

Report from the CMD(h) meeting held on 26th and 27th May 2009

Recommendation on extension of shelf-life for Relenza

A variation to extend the shelf life of Relenza (zanamivir), inhalation powder from five to seven years has been approved via mutual recognition procedure.

In view of the recent outbreak of the novel influenza A/H1N1 virus, the CMD(h) has also reviewed ways to use Relenza in case of a shortage. The CMD(h) recommends that Relenza that is already on the market may be used for up to two more years after its current expiry date during a declared pandemic. Patients who have Relenza that has recently expired should not throw it away, as it might be needed during a novel influenza A/H1N1 pandemic.

Sub-group meeting on Harmonisation of SPCs

There was a meeting of the Sub-Group on harmonisation of SPCs, to discuss the proposals from Member States for products for which a harmonised SPC should be drawn up.

The Group agreed to prepare the rationale for selection of the products to be included in the list for SPC harmonisation, addressing the agreed criteria, for discussion at the July Sub-Group meeting. The Group agreed also to consider differences in information on pregnancy and lactation and to take into account patients' perspectives when considering differences in SPCs between MSs.

The CMD(h) Sub-Group on harmonisation of SPCs will continue its work with a view to laying down a list of medicinal products for which a harmonised SPC should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended.

EU Work-sharing Article 45 of the Paediatric Regulation - Public Assessment Report

The CMD(h) has agreed the first public assessment report for paediatric studies submitted in accordance with Article 45 of the Paediatric Regulation.

The paediatric public assessment report for salmon calcitonin, including a recommendation for the text to be included in the SmPC, will be published on the CMD(h) website, under Paediatric data assessment, Assessment reports on paediatric data.

Marketing Authorisation Holders of medicinal products with the same active substance and pharmaceutical form are requested to include this information in their SmPCs within 90 days of publication of the public assessment report, in accordance with the Best Practice Guide – Article 45, EU Work-sharing procedure.

CMD(h) Recommendation for applications submitted according to Article 10 when the strength and/or the pharmaceutical form of the reference medicinal product differs between RMS/CMS(s)

The CMD(h) has agreed an updated version of the above mentioned recommendation, aimed at facilitating submission of applications under Article 10(1) and 10(3) of Directive 2001/83/EC, as amended.

Applicants are reminded that they should submit the same dossier in all MSs, even if some information is not necessary for a particular MS, as the strength and/or form is already licensed on their market.

Recommendations for Mutual Recognition Procedure after finalisation of a referral procedure with a positive decision by the European Commission

The CMD(h) has considered the comments received from Interested Parties during the public consultation of the above mentioned document and agreed a final version of the document, which will be published on the CMD(h) website, under Procedural guidance, post referral phase.

The CMD(h) recommendation covers the implementation of the Commission Decision, allocation of reference member state (RMS), maintenance of harmonisation following the referral, information on the handling of medicinal products not involved in the referral procedure, etc.

Information on applications referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended

Information on the name of the product in the RMS, active substance, pharmaceutical forms, procedure number, CMS, legal basis, grounds for referral to CMD(h), Day 60 and outcome of the procedure, for the referrals to the CMD(h) finalised on 29.04.2009 will be available on the table with information on all applications referred to the CMD(h), published under 'CMD(h)-Referrals'.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **21** Mutual Recognition Procedures were finalised during the month of April 2009. No Mutual Recognition Procedures were referred to CMD(h) in this period. There were **no** Mutual Recognition Procedures referred to CHMP in this period.

The status as of 30th April 2009 of procedures under Mutual Recognition is as follows:

Year	New applications finalised ¹	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h)		Withdrawn during CMD(h) referral	Applications referred to CHMP	
				For procedures referred in 2008	2009		For procedures referred to CMD(h) in 2008	2009
2009	117	75	5	2	2	0	0	1

28 Mutual Recognition Procedures (regarding **51** products) started in April 2009. The categories of these procedures are as follows:

23 abridged applications, including **1** multiple and **13** repeat use applications.

3 known active substance applications.

2 Line Extension applications, which are all repeat use applications.

The new procedures started in April 2009 related to **3** full dossier, **21** generic **1** bibliographic, and **3** hybrid applications.

27 of these procedures consisted of chemical substance products and **1** procedure consisted of a biological blood product.

¹ Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. The applications referred to CHMP are included in the 'new applications finalised.'

27 of these procedures related to prescription-only medicinal products and 1 procedure related to a non-prescription medicinal product in the reference Member State².

New applications in Mutual Recognition procedure started in April 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	1	8
Belgium		6
Bulgaria		8
Cyprus		5
Czech Republic	2	11
Denmark	3	6
Estonia	2	6
Finland		3
France	2	7
Germany	4	13
Greece		7
Hungary		11
Iceland		2
Ireland		4
Italy	1	8
Latvia		7
Lithuania		5
Luxembourg		5
Malta		4
Netherlands	8	13
Norway		2
Poland		10
Portugal	2	8
Romania		7
Slovak Republic		9
Slovenia		4
Spain		5
Sweden	3	8
United Kingdom		4

Decentralised Procedure

The CMD(h) noted that there were **54** Decentralised Procedures finalised with a positive outcome and **1** procedure finalised with a negative outcome. **4** Decentralised procedures were withdrawn after day 120 during the month of April 2009. No Decentralised Procedures were referred to the CMD(h) in this period. There were **3** Decentralised Procedures referred to the CHMP in this period.

The status as of 30th April 2009 of procedures under Decentralised Procedure is as follows:

Year	New applications finalised ³	New applications withdrawn (After day 120)	New applications in process	Referred to CMD(h)	Agreement reached in the CMD(h)		Withdrawn during CMD(h) referral	Referred to CHMP	
					For procedures referred in 2008	2009		For procedures referred to CMD(h) in 2008	2009
2009	258	17	1852	6	8	0	0	1	3

160 Decentralised Procedures (regarding **404** products) started in April 2009. The categories of these procedures are as follows:

157 abridged applications, including **42** multiple applications.

² In this category products are classified as prescription-only or Non-prescription (OTC) products when the RMS has approved them accordingly, although the legal status is not part of the Mutual Recognition Procedure.

³ Due to late database updates cumulative yearly figure differs from the monthly figures. Cumulative yearly figure includes late database updates on finalised procedures not captured in the monthly figures published in press releases. This cumulative figure includes positive and negative procedures as well as those referred to CHMP.

3 known active substance applications.

The new Decentralised procedures started in December related to **141** generic, **3** bibliographic and **16** hybrid.

All of these procedures consisted of chemical substance applications.

156 of these procedures related to prescription-only medicinal products and **4** procedures related to non-prescription medicinal products in the reference Member State⁴.

New applications in Decentralised procedure started in April 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		42
Belgium	8	37
Bulgaria		40
Cyprus		16
Czech Republic	1	55
Denmark	10	35
Estonia	1	25
Finland		32
France	6	38
Germany	27	81
Greece		33
Hungary	6	48
Iceland		3
Ireland	2	25
Italy	4	51
Latvia		28
Lithuania		29
Luxembourg		15
Malta		3
Netherlands	25	57
Norway	6	33
Poland		63
Portugal	16	46
Romania		39
Slovak Republic	1	45
Slovenia		21
Spain		38
Sweden	12	36
United Kingdom	35	53

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **561** type IA variations, **353** type IB variations and **313** type II variations were finalised during the month of April 2009. **56** renewals were finalised in this period. There were **no** procedures referred to the CHMP in this period.

⁴ In this category products are classified as prescription-only or Non-prescription (OTC) products as applied for in the RMS, although the legal status is not part of the Decentralised Procedure.

The status as of 30th April 2009 of variations and renewals under Mutual Recognition is as follows:

Year	Procedures from Type IA variations finalised	Procedures from Type IB variations finalised	Procedures from Type II variations finalised	Renewals finalised	Applications referred to CHMP
2009	2164	1148	1020	176	1

All documents mentioned in this press release can be found at the CMD(h) website under the heading *Press Releases*.

Information on the above mentioned issues can be obtained from the chair of the CMD(h) or from the CMD(h) Secretariat:

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<http://www.hma.eu/cmdh.html>