PINK SHEET
CITELINE REGULATORY

09 Sep 2020 | **News**

UK Regulator Explains Data Requirements For Converted EU Approvals

New Portal Planned For Information Submission

by Ian Schofield

In another of the many guidances it has issued on medicines regulation in the post-Brexit UK, the MHRA explains the additional information it will need from companies whose EU marketing authorizations are converted into national MAs in January 2021, and the new labeling requirements for those products.

Updated guidance issued by the UK regulator, the MHRA, explains the "essential baseline data" that pharmaceutical companies will have to provide for products with EU centralized approvals that are converted into Great Britain marketing authorizations at the beginning of next year.

The data will need to be submitted within a one-year period starting on 1 January 2021, through a new "national portal" that the MHRA says will be ready by 1 January. There will also be strict deadlines for submitting any labeling changes needed as a result of the conversions.

These changes are required because the MHRA will become the UK's standalone medicines and medical devices regulator once the Brexit transition period expires on 31 December and will begin carrying out many functions that are currently dealt with at EU level. This new *guidance* is one of dozens released by the MHRA last week on the post-Brexit regulation of medicines and other issues, many of them based on guidance originally issued last year and withdrawn after the Withdrawal Agreement was signed.

As part of the shift to a freestanding UK regulatory system, all existing EU centrally authorized products (CAPs) will be automatically converted into "Great Britain" marketing authorizations, with a new MA number, on 1 January (unless the company opts out of the process). These MAs will only be effective in England, Scotland and Wales because EU approvals will remain valid in

Northern Ireland. No fee will be charged for the conversion.

To facilitate the "grandfathering" process, the MHRA says it will issue one or more product license (PL) numbers to CAPs based on the existing UK practice for determining how many separate licenses are needed across a product range. "In most cases this means that fewer UK MA numbers will be needed in comparison with the number of European Commission authorizations because all pack sizes for a presentation will be covered by a single MA number," the agency explains in its guidance.

Information Required From Companies

Within a year from 1 January 2021, holders of converted EU marketing authorizations must send a data submission package to the MHRA, as specified in paragraph 9(3) of the new Schedule 33A of the Human Medicines Regulations 2012.

The following information is required:

- A cover letter identifying the filing as a "CAP Grandfathering Submission."
- A single electronic common technical dossier (eCTD) "initiating sequence" for the converted EU MA; where more than one dosage form or strength is converted for the same product trade name, these will be handled as one eCTD dossier. If the product dossier refers to an active substance master file, the MAH must ask the active substance supplier to submit that to MHRA if they have not already done so.
- A completed electronic application form for each converted EU MA.
- A summary of all historical regulatory activity from the grant date of the original CAP until the data are submitted. This will include the type of submission (eg initial MA application, variation), date of original submission to the European Medicines Agency, summary of that submission, the regulatory outcome (granted or not granted) and the date of the outcome, and the eCTD sequence number.
- Information as to whether or not the converted product is on the GB market at the time of notification, and if not whether it has been on the GB market after 1 January 2021, and if so when it was withdrawn.
- The EU summary of product characteristics.
- Approved pack labels and patient leaflets.

PINK SHEET
CITELINE REGULATORY

"We have developed a new national portal to be ready by 1 January 2021 and expect that submissions will be made via this portal" – MHRA

Except for applications made through European procedures to market products in Northern Ireland, the MHRA "does not expect to be able to receive submissions through the Common European Submission Portal (CESP)," the guidance states. The CESP, which provides a simple, secure mechanism for the exchange of information among applicants and regulators, allows one submission to go to all relevant agencies and reduces the burden on both industry and regulators.

"We have developed a new national portal to be ready by 1 January 2021 and expect that submissions will be made via this portal. Information on the use of this portal will be published in advance of 1 January 2021," the MHRA declares.

Variations And Renewals

In general, the MHRA says, it will not look at variations to converted EU MAs before at least a minimal initiating sequence and the data submission package have been submitted. However, it may assess a variation application before that in certain cases, for example on urgent safety grounds or to maintain supplies of a particular medicine in GB.

Where variations were submitted to the EMA but not granted before 1 January 2021, the MHRA says it has adopted a "pragmatic approach" to simplify their handling.

For example, minor variations (Type IA and IB) can be implemented for the converted MA at the same time as for the EU MA, and the variation must be included in the initiating sequence submission "as if it had already been accepted in Great Britain."

For major variations (Type II), the procedure will depend on whether the variation application had reached the stage of an opinion from the EMA's drug evaluation committee, the CHMP, before 1 January 2021.

As for renewals, the guidance says that converted EU MAs will be treated as if they were granted on the date on which the corresponding EU MA was granted, and will therefore have the same renewal date. Renewals for converted MAs will only be considered once the necessary documentation has been received (with the same exceptions as for variations). (Also see "*UK Explains Approach To Renewing Converted EU Drug Approvals in 2021*" - Pink Sheet, 4 Sep, 2020.)

For converted CAP MAs with a non-UK marketing authorization holder, there is a requirement to establish an MAH in the UK by 1 January 2023. This can be done either by submitting a change of ownership application (COA) within 21 months of 1 January 2021, or by including the COA in the initiating sequence as if it had already been approved by the MHRA.

Labeling Issues

Companies that have been issued with a converted MA will have two years from 1 January 2021 in which to submit amended labeling for approval, and three years to ensure that all products released onto the GB market are in compliant packaging, according to separate MHRA *guidance*.

If only the name and address of the marketing authorisation and/or the manufacturer for batch release are being changed, this can be done as part of a Better Regulation of Medicines Initiative (BROMI) notification.

"If you are making any other changes to the statutory information or the pack design (which are not consequential to a change to the Summary of Product Characteristics (SmPC)), you will need to submit the artwork for full assessment to the Product Information Quality Unit under change code P2," the guidance says. "Normal fee arrangements apply."

The agency adds that product packs bearing the safety features required under the EU Falsified Medicines Directive will still be accepted, provided that they are in line with other UK packaging requirements. Multi-country packs, including those with information in more than one language, will also continue to be allowed, "provided that the entirety of the information is in compliance with the UK requirements."

The guidance documents were published on the MHRA website last week, and more are being added. Other topics covered include how the MHRA will handle EU CAP applications still pending as of 1 January 2021, and a new system for conditional drug approvals. (Also see "*UK To Have Own Conditional Drug Approval Scheme in 2021*" - Pink Sheet, 3 Sep, 2020.)