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Baker McKenzie's Insight

Transferring marketing authorizations as a result of Brexit: key tax considerations

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1. Background

Developing, producing and marketing medicinal products involves a significant amount of regulation grounded in EU law for pharmaceutical companies to navigate. The regulatory landscape has become even more challenging in light of Brexit as pharmaceutical companies grapple with what they urgently need to do in order to continue to bring medicinal products to the EU market post-Brexit. Following the UK's decision to leave the EU, the European Medicines Agency (**EMA**) confirmed that it will move from London to the Netherlands - following various rounds of highly competitive bids and close votes - and that businesses should not look to rely on any transitional period after the UK officially leaves the EU on 30 March 2019.

As a consequence of the withdrawal of the UK from the EU, pharmaceutical companies are acutely aware of the need to transfer certain functions outside of the UK to the EEA by 30 March 2019 purely for regulatory reasons in order to continue to market and distribute medicinal products across the EEA.

This in turn has wider ramifications for the group to navigate, including tax issues that arise from the restructuring and changes to existing supply chains. In this article, we consider some of the key tax issues that arise from the transfer of such functions and assets, particularly in relation to European centralised marketing authorisations (**MA**).

2. Centralised marketing authorisations: regulatory framework

In order to bring a medicinal product to market in the EEA, it must be approved by the EMA or a national regulator to hold MA via a national, decentralised or centralised procedure. A centralised MA is required for certain types of medicinal products (such as oncology) and gives its holder a single licence that can be used to market the relevant product across the EEA for a prescribed period (typically 5 years). Under EU law, the entity that holds the marketing authorisation (**MAH**) must be established in the EEA. This means that as a result of Brexit, centralised MAs currently held by an MAH in the UK must be transferred to an MAH based in the EEA prior to 30 March 2019. Prior to the UK Referendum on Brexit, around 40% of centralised MAs were held by UK entities and according to a press release issued by the EMA on 10 July, 58% of existing MA holders are moving forward with this process.

Broadly, in order to re-register the centralised MA, the new holder of the MA (the **New MAH**) is required to submit an application to the EMA. As part of this process, the New MAH must demonstrate that it is established in the EEA. The EMA suggests that companies should allow 90 working days for the re-registration process to be completed. The UK regulator, the MHRA, has issued guidance indicating that it is confident of the transitional Brexit implementation period being upheld and that therefore there is not a rush to transfer centralised MAs. However, the EMA has warned companies that they should not assume a transitional period will apply and therefore need to press ahead quickly with this process in order to ensure that the process has been completed on or before 30 March 2019.

3. Marketing authorisations: key tax considerations

From a tax perspective, this presents a key question as to whether the re-registration of the MA in this way could give rise to a tax charge for the existing MAH. Whilst the position is fact dependent (and depends, for example, on whether other functions are transferred), we believe the better view is that there should be no specific value attributable to the MA. This analysis is reached on the basis that:

(a) an MA is not transferable in the sense that a re-registration as opposed an actual legal transfer is required;

(b) there is no (immediate) need to transfer any functions (albeit that, as a matter of fact certain assets/functions may be transferred); and

(c) there is no legal requirement to transfer any IP or data to support the MA.

The key point is to understand whether any other assets / functions may also be transferred as part of this process (e.g. data, personnel, valuable contracts, etc.) and what this in turn means from a tax perspective. On a going forward basis, the expectation is that the New MAH would recharge the costs of obtaining and maintaining the MA to the relevant affiliates in the group.

In terms of the location of the New MAH, the potential non-tax factors that are likely to drive the new location include (i) proximity to the EMA (ii) whether the group has a significant presence or concentration of functions in a particular location (iii) cost / synergies and (iv) access to talent / willingness of existing personnel to relocate. Potential tax drivers could be the possibility of amortizing the costs of the transfer or controlling the risk of taxation of a gain upon a future transfer of the MA, for example through a ruling with the local tax authorities; see the further analysis below. In our view, it is likely that the non-tax factors will outweigh the tax factors for many pharmaceutical groups when selecting the location of the New MAH.

4. Transfer of other key regulated functions

In addition to MAs, there are other assets/functions that need to be transferred from the UK to an EEA state as a result of Brexit and by 30 March 2009. For example, pharmaceutical companies seeking to market and distribute medicinal products in the EEA must adhere to the following:

(a) the Qualified Person for Pharmacovigilance (**QPPV**) must reside and carry out his/her functions in the EEA (broadly, the process of detecting and preventing adverse effects of medicinal drugs) in the EEA and the Pharmacovigilance Master File (**PSMF**) must also be located within EEA; and

(b) the Qualified Person for Batch Release (**QPBR**) must reside and carry out his/her functions in I the EEA (broadly, the quality control process / verification that products meet necessary standards);

(c) an EEA entity must hold a manufacturing licence in order to import medicinal products from third countries (including the UK as of 31 March 2019); and

(d) an EEA entity must hold the wholesale licence for distributing medicinal products in the EEA.

The UK tax consequences of the disposal of each of these functions will need to be considered on a case by case basis and as these functions are likely to be valuable, it is important that the potential tax

consequences are assessed at an early stage in the overall planning. This may also result in a change to the supply chain/wider restructuring e.g. where the wholesale licence (and therefore, the sale of the product) moves from the UK to another EEA state. Companies should be alive to the tax issues that may arise as early on in the process as possible.

5. Key tax considerations from the perspective of the New MAH based in the EU/EEA region

The preferred location for the New MAH will depend on several factors, but for example Germany, Italy, Spain or France can be logical candidates due to the size of the market, or the Netherlands or Belgium due to the distance to the EMA. The following factors could be considered from a tax perspective:

5.1 Attribution of value to an MA?

According to (for example) the Dutch civil code (Article 2:365, based on Directive 2013/34/EU) the costs of a permit or license are to be included on the balance sheet as an intangible asset. Under German tax law, for an "asset" to be present it is not necessary to be separately transferable. In Italy, normally no value is attributed to a MA; they are just administrative permits with no intrinsic value. For permits or licenses usually an annual fee is paid that represents the use during the particular year. For the transfer (actually the re-registration) of an MA, the EMA charges a basis fee of EUR 7.200. The annual maintenance fee for the MA amounts to EUR 102.900[1]. Other than these regulatory charges from EMA there is no specific value to be attributed to the MA "as such", despite it being indispensable for the company (without an MA it is out of business). This part must probably be attributed to the medicinal product and the underlying research conducted for which the MA is granted and not to the MA itself.

As already mentioned, the EMA provides detailed rules (for the transferor and the transferee) on how the transfer of the MA is to be realized[2]. In this process of transfer, effort is needed from the parties concerned (transferor and transferee) to comply with EMA's rules, resulting in the necessary (internal and external) costs. In that regard, the OECD transfer pricing guidelines may be applicable, entailing a further analysis of the transfer, which may include functions and assets that go with the MA (i.e. value may be attributed if the MA is bundled with other tangible and/or intangible assets).

This matter of value is of particular importance when the MA is to be transferred again to an affiliate or to a third party in case of an "exit transfer". For example in Germany, also the transfer of a "business opportunity" may result in a taxable capital gain for the transferor, if significant support is given or needed for the transfer (or de-registration) of an MA. Similar discussions may arise in France in case of transfer of an MA and in particular functions surrounding it. Carefully documenting the transaction involving the de-registration of an MA is therefore of critical importance.

[1] General Fees payable to EMA/57364/2018

[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000063.jsp&mid=WC0b01ac058002da5b#

5.2 If the MA has a value, is it possible to amortize the expenses?

Generally, intangible assets are amortized over their useful life (for example, in Belgium a minimum period of five years applies). For Dutch tax purposes, a license or permit can qualify as a "business asset" for tax purposes that can be amortized.

5.3 Would the MAH be required to recharge costs of obtaining and maintaining the MA to affiliates?

The centralized MA is granted for the entire EU / EEA region, and therefore it would be appropriate (at arm's length) to recharge the costs to the other commercial affiliates (i.e. on the basis of sales volume). For example in Spain, such split of the (periodical) costs could be done without a mark-up if the Spanish MAH just invoices a cost charged by third parties (EMA) to obtain and maintain the MA. However, if it carries out some functions and assumes certain risks related to the MA then an arm's length mark up will have to be charged.

5.4 Are there any other tax implications for an inbound transfer of an MA?

If the current UK transferor of the MA would invoice for the transfer of the MA, the transferee will have to self assess VAT on the remuneration.

5.5 Will local tax authorities be willing to provide an advance confirmation (ruling) on the tax treatment, including a future disposal?

In the Netherlands and Belgium the ruling practice is well developed; in Belgium it would be possible to obtain an advance tax ruling provided the transaction did not yet produce its legal effects for tax purposes. In Spain it is possible to obtain an APA with respect to the arm's length price of the transfer and/or the tax implications in connection with such transfer. In Italy, the future disposal within group companies may be the subject matter of an APA. Also in Germany an APA could probably be obtained (although against a fee payable to the tax office), where the attitude of the tax authorities has notably become more foreign investor oriented.

Given the cross border element, such ruling may result in automatic disclosure within EU member states. Because of the recently adopted EU Directive 2018/822 on mandatory automatic exchange of information by intermediaries , this even may be a reportable cross-border arrangement in particular if the MA may be seen as a "hard to value" intangible.

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