be structured into:

- > General Information
 - Table of Contents, Purposes of Application, Summary of Product Information
 - Full Registration Status, Certificate from Country of Origin and Others
 - Approved Original Label, Proposed Label for South Africa
- > Pharmaceutical Data
 - Chemistry
 - Formulation and Manufacturing
 - Stability Data (Shelf-Life Determination)
- > Pre-clinical Data
- > Safety Data: Occupational Health, Target Species
- > Efficacy Data or Bioequivalence Data
- > Residue Data (For Food Producing Animals)
- > For Biologicals, there is a special set of specific Efficacy Data requirements, which include:
 - Biological Properties of Organisms
 - Proof of Efficacy of Product with Respect to Composition
 - Efficacy and Minimum Age of Administration of Vaccine
 - Proof of Efficacy with Respect to Species
 - Proof of Efficacy with Respect to Route of Administration
 - Efficacy Data with Respect to Minimum Guaranteed Titres
 - Laboratory and Field Efficacy Data
 - Trial Data

> **Facts on the submission**

- > Applications should be made in English.
- > A printed version should be submitted.
- > Expert reports have to be included.
- > In the case of products containing genetically modified organisms (GMOs), an approval for the use of those ingredients should be obtained from the Genetic Resources Directorate within the Department of Agriculture, Forestry and Fisheries.
- > This GMO approval is required before the registration process can start. The GMO approval procedure includes a public consultation phase. The applicant should therefore be mindful of the additional time required if the product contains a GMO.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> **First time application**

Complete documentation as per guidelines	Pack samples and copies of package inserts & labels
Registration Certificate from country of origin	Index
Application fees	

> **Application for variation of a registered product**

Ten situations are described in the legislation. The data requirements for each are provided below.

1 Change in formulation

Formulation and manufacturing data	Target species safety data (depending on the change)
Where necessary: batch comparison & stability data	Residue data (for food producing animals) (depending on the change)
Efficacy data (depending on the change)	

2 Change in source of active pharmaceutical ingredient

Method of synthesis	Pharmaceutical and chemical equivalence
Certificate of analysis	

3 Change in the manufacturing process/site/manufacturer

GPM Certificate where possible in the case of site/manufacturer change, plus sworn statement that process has not changed	Any other relevant information
Certificate(s) of analysis: For change in site/manufacturer or additional site/manufacturer, the certificates of analysis must be from the current site/manufacturer as well as from the new site/manufacturer or the additional site/manufacturer. Both certificates must be recent.	

4 Change in specifications of final product

Substantiation for change in specifications

5 Additional target species

Safety data for that particular species	Residue data for that particular species (for food animals only)
Efficacy data for that particular species	

6 Additional therapeutic claim with no change in dosage

Efficacy data

7 Change in dosage

Target species safety, efficacy and residue if applicable

8 Change in the withdrawal period

Residue data

9 Change in shelf-life of the trade name product

Stability data

10 Change in packaging material or pack size of the trade name product

Packaging specifications

Stability data

> Application for renewal of registration

There is currently no renewal procedure that requires a dossier. Product registrations are “renewed” locally on an annual basis. This is administrative and is subject to a minor fee.

> Address for submission of applications

The Registrar: Act 36 of 1947
Private Bag X343
Pretoria, 0001
South Africa

or if hand-delivered, to:
The Registrar: Act 36 of 1947
Agriculture Place
20 Steve Biko Street
Arcadia, Pretoria
South Africa

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees: 682 USD

Dossier alteration fees: 360 USD

Application renewal fees: 342 USD

Officially the registration process takes up to one year, but the reality is that it has been taking more than two years; once a query is raised, the process is halted.

Once issued, a registration is valid for one year; the renewal is every three years.

PRACTICES

- > The biggest challenge in registration in South Africa is the time it takes for processing of dossiers; there is no predictability for the evaluation timeframe.
- > There are two regulatory bodies, which further complicates the registration process.

Review of requirements and processes for registration of veterinary products in **South Sudan**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

South Sudan has no actual registration authority in place for the registration of veterinary medicinal products (pharmaceuticals and vaccines).

Normally registration of veterinary medicinal products is mandated by the Ministry of Health in Juba through the Drug and Food Control Authorities (DFCA), but this body has no actual infrastructure and no human resources to create a registration authority. South Sudan acceded to the East African Community in 2016 and hopes to be part of the Mutual Recognition Procedure being introduced in that region.

APPLICABLE LEGISLATION

Southern Sudan Pharmacy and Drugs Act (2014): regulates the registration of human and veterinary products, but there is no real Ministry of Health and no ministry responsible for veterinary services to implement this Act.

Regulatory procedures are still under development for its implementation.

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

Currently no registration procedure in place.

PHARMACEUTICALS

Currently no registration procedure in place.

PRACTICES

- > Many poor quality and/or counterfeit veterinary drugs are available on the market (many of Chinese and Indian origin), which are coming into South Sudan from neighbouring countries, mainly Kenya.
- > Most veterinary drugs are imported through Kenyan distributors and wholesalers which are very well known in South Sudan (e.g. Medina Chemicals Ltd., Nairobi).
- > Several NGOs present in South Sudan are importing veterinary drugs directly from Kenya to help South Sudanese farmers.

Review of requirements and processes for registration of veterinary products in **Sudan**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Sudan has a National Registration System.

The National Medicines and Poisons Board (NMPB) under the Ministry of Health has the mandate to regulate food, human drugs, veterinary drugs and medical devices and to ensure adequate and effective standards.

Website: www.nmpb.gov.sd

APPLICABLE LEGISLATION

Medicines and Poisons Act (2001)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** The product owner or licence holder.
- > **Local Representative (Local Agent):** An applicant not resident in Sudan must nominate an authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in Sudan to be a Local Representative for communication with authorities and for monitoring the product on the market.
- > **Documentation**
 - > Part I: Application Form and Summary of Product Characteristics
 - > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product
 - > Part III: Safety
 - > Part IV: Efficacy
 - > Part V: Bibliographical References

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Representative.

> **Documentation**

Volume I:

- > Application Form and Summary of Product Information
- > Safety and Residue Studies
- > Pre-clinical and Clinical Data

Volume II:

- > Chemistry, Manufacturing and Quality Data

> **Facts on the submission**

- > Applications should be made in English or Arabic.
- > Applications should include one paper copy, along with two paper copies of the application form.
- > Expert reports can be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines on website	Ten commercial samples for pharmaceuticals; enough samples for biologicals to conduct the necessary studies in Sudan
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Drug master file
GMP Inspection fees	Ten pack samples and copies of package inserts & labels

> Application for variation of a registered product

Alteration application form	Ten commercial samples of the altered product
Detailed description of the alteration with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 45 days before expiry of registration	At least five commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee
Current drug master file	

> Address for submission of applications

Secretariat General
National Medicines and Poisons Board
Khartoum
Republic of Sudan

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 2,000 USD	Application renewal fees, foreign product: 1,400 USD
GMP inspection fees, foreign company: not indicated	

Processing time is officially 12 months; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection is required before finalising the registration. In reality it is a very long process which takes at least two years, and often longer. A Local Agent could speed up the whole registration process if they have access to NMPB and the National Veterinary Committee.

Once issued a registration is valid for five years.

PRACTICES

- > Many unregistered products, mainly of poor quality and/or counterfeit, are available on the market (many of Chinese and Indian origin), which are coming illegally into Sudan from neighbouring countries.
- > NMPB has no appointed inspectors to monitor the importation, distribution or sales of veterinary drugs.
- > There is a very strong perception in the livestock sector that the NMPB, being under the Ministry of Health, does not give priority for registration of veterinary products.

Review of requirements and processes for registration of veterinary products in **Tanzania**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Tanzania has a National Registration System.

Tanzania is a Member State of the East African Community (EAC). The EAC has developed a regional process for a mutual recognition of veterinary biological products which are either new or already registered in one or several EAC countries. This regional process means that if a dossier for a veterinary biological is assessed by Kenya or Uganda it could be approved in Tanzania as well after progressing through the Mutual Recognition Procedure.

The Tanzanian Food and Drug Administration (TFDA), under the Ministry of Health, has the mandate to approve and to register all medicinal products (biologicals and pharmaceuticals). The TFDA appoints inspectors and orders inspection of premises as well as promoting rational use of drugs and medical devices.

Website: www.tfda.or.tz

The Tropical Pesticides Research Institute (TPRI) is responsible for registration of pesticides.

APPLICABLE LEGISLATION

Food, Drugs and Cosmetics Act of 2003
Pesticide Control Regulations of 1984

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** This could be the owner responsible for manufacturing or those ordering the product for sell in Tanzania.
- > **Local Representative (Local Agent):** An applicant not resident in Nigeria must nominate an authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in Nigeria to be a Local Responsible Person for communication with authorities, monitoring the product on the market and handling eventual product recalls.
- > **Documentation**
 - > Part I: Application Form and Summary of Product Characteristics
 - > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product
 - > Part III: Safety
 - > Part IV: Efficacy
 - > Part V: Bibliographical References
- > **Facts on the submission**
 - > Applications should be made in English or Swahili.
 - > One Electronic version (CD-ROM) and one printed version in which each Part or Section is bound separately should be submitted.
 - > Expert reports have to be included.
 - > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person

> Documentation

- > Part I: Application Form and Summary of Product Information
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	Five commercial samples
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Manufacturing site master file
GMP Inspection fees	Pack samples and copies of package inserts & labels

> Application for variation of a registered product

Variation application form	Samples of the variation of the product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee
Current site master file	

> Address for submission of applications

The Director General, Tanzania Food and Drugs Authority
Off Mandela Road, Mabibo External
P. O. Box 77150, Dar es Salaam
Tanzania

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, local product: 600,000 TZS* (274 USD)	Dossier alteration fees, local product: 60,000 TZS (27 USD)
Registration fees, foreign product: 1,250 USD*	Dossier alteration fees, foreign product: 100-200 USD
GMP inspection fees, local: 150,000 TZS/year (68 USD/year)	Application renewal fees, local: 60,000 TZS (27 USD)
GMP inspection fees, East Africa: 3,000 USD	Application renewal fees foreign product: 200 USD
GMP inspection fees, rest of Africa: 4,500 USD	
GMP inspection fees, Europe or America: 6,500 USD	

**Fast tracking registration possible at double the fee*

Processing time is officially 180 days; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. The Local Responsible Person can speed up the process when well introduced in TFDA.

Once issued a registration is valid for five years, but an annual renewal fee of 200 USD should be paid.

PRACTICES

- Several unregistered products, usually of poor quality and/or counterfeit, are widely available on the market.
- Inspectors appointed by TFDA monitor the importation, distribution and sale of drugs.
- In the pastoralist areas, drugs are sold in drug shops that are not under the control of pharmacists.
- Animal owners have access to all medicines and either treat their own animals or get paraprofessionals to do it.
- Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
- The TFDA lacks adequate regulatory capacity for human medicinal products and has none at all for veterinary medicinal products.
- There is a very strong perception in the livestock sector that the TFDA, being under the Ministry of Health, does not give priority to registration of veterinary medicines.
- Sale of pesticides for tick control is uncontrolled, with products being sold in many types of shops.
- Once the registration dossier is submitted to TFDA, it is possible to ask for a special import licence which allows the applicant to start marketing the veterinary medicinal product in Tanzania. A very motivated and very well introduced Local Responsible Person in TFDA and Veterinary Services can easily arrange this special import licence. Commitment of Veterinary Services is necessary to obtain this special import licence.



Photo: GALVmed/Karel Prinsloo

Review of requirements and processes for registration of veterinary products in Togo

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Togo relies on the centralised registration system of UEMOA, the West African Economic and Monetary Union. UEMOA's centralised system has been officially in place since 2006, but in practice the new system has been operational since 2010. All products registered before 2010 were allowed to circulate through a mutual recognition system within the UEMOA member countries until the end of 2014. They should then have obtained a centralised registration for circulation from the beginning of 2015. But this has not been implemented and only 79 of the more than 490 registration dossiers submitted have been examined to date and received a Centralised Marketing Authorisation.

As stated above, the situation is continually evolving with regard to the registration of products that were registered in at least one UEMOA Member State prior to the introduction of the centralised system. For all new registrations within the UEMOA the situation is clear: a Marketing Authorisation (registration) is required before the product can be placed on the market in any of the UEMOA countries. The registration procedures for new products are described below.

Websites: www.uemoa.int www.izf.net

APPLICABLE LEGISLATION

Regulation 02/2006/CM/UEMOA: outlines the procedures for authorisation to sell/market and supervision of veterinary drugs and establishes a regional committee of veterinary medicine.

Decision 009/2009/COM/UEMOA; Decision 011/2009/COM/UEMOA; Execution Regulation 007/2009/COM/UEMOA

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

(Based on the requirements of a European Centralised Marketing Authorisation)

BIOLOGICALS

- > **Applicant:** The Company of the product responsible for manufacturing and marketing.
- > **Local Responsible Person(s):** Applicant not resident in one of the UEMOA Member States shall nominate an Authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in one of the UEMOA Member States to be legally responsible for monitoring the product on the market, communicating with authorities and handling eventual product recalls.
- > **Documentation**
 - > Part V: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part VI: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part VII: Safety
 - > Part VIII: Efficacy
 - > Part IX: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person

> Documentation

- > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in French but some reports can be supplied in English.
- > Submission should include electronic version (CD-ROM) and printed version where each Part or Section is bound separately.
- > Expert reports must be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer – except for different pack sizes of same injectable products.
- > Numbers of registration dossiers to be sent:
 - > Paper version: one original and three copies for Parts I, II and V; one original and two copies for Parts III, IV, VII, VIII and IX.
 - > Electronic version: 13 CD-ROMs containing all parts.
- > Details concerning the requirements – numbers of dossiers, packaging, samples – for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

The registration dossier has to be sent to the Permanent Secretary of the Regional Committee for Veterinary Medicines, which validates that the registration dossier is complete (contains all requested documents). Once the registration dossier is recognised as valid a Regional Committee for Veterinary Medicines (all heads of the Veterinary Services of the Member States), in consultation with the Veterinary Expert Committee, will evaluate the technical content of the dossier. An evaluation report and a SPC (Summary of Product Characteristics) will be sent to the President of the UEMOA Commission with a decision proposal. The President of the UEMOA Commission, in consultation with the Veterinary Expert Committee, will take the decision to give a Centralised Marketing Authorisation. The whole procedure may not exceed 240 days, but if the registration dossier is not complete, this period can be prolonged by several months or even several years.

The Regional Committee for Veterinary Medicines is not only responsible for the Centralised Marketing Authorisation but is also responsible for quality control systems for veterinary drugs (inspection of manufacturing and distribution of all veterinary drugs in all Member States).

> First time application

Complete documentation as per guidelines in Decision 009/2009/COM/UEMOA	At least five commercial samples
Registration Certificate from country of origin	Index of complete registration file
Application fees	Manufacturing plant master file
Inspection fees	Five pack samples and copies of package inserts & labels

> **Application for variation of a registered product**

Variation application form	Five samples of the new version of the product
Detailed description of the variation with supporting reasons	Applicable fees

> **Application for renewal of registration**

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being submitted for registration
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	

> **Address for submission of applications**

Commission de l'UEMOA
 380 Avenue du Professeur Joseph Ki-Zerbo
 BP 543 Ouagadougou 01
 Burkina Faso
 Tel: 226 50318873
 E-mail: commission@uemoa.int

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees per pharmaceutical form: 2,000,000 F CFA (3,440 USD). For each Complementary Pharmaceutical Form or Dosage Form, send at the same time: 344 USD Generic per pharmaceutical form: 1,720 USD	Dossier variation fees product (minor): 172 USD Dossier variation fees product (major): 1,032 USD
GMP inspection fees, local: 500,000 F CFA (860 USD) (not always requested)	Application renewal fees : 1,720 USD

Details concerning the fees for a product where there is more than one presentation need to be confirmed with the UEMOA authorities.

The registration process is officially 240 days. Once a query is raised, the process is halted until the questions are answered. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. In general the registration process takes much longer than 240 days, typically 12 - 18 months. In the last five years, only 79 products received a Centralised Marketing Authorisation recognised by all UEMOA Member States, while more than 490 registration dossiers were submitted in this period.

Once issued, a registration is valid for five years.

PRACTICES

- A Local Representative can try to speed up the whole registration process, but this is not easy due to the complexity of the registration system (see Submission of Registration Dossiers).
 - When questions arise, it can be difficult to know precisely what is required to answer the question – it is not always clear. In addition, it is difficult or impossible to contact the reviewer who has posed the question to have further clarification.
 - Unregistered products, usually of substandard quality or counterfeit, are widely available in all UEMOA countries.
 - A process is ongoing to appoint Inspectors to monitor the importation, distribution, quality and sale of veterinary medicines.
 - Veterinarians, farmers' organisations, NGOs and government officials often possess and distribute veterinary medicines.
 - Treatments are offered by veterinarians and paraprofessionals (technicians) under the supervision of veterinarians.
-
- Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
 - The Regional Committee for Veterinary Medicines lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported and marketed in the country and that the delay for the whole registration process of veterinary medicines is respected.
 - The Director of Veterinary Services can authorise the importation of veterinary products and vaccines, without being registered by UEMOA. Registered Dead vaccines can be imported by importers/wholesalers but Live vaccines only by the government.
 - Although not aligned with the applicable regulations (No 02/2006/CM/UEMOA) it is common practise to obtain a Special Import Permit which is issued by the DVS at the request of a local importer/distributor once the registration dossier of the product(s) is submitted for registration. This is a very easy and widely used process to import products and start marketing them in the different UEMOA countries.

Review of requirements and processes for registration of veterinary products in **Uganda**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Uganda has a National Registration System.

Uganda is a Member State of the East African Community (EAC). The EAC has developed a harmonised registration system for veterinary biological products and has adopted the concept of Mutual Recognition Procedures (MRP) in the region. It is expected that if an Applicant applies for a Marketing Authorisation through the MRP, an application assessed by Kenya or Tanzania could be approved in Uganda after progressing through the MRP, although this process has not yet been put into practice in the EAC.

The National Drug Authority (NDA) has the mandate to approve and to register human and medicinal veterinary products, appoint inspectors and order inspection of premises as well as promote rational use of drugs and medical devices. NDA also regulates pesticides.

Website: www.nda.or.ug

APPLICABLE LEGISLATION

National Drug Policy and Authority Act

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** An application for registration of a product may be made by
 - (a) The patent holder
 - (b) A licensed person
 - (c) The manufacturer
 - (d) A Local Representative

- > **Local Representative:** An applicant not resident in Uganda shall nominate an authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in Uganda to be a Local Representative for communication with authorities, for monitoring the product on the market and to handle eventual product recalls.
- > **Documentation**
 - > Part I: Application Form and Summary of Product Characteristics
 - > Part II: Manufacturing and Quality of Immunogenic Substance and Finished Product
 - > Part III: Safety
 - > Part IV: Efficacy
 - > Part V: Bibliographical References
- > **Facts on the submission**
 - > Applications should be made in English.
 - > An electronic version (CD-ROM) and printed version, in which each Part or Section is bound separately, should be submitted.
 - > Expert reports can be included.
 - > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person

- > **Documentation**
 - > Part I: Application Form and Summary of Product Information
 - > Part II: Chemistry, Manufacturing and Quality Data
 - > Part III: Safety and Residue Studies
 - > Part IV: Pre-clinical and Clinical Data

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	Five commercial samples
Registration Certificate from country of origin	Index
Application fees	Manufacturing plant master file
GMP inspection fees	Five pack samples and copies of package inserts & labels

> Application for variation of a registered product

Variation application form	Five samples of the new formulation subject to the variation
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> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee
Current plant master file	

> Address for submission of applications

National Drug Authority of Uganda
 Plot No. 46 - 48
 Lumumba Avenue
 P.O. Box 23096
 Kampala
 Uganda

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 1,000 USD	Dossier alteration fees, local product: 100 USD Dossier alteration fees, foreign product: 300 USD
GMP inspection fees, local product: 300 USD GMP inspection fees, foreign product: 4,000 USD	Application renewal fees, local: 200 USD Application renewal fees, foreign product: 500 USD

Processing time is officially 180 days; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection is required before finalising the registration. But the total registration process is much longer (over two years) because NDA gives huge priority to human medicinal product registration. The Local Representative, if well introduced in NDA, can easily speed up the registration process.

Once issued a registration is valid for five years.

PRACTICES

- Several unregistered products, mainly of poor quality and/or counterfeit, are available on the market. These arrive illegally from neighbouring countries.
- Inspectors appointed by NDA monitor the importation, distribution and sale of drugs.
- In the pastoralist areas drugs are sold in drug shops that are not under the control of pharmacists.
- Animal owners can access all medicines and either treat their own animals or get paraprofessionals do it.
- Sale of veterinary medicines is not easy to regulate, especially in the pastoral areas.
- The NDA lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported into the country.
- There is a very strong perception in the livestock sector that the NDA, being under the Ministry of Health, does not give priority to registration of veterinary medicines.
- Sale of pesticides for tick control is very often uncontrolled, with products being sold in many types of shops.



Review of requirements and processes for registration of veterinary products in **Zambia**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Zambia has a National Registration System that has recently become operational.

The Zambia Medicines Regulatory Authority (ZAMRA) is under the Ministry of Health, Department of Pharmaceutical Regulatory Authority. ZAMRA has the mandate to regulate food, human drugs, veterinary drugs and medical devices and to ensure adequate and effective standards.

Real registration of veterinary medicinal products started in 2012–2013.

Website: www.zamra.co.zm/contact/guidelines

E-mail: pharmacy@zambia.co.zm

All information about registration of human and veterinary medicinal products can be found in ZAMRA's "Guidelines for the Registration of Human and Veterinary Pharmaceuticals" and for biologicals in the "Guidelines for the Registration of Human and Veterinary Biologicals".

APPLICABLE LEGISLATION

Pharmaceutical Act, 2012 (14) of 2004

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- **Applicant:** The product owner or licence/patent holder, or those ordering the product which is manufactured for sale in Zambia.

- **Responsible Local Person:** An applicant who is not resident in Zambia shall nominate a distributor who is licensed as a pharmaceutical importer and wholesaler and resides in Zambia. The Responsible Local Person shall facilitate communication between the applicant, licence/patent holder and/or manufacturer and the Authority on matters relating to the product.
- **Documentation**
 - Part I: General Information: Application Form
 - Part II: Summary of Product Characteristics (SPC)
 - Part III: Manufacturing and Control of Immunogenic Substances
 - Part IV: Finished Biological Medicinal Product
 - Part V: Preclinical Toxicological Data
 - Part VI: Clinical Efficacy and Safety Data
 - Appendices: I to V
- **Facts on the submission**
 - Applications should be made in English
 - Two copies of the Complete Checklist and Index are required.
 - One electronic copy and one printed copy, with each Part bound separately, should be submitted.
 - Expert reports must be included.
 - Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person

> Documentation

- > Part I: Application Form and Summary of Product Information
- > Part II: Chemistry, Manufacturing and Quality Control Data
- > Part III: Preclinical Pharmacotoxicological Data
- > Part IV: Clinical Safety and Efficacy Data
- > Part V: Therapeutic Equivalence/Interchangeability (only for oral generic dosage forms)
- > Part VI: Labelling and Package Inserts
- > Part VII: Documentation for Fixed Dose Combination (FDC) Products
- > Appendices: I to V

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	At least five commercial samples with certificate of analysis
Registration Certificate from country of origin	Index of Complete Registration File
Application fees	Min. 100 mg of sealed Working Standard of new medicinal product
GMP Inspection fees	Five pack samples and copies of package inserts & labels

> Application for variation of a registered product

Alteration application form	Minimum five samples of the altered product
Detailed description of the alteration with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days but preferably 6 months before expiry of registration	At least five commercial samples of each package size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee (if requested by the authority)
Min. 100 mg of sealed Working Standard of new medicinal product	

> Address for submission of applications

Director General, Medicines Regulatory Authority
 Plot no. 6903 Tuletaka Road of Makishi Road
 PO Box 31890, Lusaka
 Zambia
 Tel: +260 211 220 429

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 2.3 million ZMW (386 USD)	Retention fees: 1.9 million ZMW (368 USD)
GMP inspection fees, foreign company: 3.6 million ZMW (696 USD)	Application renewal fees, foreign product: 900,000 ZMW (174 USD)
Importation of finished product: 1.52 million ZMW (294 USD)	Retention fees, importation of finished product: 1.9 million ZMW (368 USD)

***1 ZMW (Zambian Kwacha) = 0.0001932 USD*

Processing time is officially approximately 180 days; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection is required before finalising the registration. The Authorised Local Representative can speed up the process when well introduced in ZAMRA.

Once issued a registration is valid for five years.

PRACTICES

- There is need for a complete registration dossier.
- Official registration of veterinary medicinal products started only in 2012 - 2013.
- Many unregistered products, usually of poor quality and cheap, are available on the market (many of Chinese and Indian origin). These come illegally into Zambia from neighbouring countries.
- Inspectors appointed by ZAMRA monitor the importation, distribution and sale of drugs. There is an inspection of human medicinal products on the market but not at all for veterinary drugs.
- ZAMRA gives a huge priority to the registration of human medicinal products, but lack resources for the registration of veterinary drugs.
- Registration of pesticides is exactly the same as registration of veterinary pharmaceutical drugs.
- The authorised Local Responsible Person plays a very important role and can speed up the registration process when well introduced in ZAMRA.
- Sales and distribution of veterinary products (pharmaceuticals, vaccines and diagnostics) are conducted by the private sector.



Review of requirements and processes for registration of veterinary products in **Zimbabwe**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Zimbabwe has a National Registration System.

The Medicines Control Authority of Zimbabwe (MCAZ), under the Ministry of Health, has the mandate of regulation, evaluation and registration of both human and veterinary pharmaceutical and biological products, through its Evaluations and Registration (EVR) Unit. The EVR Unit reviews safety, quality and efficacy of medicines in accordance with the requirements of the Medicines and Allied Substances Control Act (MASCA).

Website: www.mcaz.co.zw

Pesticides are regulated by Statutory Instrument 144 of 2012 (Pesticide Regulations 2012) under the Ministry of Agriculture.

APPLICABLE LEGISLATION

Medicines and Allied Substances Control Act (MASCA) (15:03)
Medicines and Allied Substances Control Regulations (MASCR) SI 150 of 1991

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS AND PHARMACEUTICALS

- > **Applicant:** the person by, or on whose behalf, an application for registration is made. The application for the registration of a drug shall be made by the licence/patent holder, the manufacturer or their representative.
- > **Local Representative:** If an applicant is not resident in Zimbabwe, they must nominate an authorised person (licensed as a pharmaceutical importer and wholesaler) who resides or is established in Zimbabwe to be a Local Representative for communication with authorities, monitoring the product on the market and handling eventual product recalls.

> Documentation

- > Module I: Administrative Information
- > Module II: Quality Overall Summary – Product Dossiers (QOSPD) (a summary of Module III)
- > Module III: Quality
- > Module IV: Non-clinical Pharmaco-toxicological Data
- > Module V: Efficacy Data

> Facts on the submission

- > Modules I, II and III are required for all applications. Exemptions from Modules IV and V may be submitted for generic medicines, provided adequate development pharmaceuticals data was submitted in Module III and bioequivalence applications have been submitted in accordance with MCAZ Bioavailability Guidelines.
- > MCAZ has a specific regulated process for the emergency import of unregistered products, considered as emergencies. Such products can be imported even by the animal owners.
- > Applications should be made in English.
- > One paper copy and one electronic copy of the dossier, on electronic storage media, should be submitted.
- > Expert reports have to be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.
- > All veterinary medicines must be classified at the time of registration in the following categories:
 - > Prescription Preparation (PPVet)
 - > Veterinary Medicines General Dealer (VMGD)
 - > Household Remedy (HRVet)

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Cover letter and table of contents of the dossier	A completed screening checklist of all documents submitted
Completed, signed and dated MC8 form for each finished pharmaceutical product; separate form should be filled for each form of product as described by MCAZ guidelines	Samples of the smallest commercial pack(s) from one batch with batch certificates of analysis
Registration Certificate from country of origin, and marketing authorisations in other countries for each product	Master production documents and executed production documents
A copy of the invoice or proof of payment of registration fees and GMP inspection fees for facilities not yet inspected by MCAZ	Pack samples and copies of package inserts & labels
GMP inspection fees for facilities not yet inspected by PPB application	

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee

> Address for submission of applications

Director General
106 Baines Avenue
P O Box 10559
Harare
Zimbabwe

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

<p>Registration of imported finished product into Zimbabwe as:</p> <ul style="list-style-type: none"> > new chemical entity: 2,000 USD > a generic medicine: 1,500 USD > previously registered: 700 USD > resubmission: 600 USD 	<p>Registration of imported product for relabelling or repacking in Zimbabwe:</p> <ul style="list-style-type: none"> > first application: 900 USD > previously registered: 750 USD > resubmission: 600 USD
<p>GMP inspection of a sterile manufacturing unit: 6,000 USD GMP inspection of an application for the issue of a GMP certificate: 150 USD</p>	

OUTLINE OF PROCESS

Receiving of new applications	A pre-evaluation screening checklist is used to check completeness of the application files by the secretariat.
Evaluation process	The Veterinary Committee that comprises of experts from various scientific disciplines considers all applications for registration of medicines at MCAZ. This Committee meets once every other month.
Laboratory analyses of product sample	
Verification of compliance to current Good Manufacturing Practices (cGMP)	Site inspection.
Consideration by Veterinary Committee	A summary of recommendations of evaluation, laboratory analysis and GMP status reports is presented to the Committee for assessment. Normally, the first review is completed within six months of receipt. Applicants are often asked to provide additional data. This should be provided within 30 days of receiving such a request. If more time be needed, a formal request must be submitted and approved by MCAZ before the deadline.

Registration typically requires 6-18 months.

Once issued registration is valid for five years.

A local renewal fee of 400 USD is payable annually.

PRACTICES

- Despite the well elaborated legislation and regulatory system of MCAZ, registration of veterinary products in Zimbabwe is poorly regulated, and unregistered products are widely circulating.
- Products registered in South Africa tend to be accepted in Zimbabwe.
- A regional process under the Southern African Development Community (SADC) was initiated a few years ago, but hasn't been pursued due to lack of funding and coordination. All the same, the MCAZ regulation is one of the few in the region that make reference to the SADC process.

Asia



Review of requirements and processes for registration of veterinary products in **Bangladesh**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Bangladesh does not have a national registration authority which regulates veterinary medicinal products (pharmaceutical or biological). The Department of Livestock Services (DLS), which also includes Veterinary Services, has authority over regulation of veterinary products.

APPLICABLE LEGISLATION

There is no specific legislation on registration of veterinary products.

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

The requirement is that a product shall be registered in the country of origin and in any two of the 23 listed countries considered “reputable”. A Free Sale Certificate (FSC) from the regulatory authority of any of these countries is mandatory.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> Address for submission of applications

Department of Livestock Services (DLS)
Krishi Khamar Sarak, Farmgate, Dhaka-1215
Bangladesh
Phone: 9101932, Fax: 9110326

PRACTICES

- > Bangladesh has no registration system in place for veterinary products.
- > In Bangladesh there are over 50 pharmaceutical companies that are either national enterprises or subsidiaries of multinational companies. These companies manufacture or import veterinary drugs, vaccines, premixes and vitamins. Their products are simply accepted for use in the country.

Review of requirements and processes for registration of veterinary products in **India**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

India has a National Registration System which regulates human and veterinary medicinal products (pharmaceutical and biological) and pesticides.

The Central Drugs Standard Control Organisation (CDSCO) is under the Ministry of Health and Family Welfare.

CDSCO has the mandate to approve and to register all human and veterinary medicinal products (biologicals and pharmaceuticals), appoint inspectors and order inspection of premises as well as promote rational use of drugs and medical devices. CDSCO is also the regulatory body for the registration and control of pesticides.

Website: www.cdscsco.nic.in

APPLICABLE LEGISLATION

Drugs and Cosmetics Act (1940) and Drug and Cosmetics Rules 122A, 122B, 122 D, 122 E, 37, 38, 40 and Part X-A (Import or Manufacture of New Drugs for Clinical Trials or Marketing)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

The dossier format currently follows that for human pharmaceuticals.

- > **Applicant:** Could be the owner of the product responsible for manufacturing or the patent/licence holder.

- > **Local Responsible Person:** An applicant not resident in India must nominate an authorised person (a local Indian agent having a valid wholesale licence) who resides in India to be the Local Responsible Person for communication with authorities, monitoring the product on the market and handling eventual product recalls.
- > **Documentation**
 - > Module I: General Information (Application Form and Summary of Product Characteristics)
 - > Module II: CTD (Common Technical Document)
 - > Module III: Quality (Chemical, Biological)
 - > Module IV: Non-Clinical Study Reports
 - > Module V: Clinical Study Reports
- > **Facts on the submission**
 - > Applications should be made in English.
 - > Two electronic copies (CD-ROM) and two printed copies, where each Part or Section is bound separately, should be submitted.
 - > Expert reports must be included.
 - > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Responsible Person.

> Documentation

- > Module I: General Information (Application Form and Summary of Product Characteristics)
- > Module II: CTD (Common Technical Document)
- > Module III: Quality (Chemical, Pharmaceutical)
- > Module IV: Non-Clinical Study Reports
- > Module V: Clinical Study Reports

The above five module dossiers should be prepared based on the requirements mentioned in the Guidance for Industry on the CDSCO website: www.cdsc.nic.in

PROCESS FOR REGISTRATION

After submission of application with dossier to the Drug Controller General of India (DCGI):

- > DCGI sends one set of application to the Ministry of Agriculture, Department of Animal Husbandry, Dairying and Fisheries, Krishibhavan, New Delhi for technical review committee approval. DCGI issues a registration certificate after satisfactory review of application and a No Objection Certificate issued by the Ministry of Agriculture.
- > The first three batches need to be tested and certified by the Indian Veterinary Research Institute (IVRI), Izzatnagar, Uttar Pradesh. IVRI is the government testing laboratory for veterinary drugs.

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	Five commercial samples
Registration Certificate from country of origin	Index
Application fees	Plant master file
GMP Inspection fees	Drug master file
Five pack samples and copies of package inserts & labels	

> Application for variation of a registered product

Alteration application form	Samples of the altered product
Detailed description of the alteration with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 90 days before expiry of registration	Five commercial samples of each pack size being applied for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	GMP inspection fee (if requested)
Current plant master file	

> **Address for submission of applications**

Directorate General of Health Services
FDA Bhawan
Kotla Road
New Delhi 110002
India
Tel: +91 11 232 369 65
E-mail: dci@nic.in

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 1,500 USD	Dossier variation fees foreign product: 100-200 USD
GMP inspection fees, foreign country: 5,000 USD	Application renewal fees, foreign product: 1,000 USD

Processing time is officially 270 days for Form 41 registration certificate issuance; once a query is raised, the process is halted. Good Manufacturing Practice (GMP) inspection may be required before finalising the registration. The Local Agent can speed up the process when well introduced in CDSCO.

Once issued a registration is valid for five years.

PRACTICES

- > The manufacturer is owner of the registration but the importer is owner of the import licence (three years). In case of difficulties between manufacturer and importer, the import of the drug(s) to India can be completely blocked for a maximum of three years. In most other countries the manufacturer is the owner of the registration and import licence.
- > CDSCO gives priority for the registration of human medicinal products, so the registration of veterinary medicinal products is very long and time consuming. Therefore there is a huge advantage to having a very good Local Agent who has good contacts within CDSCO to push the veterinary drug registration dossier through the system.
- > Several unregistered products, usually of poor quality or counterfeit, are available on the Indian market.
- > Inspectors appointed by CDSCO monitor the importation, distribution and sale of drugs, but there is only very sporadic control of veterinary drugs on the market due to lack of human resources.
- > There is a strong perception in the livestock sector that CDSCO, being under the Ministry of Health, does not give priority to registration of veterinary medicines.
- > Sale of pesticides is almost completely uncontrolled, with products being sold in many types of shops.
- > India has a huge animal health market, but is overwhelmed by very cheap products. Lot of local manufacturers and many distribution and wholesale companies are present, which creates very strong competition and drops the prices. The Indian animal health market is very price sensitive and unfortunately not quality sensitive. There are indications that the market is becoming more quality conscious and the drug authorities have started to take notice.

Review of requirements and processes for registration of veterinary products in **Nepal**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Nepal has a National Registration System.

The Department of Drug Administration (DDA) under the Ministry of Health and Population is responsible for the registration of human and veterinary medicinal products.

Website: www.dda.gov.np

APPLICABLE LEGISLATION

Drug Act 2035 (1978)

National Health Policy (1991)

National Drug Policy (1995)

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

IMPORTANT REQUIREMENTS FOR REGISTRATION OF FOREIGN PHARMACEUTICAL MANUFACTURERS

- > Compliance to Good Manufacturing Practice as recommended by World Health Organization (WHO GMP) is the minimum requirement for applying for registration.
- > Modern Medicine: Products of manufacturers from USA, Canada, European Union, Australia and New Zealand are registered if the products are exported to any countries mentioned in article 1 submission of registration dossiers (= USA, Canada, European Union, Australia and New Zealand).

- > Products of the manufacturers from countries other than mentioned in article 1 (= USA, Canada, European Union, Australia and New Zealand) will be registered on submission of registration dossiers. Products that are not exported to those countries will not be considered for registration at present.
- > UN prequalified vaccine manufacturers (and prequalified vaccine) included in Extended Program on Immunization (DTP, Measles, Tetanus Toxoid, Oral Polio, Hepatitis B, BCG) will be registered on submission of registration dossiers.
- > Vaccine other than mentioned in article 3, audit of the factory from DDA is required.

Source: *Requirements for Registration of Foreign Pharmaceutical Manufacturer to Export their Products to Nepal*. Department of Drug Administration, www.dda.gov.np

BIOLOGICALS

- > **Applicant:** The company responsible for manufacturing of the product.
- > **Local Representative (Local Agent):** An applicant not resident in Nepal must nominate an authorised person (licensed as a pharmaceutical importer and wholesaler) who resides in Nepal, to be legally responsible for communication with authorities and for monitoring of the product on the market.
- > **Documentation**
 - > Part I: Application Form and Summary of Product Characteristics, Labelling, Insert Leaflet and Expert Reports
 - > Part II: Manufacturing and Quality Control of Immunogenic Substance and Finished Product
 - > Part III: Safety
 - > Part IV: Efficacy
 - > Part V: Bibliography

PHARMACEUTICALS

Concepts similar to Biologicals apply for Applicant and Local Representative (Local Agent).

> Documentation

- > Part I: Application Form and Summary of Product Information, Labelling, Insert Leaflet and Expert Reports
- > Part II: Chemistry, Manufacturing and Quality Data
- > Part III: Safety and Residue Studies
- > Part IV: Pre-clinical and Clinical Data

> Facts on the submission of Pharmaceuticals and Biologicals

- > Applications should be made in English.
- > Two printed copies, where each Part or Section is bound separately, should be submitted.
- > Expert reports have to be included.
- > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

> First time application

Complete documentation as per guidelines	At least five commercial samples
Registration Certificate from country of origin	Index
Application fees	Manufacturing plant master file
Inspection fees (if necessary; see requirements for registration)	Five pack samples and copies of package inserts & labels

> Application for variation of a registered product

Alteration application form	Five samples of the altered product
Detailed description of the variation with supporting reasons	Applicable fees

> Application for renewal of registration

To be submitted at least 35 days before expiry of registration	Five commercial samples of each pack size being submitted for renewal
Consolidated report of all changes, if any	Renewal application fee
Report of additional adverse drug reactions, if any	
Current site master file	

> Address for submission of applications

Ministry of Health and Population
 Department of Drug Administration (DDA)
 Kathmandu
 Nepal

Note: No real address is actually available due to the terrible earthquake that destroyed many governmental administrative buildings in 2015.

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

No data are available on the website of the DDA. After several calls with local importers of veterinary drugs, it became clear that there is actually no list available indicating the fees for registration, for renewal or for alteration of a registered product. This is certainly due to the terrible earthquake that reached almost the whole country in 2015 and which destroyed many governmental administration buildings and also their whole information system.

All importers reported that the registration fees are very high (more than 3,000 USD per product) and that the livestock market is very small.

The registration process is officially 240 days; once a query is raised, the process is halted. Once issued, a registration is valid for five years.

PRACTICES

- DDA has a strong priority for the registration of human medicinal products and has a lack of structure and human resources for the registration of veterinary medicinal products. Due to lack of expertise in veterinary biologicals, DDA will typically ask for recommendation from DLS for each application made to DDA.
- Most local importers do not go for registration but ask for a special import licence, which is very easy to obtain after presentation of the insert leaflet. DDA charges 100 Rs (93 USD) for each application made for an import permit.
- Many unregistered products, usually of low quality and cheap, are widely available on the Nepalese animal health market.
- The Nepalese livestock population is very small and is mainly kept by nomadic and semi-nomadic herders (> 95 %).

Review of requirements and processes for registration of veterinary products in **Vietnam**

REGULATORY FRAMEWORK IN THE COUNTRY

REGISTRATION AUTHORITY AND SETUP

Vietnam has a National Registration System which regulates veterinary medicinal products (pharmaceutical and biological). The authority is the Drug and Vaccine Management Division of the Department of Animal Health (DAH) in the Ministry of Agriculture and Rural Development.

APPLICABLE LEGISLATION

Decision 10/2006/QĐ-BNN dated 10 February 2006 of MARD regulating “Procedures for Production, Registration, Import and Circulation of Veterinary Drugs, Materials for Veterinary Drug Production, Biological Products (pro-biotics), Micro-organisms and Chemicals”.

REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES

BIOLOGICALS

- > **Applicant:** Most products are produced locally; therefore the application is made by the manufacturer.
- > **Local Representative:** Imported products have to be registered by a Local Representative who should have an appointment letter from the manufacturer.
- > **Documentation**
 - > Section 1: Cover Page of the Dossier (Sample 1); Index of the Dossier (Sample 2)
 - > Section 2: Application for Registration of Veterinary Products (Sample 3)
 - > Section 3: Summary of Product Characteristics
 - > Section 4: Labels of Veterinary Products

- > Section 5: Technical Information About the Product Quality
- > Section 6: Technical Information About the Safety Level and the Effects (Validity) of the Product
- > Section 7: Different Kinds of Certificates: GMP, ISO... (if the certificates are copies, they must be certified by the competent authorities)
- > Section 8: Other Relating Documents (analysis by the producers and the State Control Authorities of veterinary products, testing results...)

In case of imported products:

- > Free Sale Certificate (FSC) or Marketing Authorisation (MA) from the country of origin
- > Certificate of Analysis (CA)
- > Good Manufacturing Practice (GMP) Certificate from the country of origin
- > Appointment Letter from Manufacturer
- > **Facts on the submission**
 - > The dossier for registration of imported products must be written in Vietnamese or English. The Summary of Product Characteristics must be written in English.
 - > The dossier for registration of veterinary products must be made in three sets, printed on A4-sized paper and arranged in accordance with regulated order. Expert reports must be included.
 - > Separate applications are required for each presentation of products containing the same ingredients but made to a different specification (in terms of strength or content of active ingredients, dosage form, etc.) or by a different manufacturer; except for different pack sizes of same injectable products.

PHARMACEUTICALS

Specific requirements for pharmaceutical products include:

- Report of Pharmacokinetics Research (in case of new drugs)
- Residual Substances
- Report of Field Trials (in case of new drugs)
- Report of Pharmacodynamics (in case of new drugs)
- Toxicology (in case of new drugs)
- Certificate of Sample Analysis of National Centre for Examination of Veterinary Drugs and Vaccines (NCEVDV)
- Certificate of Analysis of Manufacturer

PROCESS FOR REGISTRATION

SUBMISSION OF REGISTRATION DOSSIERS

- **First time application**
 - The production plant must firstly be registered and certificated.
 - A registration dossier, complete with the application form for sample permit should be submitted to the DAH.
 - Samples of products should be sent to the NCEVDV for analysis.
 - For locally manufactured products, when the results of this analysis are known and the dossier assessed, then consideration can be made for approval.
 - For foreign manufacturers, the Committee of Science and Technology under the DAH deals with registration matters in general and with specific points on individual products.
- **Application for renewal of registration**
 - Documents required for renewal of registration are:
 - Application
 - Copy of Certificates and Report of Circulating Process of the Product (for the second re-registration)
 - The certificate of re-registration is valid for five years.

➤ **Address for submission of applications**

Ministry of Agriculture and Rural Development
Department of Animal Health
Drug and Vaccine Management Division
Hanoi
Vietnam

FEES, PROCESSING OF APPLICATION AND VALIDITY OF REGISTRATION

Registration fees, foreign product: 32 USD

GMP inspection fees, foreign foreign product: 1,000 USD

Application renewal fees, foreign product: 16 USD

The application should include three sets of original copies of the registration dossier. For imported products, one set should be in Vietnamese.

Officially the processing of the application takes 60 days.

Once issued a registration is valid for two years.

PRACTICES

- Vietnam has a large local veterinary product manufacturing industry.
- Vietnam has a national lab, the NCEVDV, whose mandate is to test veterinary products produced in the country or imported, and also coordinate clinical studies needed for veterinary products to be registered in the country, and maintain reference bacterial and viral vaccine strains.
- Since 2012, Good Manufacturing Practice (GMP) is a requirement for all veterinary drugs produced or imported into Vietnam.



Annex 1

This is the Schedule referred to in the foregoing Agreement between GALVmed and the Consultant.

Schedule

Terms of Reference

1 BACKGROUND OF PROJECT

The Global Alliance for Livestock Veterinary Medicines (GALVmed) is a not-for-profit product development and adoption partnership that works with key partners to make livestock health products (vaccines, medicines and diagnostics) available to and accessible by livestock keepers in Africa and South Asia.

GALVmed operates across the product development value chain and often works with private companies, universities, research organisations, etc. to develop products that are then registered in the countries that GALVmed has field operations. The process of veterinary product registration in many African countries is variable and at the moment, not clearly understood. GALVmed wishes to commission a desk study to compile and collate information related to registration of veterinary products.

2 OBJECTIVES

GALVmed seeks to understand the requirements (including timelines) for registration of veterinary products in specified countries. This study will inform GALVmed's strategies and procedures on registration of veterinary products by achieving the specific objective:

To review the requirements and process for registration of veterinary products in specified countries.

The study is expected to be explicit on the policy and practice by distinguishing the legal requirements and process from what happens in practice. It will be expected to have a practitioners' outlook rather than a theoretical/academic perspective.

3 PROJECT AREA

The desk study to be performed by the Consultant will cover 4 countries in south Asia (India, Nepal, Vietnam, Bangladesh) and 25 countries in

Africa (Ethiopia, Ghana, Kenya, Lesotho, Malawi, Nigeria, South Africa, South Sudan, Tanzania, Uganda, Zambia, Zimbabwe, Burkina Faso, Burundi, Cameroon, Comoros, DRC, Ivory Coast, Mali, Rwanda Senegal, Sierra Leone, Togo, Morocco and Mozambique). For the avoidance of doubt, this will be a desk study and will not involve any travel. The Consultant is expected to have practical experience in registering veterinary products in these countries or have credible contacts that will have this experience.

4 PROJECT DURATION

The project shall be for six weeks from 1st June 2015 to 10th July 2015. Any changes to this period must be agreed between the Parties.

5 THIRD PARTY INVOLVEMENT

There will be no third parties involved.

6 TASKS TO BE COMPLETED

In reviewing the requirements and processes for registration of veterinary products (vaccines, medicines and diagnostics), the Consultant will be required to perform the tasks:

- 1 Conduct a desk study and review legal statutes, regulations, directives, ministerial decrees, etc. and documents from regulatory authorities and other authorised bodies to identify the legal requirements and outlines processes (including timelines) for registration of veterinary products.
- 2 Compare and contrast the legal requirements and process for registering veterinary products with the actual practice (based on practical experience) highlighting gaps and challenges and how these can be addressed.
- 3 Prepare a brief analysis summarising the results. The report should not be more than 1 - 2 pages per country and information presented should be comparable across countries.

7 OUTPUTS/DELIVERABLES

- A A concise report with a brief analysis of the findings.



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GALVmed is a registered charity and not-for-profit global alliance of public, private and government partners.

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