ANNEX B to E/C.18/2024/CRP.24

Paper for approval from the Transfer Pricing Subcommittee

Appendix: Transfer Pricing Questionnaire for the Pharmaceutical Industry

1. Overview

This Appendix provides a list of potential questions that may be asked by a tax administration engaged in a transfer pricing analysis of the controlled transactions within a multinational group ("MNE group") in the pharmaceutical industry. The questions may be used in a functions, assets and risks ("FAR") analysis of the controlled entity and its related-party transactions. The questions are designed to ascertain the facts and circumstances pertinent to the controlled transactions, asking for information that has not already been provided by the taxpayer (e.g., through transfer pricing schedules or transfer pricing documentation).

The Appendix includes multiple questions, some quite detailed, which would benefit from being selected for, and tailored to, the specific transactions, taxpayer and tax audit. For example, some questions may be more relevant for generic products; others are more relevant for originator products. Similarly, some questions may be more appropriate for prescription drugs; others are more appropriate for over-the-counter (OTC) pharmaceuticals.

In addition, some questions may be more appropriately answered by a local subsidiary in the MNE group; others may only be answerable by the parent firm, depending on which entity or entities are being analyzed and whether the tax administration has jurisdiction to obtain the information. It should be noted that the entity under review may not be able to provide information relating to other entities, either because it does not have, or have access to, that information or is not authorized to provide that information. In that case, other avenues (e.g., requests for exchange of information under a treaty) may be available to collect the relevant information.

When assessing the relevance of, and responses to, each question listed below, it should be considered which entity or entities in the MNE group under review are involved in the particular function / transaction / activity, in what capacity, and which entity bears the costs and assumes the risk. While the term "entity" is used throughout the Appendix, it may be that information from multiple entities in the MNE group is relevant, where "relevant" means "relevant for the controlled entity under review." The questions should be directed to an entity under review when the entity performs that particular function. It is also useful to note that when questions are asked in a "how" or "what" format, it is understood that the questions also seek information on whether the entity under review undertakes that function

It is important to note that not all questions in the Appendix are suitable for all entities, cases and situations. In particular, the questions cannot meet the needs and fit the specifics of each country (including, importantly, the specific requirements of the domestic transfer pricing, income tax, and administrative tax law and regulations). Instead, the purpose of this Appendix is to provide options and considerations (and perhaps inspiration) for tax administrations, especially in developing countries, which can then tailor their questions to their particular domestic taxpayer, priorities, requirements, and constraints.

Lastly, more information on transfer pricing risk assessments and audits can be found in the UN End-to-End Toolkit for Transfer Pricing Compliance Assurance.[1]

The questions in this Appendix are grouped according to the main activities in the pharmaceutical global value chain, as follows: general information questions (section 2), research and development (R&D) (section 3), primary and secondary manufacturing (section 4), marketing and sales (section 5), supply chain management (section 6), and registration and regulatory affairs (section 7). Section 8

[1] UN (2024). Transfer Pricing Compliance – An End-to-End Toolkit. Available from Transfer Pricing Compliance Toolkit.pdf (un.org)

provides questions on risks and section 9 provides a non-exhaustive list of other documents that may be requested from the taxpayer to assist in the transfer pricing analysis.

2. General information questions on the MNE group

1. Please outline the overall business strategy of the MNE group and the role of the controlled entity under review.
2. Please provide an overview of the main products sold, in both value and volume, in the country of the entity under review.
3. What are the intangible assets, including major brands, of the MNE group and which entities in the group own them?
4. Have there been any recent acquisitions made by the MNE group (assets or companies) and, if yes, do these acquisitions have an impact on the entity under review?
5. Has there been any recent business restructuring within the MNE group and if yes, does the restructuring have an impact on the entity under review?
6. Please provide an overview of the global value chain for the MNE group.

3. Research and development (R&D)

The following questions may be appropriate for the controlled entity under review if it performs one or more of the following R&D activities: general R&D, drug discovery, clinical testing and / or pre-clinical testing. Other situations where these questions may be relevant for the controlled entity include where the taxpayer contributes to R&D expenses incurred by an associated enterprise (via a cost sharing agreement or otherwise) and / or pays a royalty to an associated enterprise for the use of intellectual property resulting from R&D activities. Note that questions related to the registration of R&D, including clinical trials, are included in Section 7 below.

3.1. General R&D

1. Please outline R&D activities relevant for the entity under review including steps such as the search for opportunities / drug discovery, pre-clinical testing, clinical studies and /or registration.
2. How long is the product development stage for the main products resulting from these R&D activities?
3. What is the strategic direction for these relevant R&D activities (i.e., what R&D strategy is being employed)?
4. How is the MNE group's R&D strategy determined? Does the entity under review play a role in this process?

3.2. Drug discovery

1. Assuming the R&D activities of the entity under review include drug discovery, with a stage gate process (i.e., the development process with different approval stages), please explain how the stage gate process works in practice, including approval workflow and governance.
2. Is there an R&D executive team that oversees or is responsible for these drug discovery activities and, if yes, in which entity are the team members located?
3. With respect to relevant drug discovery activities, in what capacity is the R&D undertaken, for example, as a contract R&D service provider?
4. How is the budget for these activities determined and approved? Does the budget process take place at the local level, foreign (global) level or both?

5. With respect to drug discovery activities, how are costs managed: by project, by functional area, or globally?
6. Which entity manages day-to-day R&D-related laboratory operations? Are these activities undertaken as a service provider or by the R&D entity itself?
7. How are the operational R&D activities financed?
8. Which entity owns any patents resulting from these R&D activities?
9. Which entity owns the product know-how used in and resulting from the R&D process?
10. Which entity owns the brands under which generic drugs resulting from the R&D activities are sold?
11. What is the process for handling patent protection in the MNE group? What is the process for handling patent infringement claims? Is the entity under review involved with these processes? If so, which entity bears the costs in relation to patent protection or patent infringement claims?
12. How are the results of R&D projects in which the entity under review participates shared among the entities in the MNE group?
13. Does the entity under review collaborate with health practitioners, customers, universities and / or other stakeholders in improving current drug formulations and / or developing new drug formulations / products?
14. Does the entity under review use data analytics to identify (potential) drug candidates or customers for the drugs that result from the R&D activities? If yes, please explain how data analytics are being used.
15. Does the entity under review participate in the development of these analytic tools?
16. Which data are used to run these analytic tools? Which entity is responsible for collating/collecting the data and which entity has ownership over the data?
17. Are there technology platforms that are shared between different R&D areas (for example, therapeutic areas or business units)?

3.3. Preclinical and clinical testing

1. Please describe the approval process for preclinical and clinical testing, as it affects the entity under review, and the bodies involved in the decision making process.
2. What is the process for determining the required preclinical and clinical tests?
3. Please describe in detail the process for conducting preclinical and clinical tests, noting the role played by the entity under review. If any third party is engaged in the process, describe how it is on-boarded and the activities that it performs.
4. For relevant preclinical and clinical trials please provide available information on the proportionate share of internal and external costs.
5. Are the relevant preclinical and clinical tests undertaken by the developer of the intellectual property, a contract service provider and / or another entity?
6. How are the relevant preclinical and clinical testing protocols designed and approved?
7. If preclinical and clinical tests are regulated, which entity is responsible for compliance with the applicable regulations (e.g., animal welfare regulations and ethical standards)?
8. How are the preclinical and clinical testing facilities maintained and who decides on investments in the facility?
9. How are external testing facilities selected, and by which entity?
10. How are the resources (e.g., labor, financial) allocated for preclinical and clinical testing and which entity is responsible for these resources?
11. How are the relevant preclinical and clinical testing teams managed?
12. Are there safety protocols in place and which entity sets these protocols?
13. How are the relevant clinical and preclinical testing budgets managed?
14. Which entity bears the relevant costs and expenses of preclinical and clinical testing?

4. Manufacturing

The following questions may be appropriate in cases where the entity under review performs manufacturing / production planning / sourcing functions in the country where audited, contributes to expenses incurred by an associated enterprise (via a cost sharing agreement or otherwise) related to the above efforts, and / or pays for these functions rendered by an associated enterprise.

4.1. Production planning

1. Please explain the production planning process, including with respect to production volumes, relevant for the business of the entity under review.
2. What is the policy on back-up manufacturing sites for major products that are relevant for the entity under review?
3. How does the MNE group forecast demand for relevant pharmaceutical products? Is the local entity involved in the forecast?
4. Which entity manages the overall regional or local production process, including the selection of manufacturing sites, outsourcing decisions and facilities relevant for the entity under review?
5. Which entity determines the budget for production facilities? How is the budget for production facilities allocated?

4.2. Manufacturing technology / know-how

1. Does the entity under review require any licenses or proprietary technology for the drug manufacturing process? Are they off-the-shelf or tailor-made? If yes, which entities obtain and / or utilize them?
2. Is there a process development department relevant for the entity under review? Which entity is primarily responsible for the management of product process development?
3. How are quality standards managed within the MNE group? Which department or entity is responsible for good manufacturing practices that would impact the entity under review?
4. Are there any manufacturing-related patents or know-how that are developed internally, or acquired from external sources, which are used during the manufacturing process by the entity under review?
5. At what stage of the drug production process are manufacturing-related patents or know-how utilized, and which entity develops or acquires them? Please describe the uniqueness of the relevant technologies and / or software involved.
6. Are there any further special skills needed for the production process?
7. Which entities provide the financial resources / funding to invest in manufacturing technology used by the entity under review?

4.3. Primary (API) manufacturing

1. Please explain the steps involved in the drug manufacturing process and provide an overview of the various stages from raw materials to final product.
2. Does the MNE group differentiate between primary and secondary processing in pharmaceutical production? Primary processing typically involves production of the active pharmaceutical ingredient (API), while secondary processing typically involves the packaging ("fill and finish") manufacturing stages.
3. Please describe the process for management of day-to-day production operations for the entity under review.
4. How are standards for drug testing purposes developed, and which entities are involved?
5. Please provide an explanation of the quality control and safety processes in drug manufacturing, including the entities responsible.

6. How are quality control tests conducted?
7. How is the cost effectiveness of production processes evaluated?
8. If and to the extent that manufacturing activities that take place in the country where the entity under review is located are subject to environmental regulations, what entity is responsible for compliance with environmental regulations with respect to primary manufacturing?
9. If there are outsourced primary (API) manufacturing activities pertinent to the functions or business of the entity under review, please provide what share of the production in primary (API) manufacturing is outsourced and to what entity.
10. Does the MNE group engage in third party sales of active ingredients or substances to third parties? If so, how is the pricing for such products determined?

4.4. Secondary ("fill and finish") manufacturing

1. What are the steps involved in the drug formulation process (for example, blending, granulation, tablet pressing) relevant for the entity under review, and which entities are responsible for these processes?
2. Please describe any additional processing steps such as tablet coating, encapsulation, or sterile filling, and indicate the entities responsible for these processes.
3. How does the MNE group handle the production of drug packaging, labeling, and printing, and which entities are involved in these activities as far as relevant for the entity under review?
4. Which entity decides on the packaging design?
5. Which entity manages day-to-day packaging operations?
6. Is labeling required for pharmaceutical products? If so, how is the alignment with legal standards ensured for the entity under review?
7. Which entity is in charge of product traceability and what specific initiatives are taken to ensure product traceability in line with the prevailing regulations?

4.5. Sourcing

1. What are the key raw materials, supplies and inputs required for the drug manufacturing process by the entity under review?
2. What is the structure of the sourcing process? Please indicate the entities involved, including those involved in price negotiations, supplier selection and contracting.
3. Is the entity working with any third-party wholesalers? If yes, which entity manages the contracts with third-party wholesalers?
4. Are there any hedging or foreign exchange procedures in place to manage risks related to sourcing and price fluctuations, and which entity is involved in these activities?
5. Please describe the factors that can affect sourcing prices, such as time, volume and quality relevant for the entity under review.
6. Does the MNE group have a trading strategy for sourcing, and if so, what does it cover?
7. What are the most important suppliers, especially for raw materials? Please list them for the country under review. Did the suppliers change within the last 3-5 years?

5. Marketing and sales

The following questions may be appropriate in cases where the entity under review performs marketing and / or sales activities, does so in relation to sales in the country where audited, and / or pays for these functions rendered by an associated enterprise.

5.1. Marketing

1. Please provide a description and organization chart of the marketing function for the entity under review.
2. Please indicate the reporting lines of the leader of the marketing department (full or dotted line reporting, local and/or to a regional or global organization).
3. How is the budget of the marketing organization managed in budget discussions and what are the main clusters of spending relevant for the entity under review?
4. Please explain the factors that are important for entering and competing in the market. How difficult is it for new competitors or new drugs to enter the market?
5. Please explain the market research process (including market segmentation).
6. Which entities bear the costs of market research?
7. Which entity selects and contracts the market research agencies, relevant for the entity under review?
8. Which entity is managing communication, including the contracting of external research studies to be used for marketing conducted by or relevant for the entity under review?
9. How is the participation in and contribution to the cost of global, regional and local congresses managed that are relevant for the entity under review?
10. Does the local entity receive any inputs from any other entity in the MNE group on the conduct of its advertising, marketing and promotion (AMP) activities? If yes, please describe the nature of these inputs and the mode of delivering these inputs.
11. Are the local marketing campaigns based on material prepared by global or regional teams?
12. Please provide an example of the customization of such campaigns to your country.
13. Would such customization require the approval of a global or regional organization? If yes, please provide examples of such guidance.
14. Are there campaigns based on corporate identity towards the public in which the entity under review participates? If yes, how is the material prepared and which entity bears the costs of such campaigns?

5.2. Marketing intangibles

1. Which entity conducts the advertising, marketing and promotion activities that are relevant for the entity under review?
2. Which entity is responsible for financing advertising, marketing and promotion expenses that may create marketing intangibles?
3. If local marketing and promotion expenses are incurred by the entity under review, does the MNE group reimburse or compensate the entity in any form for the same?
4. Please describe the key marketing intangibles deployed for selling the products in the market(s) relevant for the entity under review.
5. How are each of these intangibles developed / acquired / enhanced / maintained / protected/ exploited (DAEMPE)? Describe the role of each entity participating in the DAEMPE process.
6. Please explain the relevance of brands / trademarks / tradenames for the business of the entity under review. Are any of the entity's products viewed as global brands? As local brands?
7. Please explain the brand spending process, relevant to the entity under review, in terms of information gathering, strategy direction, visual identity and brand-strategy implementation.
8. Does the inter-company agreement between the entity under review and the parent have any stipulations with respect to incurring local marketing and promotion expenses?

5.3. Sales

1. Please describe a typical sales process relevant for the country or market of the entity under review.

2. Please outline the structure of the sales force relevant for the entity under review. How does the sales force cover the local market – by regions within a country, by product line, by customer group (e.g., physicians, pharmacists, hospitals), or a combination of these approaches?
3. Please describe the composition and nature of the sales force (e.g., years of experience, educational qualifications, salaries, etc.).
4. Which entity is the employer of the sales force?
5. To which entity does the sales force report? Which entity supervises the sales force?
6. What training does sales staff receive with regard to the product, and which entity provides this training? Is the training mainly global, regional or national? Which entity prepares the training material for such trainings?
7. Which entity is managing communication including external research studies to be used during the sales process?
8. Please describe the process for establishing and maintaining relationships with key opinion leaders (e.g., in scientific and medical fields) and / or governmental bodies relevant for the entity under review; for example, to communicate the importance of a particular product or to buy the product over competing alternatives through the life cycle of the product.
9. How does the local sales force respond to technical questions that health care professionals (e.g., physicians, pharmacists) might raise in respect of the marketed products?
10. Please provide a sample of the information package provided to health care professionals (for a given product or franchise) relevant for the country or market of the entity under review. Which department prepared the communication package and in which entity is this department located?
11. Are there any digital tools used by the sales force for preparing their visits or for interacting with health care professionals? If so, which entity developed these data tools?
12. How are the sales channel including OTC / prescription drugs defined?
13. What are the target customer groups (e.g., doctors / pharmacies / hospitals) that are relevant for the entity under review?
14. Please indicate the number of clients (e.g., wholesalers, hospitals, pharmacies if applicable) in the relevant territory of the entity under review.
15. Please indicate the role of data analytics and business intelligence in market segmentation relevant for the country or market of the entity under review. If available, is that data produced and processed locally or is it handled by a different entity?
16. Do key accounts exist? If yes, how were they acquired and how are they managed on a day-to-day basis?
17. Do master / framework agreements exist with customers relevant for the entity under review? If yes, please provide an overview and indicate if the terms of such agreements are defined locally or by a global or regional organization
18. Does the MNE group have a published price list?
19. Please describe the process for setting of prices of drugs sold locally. What inputs into the price setting, if any, are provided by the local entity?
20. Does the MNE group provide any guidance for sales and pricing for third parties relevant for the entity under review?
21. Please describe the budget process regarding sales and selling prices. How often are volumes and selling prices reviewed with regional or global management?
22. If applicable, please describe the escalation process regarding net selling price evolutions outside the budget review relevant for the entity under review.
23. Are any local price regulations applicable for the entity under review? Are mandatory rebate systems in place?

24. Please describe the process for conducting negotiations with the National Medicine Regulatory Authority (NMRA) or similar regulatory body with respect to price regulations relevant for the entity under review.
25. What is the role of Health Economics and Outcomes Research in putting together the file for engagement with either regulatory bodies or insurance organizations? Is the content of the file significantly amended locally or mainly globally prepared and locally amended?
26. Does the entity under review participate in tenders? If so, how is the process managed and what is the share of tenders in annual sales?
27. Are such tenders usually made on a portfolio of products?
28. Would a significant reallocation of resources (e.g., sales force and marketing, outside the budget process) from one product to another, or from one franchise to another, be subject to a decision by a regional or global department of the MNE group? If so, please describe the process. Please indicate where the department is located in the MNE group.

6. Supply chain management

The following questions may be appropriate in cases where the entity under review engages in warehousing and / or logistics, does so in relation to sales in the country where audited, and / or pays for these functions rendered by an associated enterprise.

6.1. General

1. Does the MNE group have a policy regarding supply chain management that is relevant for the entity under review?
2. Please describe the ordering, warehousing, distribution and transportation process.
3. Which entity manages day-to-day order fulfillment operations as regards the entity under review?
4. Is special know-how required for warehousing and logistics?
5. Are there service level agreements with the supply chain function in place? If so, please provide them.

6.2. Warehousing

1. Are in-house or third-party warehouses used for storing pharmaceutical products and, if yes, at which points in the supply chain, for the country or market of the entity under review?
2. In case of third-party warehouses, which entity identifies, selects and contracts the warehouse providers?
3. How is inventory management handled, and which entities have this responsibility?

6.3. Logistics

1. How is the logistics function (i.e., shipping companies, transport companies) for pharmaceutical products organized?
2. Which entity ensures timely delivery of pharmaceutical products and takes responsibility for any delays?
3. Please explain the methods of physical transport of pharmaceutical products destined for distribution, marketing and sale in the region or country of the entity under review.
4. Are there any differences between transport as it relates to products that originate within the MNE group and with external suppliers and customers?
5. Which entity bears the costs associated with the logistics function as it relates to products destined for distribution, marketing and sales in the region or country of the entity under review?

6. Please explain the process for negotiating the INCO-Terms for the logistics function as it relates to products destined for distribution, marketing and sales in the region or country of the entity under review.
7. What is the strategy for mitigating supply chain disruptions as it relates to products destined for distribution, marketing and sales in the region or country of the entity under review?

7. Registration and regulatory affairs

The following questions may be appropriate in cases where the entity under review engages in registration and / or regulatory affairs, does so in relation to sales in the country where audited, and / or pays for these functions purported to have been rendered by associated enterprises.

1. What registrations with respect to R&D (including clinical trials) are needed in the country or market of the entity under review?
2. Are there any local/sub-national requirements and / or is there a NMRA that needs to approve these R&D stages?
3. Please explain what is the contribution of the local entity in meeting registration/regulatory requirements? Are there any documents that are provided by the Group when preparing the local regulatory dossier?
4. Please explain the involvement of global regulatory and global medical affairs in the preparation of the regulatory dossier.
5. In seeking regulatory approval, is any reliance placed upon the granting (or otherwise) of regulatory approval to the MNE group by another national or supranational body, for example, by the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA)?
6. Which entity is responsible for registering drug patents within the MNE group? With which regulatory body (e.g., NRMA or patent offices) are these registrations made?
7. How are changes in government regulations that are relevant for the entity under review monitored and managed?
8. Is there a local regulatory affairs department in your country and what is its role?
9. What are the escalation processes in place regarding regulatory affairs relevant for the entity under review?
10. How are resources (e.g., labor, financial) managed and allocated for regulatory affairs?
11. How is the accuracy of regulatory documents ensured; e.g., is there oversight from another entity in the MNE group?
12. How are communications between the entity under review and the NMRAs and other regulatory bodies managed?
13. How does the MNE group deal with specific technical questions or challenges that NMRAs or other regulatory bodies might raise and that are relevant for the entity under review?
14. How is the regulatory affairs budget managed by the local entity? How is it managed within the MNE group?
15. What costs were borne over the past three-to-five years to obtain drug approvals and by which entity?

8. Risks

The following questions may be appropriate in cases where the entity under review assumes or is assigned risks, does so in relation to sales in the country where audited, and / or pays for these functions rendered by an associated enterprise.

1. What is the overall risk management strategy of the entity under review; i.e., in terms of identifying, assessing, responding to, and monitoring risks ?
2. Are there any agreements in place that are relevant for the entity under review that require or guarantee a certain production volume? Which entity bears the cost of production failures or over-production?
3. Are there relevant social and environmental standards that need to be fulfilled, and which entity is responsible for managing them?
4. Are there relevant supply chain, logistics, and transport risks and which entity manages them?
5. Are there relevant pricing, financial and foreign exchange risks and which entity manages them?
6. Are there relevant risks of obsolescence or faulty products and which entity manages them? Is there a return policy in place? Are the costs managed locally and borne locally?
7. Are there any insurance policies in place to cover these risks for the entity under review, and which entity covers the insurance costs?
8. Are there other measures taken to manage and mitigate risks relevant for the entity under review?

9. General documents

The following non-exhaustive list of documents may be requested from the taxpayer to further assess its functional and risk profile. These should only be requested if relevant for the entity under review and information has not already been provided.

1. Intercompany contracts, including intercompany financial arrangements such as loans, corporate guarantees, etc.
2. Advance pricing agreements and cost sharing arrangements
3. Registered trademarks
4. List of patented drugs including expected and actual revenue
5. Financial data including balance sheet and profit-and-loss statements
6. Organizational charts
7. Internal guidelines (for example, on production, quality, sales)
8. Operational Manuals containing detailed procedures and processes for various business functions
9. Annual marketing and R&D spending details
10. Group risk policy / internal risk reporting
11. Job descriptions of key personnel, their reporting lines, and any performance measurement mechanisms in place (including KPIs)
12. External or internal brand valuations
13. Forecasts for the product pipeline
14. Press releases