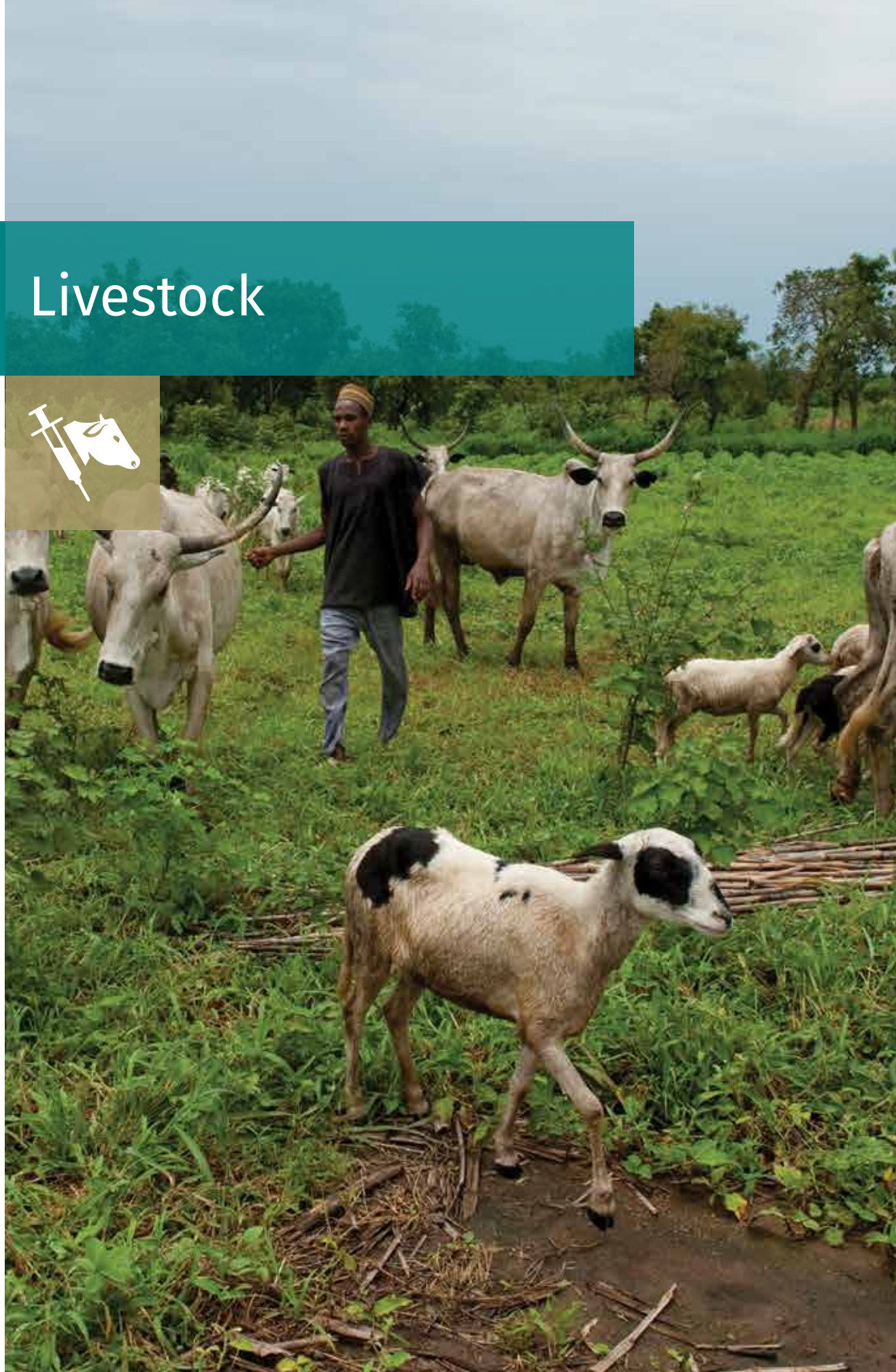
13 Livestock



Today Johnson is a successful cattle farmer in Garissa in northeastern Kenya. He started his business in 2006, but it almost did not make it. In 2006 Kenya and its neighbors, Somalia and Tanzania, experienced an outbreak of the Rift Valley Fever disease—an infectious animal disease that can also be transferred to humans. Johnson lost a significant number of his cattle herd. He was not alone in experiencing the destructive impact of the disease outbreak. By the end of the outbreak in 2007, the economic loss in Kenya was estimated to have been greater than US$9.3 million, due to the ban on livestock trade and the forced quarantine of animals.[1] Thankfully, the disease was contained within a year; Johnson purchased more cattle and was able to continue with his business.

Livestock is one of the fastest-growing agricultural sub-sectors in the world, accounting for around 40% of agricultural output in the developing world.[2] The term of livestock is used in this report to refer to domestic or domesticated animals that are raised mainly for agriculture purposes and includes, for example, large ruminants such as cattle, small ruminants such as goats, as well as pigs and poultry.[3] Aquaculture is not considered by the livestock topic.

Livestock is a main source of income for one in five people across the globe.[4] Livestock infectious diseases, therefore, pose a significant risk to that contribution if left unchecked. Estimates suggest that these diseases are responsible for more than 20% of livestock production losses globally.[5] Furthermore, approximately 70% of all new human diseases are zoonotic, transferring between animals and humans, and mostly originating from animals.[6]

Maintaining animal health is thus central to the global food system's stability and safety. Readily available preventative and curative veterinary medicinal products (VMPs) can minimize the negative economic impact of diseases and safeguard the livelihoods of millions of farmers around the world.[7] However, VMPs (biologicals and pharmaceuticals) have to be used in the correct circumstances and in accordance with prescribed conditions and dosages if they are to be truly effective. If not, for example, their use can lead to increased drug resistance and illness in humans due to drug residues in consumed animal foods.[8] Further, open borders, inadequate legal frameworks and poor law enforcement can lead to counterfeit and substandard VMPs in the market.[9]

Cattle grazing in Ta Kuti village, Nigeria.
Photo: Arne Hoel / World Bank.

Comprehensive regulations on the manufacture, registration, import, distribution, sale and/or administration of livestock medicinal products can contribute to establishing a reliable market supply of effective and safe VMPs.[10] Since research and development in the veterinary medicine sector is expensive, specialized and time consuming, most manufacturing facilities are established and owned by large companies located in specific regions of the world.[11] While large companies represent the bigger market share of VMP manufacturing, a diversified mix of private sector entities supply the market—large companies, small and medium enterprises (SMEs), breeders' organizations, and veterinarians. Given this dominant role of private sector in the development, manufacturing and market supply of VMPs, it is important that regulations are streamlined and efficient in order not to discourage them from entering and operating in markets.[12]

Access to effective and safe VMPs is just one critical input into livestock production. Other key production inputs are feed resources, productive animal breeds and veterinary services. While the focus of the livestock topic in *EBA17* is on VMPs, the topic will be further developed in the coming years to assess the impact of regulations on other relevant issues in livestock production. Once a more comprehensive data set is established, an adequate livestock scoring methodology will be developed and implemented.

What does the veterinary medicinal products topic cover?

The data collected cover regulations impacting the private sector's ability to supply the market with effective and safe VMPs. Data assess regulatory requirements for registration, importation and marketing of VMPs:

Registration of VMPs: Registration, or marketing authorization, is a critical step in a country's control system for VMPs. Most countries require VMP registration before it can be manufactured, imported, distributed and sold.[13] Data were collected on:

Institutional structure. Literature suggests that a country's ability to provide effective regulatory institutions is an important determinant of how well markets function.[14] Having multiple government institutions involved in the registration process can create a burden for the private sector, especially when roles and responsibilities are not clearly defined and the applicants are required to interact with multiple different institutions.

Registration process. Data points assess the existence of obstacles and good practices during the registration process. Unclear and irrelevant registration requirements often lead to delays in the registration process and create severe registration backlogs of products awaiting marketing authorization.[15] In addition, the private sector's knowledge of and trust in the registration process influence the decision to supply markets with VMPs and whether to participate in the legally mandated registration process.[16]

Registration output. The registration system can produce a registry of authorized VMPs and temporarily protect proprietary data submitted during the registration process for newly developed products. The registry's existence has legal consequences, given that most countries require that products must be registered prior to market entry and circulation.[17] Time-bound proprietary data provides incentives for innovation and research and development.[18] Unlike human medicinal products, the financial return for VMPs can be significantly less, given the lower sales prices and potentially smaller market size, especially for the market for small animals.[19]

Authorization of importers: In many countries, the main supply of VMPs comes from outside the country and import licenses are a useful way to impose minimum safety and qualification requirements on the companies inolved. The data collected cover import restrictions such as types of entities allowed to import VMPs and whether importers are required to employ specialized staff.

Marketing of VMPs: Labeling requirements on marketed VMPs are critical to ensuring their proper handling and administration. In addition, knowing what diseases are present in a country, their geographic location and the size of the livestock populations threatened are all key factors in determining resource mobilization of VMPs.[20] In particular, data assess:

Labeling of marketed VMPs. VMPs are often administered by veterinarians and farmers; as such, adequate labeling is of paramount importance. [21]

Information availability on animal diseases. The private sector can use information in a national disease database, beyond data available on transboundary diseases and zoonosis (diseases transferable from animals to humans) found in World Organization for Animal Health (OIE) and regional databases, to make distribution and sales decisions and to explore new market niches.

Some good practice examples are showcased in box 13.1.

Box 13.1 | Good practices for veterinary medicinal products (VMPs)

	REGULATORY GOOD PRACTICES FOR VMPS	SOME COUNTRIES WHICH IMPLEMENT THE PRACTICE
REGISTRATION OF VMPS	There is both a regulatory framework and an institution actively registering VMPs.	ALL EBA 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.	DENMARK, MEXICO, NIGERIA, POLAND, RUSSIA, SPAIN 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, ITALY, MOROCCO AND ZIMBABWE
MARKETING OF MEDICINAL PRODUCTS	Labeling requirements are comprehensive and provide distinction between what information is required to be on the outer and immediate package.[a]	MALAYSIA, NICARAGUA, PERU AND SERBIA
	Withdrawal periods are required on VMP labels to protect consumers of animal products.	DENMARK, ITALY AND NICARAGUA

Source: EBA database.

[a] Outer packaging is the packaging into which the immediate packaging is placed (for example, the box), while immediate packaging is the container or any other form of packaging that is in direct contact with the medicinal product (for example, the vial or bottle).

Some insights emerging from the data

Ensuring the predictability of registration systems for VMPs

The VMP registration system's predictability influences private sector decisions to supply a market with VMPs using the legally mandated process.[22] Ease in accessing information on registration requirements and the VMP registry, confidence that all necessary documentation are included in the application package (dossier) and awareness of the timeframe by which the registration is intended be completed, are all factors that can contribute to the predictability of the registration process.

It is vital that applicants are aware of all the registration requirements and are able to easily obtain such information. Of the 59 countries legally requiring VMP registration, 5 countries do not provide information on dossier requirements on the website of the authority mandated to register VMPs (Haiti, Malawi, Rwanda, Sri Lanka and Tajikistan). In Rwanda, the registration process is yet to start. In Haiti (currently not registering products), Sri Lanka and Tajikistan, documentation specifying dossier requirements is not on the website of the relevant authority. In Malawi, there is no functioning publicly accessible website. The three EBA countries not requiring VMP registration do not have a legal framework and are either in the process of developing a framework or are yet to commence the process (Burundi, Lao PDR and Mozambique).

Given the requirement to register products prior to market introduction and circulation, it is also important that an applicant is able to easily access information on products already authorized for market circulation in a country. Of the 57 countries actively registering VMPs, a registry is available online in 37 countries, 21 of which are high-income or upper-middle-income countries. Only 12 lower-middle-income countries and 4 low-income countries provide a registry on the registering authority's website.

In most countries, during the dossier evaluation process, each time the regulatory authority requires additional information from an applicant, the registration process is put on a hold. To limit this outcome, the application package (dossier) can be checked for completeness prior to the start of evaluation. Sixteen EBA sample countries indicate either in a legally-binding

Chicken farm near Santander, Colombia. Photo: Charlotte Kesl / World Bank.

document or in a non-legally binding guideline, that dossiers will be checked for completeness. In Mexico, for example, the 2012 Regulation of the Federal Law on Animal Health (a legally binding document) explicitly addresses issues concerning the checking of dossiers for completeness. Another example is Armenia, which does not directly state such requirement in a legal document, but rather indicates the checking for completeness in non-legally binding registration guidelines from the authority. In addition, these countries also provide timeframes within which the applicant can be contacted for missing documents prior to the start of evaluation. These timeframes range from 3 days in the Kyrgyz Republic to 60 days in Bosnia and Herzegovina.

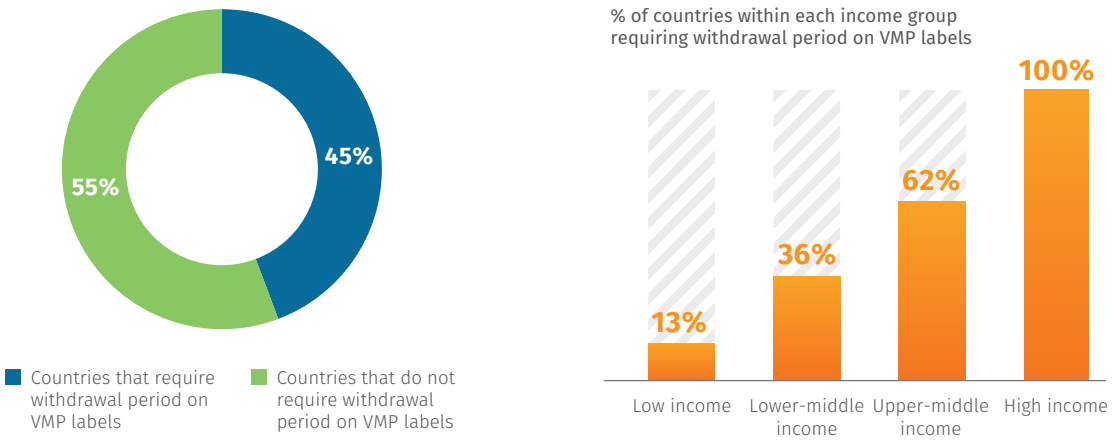
The awareness of how long the registration process can take allows the private sector to plan the market introduction of products accordingly. The expected registration times are an estimation by regulatory authorities of how long the process can take based upon the registration process adopted in a country. Some countries implement a detailed registration complete with the testing of products, while others may rely on the use of reference countries and other parameters, thus sometimes explaining the shorter expected registration time. Thirty-eight countries currently provide a time limit for the registration process in a legally binding document or a non-legally binding guideline. The time limit ranges from 30 days (Cambodia) to 365 days (Jordan and Kenya) for biologicals and pharmaceuticals.

Adhering to the expected registration time limit can be challenging in some countries. In comparing the timeframe between the expected and actual registration time, regulators could potentially use the difference to assess the efficiency and quality of the registration process. In addition, the difference could be used by applicants to hold the regulatory authority accountable.

Safeguarding animal and human health by comprehensively labeling VMPs sold

Labeling requirements help to ensure that drugs are properly used. The legal requirement can provide information on the characteristics of the product, such as the list of active substances per dosage or weight, the proper handling and storage conditions for the product, the proper use of the product and route of administration and information to ensure consumer protection such as the withdrawal period. The withdrawal period is the time between the last administration of medicine to the animal and the production and marketing of animal foods for consumption.[23] Following appropriate withdrawal periods for VMPs reduces the risks to human health associated with drug residues in products such as meat, milk, eggs and honey.[24] Only 27 out of the 60 countries studied require that withdrawal periods are included on the labeling of VMPs (figure 13.1). This number includes all high-income countries and the majority of upper-middle-income countries. Only 2 out of 16 low-income countries, or 13% of this income group, have this requirement.

Figure 13.1 | Few countries require withdrawal periods on veterinary medicinal product labels



Source: EBA database.

Note: No data were received for Egypt and Tajkistan on the requirements of withdrawal periods on VMP labels. The total sample is distributed as follows: high-income (9), upper-middle-income (13), lower-middle-income (22), and low-income (16) countries. VMP=veterinary medicinal product

Facilitating the market distribution of VMPs using national animal disease information systems

The outbreak of animal diseases directly impacts animal and human health. Therefore, it is important for countries to have a functioning animal disease surveillance and information system in place to mitigate the risk of disease outbreaks. One important dimension of such a system is the existence of national databases that can be used to monitor and track local outbreaks.[25] Sophisticated systems follow not only those diseases that are required to be notified to the World Organization for Animal Health (principally diseases that impact trade and are transboundary),[26] but also diseases that may be endemic to a local livestock population. National disease databases can be provided and maintained by national veterinary authorities and include information on when a disease was identified, its geographic distribution and spread. The private sector can then use such databases to make distribution decisions and understand the potential size of the market for a VMP.

EBA data suggest that lower-middle and low-income countries have serious gaps in terms of animal disease information systems that are publicly accessible online. At the regional level, Sub-Saharan Africa has the fewest countries with animal disease databases publically available on the responsible authority's website. None of the 21 Sub-Saharan African countries studied have an animal disease database available online. The situation is also similar in South Asia, where only Nepal has an electronically accessible database.

Conclusion

The level of transparency, predictability and efficiency of relevant regulatory systems is critical to private sector decisions to supply a market with VMPs, and thus can affect the availability of effective and safe VMPs in the market. While capacity and systems to control VMPs may vary in countries, it is vital that information needed to adhere to regulatory requirements is readily available and that the processes do not delay nor discourage market supply. It is also equally important that there is adequate infrastructure to assess the effectiveness and safety of VMPs, and effective mechanisms to ensure both animal and human safety in the context of VMP use.

NOTES

1 Muga et al. 2015.

2 Livestock Global Alliance 2016.

3 FAO 2010.

4 Livestock Global Alliance 2016.

5 OIE nd (a).

6 Wang et al. 2014.

7 Roth 2011.

8 Beyene 2015.

9 Kinglsey 2015; Luseba 2015.

10 OIE 2016; Fingleton 2004.

11 HealthforAnimals 2012.

12 Fingleton 2004.

13 *Ibid.*

14 Julilian et al. 2007.

15 Smith 2013; European Commission 2011.

16 HealthforAnimals 2005.

17 Fingleton 2004.

18 European Commission 2011.

19 Roth 2011.

20 FAO 1999.

21 Fingleton 2004.

22 HealthforAnimals 2005.

23 The World Organization for Animal Health (OIE) has developed guidelines to estimate the necessary withdrawal period for specific veterinary drugs in order to avoid excess residues in animal foods (OIE 2013).

24 Beyene 2015.

25 FAO 1999; OIE nd (b).

26 http://www.oie.int/en animal-health-in-the-world/oie-listed-diseases-2016/.

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