

Generic and added value veterinary product market in Europe 2017-2019

Market study vol. 2
by Kynetec

About this report

In 2019, EGGVP commissioned the first of a kind generic veterinary medicines market study to have reliable data on the importance, economic weight and added value of the generic veterinary pharmaceuticals in Europe. The study carried out by research company Kynetec covered the period up to 2016. This second edition is a follow up on the first and covers the period 2017-2019. Again, the study have been performed in collaboration with EGGVP and its members.

This report shows some trends and developments in the market and draws a few conclusions on these results.

About EGGVP

EGGVP is the voice of the European industry of generic and added-value veterinary medicines by interacting with authorities and decision-makers, and other stakeholders in the EU to achieve sustainable animal health policies and legislation.

EGGVP's mission is to increase the ACCESS - availability, compliance, convenience, efficacy, safety, and savings - of veterinary medicines to veterinarians, and farm and companion animal owners in Europe.

What is a generic veterinary medicine?

- Generic medicines are authorised and placed on the market after intellectual property and other protection periods associated to the originator product have expired. Often, a period of up to 25 years may lapse before the first entrance of the medicine's generic. As such, generics are produced using more modern technologies, better analytical capacities and materials complying with the most recent (and more stringent) regulations.
- Just as for originator medicines, strict EU regulations and controls ensure the quality, safety and efficacy compliance for generics – they are assessed thoroughly by the EU and national regulatory authorities before being launched on the market.
- Generics are high-quality products, offering safe, effective and affordable treatment options to veterinarians, farmer and companion animal owners.
- Value-added medicines, products that are an enhanced version of the originator in terms of dosage or administration or are applicable to new species.

What we mean by a generic company

- Holder of new veterinary medicinal product marketing authorisation registered in at least one of the targeted country
- Independent company (not a subsidiary of a major international company)
- Focused on generics businesses (although many companies can also have some R&D activities). Some companies which mainly focus activity in R&D and innovation were disregarded, even if they have a large generic portfolio.
- Note: Vast majority of companies present in the animal health sector do not necessarily focus only on generic products. A vast majority of companies have a mixed activity including both R&D originator and generic production. Companies often have other activities than manufacturing, such as distribution / wholesale activity), some companies can operate in other industrial sectors such as human health, feed supply or other chemicals. The notion of “generic manufacturer” is therefore relative.

Product scope

The term “generic” applies in this report to veterinary marketing authorisations according to Article 13 of the Directive 2001/82/EC, as amended

- *Generic*
- *Hybrid (line extension)*
- *Informed consent*
- *Bibliographic - well established use (WEU)*

Geographical scope

EU 27 + UK + Norway + Iceland + Liechtenstein (the term Europe applies to this report)

Data collection

The data was collected during 2017-2019 by Kynetec. The main data sources used were

- *Marketing authorisation data*
- *Company registration data*
- *EGGVP member survey*

Generics brought wider availability and access to treatments

The changes in the generic veterinary medicines market 2016-2019

- A slight increase in the number of generic veterinary medicines companies, but over 20% increase in the amount of their product registrations.
- A shift seen from the old markets to “new” countries.
- Generics’ authorisations represented a half of all EU authorisations.
- Growth in registrations of products for companion animals and minor species.
- Significant decrease in the share of registrations of antibiotics and to some extent of oral products.
- Increase in the share of registrations of topical products, antiparasitics and other therapeutic groups that cover a larger variety of treatments.

Generic companies are based in most European countries

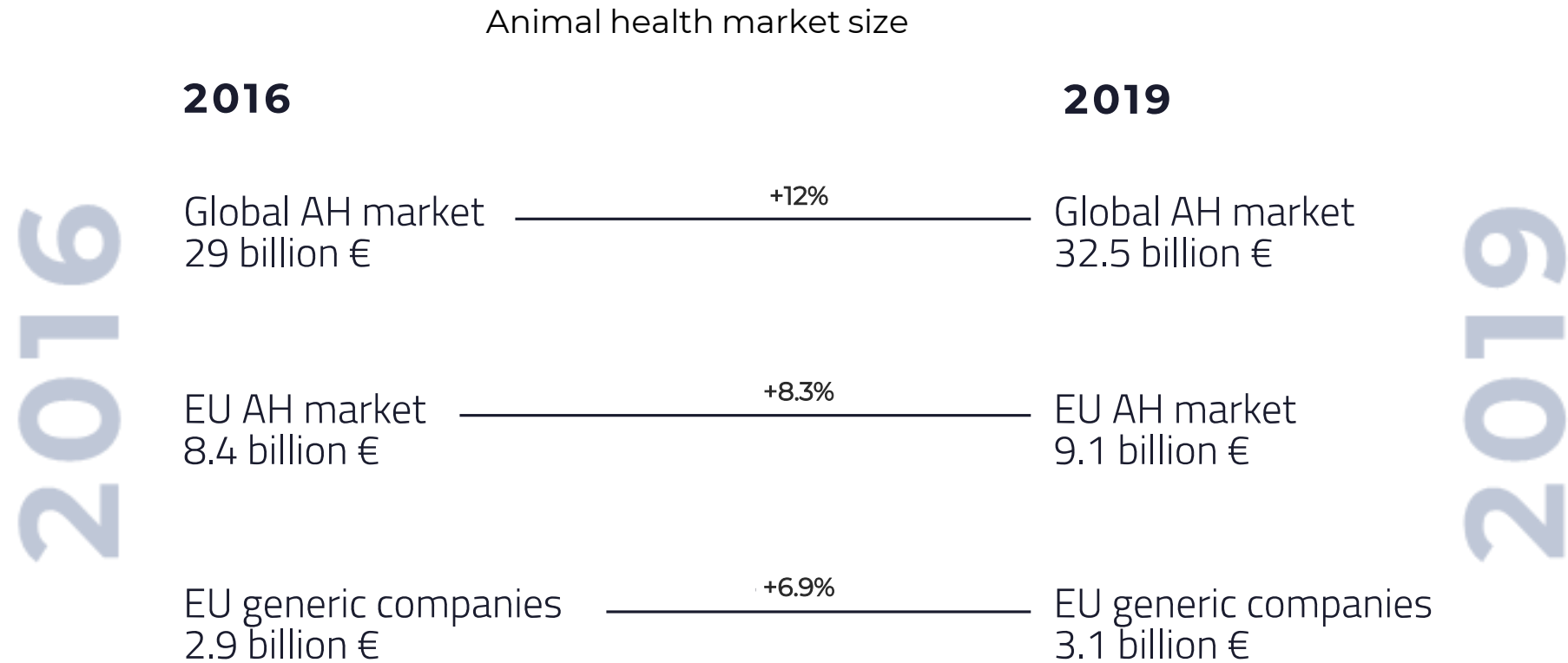
COUNTRY	No. of companies	
	2016 (1)	2019 (1)
AUSTRIA	1	3
BELGIUM	11	11
BULGARIA	8	9
CROATIA	1	1
CYPRUS	3	2
CZECHIA	4	4
DENMARK	-	1
ESTONIA	1	1
FINLAND	2	2
FRANCE	17	15
GERMANY	13	14
GREECE	13	13
HUNGARY	5	6
ICELAND	-	-
IRELAND	20	21
ITALY	12	15

COUNTRY	No. of companies	
	2016 (1)	2019 (1)
LATVIA	-	-
LIECHTENSTEIN	-	-
LITHUANIA	1	1
LUXEMBOURG	-	-
MALTA	-	-
NETHERLANDS	9	10
NORWAY	1	1
POLAND	6	7
PORTUGAL	2	3
ROMANIA	8	9
SLOVAKIA	1	2
SLOVENIA	1	1
SPAIN	25	26
SWEDEN	2	2
UK	18	17
TOTAL	185	197

(1) Number of companies identified as generic companies and having their headquarters in the listed country.

Generics have a significant share of the European market

The generic veterinary medicines companies represent 1/3 of the total value of the animal health market in Europe.



Over half of the animal health sector employees are working in the generic industry

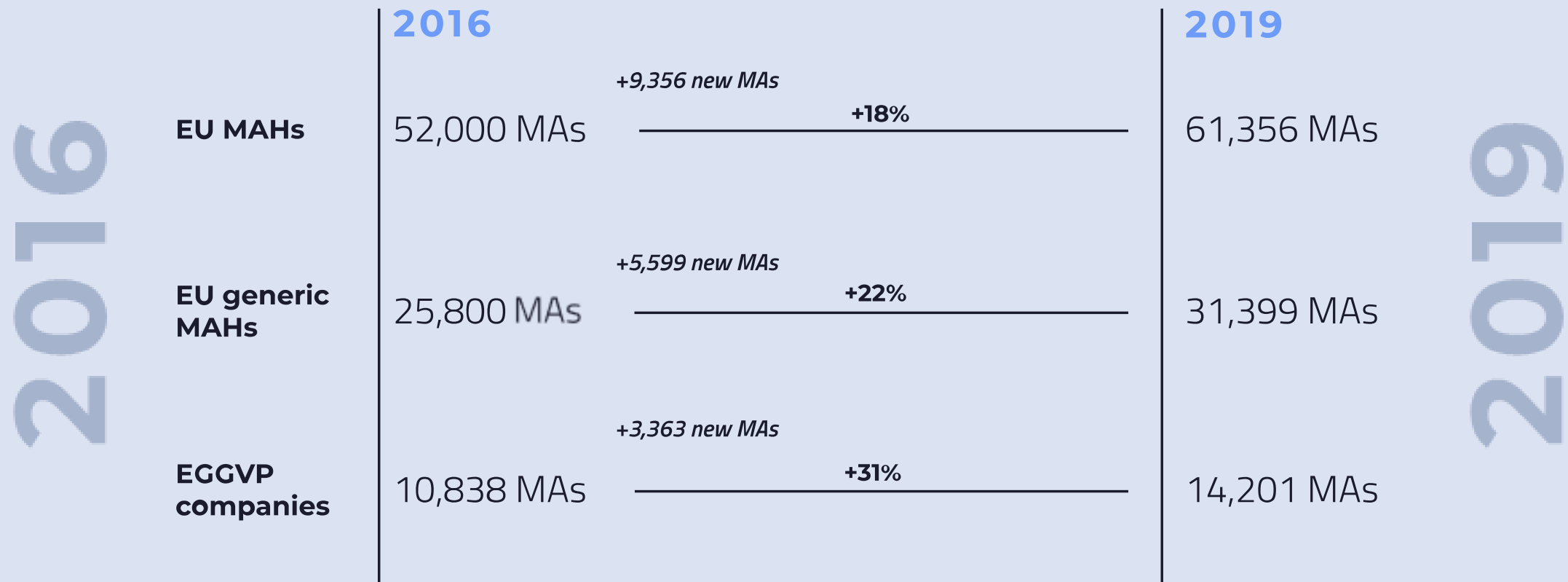
Employees – generic companies in Europe



Generic companies were active in new registrations

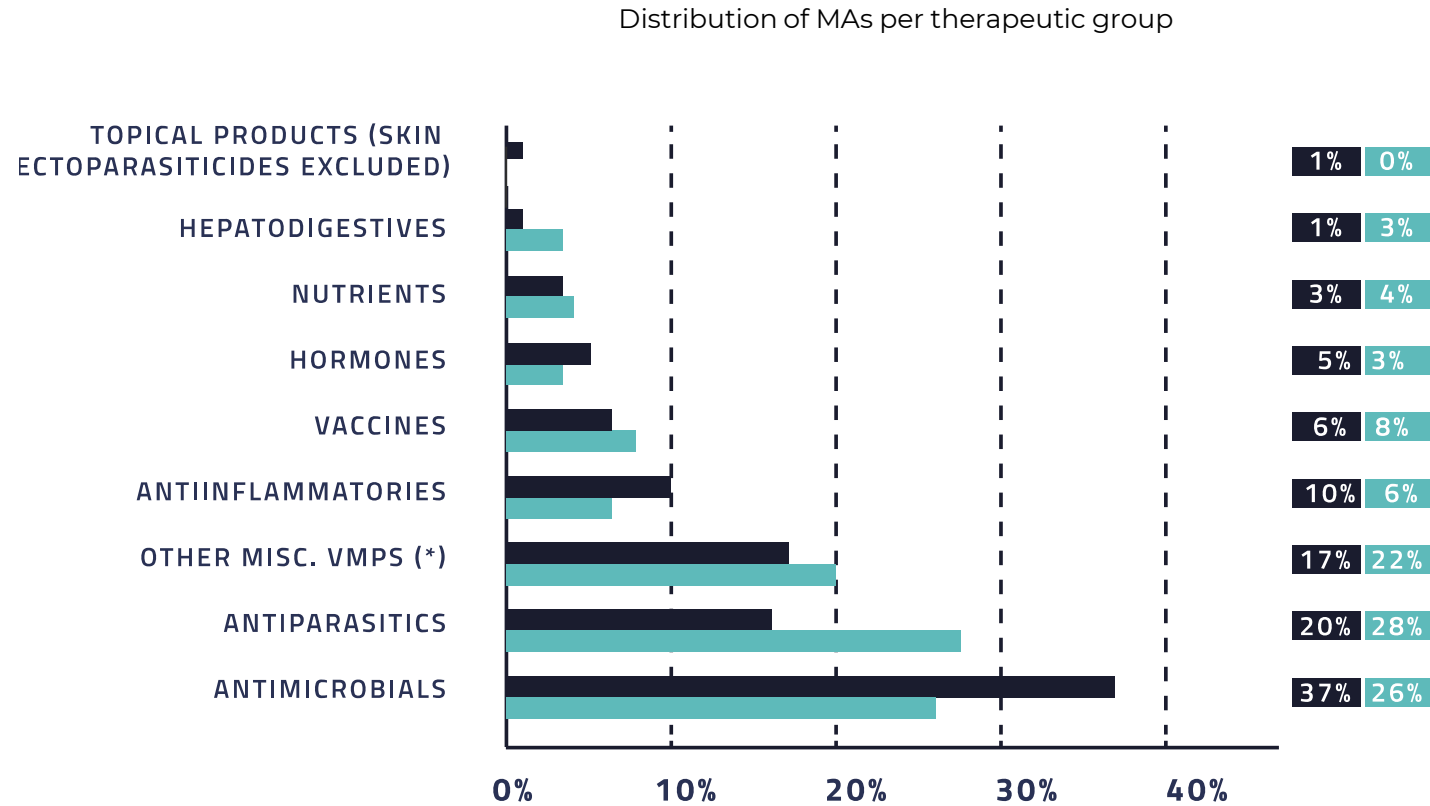
The generic industry held over half of the new authorisations during 2017-2019

Number of authorisations granted in Europe



Generic companies cover most therapeutic groups

The share of new authorisations for antimicrobials registered by generic MAHs has decreased during 2017-2019.



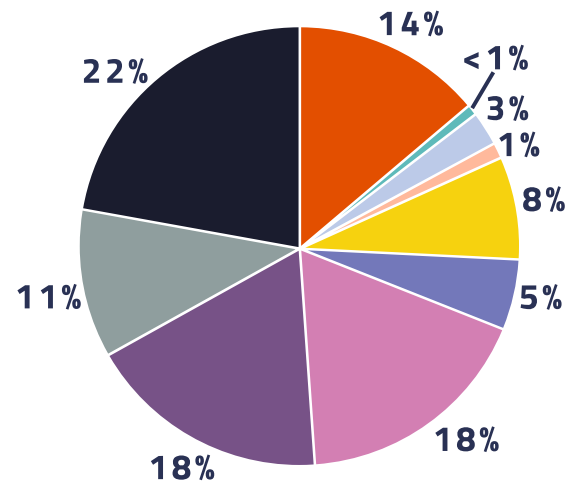
Up to 2016
2017 to 2019

(*) 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, combos (VMPS associating various therapeutics such as antimicrobials+NSAIDs)

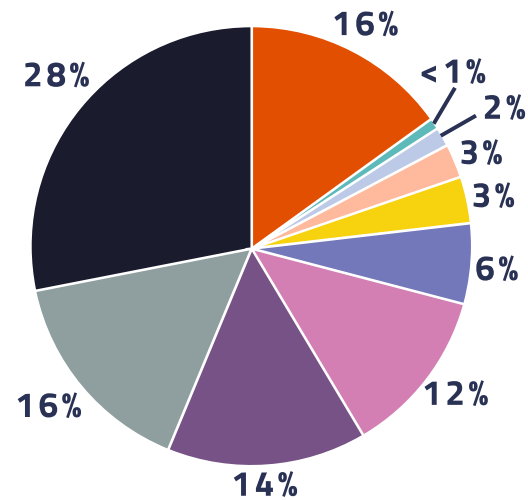
Significant increase in authorisations of products for companion animals

Decrease in food producing animal product authorisations.

Up to 2016



2017-2019



Base : MAs held by generic companies. Estimation based on 18,115 MAs for which the specie was informed.

Base : MAs held by generic companies. Estimation based on 3,066 MAs for which the specie was informed.

Generic companies have a significant impact on availability of treatments

The generics companies cover also minor species having over 4,000 authorisations for MUMs*

Authorisations held by generic companies for minor species

	Up to 2016 Number of MAs	%	2016-2019 Number of MAs	%
HORSES	809	29.3	678	45.6
OTHER EQUINES (**)	565	20.5	23	1.6
RABBITS	353	12.8	129	8.7
GOATS	336	12.2	215	14.5
ORNAMENTAL BIRDS	210	7.6	63	4.3
MULTIMINOR SPECIES / OTHER MINOR SPECIES	153	5.5	135	9.0
DUCKS	101	3.6	36	2.4
OTHER FISHES	64	2.3	17	1.1
FERRETS	46	1.7	64	4.3
BEEES	44	1.6	38	2.6
PIGEONS	32	1.1	23	1.5
GUINEA PIGS	27	1.0	26	1.8
MICE/RATS	20	0.8	27	1.8
CAMELS	1	0	13	0.8
TOTAL	2761	100%	1487	100%

* MUMs: Multi minor species: includes MAs indicated for several types of minor species (for example exotics, rodents, small mammals, reptiles). Other minor species include: reptiles, exotics, foxes.

** Other equines: includes pony, asses (such as donkey) and zebra.

Generic veterinary medicines companies at a glance

Generic veterinary medicines marketing authorisation holders in Europe 2016–2019

6.5% increase in the **number of generic marketing holders** based in Europe

197 companies

1/3 of total **European animal health market**

x

54% of animal health sector employees are working in **the generic industry.**

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