

# Assessment of the generic veterinary product market in Europe

Report developed by market research company Kynetec for EGGVP



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Content	Page
Context and objectives, scope, limitations	3
Part 1. Industry profile	9
Part 2. Added value of generic veterinary medicines	19
Part 3. Analysis of the EGGVP members survey - Portfolio	30
Appendix	35

# CONTEXT, OBJECTIVES, SCOPE, LIMITATIONS

#### Context



- EGGVP, the European Group for Generic Veterinary Products, is the association representing the veterinary generic pharmaceutical industry in Europe.
- The members of the association debate generic veterinary medicinal products policy; they also aim to formulate common positions and in relation to the industry with a view to sharing these with competent EU and National authorities.
- In order to strengthen its mission and values, the association has undertaken market research aimed at evaluating the importance, economic weight and added value of generic veterinary pharmaceuticals within the EU.

### **Objectives**





- Generate reliable data, highlighting the importance of the veterinary generics industry and its products in Europe.
- Assess the impact of the veterinary medicines regulation 2019/06.
- Use the information as support in communication.

### Scope (I)



- PRODUCT The term "GENERIC" herein after applies to veterinary marketing authorisations authorised according to Articles 18, 19, 21 and 22 of EU Regulation 2019/06:
  - > Generic
  - Hybrid (line extension)
  - Bibliographic Well established use (WEU)

### Scope (II)



INDUSTRY - The terms "GENERIC COMPANIES" and "GENERIC INDUSTRY" herein after refer to marketing authorisation holders of generic veterinary medicines in Europe (185 companies).

GEOGRAPHIC SCOPE: EU 28 + Norway + Iceland + Liechtenstein

• **TIMEFRAME** - Data collected from **2016** (unless otherwise indicated in references).



### The project is structured in 3 parts



#### 1 - Industry profile:

Gather economic data to assess the importance of the EU generic industry



#### 2 - Added value of generic VMPs:

Assess the impact of generic products on the veterinary market



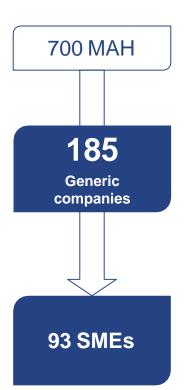
#### **3- EGGVP Members portfolio:**

By means of individual surveys to EGGVP Members, analysis of industry portfolio

### Part 1. INDUSTRY PROFILE

### In Europe, 185 companies qualify as "generic companies"

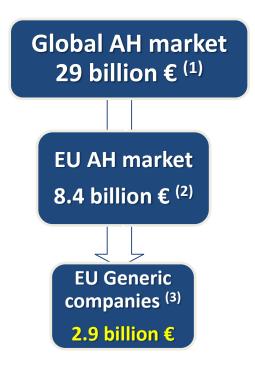




- Out of a total of about 700 MAH, 185 MAH (26,4%) qualify as "Generic companies"
- Among these 185 companies at least 93 MAH (50%) match the SME criteria (Turnover < 50 M € and number of employees < 250).</p>

### **Animal Health market size 2016**





Generic companies: significant share of the European Veterinary Medicines Market

- Represent about 1/3 of the total value of the market with a turnover estimated around 2.9 billion € in 2016
- Employ approx 30.000 employees across EU

#### Sources of information and details :

The Animal Health sector/market considered includes feed additives, pharmaceuticals and vaccines. Veterinary diagnostic is not included in these data.

- (1) Source: Research and Markets Animal Healthcare Market Growth, Future Prospects, and Competitive Analysis, 2017 2025
- (2) EU market estimated to represented 29% of the Global AH market in 2016 according to AnimalHealthEurope.
- (3) Data based on Kynetec estimations.

# Generic companies: significant input to availability and accessibility



- Hold around 25,000 VMPs marketing authorizations (48% of all the EU MAs)
- Established in most of the EU countries and hold MAs in all of the EU 28 MS
- Very active in the market; about 600 new MAs registered each year, significant input availability and accessibility
- Covering all therapeutic areas
- They also bring **innovations** to the market as their portfolios also include some originator products, as well as generics that offer an added value compared to the originator.





### **Generic companies** are present in many European countries

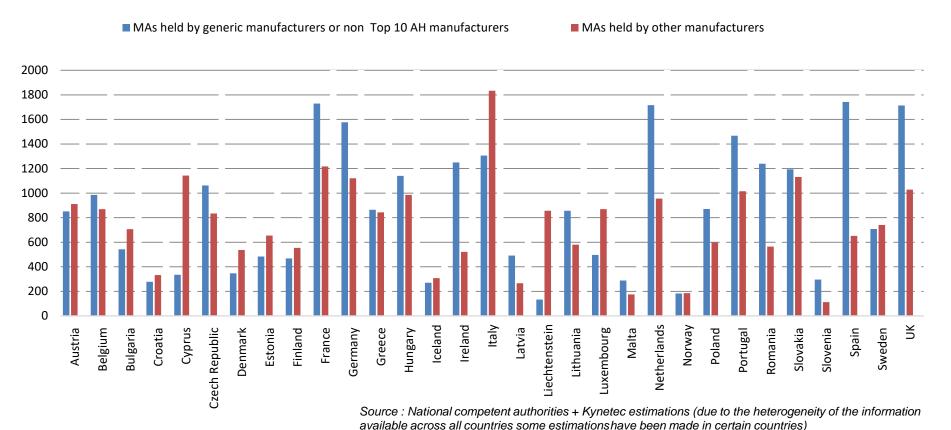
Country of HD	Number of
	companies (1)
Austria	1
Belgium	11
Bulgaria	8
Croatia	1
<b>Cyprus</b>	3
Czech Republic	4
Denmark	-
Estonia	1
Finland	2
France	17
Germany	13
Greece	13
Hungary	5
lceland	-
Ireland	20
Italy	12

	Number of
	Companies (1)
Latvia	-
Liechtenst	tein -
Lithuania	a 1
Luxembou	irg -
Malta	-
Netherlan	<b>ds</b> 9
Norway	1
Poland	6
Portuga	2
Romania	a 8
Slovakia	1
Slovenia	1
Spain	25
Sweden	2
UK	18
Total	185

Total number of MAs held by these companies across all countries: 25800 MAs

# Generic VMPs are present in all European countries. about 50% of Marketing Authorizations are held by generic companies



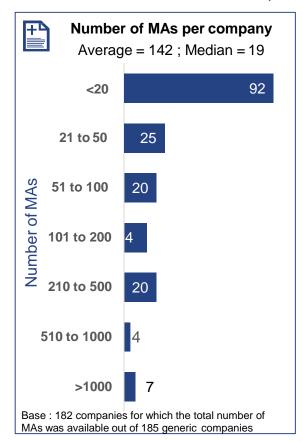


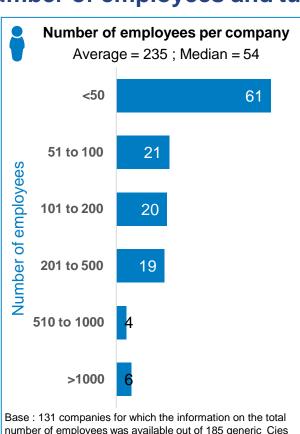


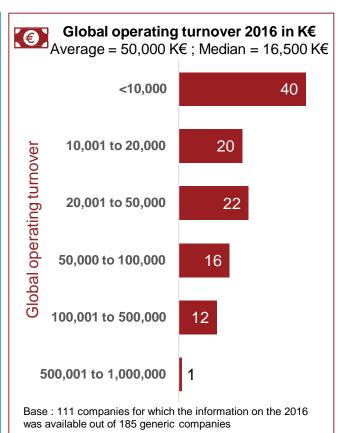
### Among generic companies, there is a wide diversity in number of MAs, number of employees and turnover











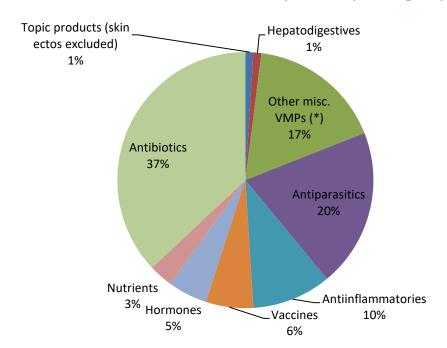


# Among generic companies, antibiotics, miscellaneous VMPs, anti-inflammatories and antiparasitics represent most of the MAs





#### **Distribution of MAs per therapeutic group**



(\*) Other miscellaneous VMPs include anaesthetics, analgesics (excluding NSAIDs and steroids), spasmolytics, euthanasia products, anti-histaminics, central nervous system products, ACE-inhibitors, sedatives and tranquilisers, diuretics, lameness treatments, mucolytics, Broncho dilatators, fluidifiants and expectorants, haemostatics

Base: MAs held by generic companies - Estimation based on 17,689 MAs

Source: National competent authorities databases

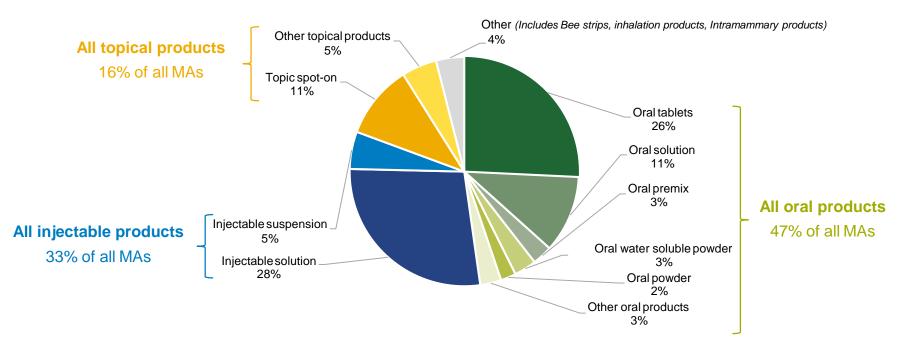


# The range of MAs held by generic companies includes 47% of oral products, 33% injectable and 16% topical





#### Distribution of MAs per Form group



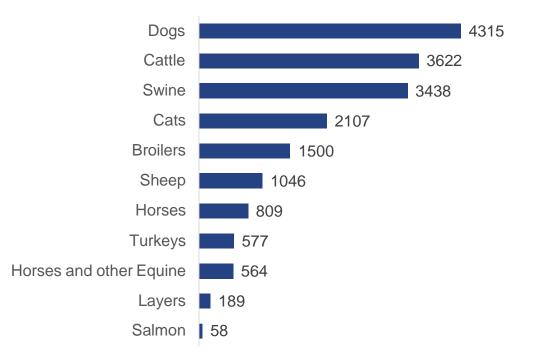
Base: MAs held by generic companies – Estimation based on 15,893 MAs for which the formulation was informed Source: National competent authorities database



# MAs held by generics companies cover all major species as well as many MAs for minor species







Number of MAs held by generic companies for minor species				
Rabbits	353			
Goats	336			
Ornamental birds	210			
Multi minor species and other minor species (*)	153			
Ducks	101			
Other fishes	64			
Ferrets	46			
Bees	44			
Pigeons	32			
Guinea pigs	27			
Mice/rats 20				
Donkeys	1			
Camels	1			

Base: MAs held by generic companies – Estimation based on 18,115 MAs for which the specie was informed Source: National competent authorities database

(\*) Multi minor species: includes MAs indicated for several types of minor species (exotics, rodents, small mammals, reptiles)

Other minor species include: reptiles, exotics, foxes.

# Part 2. ADDED VALUE OF GENERIC VETERINARY MEDICINES

# Generic VMPs can bring different innovations to the market, with many benefits for the users











# Availability

- For more species (including MUMs)
- Covering new indications
- In all EU countries (including small markets)
- Covering all therapeutic areas
- For more owners / users thanks to their affordable cost
- Sometimes available through a wider range of distribution channels





# Convenience

- Improved presentation i.e. Multi-dose vials
- improved palatability / syringeability
- improved solubility
- tablets easier to divide...
- Easier dosage and administration (i.e. generic with different concentration allows less volume to be injected)
- Easier handling / manipulation





# Compliance

- Better treatment rates:
  - New indications and species compared to originator, filling therapeutic gaps.
  - Easier treatment for owners: improved features ameliorate and facilitate adherence to therapies.





# Efficacy

• Improved formulations as well as more suitable and better adapted features can positively influence the overall outcome of treatment.







# Safety

- Improved packaging
- Users safety
- Public health: higher treatment rate
- Environmental safety (stronger regulation)







# Savings

- Treatment cost more affordable
- Shorter withdrawal period without compromising consumer safety
- Less waste (i.e. multi-dose vials, improved opening-closing system in vials)
- More rational stock management / less product to be kept in stock (same product can be used for different pet size)



# The impact of generics on market prices depends on several factors





=> In most cases, according to the MAH, the introduction of one or several generics will always lead to a price decrease in the market segment:

- at introduction: price differences range from 10% to 50% compared to the originator;
- average net price of the originator usually decreases from 10% to 50% (depending on the market and number of competitors);
- average prices on the market decrease, making the treatment more affordable for end-users.

# Most frequent pricing scenarios linked to the introduction of generics





Originator





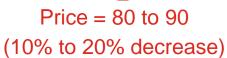
List price decrease
Or Increased discounts













Price = 40 to 50 (50% to 60% decrease)

# Part 3. ANALYSIS OF THE EGGVP MEMBER SURVEY - PORTFOLIO

Note: The following results are based on the survey completed with the EGGVP members. 20 companies have provided information on their Market Authorizations and 17 companies have answered to the interview.





- Turnover (global, sales of VMPs)
  - TOTAL ≈ 1.4 billion €
  - Average / company: 64,3 Mi €
- ≈ 5,800 employees (EU, VMPs business)
- 22 companies, all headquarters in EU
- ≈ 10,000 MA's in the EU



### **EGGVP** members portfolio - Key facts and figures





# More than 10,000 MAs held across 31 countries

- Main therapeutic categories:
  - Antibiotics (33%),
  - Misc. VMPs (19%),
  - Anti-Inflammatories (15%)
  - Endoparasiticides (11%),
  - Ectoparasiticides (10%)





Generics represent 48% of their portfolio (30% are considered originator and 14% WEU)

■ 50% of MAs were obtained from National Registration, 37% from Decentralized Procedure

■ Various pharmaceutical forms are offered: Injectables (34% of the MAs), Oral forms (52%), Topical and other forms (14%)



■ A broad range of species covered, in companion animals, livestock as well as more than 10 different minor species





# EGGVP members hold a total of 10,838 MAs across 31 European countries







#### Total number of MAs held by the EGGVP members per country

402
513
207
216
129
342
240
209
168
518
877
303
397
94
536
885

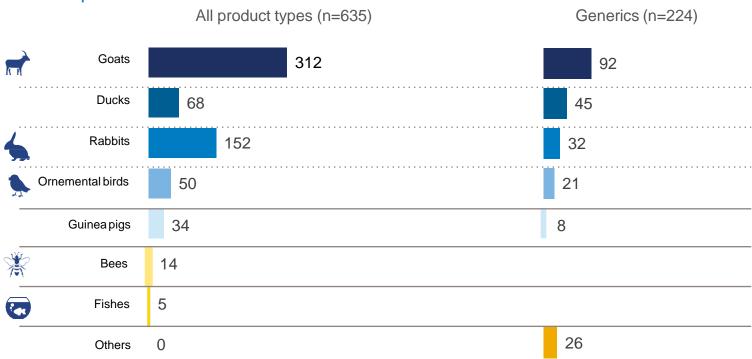
	Latvia	322
	Liechtenstein	13
	Lithuania	333
	Luxembourg	212
The state of the s	Malta	78
	Netherlands	630
	Norway	86
	Poland	388
(9)	Portugal	509
	Romania	315
	Slovakia	291
	Slovenia	195
	Spain	759
	Sweden	194
	UK	583
	Total	10,838



# EGGVP members hold 635 MAs in minor species, including 224 generics



#### Number of minor species indications



## **APPENDIX**



#### <u>List of abbreviations used in this study:</u>

- AH: Animal Health
- MA / MAs : Marketing Authorization(s)
- MAH: Marketing Authorization(s) Holder
- VMP : Veterinary Medicinal Product
- WEU: Well Established Use
- CP: Centralised procedure
- MRP: Mutual Recognition procedure
- DCP : Decentralised procedure

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- Animal health industry rankings 2013, 2015, 2016: Animal Pharm
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- Animal Healthcare Market Growth, Future Prospects, and Competitive Analysis, 2017 2025 Research and Markets
- The Economic and Social Contributions of the Animal Health Industry ndp analytics February 2018.



#### FOR QUESTIONS OR ADDITIONAL INFORMATION PLEASE CONTACT:



Elsa Vecino
Technical Director
+32 (0)2 401 87 95
info@eggvp.org