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Taxing **Questions**

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Driven by revolutionary biotechnological advances, healthcare stands poised for an unprecedented leap forward. Health outcomes for millions of people should improve as personalised medicine enables tailored approaches to prevention and care. Yet the current worldwide political and economic environment threatens to diminish the capacity of the biopharmaceutical industry to deliver on this potential benefit (see Figure 1). Unrelenting worldwide political and economic pressure to control the rising cost of healthcare delivery conflicts with the enormous investment of capital (and time) required for research and development (R&D). The cost to bring a single new biologic drug to market easily exceeds $1 billion.

Drug manufacturers are quickly losing blockbuster revenue as more patents expire. Rather than exclusively developing new products on their own, large biotechnology and pharmaceutical companies are stepping up acquisitions and licensing to strengthen their portfolios.

These companies, no longer able to 'go it alone', are reaching out not only to fill their pipelines, but also to form alliances within and outside the healthcare realm to provide services to support the use of their products. A compelling reason for this expansion 'beyond the pill' is the growing power of government and private payers to determine the value of pharmaceutical products. Payers are no longer willing to reimburse drug companies for medications that do not deliver results – and those results must come at a reasonable cost. The pharmaceutical industry's old tactic of developing 'me too' drugs that only offer marginal improvement to replace products whose patents are expiring no longer works.

Other pay-for-performance mechanisms are emerging. The French Government recently introduced a bonus scheme for physicians who meet generic prescribing targets in seven pharmaceutical categories (1). The British National Health Service has launched a flexible pricing scheme under which the prices of medicines can be raised or lowered based on the results they deliver (2). In the US, the Centers for Medicare and Medicaid Services is piloting bundled payments to cover medications and hospital and physician services to encourage collaboration, boost efficiency and improve quality. Providers share any cost savings.

To rein in spiralling costs, governments and private payers are both imposing direct and indirect price controls on pharmaceuticals. An example of an indirect price control is the US pharmaceutical industry's concession to the Obama administration to lower the cost of drugs by $80 billion over the next decade as part of the US healthcare reform effort. By covering more people than the number who are uninsured today, reform promises to add more customers for the industry, which, in theory, should lessen the impact of lower prices.

These new measures add to long-standing cost-cutting efforts, such as the use of formularies that encourage consumers to use generic and preferred brands by imposing lower copayments on those categories. Furthermore, insurers often refuse to pay for newer treatments that lack evidence of effectiveness. New comparative effectiveness research legislation in the US is expected to boost this trend.

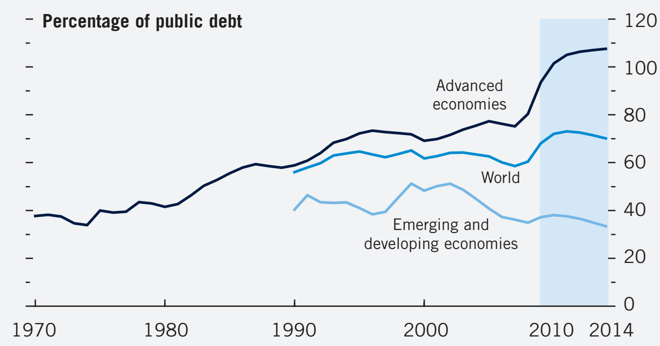
Under this increasing pressure to deliver results at lower cost, pharmaceutical companies are working on ways to improve compliance with treatment regimens. Research has shown that when patients do not take their medications as prescribed, they suffer adverse outcomes, and the cost of caring for them rises. To encourage consumers to take their medicine, manufacturers are developing pills with embedded microchips that will remind patients with a beep or a text message on their mobile phones when they miss a dose.

In addition to technological solutions, manufacturers are looking at providing in-home, technology-enabled remote monitoring services. Patients with chronic conditions, such as diabetes and respiratory and cardiovascular diseases, can prevent complications and reduce hospital visits with more in-home care and better coordinated case management. As more patients receive biologics targeted to their specific disease and genetic makeup, they will require closer monitoring and follow-up services to make sure that the treatments are working correctly and determine whether the dosage needs to be adjusted. Drug manufacturers will need to develop new expertise or find partners to assist with this type of monitoring and follow-up care.

Ultimately, the push for more outcome-focused, patient-centred care will change the way pharmaceutical companies go to market. A recent business models report suggested that two innovative structures will emerge over the next decade (3):

- Diversified – in which a large conglomerate owned by a single parent company offers widely

Figure 1: Projected level of public debt as a percentage of GDP



diversified products and services beyond traditional medicines

- Federated – in which a network of loosely affiliated companies collaborate to provide total patient care and wellness services. In a virtual variant of the federated model, a company outsources most or all of its activities; in a venture version, it manages a portfolio of investments

Either model aspires to the same goal: improved patient outcomes through the delivery of more targeted medical products and related monitoring and wellness services directly to patients (see Figure 2).

NEW BUSINESS MODELS WILL ALTER TAX OBLIGATIONS

Delivery of packages of bundled healthcare goods and services will carry complex tax implications. The report predicted that the changing business models and increasing economic and political pressure on governments to raise taxes would challenge the industry during the next decade.

Multinational companies have traditionally reduced their overall tax burden by locating some of their operations and intellectual property in countries that offer lower corporate tax rates or generous R&D tax credits and other incentives. As the industry moves in the direction of delivery of more products and services in end markets, locating profits in low-tax countries will become more difficult. Delivery of these packages of care may also create ‘permanent establishments’ in multiple countries for tax purposes, increasing the risk of double taxation in a company’s home country and in the place where the goods and services are produced or delivered.

Over the next decade, more manufacturing of high-volume, lower profit, small-molecule drugs will move to lower cost emerging markets. Production of more fragile and complex biologics, however, will need to be closer to patients, many of whom will be located in high-tax regions.

Although emerging markets offer the prospect of reaching many new customers with rising incomes, the tax regimes of those nations are neither as developed nor as clearly articulated as those of industrialised economies. Increased activity in those markets could push up direct and indirect taxes.

Cross-border activity, combined with the amalgamation of services and products, will make the assessment of value-added, withholding and other indirect taxes more complex. Goods and services are often taxed differently. In the case of value-added tax, for example, will components of healthcare packages be taxed individually, or will one component determine the rate for the entire bundle? More cross-border transactions may lead to higher customs duties and complicate the calculation of withholding taxes.

As more collaboration among federations of companies in multiple countries occurs, allocation of profits and assessment of tax liability will become more difficult. A federation might include for-profit, nonprofit, private, government and academic institutions with differing business structures and tax obligations in countries with varying tax rules.

RECESSION-WEARY GOVERNMENTS: LIKELY TO IMPOSE NEW TAXES TO RAISE REVENUE

In addition to tax complications resulting from the transformation taking shape in healthcare, the biopharmaceutical industry will face repercussions from the recent worldwide recession, which has increased government debt dramatically. To help replenish their coffers, governments are likely to consider more aggressive corporate tax policies. In the US, several tax-increasing measures, including the repeal or modification of deferral of taxes on foreign earnings, are under consideration.

Such legislation can have a dramatic impact on effective tax rates (ETRs) (4). A recent US Government Accountability Office report showed that US-based pharmaceutical companies paid a four per cent US tax (after foreign tax credits) on their foreign earnings in 2004 (5). Multinationals are allowed by US law to defer taxes on foreign income until it is repatriated. An effort is under way to modify or repeal the deferral rule.

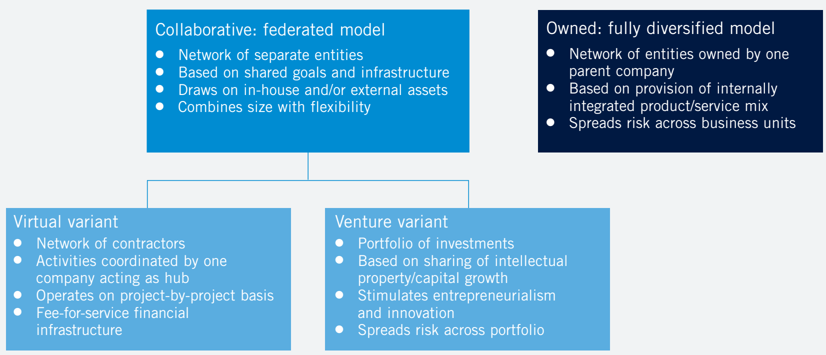
Furthermore, governments are cracking down on the use of tax havens that allow companies to move profits offshore, and authorities in different countries are cooperating in this effort. The Organisation for Economic Co-Operation and Development has taken steps to blacklist non-cooperative jurisdictions (6).

Many governments are also tightening transfer pricing rules, making it more difficult for companies to use transfer pricing to prevent possible double taxation. In transfer pricing, companies allocate income among their affiliates via the pricing of intellectual property, tangible goods, services and loans or other financial transactions. Abuse results when companies do not apply the ‘arm’s length’ principle and fail to treat intra-company transfers as if they involved independent third parties. They might shift profits artificially from high- to low-tax jurisdictions by placing more expenses in the former and income in the latter.

Also under consideration in some countries is the imposition of ‘green’ taxes to offset the environmental impact of certain industries. Governments might request that the biopharmaceutical industry help clean up water supplies contaminated by trace amounts of chemicals involved in the manufacture of their products.

The biopharmaceutical industry does have one big advantage that might help lessen the impact of rising taxes. More countries are competing for R&D investment by offering generous tax

Figure 2: Business models that are likely to prevail in 2020



incentives, especially those in the developing world that want to attract profitable industries that provide good jobs and long-term revenue streams. This heated competition for R&D investment could present many opportunities for multinationals to lower their overall tax burden.

INDUSTRY CAN TAKE STEPS TO MANAGE THE RISE OF ETRs

To effectively manage their increasing tax burdens over the next decade, biopharmaceutical companies will take different routes. A wide variance in effective tax rates for the industry today reflects the diversity of their approaches. For example, the ETRs of the world's top 10 biotechnology companies range from 12.26 per cent to 43.29 per cent. Although eligible for the same R&D tax credits, the average ETR for the biotechnology sector exceeds that of the pharmaceutical and medical device sectors.

The home country location and the geographical spread of business activities account for some of the variation in ETRs. Other reasons may relate to the effectiveness of each company's tax planning, its business model and how it structures mergers, acquisitions, licensing and other deals.

In 2020, as healthcare delivery grows more complex and more global, it will be even more critical for management to be informed about the tax implications of any business decisions. To cope with rising tax rates, some companies could choose to relocate from higher tax jurisdictions to lower tax countries.

Companies might also want to consider the following tax-planning tools:

- Examine the choice of entity. Some companies may want to choose pass-through entities (for example, partnerships, S corporations and limited liability companies) instead of corporations to achieve greater tax efficiency when forming federations to deliver goods and services globally
- Carefully structure mergers and acquisitions, taking into account the tax status of the parties involved, how dividends and incentives will be paid, and the tax treatment of interest paid on debt
- Establish or make greater use of existing regional hubs in low-tax locations or high-tax locations with generous tax incentives. Regional hubs can ramp up to handle more high-cost R&D, manufacturing and marketing activities
- Continue to offset costs by locating high-volume manufacturing in emerging markets to take advantage of the low cost bases in such locations
- Monitor tax incentives globally and advise management of their potential impact on business decisions
- Address VAT and customs issues collectively within federations to reduce the impact of higher taxation

Tax professionals who stay attuned to evolving business, healthcare, political and economic environments will be more successful in lobbying for lower tax rates and more able to advise management on how to structure business operations for greater tax efficiency. Companies that employ tax professionals with knowledge and skills extending beyond the tax ledger will be better equipped to help the biopharmaceutical industry fulfil its mission of improving the health and well-being of the world's citizens.

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