The Pharmaceutical Sector in Jordan: What is Involved in Changing a Marketing Authorisation Holder?

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The process for transferring or changing the MAH begins with the submission of an application to the JFDA, together with all the required documents explaining the justification and scientific basis for the change.

The detailed requirements for the submission of documents are beyond the scope of this article, accordingly, we focus on the overall process and key points of interest only.

Change of MAH

When there is an MAH change, the JFDA requires a separate application for each product affected. The JFDA begins the process by first accepting a general application. Once approved, the application and all the required documents are submitted along with the fees, and then transferred to the related committee. The file is then evaluated, and upon acceptance, the current MAH will be cancelled and the new MAH will be recorded for each product.

The JFDA regulations require that the application, along with the required supporting documents, are submitted by a pharmacist in charge on behalf of the supplier (Agent), or the technical manager for the factory to avoid the involvement of lay persons.

It is important to note that the requirements mentioned below are only related to changing the MAH (transferring the legal entity) – there must be no change of any kind to the product itself, to the approved method, or the site of manufacture – since such changes are likely to trigger other reporting obligations.

Change in the name or address of the MAH

As mentioned above, specific details are important to the JFDA. For instance, if the MAH change relates to a change of address, the application should differentiate between a change of address within the same country, and a change of address to a different country.

Government fees

Currently, there is a fee schedule detailing the fees associated with the change of MAH. Specifically, Regulation No.19 of 2015 imposes administrative fees for a change in the MAH or product license. These fee schedules are amended from time to time and should be ascertained before the submission of the application.

Missing documents

It should be noted that if any of the required supporting documents are not submitted along with the application, the JFDA requires the applicant to submit a justification and the scientific basis for not submitting a document.

However, If a document is simply ‘missing’ or the applicant cannot produce a required document, it is unlikely that this will be acceptable to the reviewer, with the likely consequence being that the application will be put on hold or possibly rejected.

Consequential impacts

Once the MAH has been changed, the product label must be updated to reflect the new MAH details. The amended details must be included on the internal leaflet, and on the product packaging.

It is worth noting that the Medicine and Pharmacy Law No. 12 of 2013 does not permit any tampering of product labelling thus, over-labelling is not permitted. Notably, this is a stricter approach compared to any other Gulf states, where over-labelling, or the application of a non-removable sticker with the new MAH details are permitted, and where the new labelling solutions are approved by the regulator.

Inventory already within the market

One major worry for a pharmaceutical company undertaking this process is the current inventory within the market. In Jordan, following the change to the new MAH, the JFDA will typically allow existing stock to remain on the market for a ‘grace’ period of one year, except in circumstances where any change may affect the safety and efficacy of the product.

However, in practice, the JFDA may apply its discretion to grant a longer ‘grace’ period of up to two years.

Voluntary withdrawal of the MAH

Where the MAH wishes to voluntarily withdraw its marketing authorisation, this constitutes a ’cancellation’. As a result of this cancellation, the product will be withdrawn from the market. It is also possible for the product registration will be cancelled. Hence, cancellation of the marketing authorisation and the withdrawal from the market always occur at the same time.

In such situations, the JFDA must be notified of the reason for the withdrawal. This is especially so if the withdrawal is related to efficacy, safety, quality and/or compliance issues. Additional measures may be required if the withdrawal/cancellation is due to such issues as safety, which is beyond the scope of this article.

The length of time it takes to cancel or withdraw a marketing authorisation varies depending on the reasons stated by the applicant. Generally, the JFDA is not favourable to removing products registered in Jordan, since this may result in limiting the range of products available to healthcare providers and/or consumers. However, if there are any safety or pharmacovigilance concerns the JFDA will generally react decisively and handle the cancelation or withdrawal differently.

As we can see from the above, we consider that the JFDA has developed specific regulations for the change of MAH which aim to protect the interests of pharmaceutical companies in the jurisdiction, while at the same time maintaining the highest standards of pharmacovigilance within the MENA region.