

BELGIUM

Please inform the following:

Name of Country:

- **Main Government Authority in your country directly involved with veterinary medicines regulation:**
Spanish Agency for Medicines and Health Products, Ministry of Health.
- **Main National Administrative body/institution/agency that controls veterinary medicines (evaluation, authorisation, market control, etc.). If more than one, please specify:**
Spanish Agency of Medicines and Medical Devices (evaluation, authorisation, market control).
- **Person/s (name, position, address, phone, e-mail) to get in touch with, about this survey:**
Manuel Ibarra Lorente,
Head of Department of Inspection and Control of Medicinal Products
mibarra@aemps.es
+ 34 918225201
Rubio Montejano consoil,
Head of Veterinary Medicines Department
crubio@aemps.es
+ 34 91 822 54 01

1.1. For Questions:

1.1.1. Did your country have a specific regulation for veterinary use medicines?

☒ Yes

☐ No

The legislation in force on veterinary medicinal products in Spain is Royal Decree 1246/2008 of 18 July 2006, regulating the procedure for the authorisation, registration and pharmacovigilance of industrially manufactured veterinary medicinal products and Royal Decree 109/1995 of 27 January. Both currently under review; Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, which is directly applicable in all Member States, will enter into force on 28 January 2022.

1.1.2. Do veterinary medicines compound equivalent criteria to medicines for human use (e.g. authorised manufacturers, controlled distributors, need for a veterinary prescription, distribution and/or salts under pharmaceutical control, etc.) in your country?

☒ Yes

☐ No

There are some particularities regarding dispensing and authorized centers for the custody of certain veterinary medicinal products, but in generally equivalent criteria are applied.

2.1.3. Do your country have specific regulations and/or control the use of bulk API (in food or water for pigs, poultry, fish, etc.) in veterinary medicine?

☒ Yes

☐ No

For these uses (addition to feed, drinking water or fish) only medicinal products evaluated and authorised for that purpose (premixtures, powder or concentrate for solution...) may be used.

Bulk API in bulk may not be used if it is not in the form of the authorised medicinal product.

2.1.4. Do your country have specific border control (customs control) for veterinary medicines and APIs for veterinary use?

☒ Yes

☐ No

2.1.5. Are the offers and salts of veterinary medicines through the Internet regulated in your country (including e-commerce platforms)?

☒ Yes

☐ No

The sale of prescription veterinary medicinal products cannot be made through Internet. In the case of veterinary medicinal products which do not require a prescription, this sale may take place in compliance with the provisions of Royal Decree 544/2016 of 25 November 2009, which regulates the sale at a distance to the public of veterinary medicinal products not subject to veterinary prescription.

2.1.6 Does your country have any regulation about falsified medicines for veterinary use?

☒ Yes

☐ No

The definition of counterfeit medicines does not exclude veterinary medicinal products. The manufacture, import, export, intermediation, distribution and sale of counterfeit medicines (including online sales, and regardless of whether they are for human or animal use) is considered a serious offense.

2.1.7. Do your country have an effective strategy for the control of falsified veterinary medicines?

☒ Yes

☐ No

It is difficult to estimate the effectiveness of existing monitoring and control measures to prevent the entry of counterfeit veterinary products. The impact of this problem, based on the data we have, is very low.

2.1.8. Do your country have industry-wide/distributors' database of incidents interfering with falsified veterinary medicines?

☐ Yes

☒ No

2.1.9. In your experience, which are the main distribution channels/suppliers of veterinary medicines currently existing in your country (rate from 1, less important, to 5, most important; Or N/A — not applicable):

Licensed Wholesalers	
Approved Physical Broilers (Pharmacies, merchants)	Most sales are made by the Retail Commercial Establishments (4), then by the Livestock Entities and finally by Groupings (3) and less by the Pharmacies (2).
Veterinarians (direct supply from them, if legal in your country)	Not allowed
Approved Internet retailer/supplier/pharmacy	Sales channel not very developed (2); Only approved physical establishments can sell online.
Other <i>e-commerce</i> , if legal, for veterinary medicines (e.g. eBay, Amazon, Alibaba)	Not allowed
Social media, if legal, for veterinary medicines (e.g. Facebook, Twitter)	Not allowed
Unapproved physical broiler/merchants	Not allowed
Unapproved Internet Pharmacies	There are no exclusive internet pharmacies; Only authorised (physical) pharmacies and only medicines that do not require veterinary prescription may sell online.
Other Unapproved Internet Sources	Not allowed
Others (please describe):	

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2.1.10. Has your country included in their criminal justice regulations any specific subject on falsified veterinary medicines?

☒ Yes

☐ No

2.1.11. Is there any regulated and routine control on falsified veterinary medicines and falsified veterinary APIs by:

Customs/Border control authorities at entry ports/airports/terrestrial frontiers alone or in conjunction with other agencies e.g. Interpol/Europol/World Customs Organisation, national enforcement or veterinary medicines/pharmaceutical control agencies	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not specifically
Regulators/Veterinary medicines agency	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not specifically
National enforcement officers at destination market	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not specifically
Approved Internet retailer/supplier/pharmacy controllers	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not specifically
Combined operations, including against falsified websites	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not specifically
Regulators and enforcement agencies together (federal and state, in case)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not specifically
Others (please describe):	

2.1.12. Is there national cooperation and information exchange between veterinary medicines agency (or equivalent), law enforcement, and other competent authorities?

☒ Yes

☐ No

There is cooperation between the Spanish Agency for Medicines and Health Products and the State Security Forces. There are specific sections within these Forces specialized in crimes against animal health and public health.

2.1.13. Do your country have regulations regarding corporate liability (legal person liable under conditions) for the reasons related to falsified veterinary medicines?

☐ Yes

☐ No

2.1.14. If your country has regulated sanctions for fences related to falsified veterinary medicines, please specify the type (choose all that applies):

Administrative x

Civil ☐

Criminal/criminal x

Others (please describe):

2.1.15. Do the following actors have access to regular training in the field of falsified veterinary medicines for (check that it applies)?

Veterinary regulatory Agency ☐

Pharmacists ☐

Providers ☐

Police/Enforcement agencies x

Judges ☐

Veterinary/pharmacist Associations ☐

Civil society ☐

Others (please describe):

Veterinary Professionals ☐

Manufacturers ☐

Distributors ☐

Custom/border control ☐

Prosecutors ☐

Relevant Authorities (politicians) ☐

2.1.16. Does your country have policies or strategies implemented to promote or conduct awareness-raising campaign taken to the general public about falsified veterinary medicines?

☐ Yes

x No

Please share any other consideration, comments or aspects that could have been taken for this survey: