AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

Tavola Rotonda su Brexit - 58° Simposio AFI

Maria Vitocolonna

07/06/18

Dichiarazione di trasparenza/interessi*

Le opinioni espresse in questa presentazione sono personali e non impegnano in alcun modo l'AIFA

Interessi nell'industria farmaceutica	NO	Attualmente	Da 0 a 3 anni precedenti	oltre 3 anni precedenti
INTERESSI DIRETTI:				
1.1 Impiego per una società: Ruolo esecutivo in una società farmaceutica	X	☐	☐	☐ obbligatorio
1.2 Impiego per una società: Ruolo guida nello sviluppo di un prodotto farmaceutico	X	☐	☐	☐ obbligatorio
1.3 Impiego per una società: altre attività	X	☐	☐	☐ facoltativo
2. Consulenza per una società	X	☐	☐	☐ facoltativo
3. Consulente strategico per una società	X	☐	☐	☐ facoltativo
4. Interessi finanziari	X	☐	☐	☐ facoltativo
5. Titolarità di un brevetto	X	☐	☐	☐ facoltativo
INTERESSI INDIRETTI:				
6. Sperimentatore principale	X	☐	☐	☐ facoltativo
7. Sperimentatore	X	☐	☐	☐ facoltativo
8. Sovvenzioni o altri fondi finanziari	X	☐	☐	☐ facoltativo
9. Interessi Familiari	X	☐	☐	☐ facoltativo

* Maria Vitocolonna, secondo il regolamento sul Conflitto di Interessi approvato dal CdA AIFA in data 25.03.2015 e pubblicato sulla Gazzetta Ufficiale del 15.05.2015 in accordo con la policy EMA /626261/2014 sulla gestione del conflitto di interessi dei membri dei Comitati Scientifici e degli esperti.

N.B. Per questo intervento non ricevo alcun compenso.

Regulatory Network should be ready for a Hard Brexit

As per the CMDh Notice to Marketing Authorisation Holders (MAHs) a “HARD BREXIT” approach should be followed until the outcome of negotiation is disclosed.

UK will become a “Third Country” with legal consequences to be considered:

1. EU law requires that marketing authorisation holders are established in the EU (or EEA);

2. Some activities must be performed in the EU (or EEA), related for example to pharmacovigilance, manufacturing, import etc.

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

Notice to marketing authorisation holders of national authorised medicinal products for human use

Doc. Ref.: CMDh/360/2017
02 May 2017

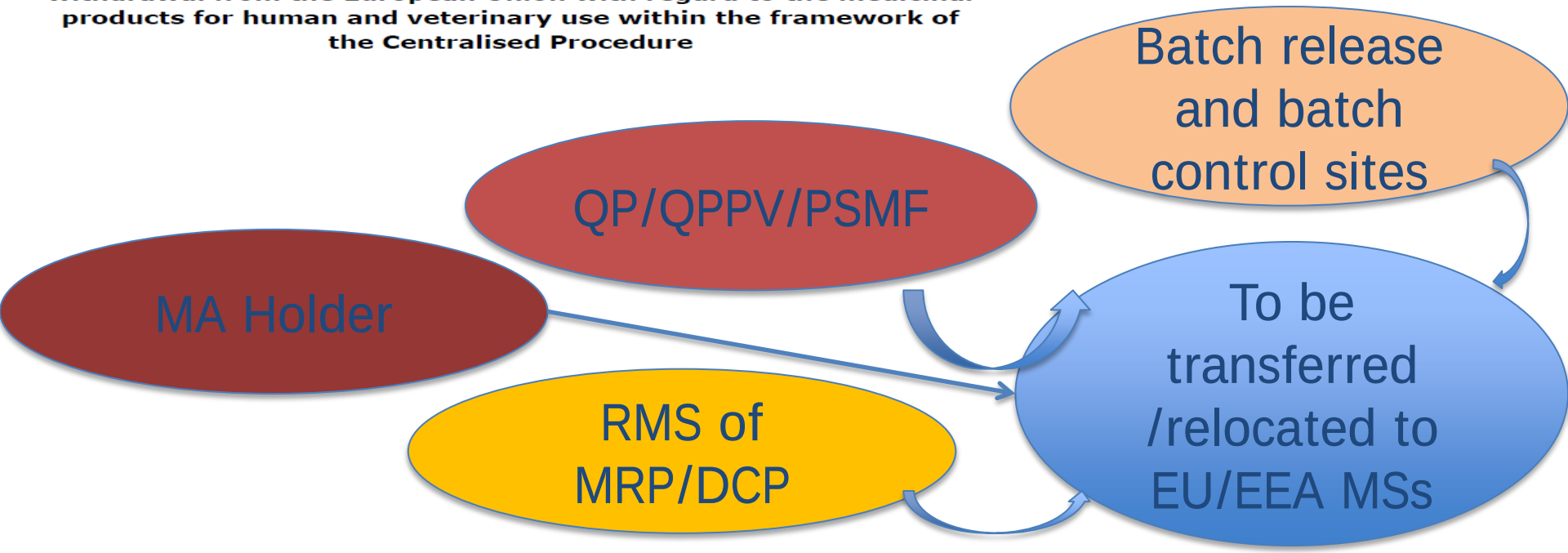
Legal requirements confirmed by EC: Q&A on Brexit

EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH AND FOOD SAFETY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Rev 02, published on 29 January 2018

Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure



Questions 10-11: Reference Product for generic/hybrid applications and BE studies

- *Generic/hybrid applications for which marketing authorisations will be granted after 29 March 2019 should refer to a RefMP that is or has been authorised in a EU-27 Member State or a contracting state of the EE*

- *Bioequivalence studies that have been conducted with a medicinal product sourced in the UK can be used in generic/hybrid marketing authorisation applications only if the marketing authorisation for that application will be granted before 30 March 2019.*

Implementation of Brexit-related changes

- Huge economic burden and time-consuming process for Pharmaceutical Industries
- Increase of regulatory burden and investment in terms of training/resources for National Competent Authorities (NCAs)

Cooperation between NCAs and Pharmaceutical Industries is needed to allow regulatory actions are taken in due time without compromising the access of medicines to patients

What industries ask NCAs?

1. Transparency for capacity (e.g. willingness to act as/become RMS for MRP/DCP)
2. Clear harmonized doc requirements for Brexit-related changes (such as MA transfers and RMS switch)
3. Flexibility in the process (e.g. allowed RMS-switch with pending procedures)
4. Adherence to timelines/timely implementation of changes
5. Brexit-related expedited procedures (e.g. art 61.3 notifications for FMD implementation, renewals)

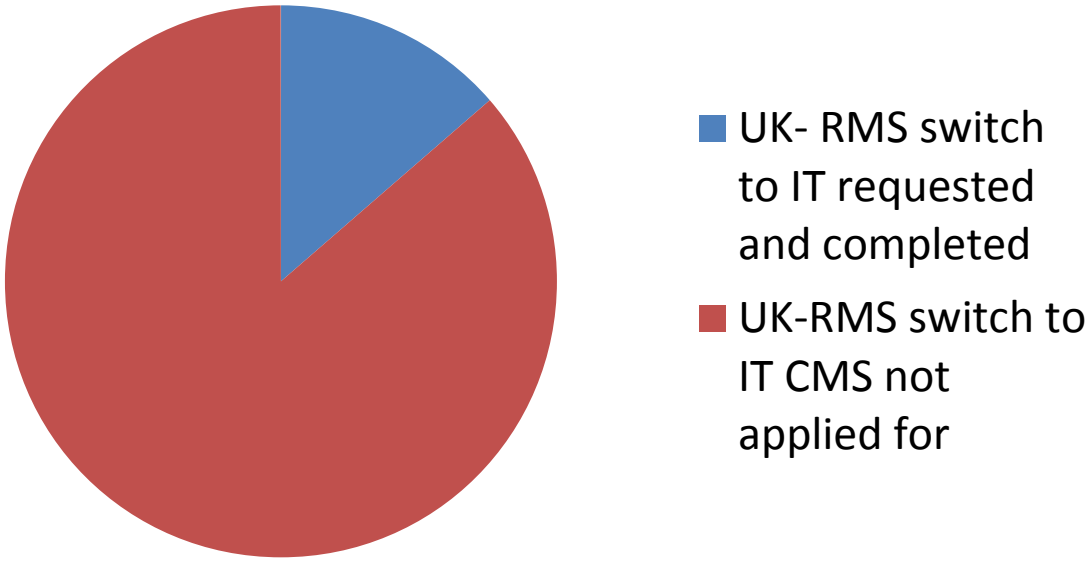
What NCAs expect from industries? (1)

1. Take action in due time
2. Information/Transparency on redistribution/relocation of activities and procedures

Early and planned submissions allow the NCAs to predict the regulatory burden and optimize resources

What NCAs expect from industries? (2)

Passive attitude should be abandoned:
Only for 6 out of about 50 MRP/DCP with UK-RMS and Italy as the only CMS the switch has been requested and completed in 2017-2018



Actions for Brexit
What has the CMDh done?

To ease the process and give clear instructions to the Companies, the *CMDh Procedural advice on changing the RMS* has been updated and additional Pratical Guidance for Brexit-related procedures have been published, a document with Link to national website on MAH transfer has been compiled

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

February 2018
CMDh/039/2002, Rev.6

CMDh procedural advice on changing the Reference Member State

April 2018
CMDh/373/2018, Rev.0

Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP

CMDh Procedural advice on changing the RMS updates

-Trigger of art 50 of Union Treaty as a justification for RMS-switch
-New template for RMS-switch requests
-Link to the list of contact points' email addresses in EU/EEA MS
-Instructions on switch when no CMS has all strengths (RUP with current RMS or multiple switches)
- Instructions/timelines for referring the appointment of the new RMS to the CMDh when no CMS is willing to accept the reference-ship
- Compiled list of links to NCAs' websites for national requirements for MAH transfers

Pratical Guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP

- *To implement the switch of the RMS it is sufficient that the DCP/MRP/RUP is finalized*

- *The switch can be applied for at ANY TIME after the end of a DCP/MRP/RUP procedure but it should be implemented after the pending procedure are closed*

- *When there are several MAHs in one MRP/DCP it is the task of the MAH in the current RMS to initiate the process*

Actions for Brexit
What has AIFA done?

Investment in terms of new resourses :

- Selezione a progetto 2018 - Progetto Brexit

n. 5 incarichi di collaborazione coordinata e continuativa della durata di 24 mesi (Sanitario)
n. 1 incarichi di collaborazione coordinata e continuativa della durata di 24 mesi (funzionario)
n. 1 incarichi di collaborazione coordinata e continuativa della durata di 24 mesi (medico)

- Concorsi AIFA 2018

n. 14 posti a tempo indeterminato e pieno nel profilo di dirigente chimico
n. 33 posti a tempo indeterminato e pieno nel profilo di dirigente farmacista
n. 4 posti a tempo indeterminato e pieno nel profilo di dirigente medico
n. 4 posti a tempo indeterminato e pieno nel profilo di dirigente medico
n. 2 posti a tempo indeterminato e pieno nel profilo di dirigente medico

Discussion on-going

- Art 126 a – *alternative options?*

- generic/hybrid marketing authorization (MA) with UK-ref product (ERP) should be granted before 30.3.2019 – *what about EoP for MRP/DCP?*

-MA for generic/hybrid applications submitted with BE studies conducted with reference products sourced in UK should be granted before 30.3.2019 (but accepted if ongoing at 30.3.2019) *– what about if*

-

- *MRP/RUP with ref product sourced in UK are submitted after 30-3-2019?*

- *ref product sourced in UK was authorized with MRP/DCP before 30.3.2019?*

Can unnecessary repetition of BE studies be avoided?

(EC new batch of Q&A/clarifications awaited)

Thank you for your attention!