



IBFD Journal Articles

IBFD's high-quality journal articles support your research and daily practice by helping you keep abreast with the latest developments in international tax. Selected and thoroughly reviewed by our team of editors, our journal articles form an integrated set with our worldwide news coverage and our in-depth analyses of tax systems and treaty networks across the globe.

IBFD's journal articles originate from the following well-respected journal titles: *Asia-Pacific Tax Bulletin*, *Bulletin for International Taxation*, *European Taxation*, *Finance and Capital Markets (formerly Derivatives & Financial Instruments)*, *International Tax Studies*, *International Transfer Pricing Journal*, *International VAT Monitor* and *World Tax Journal*.

International

Philippe Paumier^[1]

Transfer Pricing in the Pharmaceutical Industry

Through economic and value chain analysis, this article aims at depicting some of the specific transfer pricing issues in an industry that has generated a substantial level of tax controversy over the last decades: the pharmaceutical industry.

1. Introduction

Over the last three decades, the pharmaceutical industry has crystalized many of the political and technical tensions between tax administrations and taxpayers in the realm of international tax and transfer pricing. In the last decade, these tensions have increasingly also extended to policymakers and public opinion.

The purpose of this article is to better understand the sources of these tensions as they relate to three main aspects:

- product and profitability: pharmaceutical products present certain characteristics that deeply impact supply and demand behaviour, with a high level of regulation and intermediation (section 2.1.). They are also characterized – when they gain approval and are successfully launched – by the profitability they yield, a profitability that is perceived as above average (section 2.2.);
- the coherence between the value chain of the industry and the most common transactional framework in pharmaceutical multinational enterprises (MNEs) (sections 3. and 4.), including the entitlement to residual profits or the impact of certain facets of operational transfer pricing; and
- common transfer pricing issues (comparability and benchmarking, intangibles valuation) that are exacerbated by certain features of the industry, including its diversity and of course, its profitability.

Because the pharmaceutical and life science industry include a significant number of sub-segments, the focus of this article is on the prescription drugs (Rx) segment. However, section 5.3. also attempts to analyse the reach of certain sub-segments' differences on transfer pricing policies.

2. Economic and Financial Aspects

2.1. By nature, a highly regulated market

From an economic standpoint, pharmaceutical products are not easily characterized as either public goods, merit goods or private goods. This complexity partially relates to the extreme diversity of pharmaceutical products and their therapeutic areas. But because access to effective and quality medicines is an essential element of the right to health, many countries have developed a regulatory framework that affects both supply and demand factors of the pharmaceutical market. Different models for regulation exist and these are generally determined by the size of the pharmaceutical market and the availability of resources, as well as public health needs.^[1]

Among the common features of the regulatory models is the separation, on the demand side, of roles across four parties:^[2] the patient, the ultimate consumer of the product; the physician, serving as an agent on behalf of the consumer; insurers, private and/or public who cover the costs of the drugs;^[3] and the pharmacist, the dispensing point of the product, who is also qualified to provide additional information to the patient and in some cases empowered to select the version of the drug ultimately given to the patient. One of the main purposes of this segmentation has historically been to avoid the potential market failures associated with information asymmetry.

Regulations in the industry are also prevalent on the supply side:

- intellectual property protection usually embeds incentives to product substitutions (generics), and incentives to ensure a large spectrum of innovation;^[4]

* Philippe Paumier is a partner at VECTOR TP, Paris.

1. P.-L. Lezotre, *International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations* (Academic Press 2014).

2. S.O. Schweitzer & Z.J. Lu, *The Demand for Pharmaceuticals in Pharmaceutical Economics and Policy: Perspectives, Promises, and Problems* (3rd edn., Oxford Academic 2018).

3. Note the increasing importance of co-pay systems, the requirement of out-of-pocket expenditure from patients, or systems in which patients are the sole payers.

4. Examples being: research and development (R&D) tax incentives, general or for certain therapeutic areas, but also pediatric extensions or specific dispositions on exclusivity for orphan drugs or rare diseases.

- effectiveness and quality validation by public bodies (Federal Drug Administration (FDA), European Medicines Agency, country agencies),^[5] including continuous safety monitoring, applicable to innovation and research processes (good development practices) as well as to manufacturing (good manufacturing practices);
- price control regulations in many countries (applying different methods)^[6] and cost containment measures; and
- the stringent regulation of pharmaceutical marketing activities regarding content and promotional channels,^[7] complemented by industry- and country-specific codes of conduct.

In addition to health imperatives such as access to medicines, the multiple regulations and intermediations in the pharmaceutical market stem from the fact that medicines can be characterized as experience goods, where patients may not be able to reliably evaluate the product attributes until after consuming the good, or as credence goods, where the quality of the product may still be difficult to evaluate after consumption. Health authorities pre-qualify the products based on efficacy and safety, significantly narrowing the asymmetry, and physicians – who are insulated from the sale of the product to avoid agency problems^[8] – act as informed experts/agents for the patient.

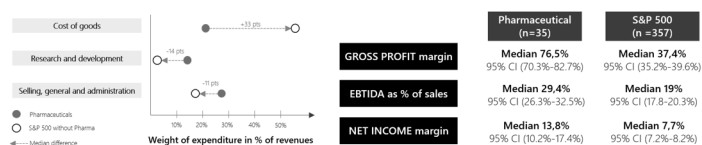
Because the information on drugs is not fluid or consolidated, physicians rely on approval documents, congresses, key opinion leaders and on the information provided by pharmaceutical manufacturers. Hence the importance of the regulation of pharmaceutical marketing and the necessity for pharmaceutical MNEs to ensure the optimal degree of fluidity of information, which includes reaching a large volume of healthcare practitioners and providing multiple updates.

2.2. Financial aggregates

The above-average profitability of the pharmaceutical industry when compared with other industry segments has been established in several studies.^[9] In one of the most recent studies, Ledley et al. (2020)^[10] conducted a statistical review of financial aggregates (gross profit, EBITDA (earnings before interest, tax depreciation and amortization) and net income) from 2000 to 2018 for 35 pharmaceutical companies and compared them to average and other industry segments of the S&P 500.^[11]

The study reported the median values and median differences between pharmaceuticals and the S&P 500, as shown in Figure 1.

Figure 1 – Financial indicators, pharmaceuticals v. the S&P 500



Note 1: Charts derived from values in F.D. Ledley et al., Profitability of large pharmaceutical companies compared with other large public companies, JAMA (American Medical Association 2020), p. 4.

Note 2: Please note that profitability derived from the sum of median cost of goods sold (COGS), research and development (R&D) or selling, general and administrative expenses (SG&A) differ from the median of EBITDA and net income (sum of medians is not equal to the median of the sum).

When comparing expense levels by macro-category, the significant median gap on cost of goods sold (COGS) (32.6%) between pharmaceuticals and the index is partially offset by higher levels of median expenditure in terms of research and development (R&D) and selling, general and administrative expenses (SG&A). The study identifies a gap of 10.4 and 6.1 points respectively at EBITDA and net income levels between pharmaceuticals and the S&P 500. When controlling for variables such as company size,^[12] such gaps fall to 8.6% and 4.1% respectively but remain significant.

While corroborating the fact that the pharmaceutical industry is the most R&D-intensive industry, highlighting the role of innovation (and therefore of intellectual property) in the value creation of life science firms, the study shows that SG&A expenditure in pharma – expressed

5. For the approval of products and for continuous safety monitoring.

6. See section 3.3.

7. The most notorious feature is the forbidding of direct-to-consumer advertising for prescription drugs, which only occurs in the US and New Zealand markets.

8. L. Balafoutas & R. Kerschbamer, *Credence goods in the literature: What the past fifteen years have taught us about fraud, incentives, and the role of institutions*, 26 *Journal of Behavioral and Experimental Finance* (2020).

9. See for example: United States Government Accountability Office, *Drug industry: profits, research and development spending and merger and acquisition deals*, GAO-18-40 (Nov. 2017).

10. F.D. Ledley et al., *Profitability of large pharmaceutical companies compared with other large public companies*, JAMA (American Medical Association 2020).

11. Excluding pharmaceuticals, composed of 357 companies.

12. Given the fact that the 35 pharmaceutical companies in the sample were large multinational enterprises (MNEs).

as a percentage of revenues – was higher than the S&P 500 median by almost 11 points, reaching 28.2% as opposed to 17.5% in the S&P 500, fuelling the idea that pharma is driven more by SG&A (including marketing) than by R&D. Such is the pharma paradox.

In a subsequent study, Sood et al. (2021)^[13] reviewed the 2013-2018 financial data of pharmaceutical and biotech companies to assess the level of excess returns – calculated as the difference between the return on invested capital and the expected returns given risk (weighted average cost of capital) and compared the results of the pharmaceutical industry to the S&P 500 values. Unadjusted measured excess returns were 4.7% for pharmaceuticals and 4.2% for other S&P 500 values.

The authors also calculated adjusted excess returns treating R&D expenses as investments (instead of expenditure). Adjusted excess returns for the pharmaceutical segment for the period were around 1.7%, compared to the S&P 500 rate of 3.6% (respectively 4.7% and 4.2% unadjusted excess returns). Biotech-adjusted excess returns were 9.6% (13.1% unadjusted) but were significantly more volatile (below the S&P 500 in 2017 and above by 13 points in 2015),^[14] emphasizing the key role of R&D on the economics of pharmaceutical MNEs.

The weight of SG&A expenditure on sales (“excess spending”) has constantly fuelled transfer pricing controversy on the role of marketing in the value chain and the role of the local marketing and distribution affiliates of pharmaceutical MNEs. Two objective observations can be formulated based on financial metrics:

- based on Figure 1 data, pharma spends 37% of its gross profits on SG&A, whereas the S&P 500 spends an average of 40%.^[15] As such, it could be argued that pharma spends proportionally less in SG&A than the average S&P 500 company, in terms of the percentage of its available commercial cash-flows; and
- calculations made by the author^[16] suggest that the ratio of SG&A to R&D expenditure for the pharmaceutical segment was 1.6 (and 0.8 for the Biotech segment), significantly below other industries^[17] (average ratio for total industries without financials of 5).

The pharma paradox is partially explained by the fact that MNEs spend on average 15/20% of their revenues in developing a limited number of candidates globally, have large global functions that can account for between 5% and 8% of their revenues^[18] and allocate between 20% and 23% of their revenues to promote a large number of products in a very large number of jurisdictions, a magnitude that is not abnormal based on the features described in the previous section.

3. High-Level Value Chain in the Pharmaceutical Industry

Value chain analysis usually revolves around three pivotal functions: R&D, manufacturing and marketing. There is a case in the pharmaceutical industry for the introduction of a fourth segment to account for the value proposition of the products. See Figure 2.

Figure 2 – High-level value chain in the pharmaceutical industry



Indeed, when compared to other industries, the typical end-to-end pharmaceutical value chain has at least two main idiosyncratic features. The first one is that there is a large ecosystem of agents of critical importance operating outside the multinational as a result of the market intermediation described in section 2.1. The second particularity stems from the highly regulated environment in which pharmaceutical companies operate. Such features have generally prompted the roll-out of highly centralized global functions, and more specifically functions in charge of the value proposition definition and management of products, to ensure global alignment – during the life cycle of the product, from development to maturity – when addressing the multiple external stakeholders.

The globalization of pharmaceutical markets and the increased interconnection between markets^[19] has fostered the necessity for a globally managed value proposition. Hence the inclusion of this segment in the value chain within the commercialization and marketing cluster.

13. N. Sood, K. Mulligan & K. Zhong, *Do companies in the pharmaceutical supply chain earn excess returns?*, International Journal of Health Economics and Management 21, pp. 1-16 (2021).

14. Such approach is in line with A. Damodaran, *Research and development expenses: Implications for profitability measurement and valuation*, NYU Working Paper No FIN-99-024 (1999): “[i]n firms where R&D expenses have been increasing rapidly over time, reclassifying R&D can push up operating income significantly and can make return on capital a much higher number. In mature firms, where R&D expenses have been stable over time, the return on capital may decrease when R&D is reclassified”.

15. Respectively $(28.2/(100-23.5))$ and $((28.2-10.7)/(100-(23.5+32.6)))$. Calculations are proposed as an illustration of aggregates; they are not included in Ledley et al.

16. Based on Prof. Damodaran's global data set of financial metrics by industry segment, available at https://pages.stern.nyu.edu/~adamodar/New_Home_Page/datacurrent.html (accessed 2 Oct. 2022).

17. Ratios were for example of 1.9 for systems and applications software, 2.1 for computers and peripherals, 3.3 for online retail, 3.7 for healthcare products and healthcare IT, 5 for diversified chemicals or 6.2 for machinery.

18. Based on this author's observations.

19. Linked, for instance, to international reference pricing.

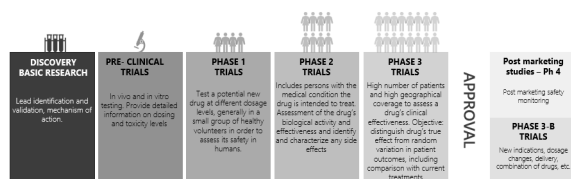
3.1. R&D and intellectual property (IP)

R&D spending in the pharmaceutical industry covers a variety of activities, including the following:

- invention, or research and discovery of new drugs;
- development, or clinical testing, preparation and submission of applications for regulatory approval, and design of production processes for new drugs;
- incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications;
- product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and
- safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development.

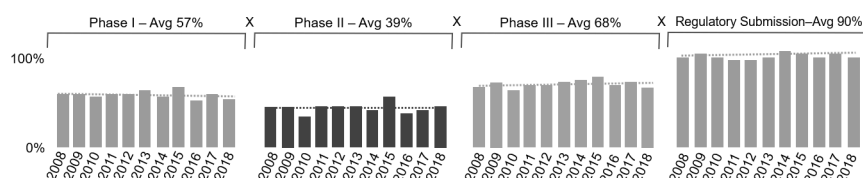
Clinical trials are extensively regulated to ensure the safety of patients and to properly evaluate the clinical benefit of a given drug. The process is illustrated in Figure 3.

Figure 3 – Pharmaceutical research and development



R&D and IP generation is one the most critical business risks in the pharmaceutical industry. Not only does it involve very significant (monetary) at-risk investments combined with state-of-the-art science, but the approval process is sequential, long and most importantly, has limited probabilities of success.

Figure 4 – Transition probabilities in development (data from 2008 to 2018)



Note: IQVIA, The Changing Landscape of Research and Development (Apr. 2019).

Figure 4 therefore indicates the transition rates: the probability that a drug in phase 1 trials enters phase 2 trials was on average 57% for the 2008-2018 period. The probability of a drug being approved in phase 1 is therefore the multiplication of all the transition rates: around 13%. The appraisal of risk also requires the consideration of the length of the development process, which has on average taken between 10 and 14 years from the launch of the first phase 1 study to the regulatory approval. Studies equally suggest that the total time from phase 1 to regulatory decision, regardless of product failure or success,^[20] has increased 26% since 2010.^[21] Phase 3 trials are by far the most expensive trials to conduct, hence the importance of the proof of concept (in phase 2) given the investments and risks at stake.

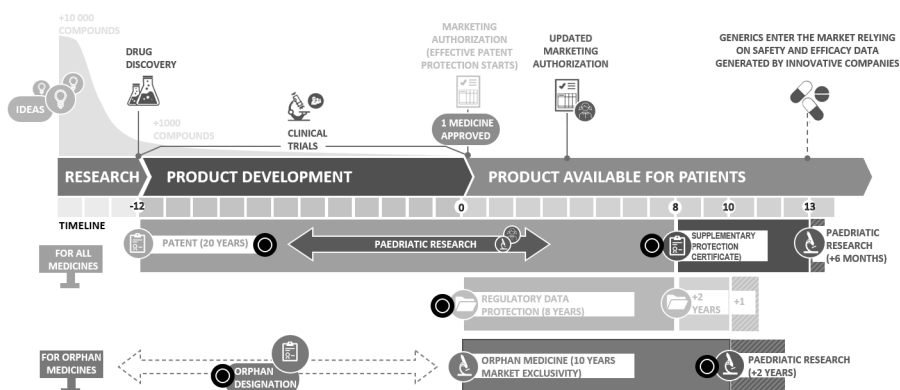
Once approved, pharmaceutical MNEs enjoy a limited period to recoup the investments made during the 10-plus-year development phase and generate profits to be reinvested in subsequent R&D programmes. Most jurisdictions have implemented similar regulations regarding

^{20.} At the regulatory level.

^{21.} IQVIA, *The Changing Landscape of Research and Development*, IQVIA Institute for Human Data Science (Apr. 2019).

the exclusivity of IP rights on pharmaceutical drugs based on patents, data exclusivity and regulating the entry of generic drugs in the market. See Figure 5.

Figure 5 – Protection and exclusivity for a typical compound



Note: EFPIA, The Pharmaceutical Industry in Figures (Key Data 2021).

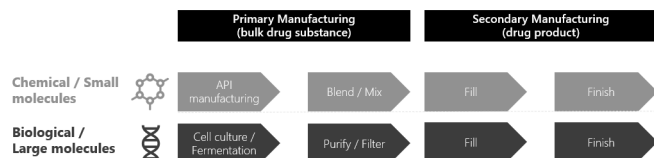
The competition^[22] for a newly approved compound can typically take the following forms:

- existing proprietary drugs (Rx) in the same therapeutic segment: drugs that are still protected by patents, exploited by the originator company that gained approval before the newly approved compound. This is referred to as “between patent” competition, based on the clinical cost/benefit determined by the different stakeholders;
- generics: drugs that have the same active pharmaceutical substance (or a combination of substances) and the same form of administration as the original patented medicinal product, and are entering the market after the originator product. In many countries, generics (Gx) can be substituted for proprietary products either at the moment of prescription or at the point of distribution (pharmacy for example); or
- biosimilars: a biosimilar is a biological medicine highly similar to another biological medicine already approved (usually called the “reference medicine”) in terms of structure, biological activity and efficacy, safety and immunogenicity profile (the intrinsic ability of proteins and other biological medicine to cause an immune response). Depending on the jurisdiction, biosimilars may or may not be substitutable for originator drugs.

3.2. Manufacturing and supply chain

In the pharmaceutical industry, chemistry and biology are at the heart of manufacturing. Manufacturing advances are necessary to cope with the sophisticated enhancements embedded in these fundamental processes. A new molecule may for instance require new know-how and processes to synthesize the molecule, the scaling up of production (for biologicals) or improved facilities and equipment with significant upfront investments. See Figure 6.

Figure 6 – Overview of manufacturing in the pharmaceutical industry



^{22.} Please note that this article does not address the specific issues of counterfeiting and parallel trade, and the impact of the latter on operational transfer pricing aspects.

Most small molecule drugs are manufactured through organic or inorganic chemical synthesis, whereas large molecule (biologic) drugs are manufactured through live cellular expressions. To produce small molecule drugs, the manufacturer combines specific chemical ingredients to make the drug substance or active pharmaceutical ingredient (API). To produce large molecule (biologic) drugs, however, the manufacturer uses live microbial cells (plant- or animal-sourced cells) to synthesize a biological drug substance or API. The resulting biologic is a very large, complex molecule (often 200 to 1,000 times as large as a small molecule and usually comprised of proteins).^[23] Given the size and complexity of such large molecules, manufacturers often face substantial manufacturing challenges and risks.

The manufacturing function is highly regulated: current good manufacturing practice regulations outline the minimum quality standards for the manufacturing of drugs, including biologics, and are established to ensure that products are safe and effective for human use. The definition and management of manufacturing processes are therefore key to maintaining quality standards and ensuring the scale-up capabilities of the manufacturing network of pharmaceutical MNEs. Specifically on biologics, immunogenicity, adverse events and efficacy can all be affected by even the slightest process change because a biologic is defined by its process. As such, industrial processes need to be robust enough to ensure that the same output is obtained when it is run for the first time or the hundredth time.

Finally, pharmaceutical supply chains have become global and complex and must deal with three major imperatives: avoid disruptions, ensure traceability and manage temperatures (cold chains). With more outsourcing, new modalities and novel ways to reach patients, it's critical to ensure that they can withstand shocks to avoid product shortages that can have severe consequences for patients and society. Pharmaceutical supply chains span across continents and involve many actors: material/API suppliers, manufacturers, wholesalers, traders, pharmacies and hospitals. To remain effective, supply chains need to ensure high standards in terms of connectivity, data management and traceability to minimize product losses and ensure the safety of the patients.

3.3. Promoting and marketing an intangible: From value proposition to distribution

While a product approval is a critical milestone for pharmaceutical companies, it does not constitute a guarantee of success, as significant risks are embedded in the commercialization phase of a newly approved compound. A 2020 study^[24] has for instance suggested that about half of all products launched over the past 15 years have underperformed pre-launch consensus forecasts by more than 20% and that a missed product launch can be challenging to overcome, especially as competition continues to intensify across most disease areas.

To put it simply, value propositions in the pharmaceutical industry are composed of two core elements with variable degrees of correlation: clinical benefits to patients and society (quality and efficacy), and price/cost.

Because of the nature of the product, customer and stakeholder engagement in the pharmaceutical industry requires the deployment of content-based marketing strategies (on validated clinical attributes of the product). Moreover, treatment decisions are increasingly co-governed by payers, who influence doctors' behaviour through drug formularies and therapeutic guidelines. Finally, patients – through access to a higher volume of information through digital tools – play an increasing part in the prescription process. These trends have led pharmaceutical companies over the last decade to deploy more customer-centric organizations and progressively depart from the traditional detailing model largely based on detailing through sales representatives' visits to healthcare professionals.

The value proposition of novel products needs to produce a market-shaping impact through the generation of compelling evidence to ensure a proper level of disease understanding and the maximization of market access by integrating real world evidence generation strategies into the process. Increasingly, the value proposition includes the identification with customers and stakeholders of solutions to optimize care pathways for patients. The value proposition in the industry also aims at activating demand through advocacy (for example key opinion leaders) and through a superior patient experience (patient communities, education, support programmes). Finally, it involves a deeper integration of the MNE in an ever more complex healthcare ecosystem.

The first component of the value proposition is therefore aimed at fostering market acceptance of a new therapeutic solution (once it is approved and once the market authorization is granted). An acceptance that can also be affected by pricing. The methodologies for the pricing of pharmaceutical products are usually defined by the health administrations of jurisdictions. Additional stakeholders can be involved in the price setting and price evolution, depending on funding systems in a given country and distribution channels (insurance companies, pharmacy benefit managers in the United States, etc.). One of the most common pricing methods is external referencing, which consists in using the price of a pharmaceutical product in one or several jurisdictions to derive a benchmark or to set a reference price. Pricing systems can also be based on markup regulations across the supply and distribution chain,^[25] or on internal referencing,^[26] or simply on negotiations (including through tenders).

23. Deloitte, *Advanced Biopharmaceutical Manufacturing: An Evolution Underway* (2015), available at <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-advanced-biopharmaceutical-manufacturing-white-paper-051515.pdf>.

24. P. Rosenom et al., *Biopharma Launch Trends — Lessons Learned From L.E.K.'s Launch Monitor*, XXII L.E.K Insights 87 (Dec. 2020).

25. A percentage or fixed mark-up could be specified at any point along the supply chain (e.g. ex-factory mark-up; and incorporating fee-for-service remuneration such as fees for dispensing or service quality). Other types of price regulation, such as direct price controls, could be set at any point along the supply chain, with a view to specifying the maximum prices, also referred to as price caps or price ceilings.

26. Using the prices of a set of pharmaceutical products that are therapeutically comparable and interchangeable to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement rate of a product.

However, the trend has been a move towards value and evidence-based pricing, which is an approach that aims to set prices for pharmaceutical products based on the value or worth that patients and healthcare systems attribute to the pharmaceutical products.[27] The shift over the last decade to value-based and evidence-based pricing has put an emphasis on real-world data and real-world evidence, increasing the importance of globally managed health economics and outcomes research, medical and market access departments with responsibility for generating evidence of the value of new interventions for reimbursement agencies and local healthcare payers with the aim of managing and securing the product's acceptance, approval and authorization.

While it can be acknowledged that in certain jurisdictions reality can be more complex: (i) in general, price negotiations tend to occur within price tunnels that are globally defined; (ii) promotion is performed through the communication of the clinical value proposition of the product; (iii) products are approved by regulatory bodies and defined by chemical or biological attributes; and (iv) the place of dispensing is highly regulated for prescription drugs. Hence the fundamental distinction that can be made between the functions involved in the definition of the value proposition and those ensuring that it is effectively and efficiently disseminated.

It could be legitimately argued that such an assertion is mainly valid for large products or franchises in MNEs, whilst the commercial management of mature portfolios or tail products is more decentralized. Industry statistics on 16 large pharmaceutical and biotech MNEs[28] nevertheless illustrate that the top three products account for around 40% of their revenues, and probably a more significant share of profits. This suggests that even if such a model were only applicable to the top ten products of a firm, it would remain a relevant business feature for transfer pricing purposes.

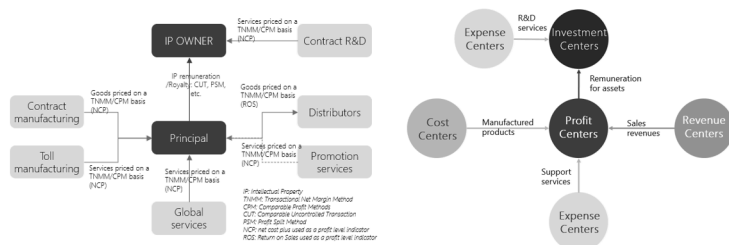
4. Typical Intercompany Transactional Model in the Pharmaceutical Industry

4.1. The rationale for centralized models

The rationality of the transactional models implemented within multinationals can be appraised through at least two prisms that tend to be intertwined: (i) a managerial view on the different functions and (ii) the existence of market templates.

The figure below illustrates the most common transactional framework observed in large pharmaceutical MNEs. Variations of this model include the presence of regional/specific principals operating in defined geographic areas or in a specific business area (e.g. a therapeutic area or industry sub-segment).[29] In addition, in some cases, the principal – acting as an operations and commercial entrepreneur – can also be the owner of the intellectual property of the products.

Figure 7 – Commonly observed centralized transactional framework in pharmaceutical MNEs



The management control system framework can be a simple and useful tool to analyse the functions/roles outlined in Figure 7 and described in section 3. For instance, in cost centres[30] the performance measurement requires the specification of standard quantities of direct labour and materials required for each unit of output, and managers are responsible for minimizing the variance between actual costs and standard costs on a yearly basis. Such features correspond to how manufacturing and services are managed within pharma MNEs.

Revenue centres would be units in which managers are responsible for maximizing sales volumes while respecting a budget commitment on expenses but not having the authority to significantly lower prices to increase volumes.[31] Within the pharmaceutical industry, distribution and promotion entities would typically fit the revenue centre characterization, given the lack of control they have in the product portfolio, and the formation and the management of the selling price in many jurisdictions where prices are directly or indirectly regulated and globally managed. Under such a model, the effect of the transactional model is to allocate residual profits to profit and investment

27. For more details on pricing, see WHO, *WHO guideline on country pharmaceutical pricing policies*, Web Annex B, Evidence-to-decision tables (2nd ed., World Health Organization 2020).

28. V. Patel et al., *How Business Strength Varies Across The Top Pharma Companies*, S&P Global Ratings (27 Aug. 2020).

29. Such would be the case for instance for a principal dedicated to prescription drugs or specialty care, and another one operating in generics and biosimilars or on consumer healthcare.

30. Or standard cost centres.

31. R.F. Vancil, *What Kind of Management Control Do You Need?*, Harvard Business Review (Mar. 1973).

centres who make cross-functional and integrative decisions as well as capacity decisions (on resources and asset investments that commit the organization over time). Note that a unit can be a profit and an investment centre, either fully acting as both, or in the context of cost-sharing agreements.

The rationality of such a model can also be corroborated by market templates in the pharmaceutical industry. In the area of R&D, pharmaceutical companies have for a long time resorted to clinical research organizations (CROs). The clinical trials segment of the CRO market is estimated to have reached USD 32 billion in 2021.^[32] Similarly, pharma MNEs have outsourced a significant part of their manufacturing to contract development and manufacturing organizations. The contract development and manufacturing organization (CDMO) market was estimated at USD 90 billion in 2019,^[33] 12% of which accounts for manufacturing services towards clinical development activities and the rest to commercial manufacturing. In addition, it should be noted that the market for contract packaging is deemed to match the size of CDMO (circa USD 60 billion). While less mature than the CRO and CDMO markets, contract commercialization outsourcing (estimated at USD 27 billion in 2019)^[34] embeds sales activities (external sales force, key account and key opinion leader management) and medical, market access and marketing services.

It could therefore be concluded that the centralized transactional framework depicted in figure 7 reflects the transactions pharma MNEs engage in with third parties. Moreover, absent any specific competitive advantage, the result is that remuneration policies based on costs for manufacturing and service provider operators and based on sales for distribution and promotion entities generally fit the management control systems framework. As such, the model embeds a reasonably high level of economic rationality.

It is worth noting that one of the business benefits of such a transactional model is to accommodate the integration of acquisitions with a fully automated transactional model in which the individual segments of the acquired business can be linked to the appropriate transactional module.

The review of market templates in the pharmaceutical industry is also likely to evidence the particular role of capital-based transactions. Over a decade, transactions such as royalty securitization or venture capital funding targeting specific portfolios of development programmes have been on the rise. They evidence that in this industry, capital investments – at risk – can attract remunerations based on third-party sales without a major control over DEMPE (development, enhancement, maintenance, protection and exploitation) functions.

4.2. Entitlement to residual profits

Given the weight of intangibles in pharmaceuticals, their remuneration and the determination of the entities within an MNE group that are entitled to the revenues rising from the exploitation of intangibles is critical. As specified by the OECD Guidelines,^[35] the exploitation of an intangible includes both the transfer of the intangible or rights in the intangible and the use of the intangible in commercial operations.^[36] There are two critical stakes:

- the allocation of the R&D risks and expenditure – 15% of the MNE's annual sales – and their effective deduction; and
- the allocation of residual operating profits^[37] derived from commercialized compounds: around 30/35% of third-party sales. Note that a 2-to-3-point impact from OECD's Pillar One^[38] would only marginally reduce the relevance of this issue.

Thus, the contribution of the 2017 OECD Guidelines^[39] on the entitlement to residual profits, through the analysis of DEMPE functions and the effective control over risk, require particular attention in the pharmaceutical industry. These ideas can be considered some of the most intrusive transfer pricing measures in the sense that they require an in-depth analysis of how MNEs are run with limited guidance.

When launching such an analysis, one suggestion is to reverse-engineer the process, starting with the identification of significant economic and operating risks. If the degree of exposure to certain risks can vary from MNE to MNE, the review of the risk management sections of annual reports yields a rather uniform list of risks among which DEMPE-related risks can be identified:

- patient safety monitoring;
- R&D success and portfolio regeneration;
- manufacturing quality standards;
- continuity of supply: supply shortages and other disruptions risks;

32. K. Brookes, *CRO Industry Market Report*, Contract Pharma (6 July 2022), available at https://www.contractpharma.com/issues/2022-06-07/view_features/cro-industry-market-report/ (accessed 11 Oct. 2022). Including early research, lab support and analytics, the market is deemed to be worth between USD 50 and 60 billion.

33. K. Bottomley & A. Newrzella, *Outsourced Pharmaceutical manufacturing 2020, Current Trends and Future Prospects*, Results Group LLP (22 Nov. 2019).

34. *Pharmaceutical Contract Sales Outsourcing Market Size, Growth, Trends, Forecast 2021-2030*, BioSpace (10 Aug. 2022), available at <https://www.biospace.com/article/pharmaceutical-contract-sales-outsourcing-market-size-growth-trends-forecast-2021-2030/> (accessed 11 Oct. 2022).

35. *OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations* (OECD 2022), Primary Sources IBFD [hereinafter *OECD Guidelines* (2022)].

36. *Id.*, at para. 6.32, footnote 3, p. 255.

37. Solely for the purpose of illustration, we will assume an EBIT (earnings before interest and tax) of 25%, therefore a pre-R&D EBIT of 40% of third-party sales, where 5% are allocated to distributors/markets, 3% to manufacturers and 2% to diverse service providers, with therefore a residual profit of 30% of sales.

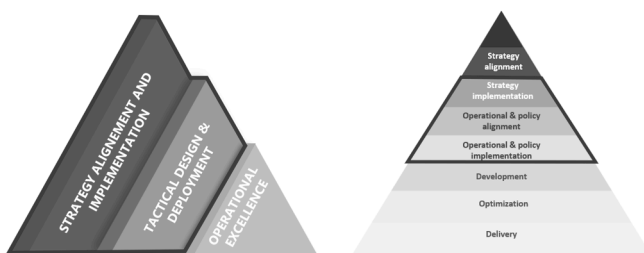
38. Example: 25% x ((between 20% and 25%)-10%), bearing in mind that Pillar One metrics apply on adjusted net income, not EBIT.

39. And included in the *OECD Guidelines* (2022).

- integration and success of acquisitions and alliances;
- managerial and operational efficiency;
- risks arising from the increased digitalization of operations;
- reliance on third parties;
- market competition: patent protection and generic/biosimilar entries;
- pricing and reimbursement policies/cost containment measures;
- international operations with a large footprint;
- credit risk;
- ethics: respect of codes of conduct through the value chain;
- environmental, social and governance matters; and
- reputational risks.

The subsequent step is – within the identified functions managing the selected DEMPE risks – to determine the adequate level of analysis. Focus could be placed on architectural competencies^[40] and integrative or combinative capabilities^[41] that can provide meaningful guidance on how MNEs preserve and develop their competitive advantage, enabling the generation of significant residual profits, as opposed to component competencies that are essential for day-to-day problem solving at a local or component level.

Figure 8 – Illustrations of the proposed level of functional analysis for the allocation of residual profits



As depicted in Figure 8, within the DEMPE functions, a priority could be given to high to intermediate levels of management, focusing on strategy implementation and operational alignment, where those architectural competencies might be captured. An analysis carried out solely at the strategy alignment level might not provide enough guidance on control over risk aspects, as such a level might be mainly devoted to strategic decision making.

From a practical standpoint, in large MNEs, a starting point could be the governance bodies that oversee key aspects of IP generation, launch and commercialization. Typically, such bodies are cross-functional bodies that supervise the IP R&D pipeline, prepare the clinical evaluation of the projects and govern resource allocations of the R&D functions, including but not limited to the committee that approves development phase transitions or project prioritization. From a commercial standpoint, functions such as launch excellence, market access and pricing, and medical evidence generation could be the centre of attention.

Further guidance on the nature of functions and the identification of significant risks could be sought from the increasingly complex collaboration agreements between pharmaceutical operators, but also from simpler licence agreements when the DEMPE analysis is only carried out on IP. Sophisticated alliances that involve a continuous collaboration between parties on key aspects of the development, manufacturing and commercialization of a drug are likely to provide deeper evidence of how functions are allocated, and of how risks are managed between third parties in a collaborative environment, pursuing common and particular interests. Indeed, governance through the delineation of joint committees could allow practitioners to (i) focus on the relevant DEMPE (those that are agreed with third parties), and (ii) to provide market templates to tax administrations on allocations of functions and risks that can take different forms. Similar analysis can subsequently be duplicated, with the same set of functions and risks, within the MNE, to substantiate (or to test the substance) of the transactional framework of the MNE.

40. T. Chi & J. Zhao, *Equity Structure of MNE Affiliates and Scope of Their Activities: Distinguishing the Incentive and Control Effects of Ownership*, *Global Strategy Journal* (2014).

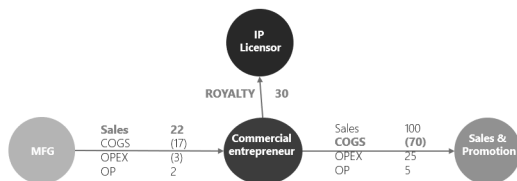
41. R. Henderson & I. Cockburn, *Measuring competence? Exploring firm effects in pharmaceutical research*, *Strategic Management Journal* 15, pp. 63-84 (1994).

DEMPE and control over risk in the review of residual profit allocations could become one of the most important challenges for the pharmaceutical industry, and evidence from third-party behaviour might be the most reliable way to document the level of granularity of the analysis, as well as the relevant functions and risks.

4.3. Operational transfer pricing

While operational transfer pricing is not an issue specific to the pharmaceutical industry, it is of great importance given the centralized transactional framework depicted in section 3.1 and the magnitude of the margins embedded in transfer prices, and more specifically in transfer prices to distribution and promotion entities.

Figure 9 – Illustration of transfer pricing transactions in a centralized model



In this example,^[42] the implementation of transactional net margin method (TNMM)-based policies for manufacturing and sales and promotion functions generates a high intensity intercompany framework where for 100 third-party sales, intercompany transactions of 122 are necessary. One of the specificities in pharmaceutical (and in general to intangible-intense segments such as high-tech products^[43] or luxury) is the relatively reduced number of API or drug substance manufacturing sites, which tends to maximize the impact of such a model in terms of intercompany activity.^[44] The complexity can be increased by dedicated primary and secondary manufacturing sites that need to transact before the acquisition by the licensor (in this example).

The exposure within pharmaceutical MNEs is high, commensurate with the intensity of its transactional framework, thus increasing the stakes related to compliance on taxes that are pegged to transactions, such as VAT and customs duties. The sensitivity of the matter is finally augmented by the high number of SKUs (stock keeping units) in large pharmaceutical MNEs, which is driven by several factors such as several dosages per drug and important regulatory constraints (labelling, drug information). Such intricacies explain the fact that pharma MNEs have tended to be early adopters of technology and processes for operational transfer pricing.

In the implementation of transfer pricing policies, and more specifically in the case of TNMM/comparable profit method (CPM), for promotion and distribution companies, the question of the granularity of the calculation is often raised: on a product-by-product basis, or on a portfolio basis. The portfolio basis is the most encountered approach for the determination of transfer prices, as it is on a par with the actual management of distribution affiliates,^[45] with a likelihood of having relevant financial data for the transfer pricing calculations that is therefore increased. With the metrics of Figure 9, assuming that the 100 is now generated by a portfolio of products, the transfer prices would be calculated to generate a gross margin of 30% for the affiliate.

Mechanically, it implies that regardless of their maturity (launch phase, mature), the products could yield the same gross margin, and as such, the prices of individual products become highly interdependent. If such approach is retained, it should be supported by evidence on how the business is effectively run from a managerial standpoint, and most importantly, properly documented in the intercompany supply agreement. These are both factors that can be of assistance when entering discussions with tax or customs administrations on individual pricing. Moreover, there are markets in the pharmaceutical industry that have implemented regulated margin systems,^[46] whereby import prices are expressed as a fixed percentage and transactional models need to be adapted.

Finally, particular attention should be paid to TNMM/CPM-based transfer prices on active ingredients sold to distribution affiliates that are equally in charge of secondary manufacturing. This particularly applies to prescription drugs that are no longer protected by patents and for which analogues could be traded in the free market. There are many valid reasons to deviate from analogue prices, based on comparability criteria such as quality, purity, concentration and embedded intangibles or economic attributes (such as selling price differentials in the market), provided they can be documented and quantified. The difficulty remains with TNMM policies based on portfolio approaches, given the interdependency of transfer prices between products that can impact the pricing of specific APIs imported by pharmaceutical MNE affiliates.

42. Using metrics derived from Figure 1, and using a 10% net cost plus mark up for manufacturing and a 5% return on sales solely for illustration purposes.

43. For high-tech components.

44. In comparison with industries that have large webs of manufacturing sites to supply local markets.

45. Even if in some cases, promotion and distribution entities can be managed by therapeutic business units.

46. Not for tax or transfer pricing purposes (unlike Brazil, for instance).

5. Selected Transfer Pricing Issues in the Pharmaceutical Industry

5.1. Can benchmarking still make the cut for intangible valuation in pharmaceuticals?

Between January 2018 and May 2020, a median monthly number of 55 licensing deals were concluded in the pharmaceutical industry.^[47] Business-oriented^[48] databases^[49] are widely used by pharma operators for the calibration of their in- and out-licensing transactions and can contain up to more than 100,000 data points. Large databases are therefore able to accommodate granular searches according to therapeutic area (if relevant), development phase or geographic scope criteria. Despite the liquidity of the market, tax administrations have expressed serious concerns about the use of the comparable uncontrolled price (CUP) method for the valuation of IP assets in the pharmaceutical industry.

Two main shortcomings are usually invoked on the application of the CUP method: (i) the uniqueness of the assets which prevent the satisfaction of comparability criteria; and (ii) unaccounted differences in profit potential between assets which can alter the comparison.

However, given the large number of observations in the market, benchmarking could still be the foundation of the delineation of relevant metrics, if it is not based on the sole contractual royalty rates of third-party licence agreements. Indeed, elements such as tiered royalties, upfront payments and development and/or commercial contingency payments (milestones) are ubiquitous in the pharmaceutical licensing agreements. The first step should therefore be the computation of an effective royalty rate, which can be achieved through financial modelling involving sales curves that can be pegged to sales triggers of milestones and can also embed profitability assumptions to derive proxy levels of profit split metrics. In practice, wide ranges could be indicative of comparability issues and their relevance could be discarded by tax administrations.

The best alternative means to overcoming data-related limitations is the review of internal comparables, for which the MNE (as a licensor or a licensee) has prepared contemporaneous data sets reflecting the expectations of the parties. Such data sets should allow the transfer pricing practitioner to narrow the external benchmark range through more accurate economic adjustments, or – beyond the royalty rate – to establish arm's length profit-split ratios that could substantiate the selection of a point in the benchmark range or drive the modelling of options realistically available to the firms.

Benchmarking could as such remain a powerful starting point for the valuation of intangibles in the industry, provided the results are corroborated by a secondary method, usually a profit split method, where internal comparables or alternative financial valuation methods play a critical role.

One significant limitation is related to the fact that a large share of third-party licensing deals are concluded at either pre-clinical or phase 2, with a lower number of transactions for approved drugs. It is also worth noting that the CUP method can prove difficult to apply to transversal assets such as technology platforms, where the value is derived from the ability of the licensor to combine those assets with its own assets or the functions owned or performed by the MNE.

5.2. Projections v. actual results on intangible valuations: Adjustments?

Regardless of the method used for the determination of the remuneration of an intangible asset – CUP/comparable uncontrolled transaction (CUT) method, discounted cash flows, profit splits, Monte Carlo simulations, real options – financial projections are of the utmost importance, as they represent the expectations of parties at the inception of the transaction.^[50] It applies in the context of a straightforward licensing or in a more complex structure such as cost sharing or cost contribution agreements. Because those transactions are usually entered into for long periods, and spread over several audit cycles, the comparison of the initial projections and the actual outcomes are often a point of tension between tax administrations and taxpayers, with a high potential for hindsight. The asymmetry of information that exists between third parties in third-party deals is replaced on intercompany transactions by an information asymmetry between the taxpayer and the tax administrations.

The US tax administration (Internal Revenue Service, IRS) and more recently the OECD have provided guidance on how tax administrations and taxpayers should assess the relevance of significant divergences between initial projections and actual results for intangible valuations: the periodic adjustment sections in US Treas. Reg. §1.482^[51] and the hard-to-value intangibles section in the OECD Guidelines (2022).^[52] While the use of actual results to question ex ante projections is an appealing concept, it is questionable from an economic standpoint.^[53] The main reason would be the resulting gap in the appraisal of risks (including R&D, technology, commercial or

47. Torreya, *Biopharmaceutical Sector Update on the Financing and Deal Environment*, Torreya (29 May 2020).

48. Non transfer pricing-driven.

49. Examples: current agreements, Cortellis Deals Intelligence, IQVIA Pharma Deals, DealForma.

50. A specific difficulty has been noted on previously mentioned transversal assets such as technology platforms, for which financial valuations are particularly difficult to elaborate. Alternative appraisal methods, such as Shapley values, could be pursued. See V. Hahn et al., *Shapley Value: A Fair Solution to the Value Creation Puzzle in Transfer Pricing?* (18 Oct. 2021), reprinted from Tax Notes International (18 Oct. 2021, pp. 291-306) with permission from Tax Analysts, available at: <https://ssrn.com/abstract=3969517> (accessed 11 Oct. 2022).

51. Treas. Reg. §1.482-4(f)(2) for intangible valuation and Treas. Reg. §482-7(i)(6) for cost sharing agreements.

52. Ch. D-4, paras. 6.186 to 6.195 *OECD Guidelines* (2022).

53. P. Penelle, *The OECD Hard to Value intangible guidance*, *Intangibles*, p. 13 (3rd ed., *International Tax Review* 2016).

macro-economic risks). Indeed, ex ante projections embed assumptions on risks and proxies to control for those risks in the valuation, whereas actual profits are by nature de-risked.

A candid interpretation of the periodic adjustment mechanisms would be to evaluate whether actual numbers that significantly depart from projections are indicative of an obvious (or deliberate) distortion at the inception of the transaction. If the comparison could trigger a reasonable doubt on assets for which no IP generation is involved, the impact of the probability of success on – for example – a portfolio of developed and in-development assets that are licensed, cost-shared or sold, is such that it could render the exercise tremendously perilous for taxpayers.

While there are many differences between the IRS and OECD approaches, to properly rebut the presumptions on initial projections or to adequately engage with tax administrations, it is necessary that taxpayers devote significant efforts to substantiating the main assumptions behind the financial projections. In the pharmaceutical industry this could be achieved through the documentation of the following items:^[54]

- patient-based models: documentation of the prevalence of the disease, population, treatment per day and dosages;
- competition landscape: expected market shares, existing and anticipated competition and pricing assumptions and impact on revenue curve;
- pricing assumptions per main territory (usually the United States and the rest of the world);
- review of the probability of success rates if development activities are involved with proper internal or external benchmarks;
- expected weight of COGS and operating expenses (OPEX) (avoiding normalized rates if possible);
- segmented profit and loss statements (P&Ls), where significant differences in profitability exist between territories;
- decay assumptions when reaching the loss of exclusivity (price and volumes); and
- the word on the street: corroboration by external financial analyst notes or consensus.

The main value of the clear definition of such parameters would be to provide the ability to derive different valuation scenarios when establishing the arm's length conditions of licensing, to delineate the risks borne by each party and to illustrate on an ex ante basis the entitlement to profits of each party based on the materialization of certain assumptions.

Significant variances between projections and actuals can stem from single events (failure of an indication, accelerated approval, adverse events) or from a larger number of smaller impact events. Taxpayers ought to properly be prepared to bridge the gap between actuals and projections and establish that the latter were established in good faith and delineate the variances that are part of the normal conduct of business for each party to the transaction. This shall be the case whether third parties would have renegotiated the terms or not, which can also be documented through the review of internal or external comparables.

5.3. Pharma(s)

So far, this article has addressed pharma as a single business segment, whereas the industry is composed of several sub-segments that can have economic attributes that can influence the economic analysis of the different operators of the value chain.

The main segments that can be mentioned are the following (bearing in mind that operators in the market can be diversified or specialized):

- prescription drugs (Rx): the biopharma segment is composed of traditional pharma MNEs increasingly present in biologicals, as well as pure biotech players at different stages of development. While some groups are increasingly leaning towards specialty care, some smaller companies remain active mainly on primary care;
- generics account for the vast majority of volume in the pharma industry. They are mainly present in small molecules, a quality- and volume-driven business where capital expenditure, R&D and marketing expenditures are lower than in biopharma. The rise of biosimilars is generating different market patterns (higher investments and hence lower price decreases when reaching the market); and
- unlike the previous segment, consumer healthcare products (over the counter, OTC) are not prescribed products, with prices that are less (or not) regulated, with significantly less investment in R&D and a higher reliance on branding. They nevertheless share similar distribution channels with the other segments.

The main question that arises is whether the economic attributes of the different segments differ in such a magnitude that they would require a significant overhaul of the transfer pricing framework of prescription drugs. The most important differences are the weight of R&D and intellectual property on the value chain (even if for biosimilars – depending on the approval route that is taken – significant studies need to be carried out) and that R&D is also performed for OTC products, though to a much lesser degree. However, it should be

54. In addition to general financial elements such as the discount rate.

noted that all categories of products require a formal approval process^[55] – although less complex than Rx drugs – and rely on a market authorization delivered by a regulatory body to ensure the safety of the patients and the quality of the products.

The main differences could be related to the marketing function, given the differences that exist in terms of pricing dynamics and promotion intensity. For instance, the progressive deregulation of OTC distribution (allowing the distribution of products outside pharmacies) combined with free pricing could shift the segment closer to fast-moving consumer goods. Generics evidence a different marketing profile, as they rely significantly less on promotion, and more on volume and quality to ensure a proper substitution of off-patent branded drugs. This is a substitution at the point of sale that is often encouraged by health authorities or may even be mandatory.

As such, differences exist, because the value chains tend to differ between the segments. The main issue is related to the lack of homogeneity in the Gx and OTC markets, driven either by different consumer behaviours and/or regulations. In the European Union, the regulatory framework with articles dedicated to promotional activities and advertising of medicinal products is regulated by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, applicable to OTC products. In the United States, the FDA regulates the labelling of non-prescription drugs, but it does not regulate the advertising; that responsibility largely rests with the Federal Trade Commission, except for certain OTC drugs approved under new drug applications. In addition, there is not a harmonized classification of Rx/OTC products, and in some countries, OTC products can be both prescribed and available on pharmacy shelves.

Rather than developing a whole new framework for OTC and generics, a sound recommendation could be to ensure that at the very least promotion and distribution benchmarks include OTC and Gx products. But again, because in many countries they follow the same distribution routes as Rx products, this approach also has its limitations, as local operators tend to be involved in several market segments.

5.4. Benchmarking (other than intangibles)

As suggested by section 4.1., an important number of market templates exist for clinical research and manufacturing functions. Despite the ongoing consolidation and the vertical integration in both segments, databases shall continue to yield rational results for the benchmarking of both functions. The difficulty of the exercise can nevertheless be more connected to evolutions within the pharmaceutical MNEs, with more agile and interconnected R&D models and with the ever-increasing prevalence of biological manufacturing, for which market templates are rarer and for which risks tend to diverge from chemical manufacturing.

For the promotion and distribution function, adequate benchmarking can be problematic as market templates are scarcer, reducing the number of hits returned by databases for certain territories once certain filters are applied for the search, to exclude operators with high R&D-to-sales ratios or agents with insufficient OPEX-to-sales ratios.^[56] The number can be further reduced during qualitative reviews regarding the pharmaceutical segment they operate in to ensure a minimum alignment with the activities carried out by the tested party. In many instances, the searches are likely to yield a limited number of comparable companies, unless criteria is loosened, either on the operating sub-segment or on the geographical scope. Both elements in many cases lead to difficult discussions with tax administrations.

The relative lack of comparables in the market is likely to lead to objections on the use of TNMM/CPM methods and encourage the use of the profit split or residual profit split methods, with the OECD's Pillar One being only the most structured attempt to generalize the concept through the allocation of a portion of "excess profits".^[57] Another approach would be to normalize returns for promotion and distribution entities in the industry (Amount B within Pillar One to some extent) or to encourage/incentivize MNEs through pre-established metrics. The Australian Taxation Office, for example, has partially addressed the matter through the issuance of its Practical Compliance Guideline's risk assessment framework for life science distributors in its territory^[58] where – for risk assessment purposes – ranges of operating profits have been disclosed depending on the functions undertaken by the local affiliate.

From a practical standpoint, the question remains how compliance through benchmarking can be enhanced for the promotion and distribution function, after^[59] or without^[60] Pillar One's implementation. Several leads could be taken into consideration:

- broad categories of markets could be defined based on the economic attributes that could impact the economic return of an independent distributor, through pricing, market structure, the reimbursement system, wholesaling practice (or margin distribution between wholesales, pharmacies, etc.). To be efficient, such an approach would need to yield quite a limited number of categories;
- more meaningful results could be yielded through a broader functional scope in benchmarking: in line with the remarks in section 5.3., it could be that a larger number of companies that might differ in the sub-segment in which they operate would yield a more meaningful

55. For example, in the US territory, the review of over the counter (OTC) products is handled by the US Food and Drug Administration's Division of Drug Information (CDER), the Office of Drug Evaluation and the Nonprescription Drug Advisory Committee. These bodies assess and review OTC ingredients and labels. A drug monograph is established for each class of product. The monograph is composed of acceptable ingredients, doses, formulations and labeling. New products that are in conformity with existing OTC drug monographs can be launched in the market without further review. Those OTC products that do not must obtain an approval through the FDA's New Drug Approval System.

56. Or with revenue thresholds to avoid size distortions.

57. To avoid confusion with the term "residual", which is used in a different manner for transfer pricing purposes.

58. ATO Practical Compliance Guideline, PCG 2019/1, transfer pricing issues related to inbound distribution arrangements: not specific to the life science industry but containing specific guidance for certain industries including life sciences.

59. After for those pharmaceutical MNEs that are not in the scope, mainly due to the revenue threshold or profitability threshold in the case of emerging MNEs.

60. Because it is very likely that without Pillar One implementation the trend towards residual profit split or profit split methods will only increase, fostered by the analysis carried out by the OECD and in the Inclusive Framework.

statistical result than a benchmark on a reduced number of observations. Across business sub-segments, the similarities (distribution channels, point of sale, regulatory environment) should bear a sufficient weight to partially neutralize product differences (promotion to consumers for OTC, pricing). Undoubtedly, additional evidence would be necessary to corroborate such an assumption;

- SG&A-to-sales ratios are likely to require adjustments should the comparable companies yield significantly lower or higher ratios. As noted in section 2.2., SG&A to sales ratios are significant in the industry and need to be accounted for. While it could be argued that large deviations could be indicative of functional differences, an economic adjustment for the differential of SG&A/OPEX could be an interesting alternative to resorting to bilateral methods; and
- if the three previous steps can contribute to partially cope with the difficulties of benchmarking in the industry, they still do not address the lack of comparables in emerging economies, which prevents a balanced discussion between tax administrations and pharmaceutical MNEs. An interesting option to consider could be derived from the roll out of country risk adjustments⁶¹ on globalized benchmarks.

The crux of the issue is that in a post-BEPS, pre-or-post-Pillar One environment in a complex and exposed industry like pharmaceuticals, there will be a growing need to provide additional evidence of the rationality of the benchmarking exercise. Failing to do so might just contribute to accelerating the proliferation of non- or less-than-arm's-length-based solutions and transfer pricing controversy.

6. Conclusions

There is no doubt that the pharmaceutical industry is highly exposed from a transfer pricing standpoint, with high stakes associated with the high profitability of the industry.

Such exposure can be associated with:

- a lack of understanding of the economics prevailing in the industry and the lack of homogeneity of certain pharmaceutical markets or segments. This can lead either to the overemphasis or underestimation of the impacts of markets and/or segment differences on transfer pricing policies;
- its high reliance on the complex generation and exploitation of intangibles: generating multi-year exposure with often multifaceted valuation aspects that need to be at the same time technically accurate and fit for discussions with tax administrations;
- complex business models with either vertically integrated MNEs or niche operators, specialized MNEs or highly diversified companies. Such models can generate a significant data constraint for transfer pricing practitioners that needs to be factored when designing transfer pricing policies; and
- a transfer pricing-intense transactional framework to ensure an adequate allocation of high system profits on a large spectrum of jurisdictions: transfer pricing in pharmaceuticals is a pull system, where profits are pulled from markets for upstream reallocation, creating a high-risk environment in many jurisdictions.

In line with the 2017 and 2022 OECD Guidelines, transfer pricing policies within the industry need to be increasingly sustained by real world evidence, stemming from business operations, market templates (third-party behaviour) and grounded economic and financial analysis. It is only through such efforts that transfer pricing models, policies and methods will be able to overcome the next generation of changes in the value chain, as well as the functional and economic analysis arising from the digitalization of pharmaceutical MNEs.

It is nevertheless necessary to mention that industry practitioners face a large spectrum of challenges: complex and technical challenges (US cost-sharing regulations, intangible valuations, DEMPE functions tests) in a limited number of jurisdictions, while in many emerging markets basic issues such as disagreements on value chain (marketing mainly), industry-specific facts and circumstances or a lack of comparables can lead to substantial controversy.

In this respect, the work initiated by the UN Subcommittee on Transfer Pricing with the release of the Practical Manual on Transfer Pricing for Developing Countries in 2021, and the future work on industry-sector guidance on pharmaceuticals, could prove key in setting a common ground between pharmaceutical MNEs and the tax administrations of emerging countries.

61. B. Steens et al, *Transfer pricing comparables: Preferring a close neighbor over a far-away peer?* Journal of International Accounting, Auditing and Taxation 47 (2022).



About IBFD

The global source for accurate, independent tax publications.

The International Bureau of Fiscal Documentation (IBFD) is the world's foremost authority on cross-border taxation. We offer tax professionals high-quality information and education that enable them to work on the basis of up-to-date and accurate tax knowledge.

Our customers, ranging from multinational corporations to leading universities, tax advisories and government tax agencies, come to us for comprehensive international tax information that helps them achieve the best solutions to their taxation needs.

Interested in subscribing to our online Journal collections? Check our website (www.ibfd.org) or contact our Sales team (sales@ibfd.org).
