KPMG

Pillar 1 – Amount B: Application of proposed scope criteria to the life sciences industry

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On December 8, 2022, the Organisation for Economic Co-operation and Development (OECD) released a public consultation document on Pillar 1 – Amount B, a proposal to simplify and streamline the application of the arm's length principle to baseline marketing and distribution activities.

Across the life sciences industry, there are frequent disputes about the pricing of baseline (or routine) marketing and distribution activities, with tax administrations arguing that the detailing, regulatory and market access characteristics of the industry justify high returns on sales for distribution entities.

This article considers the potential application of Amount B to businesses in the life sciences industry. It is premised on the understanding that, as currently proposed, the criteria used to determine which entities fall within the scope of Amount B are likely to exclude most distribution entities within life sciences, including distributors that would be considered baseline in the context of the economically relevant characteristics for the life sciences industry. The article considers the policy considerations for the application of Amount B to life sciences multinational enterprises (MNEs) and the difficulties which arise from excluding distributors which perform *"any regulatory activities that are valuable and material to the ability to conduct the distribution activity in the market".*[1] Finally, we suggest that rather than scoping out life sciences distribution entities, an alternative industry-specific approach should be considered in view of the fact that the life sciences sector is prone to resource-intensive disputes between taxpayers and tax administrations.

A tax and policy perspective on the scope of Amount B

From both a tax and public policy perspective, there are a number of reasons why the life sciences industry should be included in Amount B.

Pillar 1 has previously been presented as a package comprising Amount A and Amount B, with Amount A allocating additional taxing rights to market jurisdictions and Amount B providing additional tax certainty to taxpayers and tax administrations. Life sciences constitute approximately 20 percent of the groups in scope of Amount A. Excluding life sciences from the scope of Amount B will leave this industry facing the additional complexity of Amount A, without the certainty benefits of Amount B.

The benefits of Amount B to low-capacity jurisdictions (LCJs) will be reduced if Amount B does not cover distributors that perform some regulatory activities. Distributors across a range of industries, including life sciences, food, cosmetics, chemicals, energy and transportation, must comply with regulations to distribute some or all of their products.

[1] OECD (2022), Public Consultation Document: Pillar One – Amount B, p. 11

Finally, Amount B has added importance as we understand its scope will not be restricted to MNE groups which meet the revenue threshold for Amount A. This means the potential benefits available to MNEs and tax administrations will be greater with a broader scope of Amount B, particularly in view of the continued emphasis placed on arm's length transfer pricing under Pillar 2.

Performance of regulatory activities by distributors in the life sciences industry

Regulatory activities and ownership of market access rights or regulatory licenses

It is important to note that where local life sciences distributors support a central intellectual property (IP)-owning entity with obtaining and maintaining product registrations and/or approvals in particular markets, they will typically only be requested to provide such support after the relevant governance decisions have been taken to seek regulatory approval. Regulatory filing decisions are generally considered as part of global and regional strategy, and as such are an "above market" function that is not performed by distributors.

A medicinal product may only be placed on the market when a health authority has issued a license. The International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)[2] publishes scientific guidelines on human medicines that are harmonized across ICH regions. ICH aims to achieve greater harmonization worldwide for the development and approval of safe, effective, and high-quality medicines in the most resource-efficient manner. These guidelines inform life science companies globally of the technical data required for approval of a medicinal product and the data generated are presented in a format that is internationally recognized: The Common Technical Document (CTD). The CTD format was set by ICH and agreed by the Regulatory Agencies of Europe (including the UK), Japan and the US: the priority markets for launch of new medicinal products. Many health authorities globally formally recognize the CTD format, which therefore limits the duplication of effort when companies file marketing authorization applications outside of Europe, Japan and the US.

Market access rights

The clinical and other data required to obtain approval will generally be held centrally and the rights pertaining to such data belong to the IP-owning entities which assume the investment risk in relation to associated research and development activities. This supporting data would need to be provided to regulatory affairs personnel undertaking operational tasks aimed at obtaining necessary registrations and approvals required to market and sell the products in a particular jurisdiction. Consequently, it is the IP-owning entities which control the barrier to entry for the sale of proprietary pharmaceuticals and medical devices into the markets.

Product registrations and approvals would not typically be obtained and maintained in the name of each local distributor unless there are restrictions on entities incorporated outside of the market jurisdiction holding these registrations. In such cases, the distributor may be requested to obtain and maintain the registrations in its own name but exclusively for the benefit of an entity outside of the market jurisdiction (e.g. the owner or licensee of the product IP), such that the distributor cannot assign or transfer the registrations to another person unless it is (i) at the request of the controlling party, and (ii) it is legally permissible to do so. Whether the registration is held locally or centrally, the arm's length returns associated with obtaining market access would be determined by the functional analysis, and particularly the location of the key functions, assets and risks, not just the identity of the person named as registrant.[3]

It is important therefore that the rules are able to differentiate between being named as a license holder and which entity should be treated as economically owning and controlling the license and the rights conferred by that license. This distinction is one that is explicitly recognized by the OECD Transfer Pricing Guidelines (OECD TPG).

[2] The current ICH Association Members and Observers include the medicines regulatory authorities from many Inclusive Framework member countries.

[3] In this regard, we note that Chapter 6, paragraph 6.42 of the OECD Transfer Pricing Guidelines, which states: "For transfer pricing purposes, legal ownership of intangibles, by itself, does not confer any right ultimately to retain returns derived by the MNE group from exploiting the intangible, even though such returns may initially accrue to the legal owner as a result of its legal or contractual right to exploit the intangible."

Regulatory activities

It is important to recognize at the outset that regulated business activities are not per se more profitable than non-regulated business activities and that the opposite may be observed as regulated businesses face higher operating costs in order to comply with regulations and reporting. As noted above, the food industry is also regulated but is characterized by very thin margins and where industries are subject to increased regulation, it tends to put downward pressure on margins (e.g. in the case of investment banking). Other factors such as patent protection of key molecules that create barriers to entry are more likely to be correlated to higher profits in the life sciences industry.

The proposed exclusion for regulatory activities states that the distributor should not perform "any regulatory activities that are valuable and material to the ability to conduct the distribution activity in the market".[4] This exclusion could be read as widely drawn and involves subjective criteria (e.g. what is valuable and how valuable does it need to be). These are also issues where there are already frequently disputes between taxpayers and tax administrations, as well as disputes between tax administrations. Moreover, we have concerns about how this aligns with the existing transfer pricing principles in the OECD TPG, which are explained below.

In the context of assessing the impact of a regulatory license, paragraph 1.170 of the OECD TPG states that it may be important to consider the contributions of the various parties in supplying the capabilities necessary to obtain a license.[5]

Paragraph 7.49 of the OECD TPG provides examples of services that would likely meet the definition of low value-adding services (as defined in paragraph 7.45) and includes inter alia:

- Monitoring and compilation of data relating to health, safety, environmental and other standards regulating the business; and
- Legal as well as administrative work for the registration and protection of intellectual property.[6]

Regulatory affairs services are also among the categories of services which are eligible for treatment as specified covered services for the Services Cost Method[7] under the US transfer pricing regulations, which allows certain low-value intercompany services to be charged at cost without a markup. The list of specified covered services eligible for the Services Cost Method specifically includes "gathering information and preparing documentation relating to eligibility for or compliance with laws and regulations governing contracts, licenses and permits."[8]

In the pharmaceutical sector, regulatory affairs outsourcing is increasingly common and covers both operational tasks and more strategic advisory services. According to a report by Grand View Research,[9] the global regulatory affairs outsourcing market size was estimated at US$6.5 billion in 2021 and is anticipated to expand at a compound annual growth rate of 8.9 percent from 2022 to 2030. The report notes that the outsourcing of regulatory affairs has become an increasingly important practice in the healthcare industry and is primarily driven by pressures on life sciences companies to reduce costs. The trend towards international harmonization as described above is also a growth enabler.

Many companies now outsource a range of operational tasks, including pharmaceutical chemistry and clinical regulatory writing, literature searches for submissions, preparation and compilation of regulatory applications, compliance activities such as standard operating procedure (SOP) writing, audit readiness and regulatory training, and liaising and negotiating with regulatory authorities.

Contracting and pricing models vary but are typically based on the service provider's actual or budgeted costs of performing the services (cost models), and where there are contingent aspects (e.g., bonus or penalty provisions based on whether filings are made on time) these are not calculated by reference to revenues or profits earned by the client.

In our view, the proposed treatment of regulatory activities for Amount B is inconsistent with real world market trends where the activities are increasingly viewed as non-core and are outsourced, such that treating them as ancillary with appropriate quantitative threshold safeguards would seem a more appropriate course of action.

[4] OECD (2022), Public Consultation Document: Pillar One – Amount B, p. 11

[5] OECD (2022), OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations 2022, paragraph 1.170.

[6] OECD (2022), OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations 2022, paragraph 7.49.

[7] The Treasury Department and IRS recognized that because the section 482 services regulations potentially affect a large volume of intragroup back office services that are common across many industries, it is in the interest of sound tax administration to minimize the compliance burden of such services, which would typically bear low arm's length markups. The Services Cost Method evaluates whether the price for covered services, as defined pursuant to Treasury regulations, is arm's length by reference to the total services costs with no markup.

[8] See paras. 3.45-3.52 of Rev Proc 2007-13 and in particular para. 3.46.

[9] Regulatory Affairs Outsourcing Market Size Report, 2030 (grandviewresearch.com)

Including distributors in the life sciences industry in the scope of Amount B

The simplification benefits of Amount B would be greater, for businesses and tax administrations, if life sciences distributors were included in scope. We think this is not only desirable, but eminently feasible.

In our experience, local regulatory affairs activities represent a small proportion of the headcount and cost base of a typical local distribution entity, and transfer pricing audits and Bilateral Advance Pricing Agreements are generally concluded on the basis that the return for such activities can be included in the return on sales margin for the primary distribution and marketing activities. In other cases where regulatory activities are performed by a marketing services entity that is not a buy-sell distributor, the arm's length price would typically be based on cost plus a margin.

We think a more balanced and proportionate response to concerns about regulatory affairs activities carried out by distribution entities would be not to scope out life sciences distributors entirely through a blanket exclusion and instead consider whether an industry-specific simplified approach to pricing baseline distribution related activities can be developed.

If there is a need to have a specific scope requirement related to regulatory activities, then we would suggest that consideration is given to adopting a tolerance threshold for such activities based on a percentage of an entity's operating expenses. Such percentages would be best determined following further consultation with businesses across all industries in which distributors commonly perform some level of regulatory activities. We note that where entities fall outside of these thresholds and hence would not be eligible for Amount B, it should be made clear that the Amount B pricing methodology cannot be used to set returns for such entities and does not represent a floor for the returns that such entities should be allocated, nor does the exclusion mean the activities in question are non-routine in nature.