EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 January 2014
EMA/716205/2013

Annual Report from the SME Office 2013

Focus on Veterinary SMEs

The European Medicines Agency launched an initiative to provide financial and administrative assistance to micro, small and medium-sized enterprises (SMEs) in December 2005.

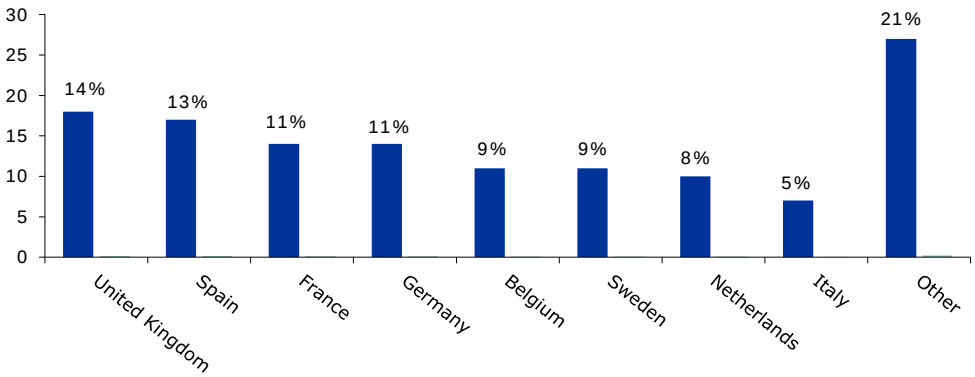
This year's overview of experience focusses on SMEs active in the veterinary field.

An overview of registered SMEs active in the veterinary field

A total of 1258 SME companies were registered with the EMA at year end. The large majority of companies registered with the EMA are developing medicinal products for human use (75%), 4% [52] are veterinary companies, 6% [77] companies are developing products for both human and veterinary use and the remaining 15% can primarily be categorised as service providers.

The relative size of registered companies active in the veterinary field was 39% of micro-sized companies (<10 staff), 32% small-sized, and 29% medium-sized. The average headcount was 43; the average turnover: 8.7 mil €; the average balance sheet total 14 mil €). The highest proportion of companies was based in the United Kingdom, Spain, France and Germany (Figure 1).

Figure 1: Place of establishment of SMEs active in veterinary field



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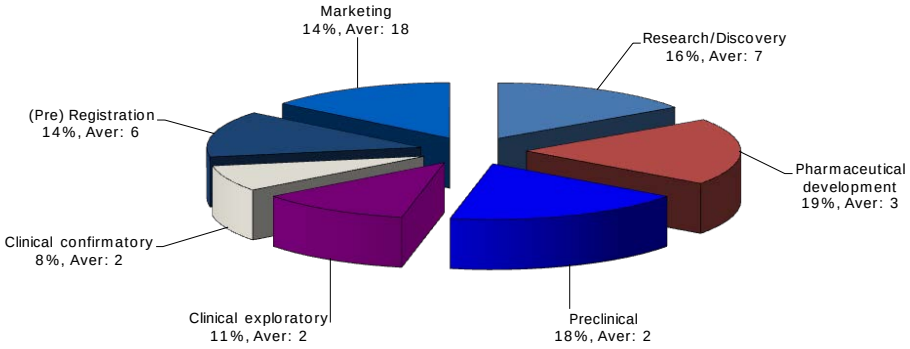
The large majority of veterinary SMEs are research and development stage companies (see Figure 2). Therapeutic medicines account for the highest proportion of the pipelines (76%), with vaccines representing 17% and diagnostics 7%. Looking at the types of product under development, the broad breakdown into chemical entities vs. biologics is 59% and 41% respectively.

Figure 2: Phase of product development of SMEs, including average number of products per phase



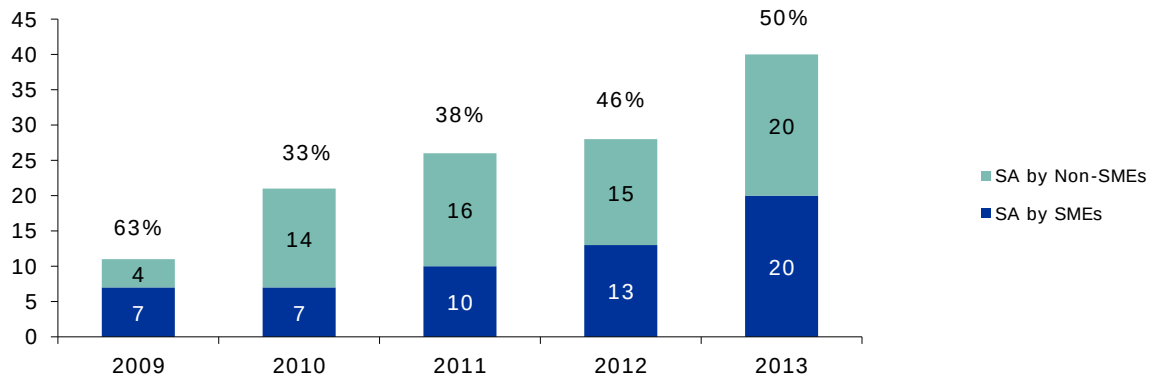
Scientific advice, Minor use / Minor species policy and Innovation Task Force for veterinary medicines

A policy aimed at stimulating applications for Minor use/Minor species (MUMS)/limited markets was introduced in September 2009. In 2013 a total of 23 requests were received, with 7 originating from SMEs (30%).

The number of scientific advice for veterinary medicines submitted by SMEs increased over the last 5 years in absolute terms and as a percentage of overall requests. In 2013 advice was provided on efficacy (39%), safety (33%), quality (18%) and MRL issues (10%). Sixteen requests related to products classified as MUMS by CVMP.

34 CVMP advice letters were issued in 2013 one of which was a parallel SA with FDA. A number of requests for scientific advice related to innovative veterinary products and new classes of therapeutics for animals including monoclonal antibodies, bacteriophages and stem cell products.

Figure 3: Figures for scientific advice received



Innovation Task force

The scope of the Agency's Innovation Task Force (ITF) was extended in 2013 to veterinary medicines. The ITF is a multidisciplinary group that provides a forum for early dialogue with applicants, in particular SMEs, to identify scientific, legal and regulatory issues relating to emerging therapies and technologies. It holds briefing meetings with applicants to cover issues arising in the development of innovative medicines or technologies. It aims to facilitate informal information exchange and early provision of guidance in the development process.

SME outcomes through the centralised procedure

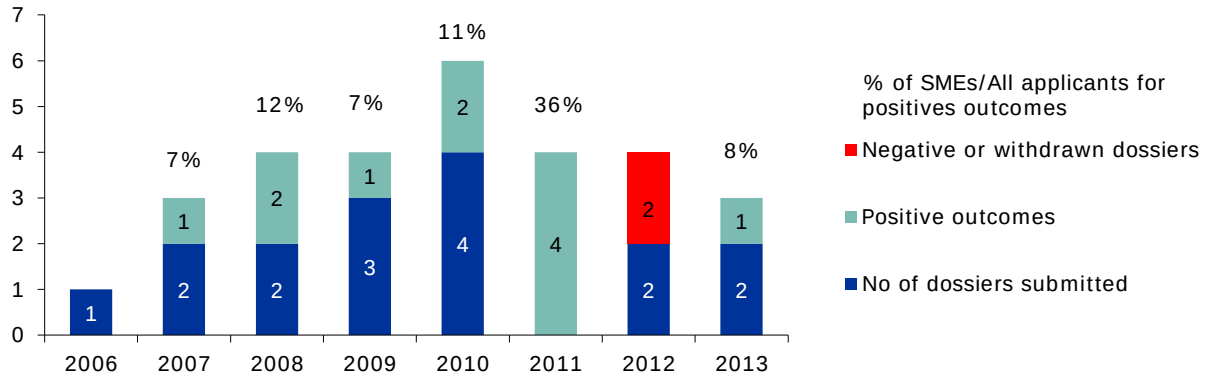
From December 2005 to December 2013, 16 marketing authorisation applications (MAAs) were submitted by SMEs for veterinary medicinal products.

To date, for veterinary medicines, there have been 11 positive and 2 negative outcomes (withdrawals), with three applications currently on-going.

The profile of products authorised includes 1 new chemical entity, 2 vaccines and 8 generics.

Future applicants are encouraged to contact the EMA's veterinary division to discuss their strategy for submitting marketing authorisation applications (vet.applications@ema.europa.eu)

Figure 4: SME applicants - MAA outcome by year for veterinary medicines (2006-2013)



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