

Report from the CMD(h) meeting held on 20th and 21st July 2009

Relenza Rotacap/Rotahaler – Outcome of application for temporary distribution (Article 5(2), Dir. 2001/83/EC, as amended)

GSK, as marketing authorisation holder for Relenza Rotadisk/Diskhaler, has submitted applications to EU Member States in order to get a temporary authorisation to distribute Relenza with an unauthorised device (Rotacap/Rotahaler) during an influenza A(H1N1) pandemic situation.

The reason for the application is that the demand for Relenza cannot be met with the currently approved device (Diskhaler) because of limitation of production capacity. The legal basis for the application is Article 5(2) in Directive 2001/83/EC, as amended. The RMS has evaluated the application and is positive to the temporary authorisation to distribute under certain conditions. The conditions include the follow up in accordance with the risk management plan and collecting more in vitro data on performance at different flow rates.

The CMD(h) has coordinated the procedure with help from the RMS but it is up to the National Competent Authorities to decide whether the national distribution and use of the Relenza Rotacap/Rotahaler can be temporarily authorised during the pandemic taking into account the RMS assessment report and recommendation.

List of medicinal products for SPC harmonisation – Consultation with Interested Parties

The CMD(h) has agreed a new 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.

The list of medicinal products for SPC harmonisation will be published on the website for an eight week period for public consultation.

Any comments on the list of medicinal products for SPC harmonisation should be sent to the CMD(h) secretariat (H-CMDhSecretariat@emea.europa.eu) by **Tuesday, 22 September 2009**, coordinated where possible by trade associations.

CMD(h)/EMEA Sub-Group on Paediatric Regulation

The CMD(h) has agreed a document with Recommendations on Paediatric Use Marketing Authorisations (PUMAs), addressing background, legal basis of applications, accompanying documentation and rewards associated with PUMAs.

The document will be published on the CMD(h) website under Paediatric Regulation, Guidance Documents.

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

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

The paediatric public assessment report for simvastatin, including a recommendation for the text to be included in the SmPC and package leaflet, will be published on the CMD(h) website, under Paediatric Regulation, Assessment reports.

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

MRP/DCP started in the first two quarters of 2009 – Statistical information

The CMD(h) has agreed to publish statistical information on the MRP and DCP started in the first two quarters of 2009 per type of procedure, per type of product, per legal basis and per prescription status.

This information will be published on the CMD(h) website under 'Statistics'.

Referrals to CMD(h) in the first semester of 2009 – Statistical information

The CMD(h) has agreed to publish statistical information on the applications referred/concluded by the CMD(h) in the first semester of 2009, addressing referrals to CMD(h) per type of procedure (MRP vs DCP), per type of product, per legal basis, per therapeutic area, per grounds and per outcome. This information will be published on the CMD(h) website under ‘Statistics’.

CMD (h) guidance documents published on the website

Further to the evaluation of the functioning of the CMD(h) and in order to facilitate the search for guidance documents, the CMD(h) has agreed to publish the list of available documents that can be found under the respective headings.

This list will be published on the CMD(h) home page and will be updated on a regular basis.

Joint CMD(h)/Pharmacovigilance Working Party Working Group

Further to the evaluation of the functioning of the CMD(h), the CMD(h) agreed to make public the mandates and objectives of the various CMD(h) Sub-groups/Working Groups.

The CMD(h) has agreed to publish the mandate of the joint CMD(h)/PhVWP Working Group on the CMD(h) website, under CMD(h) Sub-groups.

NEW APPLICATIONS

Mutual Recognition Procedure

The CMD(h) noted that **35** Mutual Recognition Procedures were finalised during the month of June 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 June 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	182	79	9	2	4	0	0	1

24 Mutual Recognition Procedures (regarding **46** products) started in June 2009. The categories of these procedures are as follows:

12 abridged applications, including **3** multiple and **4** repeat use applications.

10 known active substance applications, including **1** multiple and **3** repeat use applications.

2 Line Extension applications.

The new procedures started in June 2009 related to **8** full dossier, **11** generic, **4** bibliographic and **1** hybrid application.

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.’

20 of these procedures consisted of chemical substance products, **2** procedures consisted of a biological vaccine product and **2** procedures consisted of a biological other product.

22 of these procedures related to prescription-only medicinal products and **2** procedures related to non-prescription medicinal products in the reference Member State².

New applications in Mutual Recognition procedure started in June 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria		7
Belgium		4
Bulgaria		6
Cyprus		1
Czech Republic	1	7
Denmark	4	7
Estonia		7
Finland	4	8
France		1
Germany	3	12
Greece		4
Hungary	1	8
Iceland		1
Ireland	1	5
Italy	1	5
Latvia		6
Lithuania		6
Luxembourg		4
Malta		1
Netherlands	5	10
Norway		3
Poland		5
Portugal		5
Romania		5
Slovak Republic		6
Slovenia		2
Spain		5
Sweden	4	7
United Kingdom		5

Decentralised Procedure

The CMD(h) noted that there were **89** Decentralised Procedures finalised with a positive outcome. **1** Decentralised Procedure was withdrawn after day 120 during the month of June 2009. **1** Decentralised Procedure was referred to the CMD(h) in this period. There were **no** Decentralised Procedures referred to the CHMP in this period.

The status as of 30th June 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	479	18	1813	8	8	3	0	1	3

103 Decentralised Procedures (regarding **218** products) started in June 2009. The categories of these procedures are as follows:

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.

97 abridged applications, including **28** multiple applications.

3 known active substance applications.

1 line extension application.

2 applications for a new active substance.

The new Decentralised procedures started in December related to **74** generic, **4** full dossier, **2** bibliographic and **23** hybrid.

102 of these procedures consisted of chemical substance applications and **1** procedure consisted of a biological other product.

102 of these procedures related to prescription-only medicinal products and **1** procedure related to a non-prescription medicinal product in the reference Member State⁴.

New applications in Decentralised procedure started in June 2009.

Member State	Number of times involved in a procedure as RMS	Number of times involved in a procedure as CMS
Austria	7	33
Belgium	1	36
Bulgaria		18
Cyprus		10
Czech Republic	2	35
Denmark	6	25
Estonia		12
Finland		19
France		38
Germany	25	68
Greece		22
Hungary	3	31
Iceland	7	9
Ireland		18
Italy		39
Latvia		11
Lithuania		13
Luxembourg		24
Malta	1	7
Netherlands	12	43
Norway		16
Poland		35
Portugal	4	38
Romania		30
Slovak Republic		28
Slovenia		12
Spain		40
Sweden	3	26
United Kingdom	32	56

VARIATIONS AND RENEWALS

Mutual Recognition and Decentralised Procedures

The CMD(h) noted that **686** type IA variations, **296** type IB variations and **248** type II variations were finalised during the month of June 2009. **55** 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 June 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	3349	1718	1593	275	2

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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Or you could visit the CMD(h) web site at:

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