



ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES

## The Veterinary Medicine Directorate – Work as a Reference Member State

### Background

There are a number of procedures by which national Marketing Authorisations may be obtained. The predominant procedures are Mutual Recognition and Decentralised. In both of these procedures one member state takes the lead of the assessment of the data: this member state is called the Reference Member State (RMS).

The UK regularly acts as RMS and it is one of the areas of work where the VMD focuses its scientific and administrative resource.

### Extent of experience as RMS

The VMD has acted as RMS in a significant number of both Mutual Recognition and Decentralised procedures. In the years 2006 to 2009 the VMD acted as RMS on more occasions than any other member state, acting as the RMS in 64 Mutual Recognition procedures and 55 Decentralised procedures. The VMD does, therefore, have a lot of experience which has been gained by both assessing and processing a variety of application types.

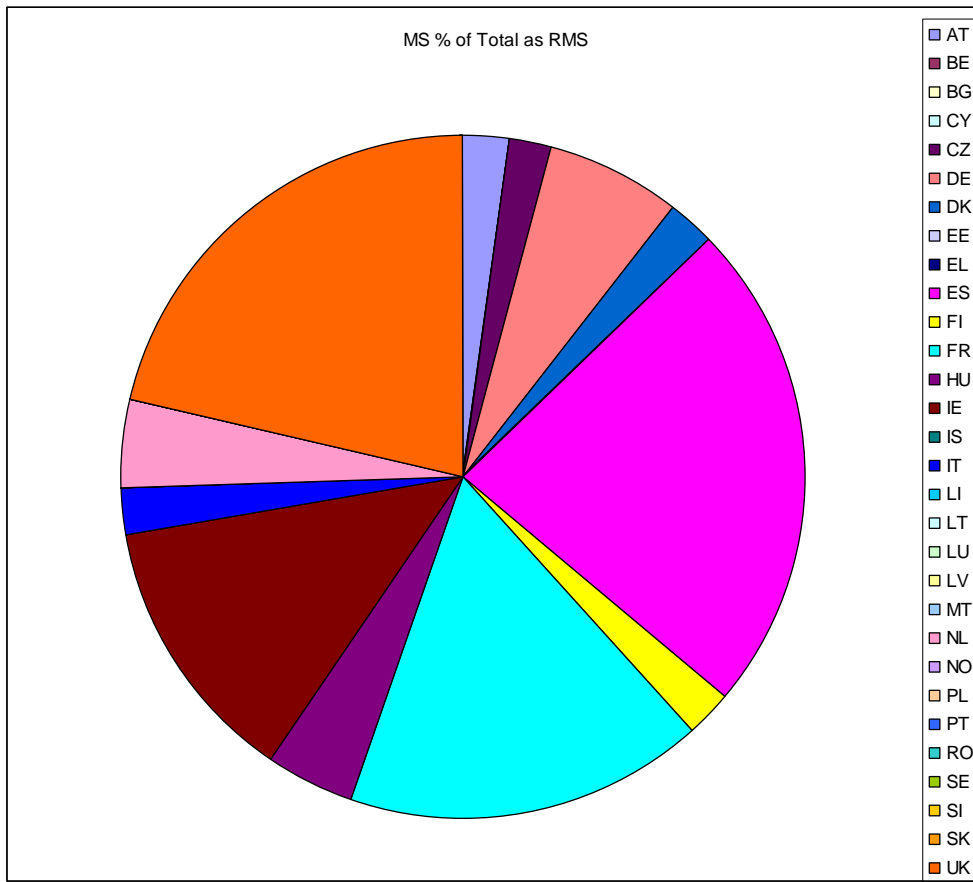
Table 1 sets out the actual number of times a member state has acted as RMS in Mutual Recognition and Decentralised procedures in 2009.

**Table 1:** Number of times a country has acted as RMS in 2009

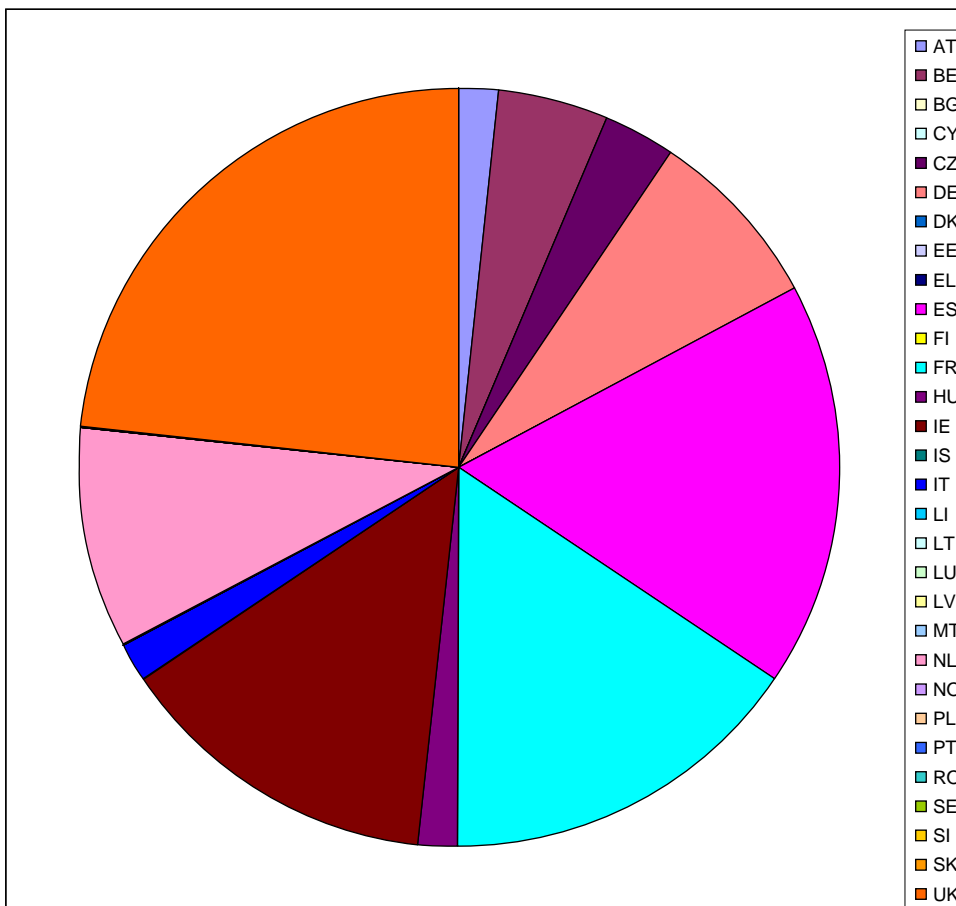
Country (code)	Mutual Recognition	Decentralised
UK (UK)	10	15
Spain (ES)	11	11
France (FR)	8	10
Ireland (IE)	6	9
Germany (DE)	3	5
The Netherlands (NL)	2	6
Belgium (BE)	0	3
Czech Republic (CZ)	1	2
Hungary (HU)	2	1
Austria (AT)	1	1
Italy (IT)	1	1
Denmark (DK)	1	0
Finland (FI)	1	0

Figures 1 and 2 below from 2009 represent the percentage of procedures in which each member state has acted as RMS as compared to the total number of procedures that member state has been involved in.

**Figure 1: Mutual Recognition Procedure (2009)**



**Figure 2: Decentralised Procedure (2009)**



## **Pharmaceutical industry views**

The VMD surveys its pharmaceutical industry customers every 2 years. The most recent survey was started towards the end of 2009 and reported on early in 2010.

The first phase of the survey, the qualitative phase, revealed that EU customers were content with the service provided and commented on the VMD's flexibility of approach, precision and willingness to go the extra mile to resolve issues quickly.

The following is a summary of the feedback from more than 25 companies that the VMD received as part of the quantitative part of the survey in terms of its performance as RMS:

- The VMD was considered to be good or excellent by more than 90% of the respondents in the areas of: approachability, courtesy and reputation in Europe.
- The VMD was considered to be good or excellent by more than 90% of the respondents in the areas of: helpfulness, quality of advice and scientific assessments, flexibility of approach, value of company meetings, and ability to leave a message and receive timely feedback.

As part of the survey people were asked how the UK compared with some of the other member states who are active as RMS. Of the 24 parameters examined, the respondents considered the VMD to be the highest performing member state for 19 of them.

The only area where the VMD was considered to be slower than some of the other member states was in the area of approval of mock-ups. This is a stage that applies when the UK is RMS or CMS. As a result of this feedback steps have been taken to reduce significantly the time the VMD takes to approve mock-ups.

## **Further information**

As of May 2010 the VMD has 170 posts, with more than 50 scientists with a very wide range of expertise in veterinary medicines. Pharmaceutical industry fees fully fund the posts held by individuals who are involved in the assessment and progression of Mutual Recognition and Decentralised procedures.

VMD scientists and regulators play a significant and prominent role within the European arena, including the CVMP and its Working Parties and the CMDv. In doing so they have developed strong links with their counterparts in other European Agencies. The VMD plays an active role in the development of guidance notes and fully understands the requirements detailed within.

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Feedback received from applicants who meet with the VMD to discuss potential products highly rate the quality of the scientific and regulatory advice provided.

If companies wish to submit an application using the UK as RMS they are free to choose the timing of this. The VMD does not operate a booking system, nor does it have a queue of procedures waiting to be initiated.

The VMD is willing to act as RMS for any application, with the sole exception of those for a generic product which relies upon a reference product for which there is no corresponding UK authorisation. The reason for this is that without full access to the underlying data for the reference product the VMD would be unable to undertake a robust assessment of the application.

When acting as the RMS in a Mutual Recognition procedure the UK defends the scientific assessment which led to the issue of a UK Marketing Authorisation. When acting as the RMS in a Decentralised procedure the UK scientifically assesses the data provided and reaches a decision on whether the veterinary medicine has a positive or negative benefit:risk balance. The VMD will help companies understand any questions that arise and will discuss potential ways in which arguments or new data can be presented to address any such questions.

If you are interested in using the VMD as the Reference Member State for a new Marketing Authorisation application and wish to organise a meeting to discuss your application then please contact Chris Abbott ([c.abbott@vmd.defra.gsi.gov.uk](mailto:c.abbott@vmd.defra.gsi.gov.uk)). Alternatively, if you wish to use the VMD as a Reference Member State and are confident that a meeting is not required then please contact Gavin Hall ([g.hall@vmd.defra.gsi.gov.uk](mailto:g.hall@vmd.defra.gsi.gov.uk)).