EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Updates on the Ireland and Northern Ireland Protocol implementation

Impact on interactions with EMA and other practical implications

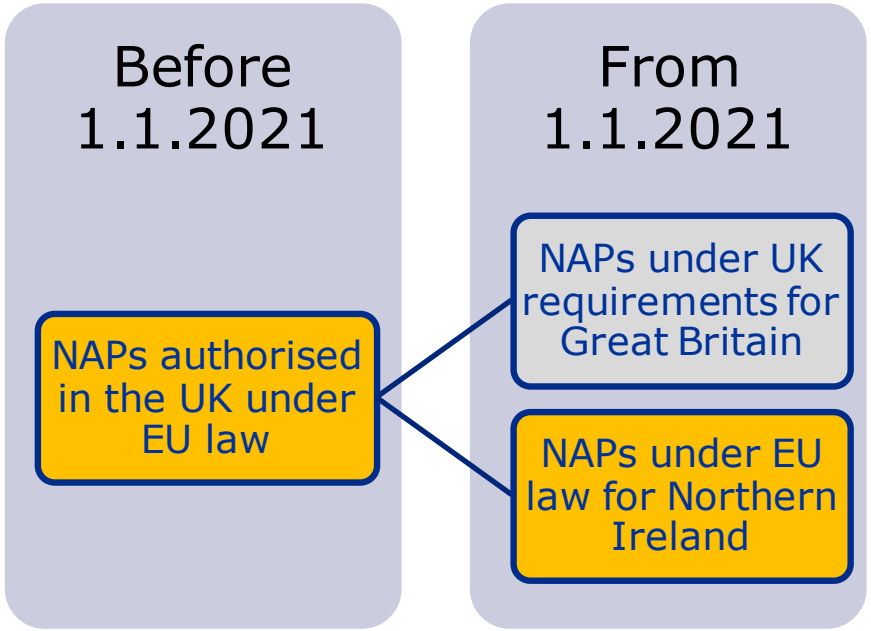
Presented by Zigmars Sebris
Scientific Administrator, Office of the Deputy Executive Director

Disclaimer

This presentation only reflects the situation as laid down in legal provisions in force on the date of its presentation, and without prejudice to any of the ongoing discussions between the Union and the UK concerning the application of the Union acquis concerning medicinal products in respect of Northern Ireland after the transition period, in light of the particular challenges that small markets historically dependent on medicines supply from or through Great Britain are facing.
In this regard it has to be borne in mind that the EMA is not participating in any of the negotiations between the Union and the UK that aim at solving – before the end of 2020 - the particular challenges that small markets face as that historically are dependent on medicines supply from or through Great Britain, notably Northern Ireland.

Contents

Information on UK nationally authorised products in Art. 57 DB



Information on **MPs authorised in line with EU law** is **mandatory** in art. 57 DB

- Authorisation country to be updated to 'United Kingdom (Northern Ireland)' (or 'XI'), where applicable, for current UK NAPs

Information on **other MPs** (authorised in third countries) is **not mandatory**

- No action needed for UK NAPs that after 1.1.2021 will only be authorised in Great Britain

Differentiation between UK(NI) and the rest of UK

UK nationally authorised products with respect to Northern Ireland

- Update authorisation country field to 'United Kingdom (Northern Ireland)' (XI)
- MAH, QPPV and PSMF can be located in EU/EEA or Northern Ireland

MAH, QPPV and/or PSMF location in Northern Ireland

- Update the country field in the address of entities located in Northern Ireland (MAH, QPPV, and/or PSMF)
- Change to be made in EMA account management portal for QPPV and in art. 57 DB for MAH and PSMF location

Calculation of fees for UK NAPs in EMA procedures from 1.1.2021

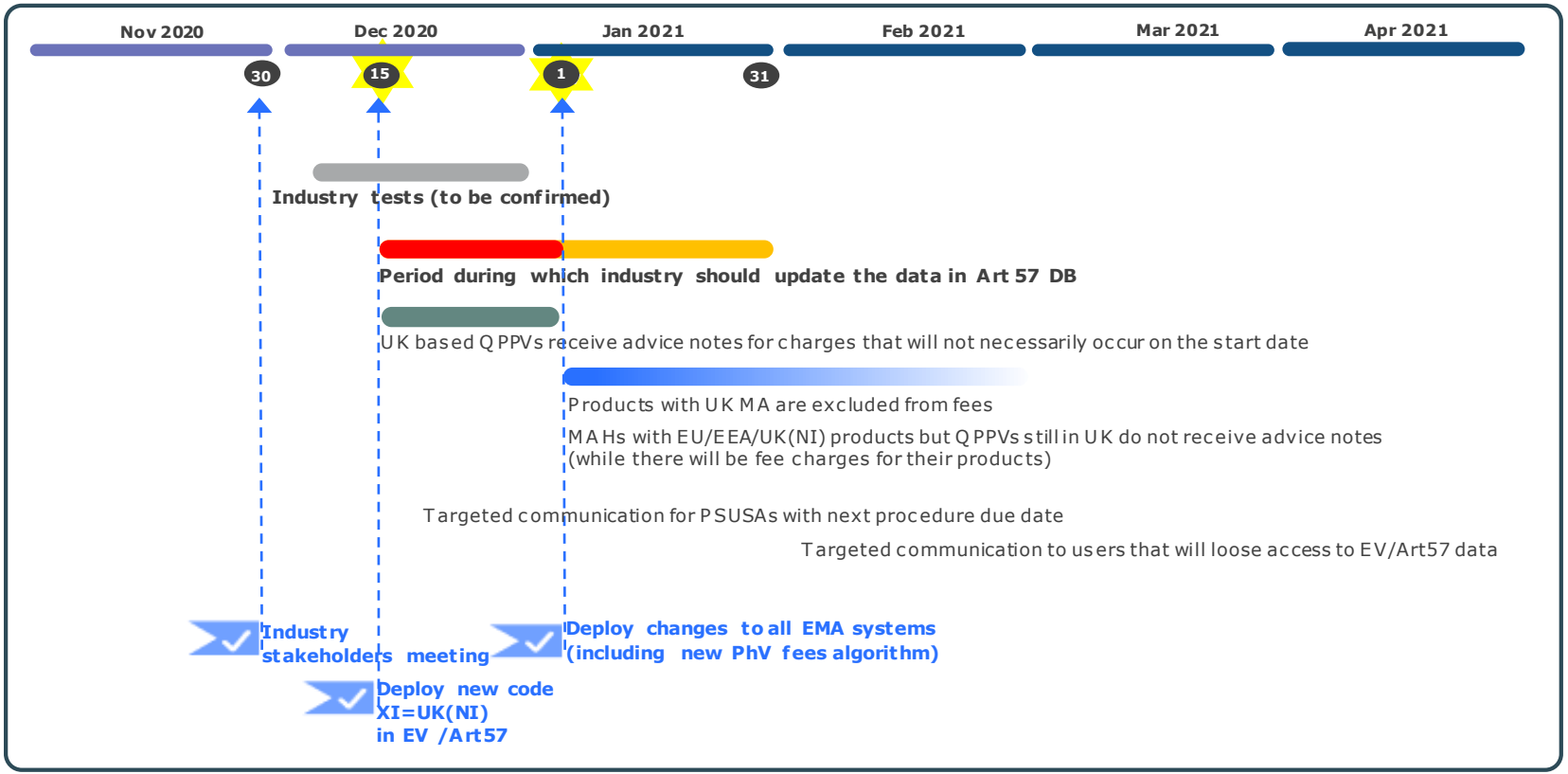
UK nationally authorised products with respect to Northern Ireland

- Included in fee calculations, as applicable
- MAH can be located in EU/EEA or Northern Ireland
- QPPV can be located in EU/EEA or Northern Ireland (if not compliant, the QPPV will not receive advice notices)

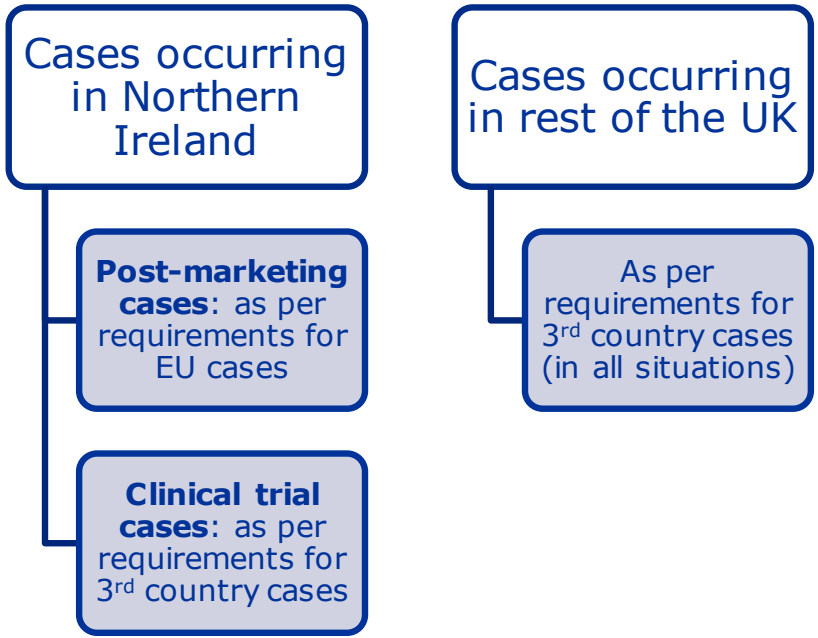
UK nationally authorised products only with respect to Great Britain

- Not included in fee calculations (not part of EU procedures)

Timelines for Art. 57 updates and changes in fee calculations



EudraVigilance reporting requirements from 1.1.2021.



Under the Protocol in Ireland/Northern Ireland, EU Pharmaceutical Law with respect to authorised products applies in Northern Ireland

However, with respect to Clinical Trial only limited scope of the EU Law applies in Northern Ireland

Where it is not possible to determine where in UK the case occurred, it should be treated as an UK (not Northern Ireland) case

Differentiation of cases from Northern Ireland and rest of UK

	Cases from Northern Ireland	Cases from the rest of UK
Primary source country field	XI (mandatory for distinguishing the cases)	GB (no change)
Worldwide case ID*	Use XI or GB	Use GB
Safety report ID	Use XI or GB	Use GB

* - for already submitted case worldwide case ID should not be changed

Access rights for the MAHs of UK NAPs for EudraVigilance

UK NAPs with respect to Northern Ireland

- Access maintained (level 2)
- Important to ensure accuracy of the data submitted in art. 57 database

UK NAPs only with respect to the rest of UK

- Such authorisations are not a basis for granting/ maintaining access
- If an entity only holds such authorisations (and no EU/EEA MAs and/or MAs with respect to Northern Ireland), the access will be terminated in early 2021

Other IT systems and tools

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eAF

- In country lists 'United Kingdom' will be removed and 'United Kingdom (Northern Ireland)' will be added, where applicable
- The options will, in some cases, depend on the procedure type chosen
- Lists are updated in Referential Management system and will change irrespective of eAF version used

PSUR repository

- Art. 57 database entries must be updated before submitting a PSUR for an UK NAP with respect to Northern Ireland
- After 31.12.2020 it will not be possible to select 'United Kingdom' as recipient of PSURs (applicable to PSURs not part of single assessment procedure)
- After 31.12.2020 it will be possible to select 'United Kingdom (Northern Ireland) as the recipient, where needed

OMS

- Addresses in Northern Ireland will be updated to differentiate them clearly from those in the rest of the UK (due to different applicable requirements)
- Entries for entities with addresses in Northern Ireland and in the rest of UK will be reorganised in two respective groups

GMP and manufacturing in Northern Ireland for centrally authorised products from 1.1.2021

	Sites in NI	Sites in the rest of UK
FP importation	Acceptable	Not acceptable
FP batch control testing for release	Acceptable	Not acceptable
FP batch certification	Acceptable	Not acceptable
EU GMP certificates (and MIA, where applicable)	Issued by UK and included in EudraGMDP; Recognised in EU/EEA	UK certificates = 3rd country inform.; New supervisory authority in EU/EEA will apply risk based approach to confirm GMP status
OMCL for OCABR/OPBR	Not acceptable	Not acceptable

FP = finished product

Incentives available for entities in Northern Ireland

Orphan designations

- In principle, an entity in Northern Ireland can be the sponsor of an orphan designation
- Incentives in the pre-authorisation phase remain available
- However, designation has to be transferred to and EU/EEA entity before submitting the marketing authorisation application

SME status

- In principle, an entity in Northern Ireland can have and SME status and benefit from the incentives
- However, incentives for regulatory activities restricted to EU/EEA entities only are not applicable (e.g. marketing authorisation applications, maximum residue limit procedures)

Reporting of marketing status of CAPs in Northern Ireland

Only marketed in Great Britain (not in Northern Ireland or EU/EEA)

- Provide an updated marketing status report immediately after 1.1.2021
- Calculation of sunset clause period will start from 1.1.2021

Marketed in Northern Ireland and/or EU/EEA

- Update the marketing status at next update (e.g. when marketing status in EU/EEA country changes)
- No impact on sunset clause

Revised template with 'United Kingdom (Northern Ireland)' instead of 'United Kingdom' to be used from 1.1.2021

Dossier submission for CAPs

- Centralised procedure marketing authorisation continue to be valid in the territory of Northern Ireland also after 31.12.2020
- No access foreseen for UK authorities to the common repository after 31.12.2020
- As of 1.1.2021, the dossier for regulatory procedures concerning CAPs is to be provided by MAHs also to the UK authorities (in view of the validity of MA in the territory of Northern Ireland)
  - Follow any guidance from UK authorities on practical modalities for this process

Any questions?

Further information

EMA Brexit guidance page

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

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