SANDOZ

With regards the renewal process of Mutual Recognision Process (MRP) or Decentralized Procedures (DCP) in Europe, please find the following explanation:

In accordance with Article 24 of Directive 2001/83/EC, a marketing authorisation (MA) is valid for 5 years and may be renewed on the basis of a re-evaluation of the benefit/risk balance by the competent authority of the authorising Member State. Once renewed, the MA shall be valid for an unlimited period unless the competent authority decides, on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product, to proceed with one additional five-year renewal. The marketing authorisation holder (MAH) shall provide the competent authority with a consolidated version of the file in respect of quality, safety and efficacy including an evaluation of data contained in suspected adverse reaction reports, Periodic Safety Update Report (PSUR) data (if applicable) and any relevant new information affecting the benefit/risk of the product together with a list of all variations introduced since the MA was granted.

If there is agreement at the end of the procedure that the benefit/risk of the product remains favourable and there are no pharmacovigilance issues that would require a further renewal, the MA may be granted unlimited validity.
Renewal documents issued will include the SmPC as amended and harmonised leaflet and label texts. In some circumstances an additional 5-year renewal may be required.

The time table of the process steps for MRP/DCP renewals is explained as follows:

Day 0	Start of procedure. The CMS are informed via CTS, there will be no additional mail
Day 40	RMS to circulate preliminary assessment report to CMS The preliminary report may also be circulated to PRAC members if appropriate (see section 3.9)
Day 55	Receive comments from CMS (and PRAC members if appropriate)
Day 59	RMS to send request for supplementary information to MA holder and CMS via e-mail (if necessary)
Clock-off up to 30 days (opportunity to prolong in exceptional circumstances only with agreement of RMS)	

Day 60	**RMS to circulate finalised assessment report with draft decision**
Day 80	CMS to advise acceptance/non-acceptance of decision
Day 90*	Issue renewal or refer to Co-ordination Group, CMDh for 60 day referral procedure End of the procedure.

Mauricio Paola

Digitally signed by Mauricio Paola
DN: SERIALNUMBER=1889672 +
CN=Mauricio Paola, OU=GX,
OU=people, DC=novartis, DC=com
Reason: I am approving this document.
Date: 2016.09.07 10:46:52 --3:00

Paola Mauricio
RA Head Sandoz SouLat

A Quien Pueda Interesar

De	Karina Rodriguez Valero
Departamento	RCC LCM LATAM
Tel.	+49 (0)80249082045
Fax	+49 (0)8024 / 908-1544
E-Mail	karina.rodriguez@sandoz.com
Fecha	**07.09.2016**

Con respecto al proceso de renovación de Proceso de Reconocimiento Mutuo (MRP, Mutual Recognition Process) o Procedimientos de Descentralización (DCP, Decentralized Procedures) en Europa, a continuación se entrega la siguiente explicación:

De acuerdo con el Artículo 24 de la Directriz 2001/83/EC, una autorización de marketing (MA, marketing authorization) es válida durante un periodo de 5 años y se puede renovar en base a una re-evaluación del equilibrio beneficio/riesgo por la autoridad competente del Estado Miembro que entrega la autorización. Una vez que se renueve, la MA deberá ser válida por un periodo ilimitado a no ser que la autoridad competente decida, con una base justificada relacionada con fármaco-vigilancia, incluyendo exposición a un número insuficiente de pacientes al producto médico para proceder con una renovación adicional a cinco años. El que tiene la autorización de MAH (MAH, marketing authorization holder) deberá proporcionarle a la autoridad competente con una versión consolidada del archivo con respecto a calidad, seguridad y eficacia incluyendo una evaluación de los datos contenidos en informes sospechosos de reacciones adversas, Los datos del Informe de Actualización de Seguridad Periódico (PSUR, Periodic Safety Update Report) (si es que es aplicable) y cualquier nueva información relevante que afecte el beneficio/riesgo del producto en conjunto con una lista de todas las variaciones introducidas desde que se otorgó la MA.

Si existe un acuerdo a fines del procedimiento que el beneficio/riesgo del producto permanece favorable y no hay temas/problemas de fármaco/vigilancia que requerirían una renovación adicional, la MA so podrá otorgar con una validez ilimitada.
Los documentos de renovación emitidos incluirían el SmPC según se modifique y un folleto armonizado y texto de la etiqueta. En algunas circunstancias se puede requerir una renovación adicional a 5 años.

La tabla de tiempo o programación de los pasos del proceso para las renovaciones MRP/DCP se explican de la siguiente manera:

Día 0	Inicio del procedimiento. Se informa al CMS por vía de CTS, no existirá ningún correo electrónico

	adicional.
Día 40	RMS para re-circular el informe de evaluación preliminar a CMS El informe preliminar también se puede re-circular a los miembros de PRAC si es que es apropiado (ver la Sección 3.9)
Día 55	Recibir comentarios de CMS (y de miembros PRAC si es apropiado)
Día 59	RMS para enviar la petición de tener información suplementaria al tenedor MA y CMS por medio de un correo electrónico (si es necesario)
Desactivación del reloj hasta 30 Días (oportunidad para prolongar el tiempo en circunstancias excepcionales solamente con un acuerdo por parte de RMS)	
Día 60	**RMS para circular el informe de evaluación finalizado con una decisión en borrador**
Día 80	CMS para asesorar aceptación /no-aceptación de la decisión
Día 90*	Emitir renovación o referirse al Grupo de Coordinación, CMDh para un procedimiento de referencia de 60 días Fin del procedimiento.

Sinceramente,

Karina Rodriguez
Gerente Regional LATAM
HEXAL AG

From:	TINE NYEGAARD-NIELSEN - 9540
To:	dk-h-mrve; "at-ages-h.mrve@at-ages-h.eudra.org"; "be-h.mrve@be-h.eudra.org"; "fi-h.mrve@fi-h.eudra.org"; "it-h.mrve@it-h.eudra.org"; "mt-h.mrve@mt-h.eudra.org"; "nl-h.mrve@nl-h.eudra.org"; "no-h.mrve@no-h.eudra.org"; "ro-h.mrna@ro-h.eudra.org"; "se-h.mrve@se-h.eudra.org"; "si-h.mrve@si-h.eudra.org"; "uk-h.mrve@uk-h.eudra.org"; "bg-h.mrve@bg-h.eudra.org"; "ie-h.mrve@ie-h.eudra.org"; "lt-h.mrve@vvkt.lt"; "lu-h.mrve@lu-h.eudra.org"; Heuschneider, Martina
Subject:	DK/H/1430, 1431, 1432/01-02/R/001, DK/H/1527, 1528, 1529/01-05/R/001- quatiapine - DK - End of procedure
Date:	27 March 2013 14:56:16
Attachments:	Final common-spc DK_H_1527-29_001-005 tracked.doc Final common-outer DK_H_1430-32_001-002 clean.doc Final common-outer DK_H_1430-32_001-002 tracked.doc Final common-outer DK_H_1527-29_001-005 clean.doc Final common-outer DK_H_1527-29_001-005 tracked.doc Final common-pl DK_H_1430-32_001-002 clean.doc Final common-pl DK_H_1430-32_001-002 tracked.doc Final common-pl DK_H_1527-29_001-005 clean.doc Final common-pl DK_H_1527-29_001-005 tracked.doc Final common-spc DK_H_1430-32_001-002 clean.doc Final common-spc DK_H_1430-32_001-002 tracked.doc Final common-spc DK_H_1527-29_001-005 clean.doc End of Procedure letter.pdf

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Dear Colleagues and Applicant,

Today is day 90 of the above mentioned procedures. The RMS FRAR II was circulated Monday 25 March 2013. RMS recommended approval of the procedures. CMS IE has informed RMS that they agree with the RMS conclusion. No other comments have been received from CMS. Consequently, the procedures have been approved today.

Please find attached the end of procedure letter and final SmPC, PIL and outer labeling in track and clean version. The clean versions have also been uploaded in CTS.

The applicant is requested to submit national translations within five working days.

Kind regards

_____

Tine Nyegaard-Nielsen
Regulatorisk koordinator
Regulatory coordinator
T (dir.) +45 44 88 95 40
tinn@dkma.dk

Sundhedsstyrelsen
Markedsføringstilladelser og Lægemiddelregulering
Danish Health and Medicines Authority
Medicines Regulation and Marketing Authorisations
T +45 72 22 74 00
sst@sst.dk

Sundhedsstyrelsen
Danish Health and Medicines Authority

Reference Member State
End of Renewal Procedure

1. This document is sent by

RMS	Denmark
Contact point project team leader	Tine Nyegaard-Nielsen
Phone	☎ +45 44 88 95 40
E-mail address	💻 tinn@dkma.dk
Date/Day of procedure	27 March 2013 / day 90

2. Product related information

DK/H/1430/001-002/R/001

Name of the product in the RMS	Quetiapin Sandoz
Name of the active substance	Quetiapine
Applicant	Sandoz A/S
Procedure number	DK/H/1430/001-002/R/001
Date of first authorisation	30 September 2009
International/European birth date	17 August 2007
Common renewal date	27 March 2013

DK/H/1431/001-002/R/001

Name of the product in the RMS	Seresano
Name of the active substance	Quetiapine
Applicant	Hexal A/S
Procedure number	DK/H/1431/001-002/R/001
Date of first authorisation	30 September 2009
International/European birth date	17 August 2007
Common renewal date	27 March 2013

DK/H/1432/001-002/R/001

Name of the product in the RMS	Quetiapin 1A Farma
Name of the active substance	Quetiapine
Applicant	1A Farma A/S
Procedure number	DK/H/1432/001-002/R/001
Date of first authorisation	30 September 2009
International/European birth date	17 August 2007

Common renewal date ..... 27 March 2013

DK/H/1527/001-005/R/001

Name of the product in the RMS ..... Quetiapin Sandoz
Name of the active substance ..... Quetiapine
Applicant ..... Sandoz A/S
Procedure number DK/H/1527/001-005/R/001
Date of first authorisation ..... 4 December 2009
International/European birth date ..... 17 August 2007
Common renewal date ..... 27 March 2013

DK/H/1528/001-005/R/001

Name of the product in the RMS ..... Seresano
Name of the active substance ..... Quetiapine
Applicant ..... Hexal A/S
Procedure number DK/H/1528/001-005/R/001
Date of first authorisation ..... 4 December 2009
International/European birth date ..... 17 August 2007
Common renewal date ..... 27 March 2013

DK/H/1528/001-005/R/001

Name of the product in the RMS ..... Quetiapin 1A Farma
Name of the active substance ..... Quetiapine
Applicant ..... 1A Farma A/S
Procedure number DK/H/1528/001-005/R/001
Date of first authorisation ..... 4 December 2009
International/European birth date ..... 17 August 2007
Common renewal date ..... 27 March 2013

3. Recommendation

a) The product is:

Renewable ..... ☒
Not Renewable ..... ☐

b) Validity of renewal:

The renewal can be granted with unlimited validity ..... ☒
One additional five-year renewal is required ..... ☐

c) Changes in the SPC, labelling or PL:

During the renewal procedure it was agreed that the MAH will submit a variation to amend the SPC, PL or labelling

Yes..... ☐

No..... ☒

d) Quetiapin Sandoz, Seresano and Quetiapin 1A Farma film-coated tablets 25 mg, DK/H/1430-32/001/DC, is authorised under the legal basis of Article 10(1) of Directive 2001/83/EC. According to the EURD list no routine PSURs need to be submitted.

Quetiapin Sandoz, Seresano and Quetiapin 1A Farma film-coated tablets 50 mg, 100 mg, 150 mg, 200 mg, 300 mg, 400 mg, DK/H/1430-32/002/DC and DK/H/1527-29/001-005/DC, is authorised under the legal basis of Article 10(3) of Directive 2001/83/EC. The next PSUR should be submitted within 90 days of DLP 2014-07-31.

4. Attached documents

Please find attached the following documents:

Approved SPC..... ☒

Approved PL ..... ☒

Approved labelling..... ☒

Anouk Sporkslede/GX/Novartis
10/08/2011 08:48

To
cc
bcc
Subject Fw: UK/H/1103,1104,1105,1106,1107/001/R/001 - Mycophenolate Mofetil and Mycot - PL 04416/0822, PL 10880/0109, PL 26062/0005, PL 16220/0006, PL 30047/0002: End of procedure

Caroline Kleinjan

----- Forwarded by Caroline Kleinjan/GX/Novartis on 08-08-2011 17:44 -----

"uk-h.mrve" <uk-h.mrve@uk-h.eudra.org>
08-08-2011 17:41

To <at-ages-h.mrve@at-ages-h.eudra.org>, <be-h.mrve@be-h.eudra.org>, <bg-h.mrve@bg-h.eudra.org>, <Cz-h.mrve@cz-h.eudra.org>, <de-pei.mrve@de-pei.eudra.org>, <de-h.mrve@de-h.eudra.org>, <dk-h.mrve@dk-h.eudra.org>, <ee-h.mrve@ee-h.eudra.org>, <gr-h.mrve@gr-h.eudra.org>, <es-h.mrve@es-h.eudra.org>, <fi-h.mrve@fi-h.eudra.org>, <fr-h.mrve@fr-h.eudra.org>, <hu-h.mrve@hu-h.eudra.org>, <ie-h.mrve@ie-h.eudra.org>, <is-h.mrve@is-h.eudra.org>, <it-h.mrve@it-h.eudra.org>, <lt-h.mrve@vvkt.lt>, <lv-h.mrve@lv-h.eudra.org>, <nl-h.mrve@nl-h.eudra.org>, <no-h.mrve@no-h.eudra.org>, <pl-h.mrve@pl-h.eudra.org>, <pt-h.mrve@pt-h.eudra.org>, <ro-h.mrna@ro-h.eudra.org>, <se-h.mrve@se-h.eudra.org>, <si-h.mrve@si-h.eudra.org>, <sk-h.mrve@sk-h.eudra.org>
cc <caroline.kleinjan@sandoz.com>
Subject UK/H/1103,1104,1105,1106,1107/001/R/001 - Mycophenolate Mofetil and Mycot - PL 04416/0822, PL 10880/0109, PL 26062/0005, PL 16220/0006, PL 30047/0002: End of procedure

Dear colleagues,

The RMS has received no further comments in relation to this procedure other than a positive endorsement from Romania.

Please therefore consider it to be closed on 08-08-2011 and find the formal end of procedure document attached together with the final SPC and PIL.

No changes have been made to the labelling.

CTS has been accordingly updated.

<<End_of_renewal_procedure_Mycophenolate 500mg.doc>> <<Final PIL.pdf>> <<Final SPC.pdf>>

Kind Regards
Dhruv Patel
MR-DC Team
Licensing Division
Medicines and Healthcare products Regulatory Agency
4th floor - T, 151 Buckingham Palace Road
London
SW1 9SZ

Reference Member State
End of Renewal Procedure

1. This document is sent by

RMS	UK
Contact point project team leader	Mrs Kathryn Austin
Phone	☎ 0203 080 6808
E-mail address	💻 Kathryn.austin@mhra.gsi.gov.uk
Date/Day of procedure	Day 90 – 08/08/11

2. Product related information

Name of the product in the RMS	Mycophenolate mofetil & Mycot 500mg film-coated tablets
Name of the active substance	Mycophenolate mofetil
Applicant	Sandoz Limited, Hexal AG, 1A Pharma GmbH, Lek Pharmaceuticals D.D & Rowex Limited
Procedure number	UK/H/1103-1107/001/R/001
Date of first authorisation	29/07/08
Common renewal date	30/06/10

3. Recommendation

a) The product is:

Renewable ..... ☒

Not Renewable ..... ☐

b) Validity of renewal:

The renewal can be granted with unlimited validity ..... ☒

One additional five-year renewal is required ..... ☐

c) Changes in the SPC, labelling or PL:

During the renewal procedure it was agreed that the MAH will submit a variation to amend the SPC, PL or labelling

Yes..... ☐

No..... ☒

d) The next PSUR should be submitted within 60 days from the next data lock point (DLP)

4. Attached documents

Please find attached the following documents:

Approved SPC..... ☒

Approved PL ..... ☒

Approved labelling..... ☐