

REPORT FOR RELEASE

Meeting of 17-18 July 2008

Survey 2007: A SUCCESSFUL YEAR!

Mutual recognition (MR) and decentralised (DC) procedures continued to operate to at least a satisfactory level, thanks to good cooperation between applicants and the Member States.

The joint CMD(v)-IFAH Europe survey reported that the MR procedure is still widely used, though a slight decrease in the number of first and extension applications was noted in 2007; the number of MR repeat use procedure has, on the other hand, more or less doubled. The number of DC procedures has increased as it represents a fast track route for applicants to gain an authorisation simultaneously in different Member States.

The efforts of CMD(v) in resolving disagreements in procedures were reflected in a decrease in the number of referrals. CMD(v) also focused its efforts on a number of issues previously identified in the 2006 survey report, and also raised separately by IFAH-Europe and EGGVP, as obstacles to the successful operation of MRP and DCP. In the joint aim at success some areas outside the direct responsibility of CMD(v) were also highlighted on which the Industry should focus.

In close collaboration with Industry and the European Commission a number of areas related to generic applications were clarified, in particular the use of the European Reference Product. The requirement of the environmental risk assessment for generic applications has negatively influenced the number of applications and has also had an impact on the number of safety questions and subsequent referrals to CMD(v). However, the European Commission also provided greater clarity on this matter as well as on the data requirements. It is hoped that this and the precedents set at CVMP might reduce the likelihood of referrals in future.

It was noted how both Member States and applicants contributed to a constantly improved authorisation process thanks to the experience gained since the revised pharmaceutical legislation (Directive 2004/28/EC amending Directive 2001/82/EC) which entered into force in November 2005. CMD(v) will continue promoting the harmonisation of national requirements.

The full report is available on the websites of CMD(v) and IFAH-Europe.

Decentralised procedures - Updated guidance

A new edition of the best practice guide on the conduct of the decentralised procedures (BPG002) has now been published. In particular the role and responsibilities of the applicant and the Reference Member State during the procedure have been further defined.

Referral to CMD(v) - Updated standard operating procedure

A new edition of the standard operating procedure (SOP001) for referring a product to CMD(v) has now been published. Further details were included on the responsibility of the Reference Member State when referring the application to CMD(v) and the possibility to finalise the

CMD(v) referral procedure earlier than day 60 if consensus is reached. Also applicants are no longer required to provide paper copies when attending CMD(v) in the event of an oral explanation.

Product discussion

In July 2008, 8 products reached day 78 of the mutual recognition procedure and a further 3 reached day 198 of the decentralised procedure. Out of these, 2 were discussed at the meeting. Four referral procedures were tabled of which 3 were discussed. Agreement was reached on granting marketing authorisations for Enrogal 50 mg/ml solution for injection from Pharmagal s.r.o. which had been referred to CMD(v) in May.

	MRP	DCP	Referrals
<i>Procedures</i>	8	3	4
Products	8	3	4
Immunological	2	0	0
Pharmaceutical	6	3	4
Discussed	1	1	3

It was noted that following the June 2008 meeting no agreement was reached on granting marketing authorisations for 3 products, all following the MRP. The products were consequently referred to CMD(v) pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

French Presidency

The next CMD(v) informal meeting under the current French Presidency will take place in Paris - La Defense in October 1-2, 2008.

The CMD(v) is thankful to Sandrine Guët for her valuable support as the French CMD(v) member. Her temporary placement will end on 31 August 2008 when Laëtitia Le Letty returns.

Information

CMD(v) documents are available on www.hma.eu/cmdv.html

For further information, please contact the secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK wim.riepma@emea.europa.eu