

EUDRAC



QUALITY FOR SUCCESS

  **BREXIT Update**  

CAP Marketing Authorisations No Deal Scenario

11 September 2020

EUDRAC Ltd
59A Monument Park
Chalgrove
OX44 7RW



Key Changes Since 2019 Guidance



- Transition period **ends 31 Dec 2020**
- Guidance now refers to **Great Britain i.e. Northern Ireland excluded** which will follow EMA route
- Ongoing CAPs
 - choice of route by Applicant
- Extended time to establish UK MAH (2 years)



CAP Marketing Authorisations

- **In Great Britain, on 1 Jan 2021:**
 - All CAP Marketing Authorisations will automatically be converted to GB MAs
 - This is being referred to as “*grandfathering*”
 - No fee is being charged for this conversion
 - The MHRA has written to all relevant MAHs to inform them of this intention
 - The MAH can opt-out



CAP Marketing Authorisations

- **Within 1 year of the GB MA**
 - All MAHs must submit an “**Initiation Package**” to the MHRA
 - This is a set of baseline eCTD sequences plus application form and other documents
 - Information on “**what**” and “**how**” to submit are included in MHRA guidance documents
 - If a variation/renewal is required, initiation package must be sent in advance and be processed by MHRA
 - MHRA likely not to have access to **Gateway** or **CESP**, so is developing a **new portal system** for submission of applications (see slide 10)

CAP Marketing Authorisations

- **For ongoing CAPs**

- For applications for which an opinion has been adopted, **MHRA** will adopt **EU** opinion unless the UK recorded a divergent decision
- 2 routes available to applicant:
 1. Parallel assessment (but independent) with EU
 2. Reliance on EU decision i.e. applicant makes an application to MHRA following CHMP positive opinion



CAP Marketing Authorisations

- **Legal Presence**

- CAP MAs with a non-UK MAH must establish a **UK MAH** by January 2023
- Full details of **submission requirements** are included in MHRA guidance documents





■ Variations

- MHRA has adopted a pragmatic approach for CAP variations that are **completed shortly before, or after, end of transition**
 - Type IA_{IN} variations are considered to be implemented
 - Type IB variations are considered authorised
 - Type II variations for which an opinion has been adopted, **MHRA** will adopt **EU** opinion
 - Type II variations for which an opinion has not been adopted, **MHRA** will continue assessment
- Specific guidance for the **different types** of variations and numerous **different scenarios** is available





■ Renewals

- Renewal date for **GB** remains as for **EU**
- For renewals submitted **before end of transition**, for which an opinion has been adopted, **MHRA** will adopt **EU** opinion
- For renewals where **no opinion was adopted**, MHRA will continue assessment
 - Renewal application should be included within the “Initiation Package”
- Also applies to renewals for **Conditional MAs**



CAP Marketing Authorisations

■ **Packaging / labelling**

- New Great Britain MA number
- 24 months to establish GB MAH
- **Additional 12 months to release** to new requirements i.e. 36 months in total
- Multi-country packs allowed providing all information is compliant with GB requirements





MHRA submissions

- **MHRA will have a separate portal system**
- Registration to “MHRA submissions” can be made in **advance** of end of transition
- There is comprehensive guidance on MHRA website (*including 3 videos and a helpline*) for registering:
 - Company Administrators
 - Company Users



We can support you



- **With EUDRAC based in UK and EU, we can help you meet all eventualities**
 - **Contact:**
 - Carole Pugh
Managing Director
EUDRAC Ltd
carole.pugh@eudrac.com

