



European Medicines Agency

EMEA/MB/301036/2009
Management Board meeting 11 June 2009
Agenda point 18 For discussion

Resource requirements of the CVMP

Background note

Having observed its workload continuing to increase since its inception, the Committee for Medicinal Products for Veterinary Use (CVMP) requested the Secretariat to carry out a study in order to quantify the evolution of the duties assigned to the Committee over the past few years.

A number of procedures considered important for the core business of the Committee have therefore been analysed in order to quantify the increase in workload. The data used for this exercise consists of procedures directly related to products, thus easily quantified, and also surrogate data for activities that are less quantifiable but still representing an increase in workload.

In recent months this exercise has gained a new urgency and importance due to a further increase in the number and size of referrals. The situation with regard to referrals has rapidly reached a point where the committee will shortly be unable to fulfil its duties within legal deadlines unless urgent measures are taken to manage the increase in workload.

Matters for consideration

After the analysis was presented to the CVMP at its February 2009 meeting, the Committee expressed its wish that this analysis be brought to the attention of the Management Board. The study showed that the overall activity has substantially increased for the period data was available (2001 to 2008). The upward trend on CVMP workload is continuing, particularly in the area of referrals, and there is no indication that it has yet stabilised. The Secretariat and the Committee have already taken a number of measures to improve efficiency and the scope for further improvement without radical changes is now limited.

The EMEA is preparing to propose measures to deal with the substantial and sustained increase in the number of referrals that will be outlined to the board when developed. Any proposed measures will require endorsement by the Management Board, the European Commission and by HMA as they will involve both identifying additional resources for scientific assessment and agreeing a mechanism whereby the number and timing of referrals is agreed in relation to the resources available to deal with them.

A Review of the Evolution of the Workload of the CVMP

Introduction

During recent years the Committee for Medicinal Products for Veterinary Use (CVMP) has noticed a considerable increase in the number of issues addressed during its monthly meetings. At the June 2008 meeting, the Head of Veterinary Medicines and Inspections (VMI) Unit was requested to prepare a study on how the CVMP workload has evolved over the years from its first composition to the present day. The Head of Unit (HoU) Support provided the data required for this report in conjunction with the two Veterinary Sectors, namely; the Veterinary Marketing Authorisation Procedures (VMAP) Sector and the Safety of Veterinary Medicines (SVM) Sector. In the sections that follow a number of procedures are examined in order to study their progress and their potential impact on the Committee's workload.

Materials and Methods

The data collected was differentiated into data on procedures directly related to products (e.g. applications, variations) and a surrogate estimate of overall activity, taken as the number of documents included in the mailing and the number of meetings the Committee members attended in the context of collaboration with other Institutions.

The CVMP deals with an extensive area of responsibilities. However, for this report, only the activities considered representative for its core business have been examined. The report also took into account the following restrictions, mainly due to the nature of these activities;

- Not all CVMP activities are quantifiable (e.g. cooperation with the EC, international cooperation – harmonisation, safety, etc). Despite the fact that the report does not include the aforementioned categories individually, Figure 8 '*Average number of documents discussed at CVMP meetings*' is intended to give the trend for general issues discussed during meetings.
- There are also activities where a simple analysis of numbers does not give an accurate estimate of their impact in terms of the workload involved because there is so much case-to-case variation in the level of complexity and input required. However, the study showed that, even in these cases, the number of such activities is increasing. For this category the following activities were examined; number of referrals submitted to the CVMP, PSURs and oral explanations.
- Finally, there are the applications that are validated by EMEA and subsequently examined by CVMP. For this type of activity the number of application should be indicative of the general trend. This category includes the number of applications submitted, the number of opinions adopted, and the number of Type I and Type II applications processed.

Results

Measures of the activity of CVMP since the inception of the EMEA are represented in Figures 1 to 9.

Figure 1 demonstrates that, notwithstanding a low number of applications submitted in years 1997 and 1999, there has been a steady increase in the number of applications submitted for the Centralised Procedure during the last thirteen years.

For the number of opinions reached (Figure 2), although we can observe a fluctuation in the number of CVMP opinions over the years, in the long run the trend is upward. The positive slope of the trendline on the graph also makes this obvious.

In the area of post authorisation activities (Figures 3 and 4) we can also observe an increase in the number of variations. This increase is more evident for Type II variations, where the respective number has more than doubled between 2006 to 2007 i.e. from 21 variations to 46; a figure that is expected to be reached also this year.

The figures that follow (Figures 5 to 7) plot the numbers of PSURs and of referrals submitted. Despite the fact that the workload involved for these procedures relates not only to their volume but also to their complexity, both indicators show an increase in absolute numbers, with a 96% increase in the number of PSURs and over a four fold increase in the number of referrals submitted between 2004 and 2008. For PSURs this is likely to be a sustained increase, for referrals it is not yet known the observed increase represents a temporary surge following the introduction of the revised legislation or is an indication of a longer term trend. For Figure 7, the peak in oral explanations for 2002 was due to a particular referral (related to benzathine penicillins) that resulted in a high number of oral explanations.

Finally, as a measure of overall activity, Figure 8 shows that there has been an average yearly growth of 19% since 2004 in the overall number of documents discussed during CVMP meetings, with a 108% increase between 2001 and 2008. In terms of CVMP collaboration with other Institutions, Figure 9 illustrates the number of meetings the Committee's members attended over the period 2001 to 2008. In this case, there was an average rate of growth of 18% per annum over this period.

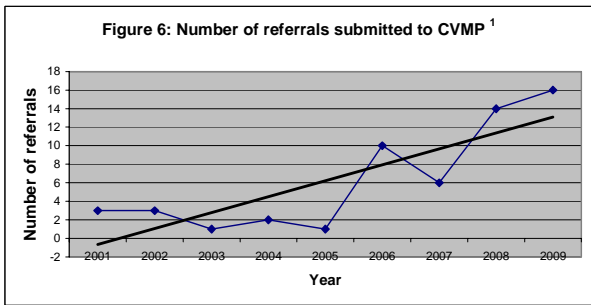
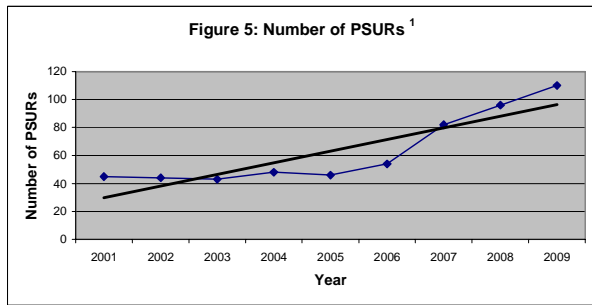
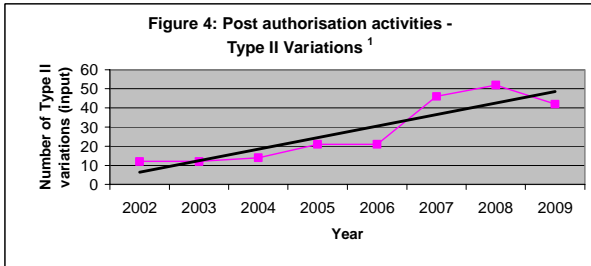
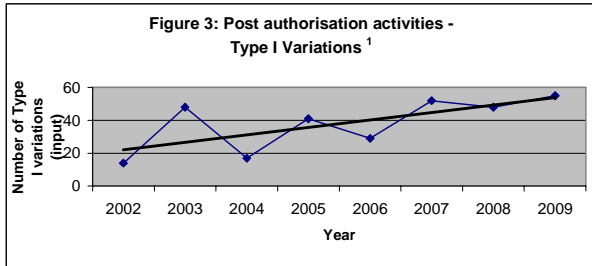
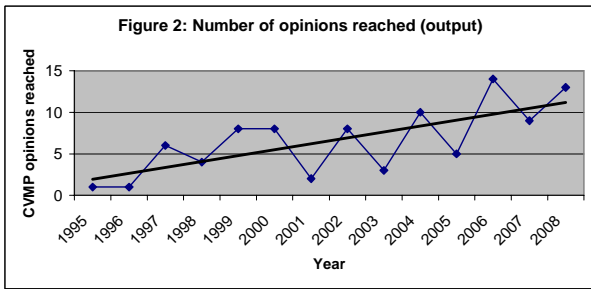
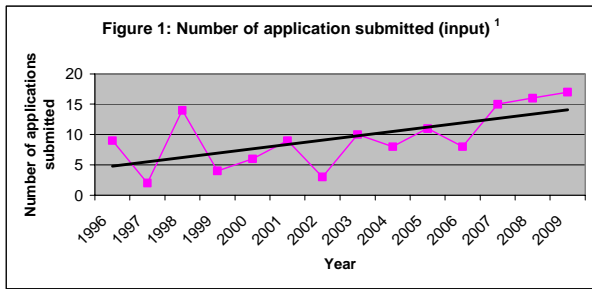
Conclusions

This report gives an outline of the CVMP workload during recent years. To that end a number of procedures considered important for the core business of the Committee have been analysed.

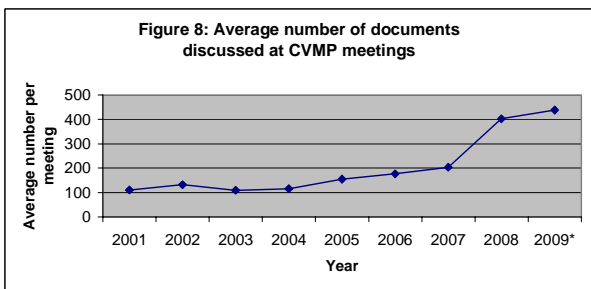
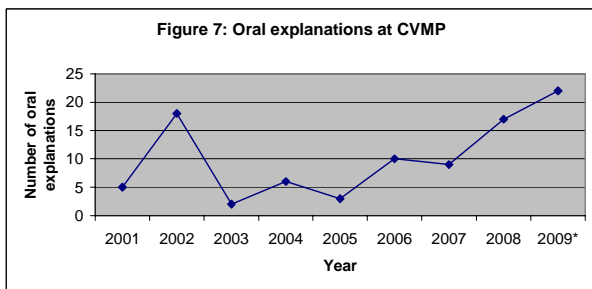
Even taking into account the semi-quantitative nature of several of the measures, it is clear that the workload of the committee, and therefore the resources required, has increased substantially. There is no indication at the present time that this trend is slowing down or reversing. The review of legislation and consequent change in composition of the committee is not considered to have been helpful in dealing with the increasing workload and may actually have exacerbated the problem.

The committee and the secretariat have introduced a number of measures to improve efficiency including longer working hours, the introduction of parallel breakout sessions, the amendment of the agenda, and the use of 'Vitero' meetings. The scope for further improvements is now limited and the Strategic Planning Group now recommends clear prioritisation of tasks to ensure that important work is progressed whilst other tasks are re-scheduled in line with availability of resources.

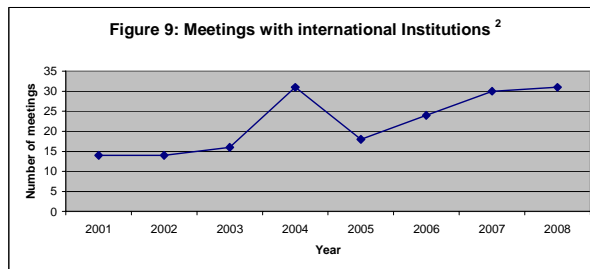
Figures of CVMP Activity



Source: EMEA 'SIAMED' database, CVMP Monthly reports, EMEA Annual Reports, Mid-year report 2008
 1 The number for the 2009 applications is based on the Work Programme 2009



Source: CVMP Agendas
 * Estimated for 2009



Source: MM&C Sector, EMEA
 2 Number of meetings of CVMP members with other institutions per year

Additional data on the increase in referrals handled by CVMP in 2009

