

## REPORT FOR RELEASE

**April and May 2009**

### SPC harmonisation pilot

CMDv has invited industry representative organisations IFAH-Europe, EGGVP and AVC to propose products for a SPC harmonisation pilot. The aim is to test a mechanism based on work-sharing and industry participation for harmonising divergent Summaries of Product Characteristics of the same (nationally) authorised product.

It is envisaged that the mechanism allows for a pragmatic approach and involves less administrative burdens as compared to referral procedures to CVMP.

SPC harmonisation is important for strengthening consumer confidence, transparency in the market place and cost reduction for industry.

### Informal meeting

In the framework of the presidency of the European Union the Czech Republic organised an informal CMDv meeting and joint CMDv/CVMP meeting in Brno on 25 and 26 April. Items discussed included:

- Referrals – optimising procedures and cooperation between committees;
- Status and implementation of the new Variations Regulation;
- Electronic dossier submission;
- Annual survey of procedures and referrals;
- The communication and tracking system for procedures (CTS Client);
- Treatment of bees;
- Immunological generics and biosimilars;
- Meeting efficiency;
- Experiences of the Reference Member State.

### Product discussion April 2009

In April 2009, 6 products reached day 78 of the mutual recognition procedure and a further 4 products reached day 198 of the decentralised procedure. Out of these, 5 were discussed.

	MRP	DCP	Referrals
<i>Procedures</i>	6	4	6
Products	6	4	5
Immunological	1	0	1
Pharmaceutical	5	4	4
Discussed	3	2	5

It was noted that following the March 2009 meeting no agreement was reached on granting marketing authorisations for 3 products following the decentralised procedure. The products were consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

### Product discussion May 2009

In May 2009, 3 products reached day 78 of the mutual recognition procedure and a further 5 products reached day 198 of the decentralised procedure. Out of these, 3 were discussed.

	MRP	DCP	Referrals
<i>Procedures</i>	3	5	3
Products	3	5	3
Immunological	0	0	0
Pharmaceutical	3	5	3
Discussed	0	3	1

It was noted that following the April 2009 meeting no agreement was reached on granting marketing authorisations for 2 products, 1 following the mutual recognition procedure and 1 following the decentralised procedure. The products were consequently referred to CMDv pursuant to Article 33(1) of Directive 2001/82/EC, as amended, for a 60 day referral procedure.

### Information

CMDv documents are available on [www.hma.eu/cmdv.html](http://www.hma.eu/cmdv.html)

For further information, please contact the secretariat at the European Medicines Agency, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK [cmdv@emea.europa.eu](mailto:cmdv@emea.europa.eu)