While fewer companies choose MRP rather than DCP today, the MRP route is still an alternative regularly used by industry. Figure 1 only covers two years, but illustrates this point – the numbers of MRPs are lower than they used to be, but MRP is still an option regularly used by industry.

The CMDv can provide the following advice to applicants to help minimise some of the common pitfalls that can cause delays to the start of the procedure or indeed its conclusion. Essentially the message is that a little preparation and research prior to triggering the MRP may save aggravation towards the close of the procedure when all parties – applicant, reference member state (RMS) and concerned member states (CMSs) – are under greater time constraints and pressure.

The following are points for consideration:

- Discuss MRP with the RMS: Prior discussion with the RMS is strongly encouraged, particularly where older products are concerned. The RMS will be able to offer advice on the data and what may be required to help facilitate MRP. The product will be new to the CMSs and therefore there is an expectation that the data package meets modern requirements.
- Homework: The CMDv would also encourage potential applicants to consider the CMSs to be included in the procedure. The applicant could reflect on issues such as the disease profile in that member state and the need for such a product (taking into account availability of alternatives) and whether this would be a factor in the decision-making process. If in doubt, speak to the

Figure 1: Numbers of DCPs and MRPs completed between September 2013 and September 2015.

Source: Veterinary Medicines Directorate.
relevant national competent authority (NCA), seeking its views on a potential application. This may or may not alter your chosen CMSs, but you would have a more rounded picture before the submission is made.

- The product name and labelling: Once the applicant has decided which CMSs to include, give some thought to the product’s invented name – would this be acceptable to CMSs? Would this be something that is better discussed upfront rather than towards the end of the procedure? Also, would some of the proposed CMSs require multi-lingual labelling? The RMS and CMSs will need to be informed of this at the start of the procedure – this should not be something that is considered at the end. Again, early consideration of CMSs’ needs may prevent questions or ease pressure during an intense period towards the close of the procedure. With agreement of the invented name, it may even prevent delays to marketing the product, or require a variation after the MRP.

- Validation: This exists, so don’t forget to take this into account when you are planning a submission, or time to market, time line. CMDv members often see that the time taken to validation is not fully thought through, particularly if the applicant wants to meet a specific procedure start date.

Applicants should refer to CMDv guidance on validation requirements; make sure the submission meets these needs. (Please see the CMDv pages of the Heads of Medicines Agencies (HMA) website for further information).

Hopefully the above will help in some small way to make things easier for applicants when submitting future MRP applications as well as for the NCAs. The CMDv will be playing its part in helping to harmonise processes and requirements across the European Regulatory Network, which will also contribute to a smoother, more efficient authorisation process.

Further information relating to the CMDv, its activities, Best Practice Guides and guidance can be found on its webpages of the HMA website (www.hma.eu/159.html). The CMDv would also encourage use of the RSS feed option to ensure you receive alerts to newly posted documents.

Further reading
1. Commission communication on the Community marketing authorisation procedures for medicinal products (98/C/229/03).

The CMDv can provide advice to applicants to help minimise some of the common pitfalls that can cause delays to the start of an MRP procedure.

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