

Towards an Enabling Regulatory Environment for Livestock Health

The World Bank Group (WBG) has initiated a flagship programme called “Enabling the Business of Agriculture” (EBA) that examines and monitors regulations impacting agriculture and agribusiness around the world. Earlier this year, the EBA released its third report, covering 12 topic areas across 62 countries.¹ The livestock chapter within the EBA2017 report focused on select regulations affecting the market supply of veterinary medicinal products (VMPs). This paper describes the issues covered by the EBA Livestock topic, discusses the importance of good regulations to encourage the registration of quality assured products, and provides a snapshot of initial results of data collection efforts for the regulation of VMPs.

Animal Health Risk and Access to VMPs

Animal health management has important implications for poverty reduction and economic growth. Infectious diseases cause at least 20% of all livestock production losses globally.³ Livestock production accounts for around 40% of agricultural output in the developing world.² Approximately one in every five people (including the extreme poor) depends on the livestock sector as a primary source of income.³ Livestock infectious diseases therefore pose a significant risk to economic gains and livelihoods.

Animal diseases also generate health costs at the human-animal-environment interface, including reductions in food safety, food security, and maternal and child health. The top 13 zoonotic diseases (transmitted between animals and humans) account for over a billion human cases and a million deaths annually.⁴ Animal diseases may also affect biodiversity by changing wildlife population dynamics for the infected animal groups, as well as for other organisms and species in shared ecosystems.⁵

Access to veterinary medicinal products (VMPs) is a key factor in mitigating the risks associated with animal diseases. In many countries, especially in the developing world, access to safe, quality and effective VMPs remains low. While a diversified mix of large companies, small- and medium-sized enterprises (SMEs), breeders' organisations, and veterinarians work to supply VMPs to livestock producers, large companies constitute the biggest market share of VMP manufacturing. Given that most VMP manufacturing facilities are established and owned by companies located in Europe, the USA, and China, countries outside of these

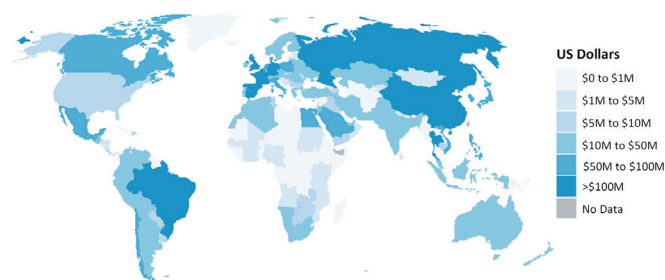


Figure 1

regions rely heavily on VMP imports for market supply. Figure 1 depicts the average annual value of imported veterinary biologicals (one of two sub-categories of VMPs) in each country between 2010 and 2014. Least developed countries account for only 2.7% of total imports, despite representing a greater share of global livestock production and the animal disease burden.

Access to VMPs alone is insufficient to reduce animal health risks; quality matters. Counterfeit VMPs are also major threats to animal health and disease controls in some countries. According to the International Institute of Research Against Counterfeit Medicines (IRACM), more than 50% of veterinary medicines marketed in Africa are fake.⁶ Moreover, if used improperly, VMPs – even if efficacious – may have limited effect or even lead to adverse health outcomes.

The Importance of a Regulatory Framework

The regulatory environment can enable access to safe, quality and effective VMPs by encouraging (and not hindering) product registration and effectively enforcing standards and quality control processes along the entire supply chain from manufacture, registration, import, distribution, sale and administration. Given the importance of the private sector at all points along the VMP supply chain, it is important that regulations are streamlined and efficient in order not to discourage suppliers from entering and operating in markets, particularly in countries with agro-based economies.

The relationship between regulation and market supply for VMPs is neither abstract nor theoretical. Figure 2 depicts the impact of the introduction of regulations on market entry and circulation of VMPs in four countries (Nigeria, Nicaragua, Tanzania and Vietnam); these countries have historically been net importers of VMPs (Table 1) over the period of 1996 to 2015. In each panel of Figure 2, values of veterinary vaccine imports are plotted from 1996 to 2015. The vertical solid bars represent the year in which a key regulatory document impacting import decisions was enacted in the country. The two dotted lines in each panel of the Figure depict the linear trend in imports prior to and after a key regulatory document was enacted. As illustrated, the trend line following the introduction of the regulatory document lies above the pre-legislation trend in each country, suggesting that imports increased following the introduction of new or reformed regulations.

Country	Exports	Imports	Net imports
Nigeria	\$8	\$1 643 427	\$1 643 418
Nicaragua	\$31 185	\$1 457 192	\$1 426 007
Tanzania	\$40 157	\$861 342	\$821 186
Vietnam	\$677 887	\$22 241 480	\$21 563 593

Table 1: Average Annual Trade in Veterinary Vaccines (1996–2015)

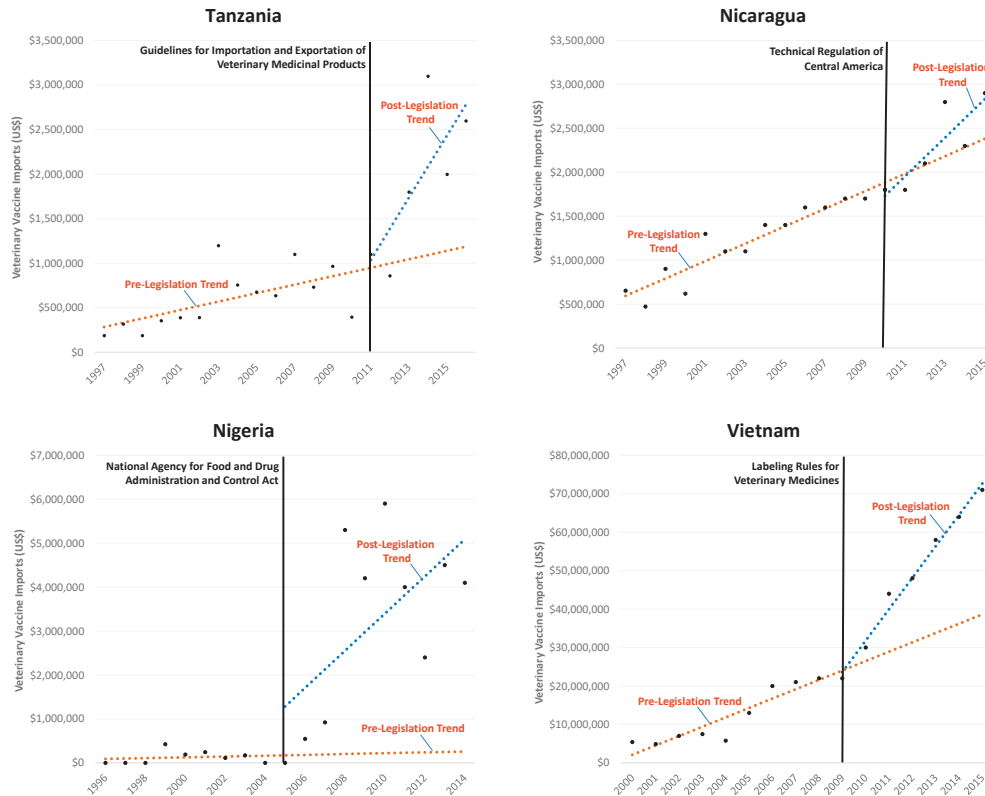


Figure 2

The Enabling the Business of Agriculture (EBA) Project

The World Bank Group “Enabling the Business of Agriculture” (EBA) project collects data on regulations influencing the agriculture sector in an effort to encourage an enabling environment for agribusiness. The EBA 2017 report covers 12 topics across 62 geographies and presents globally comparable data and indicators that measures legal barriers faced specifically by agribusinesses to enter and operate in markets. Two types of indicators are developed by the EBA project: *legal indicators and efficiency indicators*. Legal indicators are derived from the reading of relevant laws and regulations. Efficiency indicators reflect the time and cost imposed by regulatory systems on private sector entities in adhering to the regulatory framework in countries. Data and indicators provided by the EBA project can be used by governments, large companies, small and medium enterprises, investors, researchers and others interested in information provided by the project. For example, policy-makers within governments can utilise EBA data to identify barriers that impede the growth of the agriculture sector in their respective countries, compare themselves with other countries and to make informed decisions on reform.

In the EBA 2017 survey and subsequent report, the focus of the livestock chapter is on VMPs specifically, with a sub-categorisation into veterinary biologicals and pharmaceuticals. The topic assesses regulations impacting the private sector’s ability to supply safe, quality and effective VMPs. The topic covers three major regulatory areas affecting VMPs: 1. VMP registration, 2. authorisation of importers, and 3. marketing requirements. Within each of these regulatory areas, a set of “global good practices” (Table 2) is identified that should be part of a country’s regulatory framework.

1. VMP Registration

To ensure that VMPs conform to safety and other standards, most countries require that registration (or marketing authorisation) via an official registration process is obtained

before a VMP can be placed on the market. Though necessary, the product registration system can be prone to bottlenecks. As a result, private sector entities seeking to register VMPs may face unnecessary burdens, such as the time and costs associated with adhering to regulations. The absence of a good registration mechanism acts as a disincentive to market entry using officially mandated channels. In addition, lack of formal requirements gives rise to concerns regarding proprietary rights and counterfeit products flooding the market.

Data is collected on the structure and efficiency of regulatory institutions to measure these costs. For example, all else equal, having to compile and submit dossiers to multiple regulatory authorities throughout the registration process can result in duplicative efforts for the applicant (and the regulatory authorities).

Data is also collected on specific procedures required of applicants during the registration process. Unnecessary or ill-defined requirements for the registration process can create backlogs and delay market access for valuable products. Moreover, poor security of applicants’ confidential information and intellectual property can lead to discovery of product formulation and other trade secrets by competitors discouraging the use of official registration processes.

Finally, data is collected on the existence of a registry of authorised VMPs. The extent to which veterinarians and livestock producers use quality VMPs depends in large part on their awareness regarding product availability and the ability to confirm a product is legally authorised. The existence of a list has legal consequences as, in most countries, only approved products are allowed to enter the market.

2. Authorisation of Importers

Import permits and import licenses are two of the most

widely used regulatory instruments to manage the import of VMPs. Import permits are a tool to provide tighter control on VMPs entering the country. These permits require that importers obtain authorisation for each shipment or consignment of products being imported into a country. Import licences, on the other hand, are a tool to provide tighter control on the *entities importing* VMPs. Licensing refers to the formal authorisation of legal business entities engaging in (or seeking to engage in) the importing of VMPs. Import licensing is used to keep track of importers and to ensure that importers have the required credentials and facilities to handle VMPs. To assess the impact of regulations on import, the EBA 2017 Livestock survey collects data on the use of these regulatory instruments and whether importers are required to employ specialised staff.

3. Marketing of VMPs

Labelling requirements on the packaging and leaflet inserts of marketed VMPs provide information to distributors and veterinary pharmacists regarding handling and storage requirements. They also provide information to veterinarians and livestock producers about proper administration. Package labelling should provide information such as the active substance(s) per dosage or weight, the proper handling and storage conditions, the dosage and the route of administration. The EBA 2017 Livestock survey collects data on the type of information required to be included on product packaging.

If a country's registration system is not transparent, it can deter the private sector from attempting the process of registering VMPs. Applicants need to be aware of all the registration requirements and to easily obtain this information. Thus, for the predictability of the process, it is important that: (a) information on registration requirements is published and is clear, so the company can be sure that all necessary documentation is included in the application package (or 'dossier'); and (b) the timeframe by which the registration will be completed is also published.

The vast majority (95%) of the surveyed countries had legislation requiring VMP registration, but four of these countries do not provide information on dossier requirements on the registration authority's website (see Table 3).

Haiti	Currently not registering products, documentation specifying dossier requirements is not on the website of the relevant authority
Malawi	No functioning publicly assessable website
Rwanda	The registration process is yet to start
Tajikistan	Information on dossier requirements is not on the website of the relevant authority
Burundi Lao PDR Mozambique	Do not have a legal framework and are not requiring VMP registration

Table 3: Countries that currently do not provide on-line information on dossier requirements from EBA2017 report

Regulatory good practices for VMPs	Some countries that implement the practice
Registration of veterinary medicinal products	
There is both a regulatory framework and an Institution actively registering VMPs	All surveyed countries except: Burundi, Haiti, Lao PDR, Mozambique and Rwanda
Dossiers are required to be checked for completeness prior to the start of an evaluation to ensure all required documents are included.	Mexico, Nigeria, Russia, and Turkey
Applicants are provided with information on the number of days within which a VMP will be registered and expectations are adhered to.	Bosnia and Herzegovina, Georgia and Ghana
Information on registration requirements and the registry of VMPs are easily accessible to the public.	Colombia, Morocco and Zimbabwe
Marketing of veterinary medicinal products	
Labelling requirements are comprehensive and provide distinction between what information is required to be on the outer and immediate package.	Malaysia, Nicaragua, Peru and Serbia
Withdrawal periods are required on VMP labels to protect consumers of animal products.	Nicaragua

Table 2: Some examples of countries with elements of good regulatory practice from the EBA2017 report

Summary of Key Findings

Results for each regulatory area reveal a gap between regulatory reality and global good practice in many countries. Three of the 62 countries included in the sample of EBA countries (Burundi, Lao PDR, and Mozambique) do not have a regulatory framework for VMP registration. These three countries are either in the process of developing a legislative framework or are yet to start the process of developing relevant legislation.

In most countries, the dossier evaluation process is delayed, because each time the regulatory authority requires additional information from an applicant, the registration process is put on hold. To improve efficiency, the dossier should be checked for completeness prior to the start of evaluation. This process check is required in 17 EBA countries either via legislation (e.g. Mexico) or guidelines (e.g. Armenia). According to the relevant regulatory document, the official timeframe within which the

regulatory authority can contact the applicant for missing documents is 23 days on average, but ranges from three days (in the Kyrgyz Republic) to 60 days (in Bosnia and Herzegovina).

New product launches and associated marketing communications require forward planning, particularly for seasonal products. Therefore, awareness of how long the registration process will take is important to the private sector. The expected registration times will depend upon the type of registration process adopted in a country, with some countries implementing a full dossier assessment complete with the testing of products, while others may rely on the use of reference countries and other parameters. Regardless of the registration process followed in a country, applicants should be provided with an expected timeframe and that expectations are adhered to.

Of the 57 countries actively registering VMPs, 38 (67%) have published an estimation of how long the registration process should take either in a regulatory document or guideline. The estimation of how long the registration process should take for veterinary biologicals and pharmaceuticals ranges from 30 days (Cambodia) to 365 days (Jordan and Kenya). Estimation of the actual time in which VMPs are registered, provided by companies that have registered VMPs, varied in countries. For example, with veterinary pharmaceuticals, the average days for registering VMPs ranged from just 29.5 days (in Georgia) to 860 days (in South Korea).

The information provided on the packaging (typically a bottle label, package leaflet and outer carton) is critical to ensure the correct and safe use of the product, and should therefore be part of the legal requirements. As reflected in Table 4, not all countries follow "good practices" on labelling. For example, only 18 of the 57 countries require that precautions on disposal of unused or waste materials are included on the labelling of VMPs in any of the packaging locations.

Conclusion

The identification of barriers to agribusiness development is a critical step towards global improvements to animal health. The transparency, predictability, and efficiency of the regulatory system influence private-sector decisions to supply the market with health-promoting technologies. Thus, the legal framework is particularly important for agro-economies where farmers are economically dependent upon their livestock.

The objectives of the EBA 2017 Livestock topic dovetail with other international and regional efforts to encourage regulatory convergence to international standards. The Organisation for World Animal Health (OIE) runs the PVS Pathway Programme – a global programme for the sustainable improvement of countries' veterinary service compliance with international standards on the quality of veterinary services.⁷ HealthforAnimals has ongoing projects aimed at promoting regulatory good practice and regulatory harmonisation, through its series of five-yearly Global Regulatory Benchmarking Surveys.⁸ The Global Alliance for Livestock Veterinary Medicine (GALVmed) engages in similar efforts for regulatory harmonisation with respect to vaccine registration in select African countries.⁹ And finally, there is the VICH programme developing harmonised guidelines for the technical requirements for veterinary product registration.¹⁰

There is much work to be done. Infrastructure improvements and the increased provision of veterinary services must be made alongside legal reforms. Infrastructure improvements facilitate supply and distribution. Improved access to quality veterinary services is necessary to diagnose, monitor, report and treat disease, and to ensure the correct use of VMPs.

Moreover, the health of an animal is intricately linked to diet, genotype, and husbandry practices. For the purposes of livestock production, increased access to VMPs is of limited use if not coupled with high-quality feed resources and an effective breed improvement strategy. Over the 2018–2019

Information	Location on Packaging			
	Legally Required On Label	Immediate Package	Outer Packaging	No Location Specified
	(No. Of Countries)			
List of active substances per dosage or weight	49	10	12	27
Name & address of registration holder	46	6	11	29
Route of administration	48	9	12	27
Words 'for animal treatment only' or 'veterinary use'	46	9	12	25
Manufacturer's batch number	52	13	12	27
Contents (volume or number of capsules or doses)	49	8	12	29
Contraindications	31	2	6	23
Dosage	47	8	11	28
Expiry date	55	12	13	30
Name of the Drug	56	12	12	32
Precautions on disposal of unused or waste material	18	1	7	10
Official product registration number	41	5	12	24
Species the medicinal product is intended for	29	3	7	19
Storage requirements	44	5	11	28

Table 4: Examples of Labelling Requirements for VMP for EBA2017 report



project cycle, the EBA will expand to cover 80 geographies and will include additional regulatory indicators for animal nutrition and animal genetic resources.

REFERENCES

1. Enabling the Business of Agriculture 2017, World Bank Group, February 07, 2017 <http://eba.worldbank.org/reports>
2. Impact of Animal Disease on Meat and Milk Production, World Organisation for Animal Health. <http://www.rr-africa.oie.int/en/news/index.html>
3. Livestock Global Alliance. 2016. "Livestock for Sustainable Development in the 21st Century." http://www.livestockdialogue.org/fileadmin/templates/res_

- livestock/docs/2016/LGA-Brochure-revMay13th.pdf
4. Grace, Delia et al. 2012. "Mapping of poverty and likely zoonoses hotpots." p 14. https://cgspace.cgiar.org/bitstream/handle/10568/21161/ZooMap_July2012_final.pdf?sequence=4&isAllowed=y
5. FAO. "Chapter 10: Animal health and the environment." Guidelines for strengthening animal health services in developing countries. Rome, 1991. <http://www.fao.org/docrep/U2200E/u2200e0d.htm>
6. International Institute for Research Against Counterfeit Medication. 2017. <http://www.iracm.com/en/historical/>
7. PVS Pathway Programme, World Organisation for Animal Health, <http://www.oie.int/support-to-oie-members/pvs-pathway/>
8. Global Benchmarking Survey 2015 Report, HealthforAnimals, June 28, 2016 <https://healthforanimals.org/resources-and-events/resources/publications.html>
9. Regulatory Harmonisation for Vaccine Registration, Global Alliance for Livestock Veterinary Medicine, <https://www.galvmed.org/work/policy-and-advocacy/regulatory-harmonisation-for-vaccine-registration>
10. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products, <http://www.vichsec.org/>



Edna Kallon

She leads the livestock topic for the World Bank Enabling the Business of Agriculture programme. Before joining the World Bank, Edna worked with the Iraq country office of the UN Food and Agriculture Organization and with the Corporate Executive Board, a global best practice insights and technology company providing businesses worldwide with products and services.

Email: ekallon@worldbank.org



K. Aleks Schaefer

He joined the World Bank EBA livestock topic team in May 2017. In January 2018, Aleks will join the Royal Veterinary College, University of London, as a lecturer in agribusiness. He holds a PhD in Agricultural and Resource Economics from the University of California, Davis.

Email: kschaefer@worldbank.org



Felix Frewer

He was a member of the EBA livestock topic team from 2014 to 2017. Before joining the EBA in 2014, Felix worked with the UN Food and Agriculture Organization (FAO) on agricultural policies in Latin America and the Competitive Cashew Initiative (ComCashew) on strengthening the West Africa cashew value chain.

Email: ffrewer@worldbank.org