# What Role do Generics Play in Animal Health?

PEER REVIEWED

**What Is a Generic Medicine?**
Generic medicines are those whose original patent has expired and may now be produced by manufacturers other than the original innovator. Why, as consumers, do we tend to favour the brand leader products over generic competitors? Some of the reasons might include the belief that the product is better quality or that it's simply the product you've always used.

**Are Generic Drugs As Good as the Brand Leader?**
The active ingredient(s) in a generic medication must be bioequivalent to that of the brand leader. This means that it must be proven to have the same effect as the original product.

Generic pharmaceutical products in the animal health market must undergo the same rigorous processes for approval as brand leaders, known as marketing authorisation (MA). This comprises an extensive, independent and analytical review which is carried out to ensure the product is safe, efficacious and of a high quality.

Only following this in-depth review can the product be granted a marketing authorisation.

In order to obtain a marketing authorisation, a manufacturer must submit a data file which contains the results of all studies carried out to assess and demonstrate the safety, quality and efficacy of the product. To give an idea of how in-depth this is, the data file may contain anywhere between 5000 and 500,000 pages.

The review alone can take up to three years to complete due to the complexity of analysis and time required to evaluate the sheer volume of data! The whole process from inception of a product to the granting of a marketing authorisation can be anywhere from 5-15 years and cost up to £50 million. This process is ultimately designed to protect the public, animals and environment from poor-quality or unsafe pharmaceuticals, which is why it must be so thorough.

Any poor-quality, sub-standard products will be identified at this stage, refused a marketing authorisation and will never be sold. As a result, you can have confidence that any product, whether brand leader or generic, that has survived this process is safe and effective.

**The Objectives of Registration are to Ensure:**

- Safety: The product must be safe for the animals treated, the end user/consumer of any animal products, the person administering/applying the product and the environment.
- High Quality: The product must be of consistent high quality, does not deteriorate and has the stability to last until the expiry date stated.
- Efficacy: The efficacy of the product must conform with all claims made on the information leaflet and labelling.

**Product Quality and Efficacy**
Quality is paramount to ensure that the product is effective and this means that it must be manufactured according to very specific standards of purity and consistency. These standards apply throughout the production and formulation process.

In addition to proving all of the above we must also ensure that the product is stable, i.e. that if used prior to the expiry date on the label then the product will be just as efficacious, potent and safe as the day it was produced.

**Are Generics Subject to the Same Quality Control?**
Yes. All animal medicines, whether manufactured as a brand leader or as a generic, must undergo the same level of rigorous quality control. It is the responsibility of the manufacturer to ensure than an animal medicine contains only the ingredients which are specified on the data sheet in the exact proportions documented. Analytical testing is used to ensure purity and these methods are continually being assessed and improved upon.

**Generic Products will Meet Expectations**
Data must also be provided to prove that the product is effective in treating or preventing a particular medical condition. Thus the customer can be confident that, when used as directed, the product will meet its label claims. To support this claim, the product is tested extensively in the laboratory, in disease challenge trials and finally in field trials, which will demonstrate that the product works well under all scenarios.

**Scientific Assessment by Independent Experts**
During the marketing authorisation process, a committee composed of independent experts will evaluate all of the studies and information submitted in the data file. Their experience and extensive knowledge will ensure that they make objective judgements and they have the power to request further trial work if deemed necessary to ensure the correct conclusion. If any additional expertise is required, a leader in the appropriate field can be utilised to ensure that any decisions are accurate and based on the highest degree of knowledge. These experts have no conflicts of interest, meaning that the outcome of their assessment is completely unbiased.

**Pharmacovigilance**
Animal health products are also subject to strict pharmacovigilance controls. Pharmacovigilance is defined by WHO as: "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem". Manufacturers are required by law to establish and maintain a pharmacovigilance system for their products which ensure that all reports of suspected adverse reactions (or any other unexpected effects) are reported by vets, SQPs or consumers. The company must submit a regular summary report of all recorded incidents for examination. This ensures that any potential issues with a product can be detected, the impact assessed and, if necessary, action taken.

**What are the Benefits of Using Generic Products?**
Generic products cost less than brand leaders, so cost of treatment per animal is reduced.
This allows greater margin on farm while still having the same desired effect and in turn means producers can invest more in their systems and ensure greater welfare standards.

The introduction of generic products will also increase competition within the market for that active ingredient, making it more affordable to the end user.

Products under the categories POM-V* or POM-VPS*, NFA-VPS* are all subject to these strict criteria, so you can be certain of their quality and that they will meet their label claims. As a result, you should have no reservations when recommending generic products of this classification (where the active ingredient is clinically appropriate).

It's worth noting that there are many animal health products which are known as AVM GSL* items and these are not subject to the same rigorous analysis and evaluations. When you select products within this category you must do your research and, if in doubt, speak to a vet, SQP or the relevant manufacturer to ensure you are utilising a good quality product with extensive trial work which demonstrates the efficacy of the product.

To summarise, the rise of generics in the animal health industry is, in my view, a positive. Generics allow vets and SQPs to offer their clients an efficacious medicine at a lower cost.

**Definitions***
POM-V. A veterinary medicinal product (VMP) can only be supplied to a client by a veterinary surgeon following a clinical assessment of an animal (or a group of animals) under the care of the veterinary surgeon.

**CD- Controlled drugs**. Controlled drugs are those which may be subject to misuse if not properly monitored and are listed in schedule 1-5. The uses of these products must be carefully recorded by the veterinary surgeon.
**POM-VPS.** Veterinary medicinal products under this classification can be prescribed by a vet, SQP or a pharmacist. No clinical assessment of the animal is required by the prescriber, however it is their responsibility to ensure they obtain information about the animal(s) to ensure that it is an appropriate and safe use of that product.

**NFA-VPS.** This category is for products intended for non-food-producing animals (such as pets). The products in this category can be supplied by a vet, SQP or pharmacist, ensuring the prescriber obtains sufficient information to ensure that the product selected is safe and appropriate.

**AVM-GSL.** There are no legal restrictions – anyone can supply these products (Authorised Veterinary Medicine – General Sales List).

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