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CANADIAN LAWYERS

TRENDS

LIFE SCIENCES

As part of our series on current trends across different industries, we explore current changes taking place in the life sciences field.

1

Privacy & Data Protection

Personal information protection and compliance with privacy laws have taken centre stage with life sciences companies as a result of the increasing use of data in connection with a myriad of products and services, including patient support programs, wearable and other connected devices, mobile apps, digitized health care, genetic testing, and personalized medicine, along with the greater use of data mining and targeted advertising.

Although personal information has tremendous value, companies must remember that Canada has a patchwork of federal and provincial privacy laws, and any given activity may be subject to multiple privacy laws. Further, it is not just patients' private health information that is considered personal information, even information about health-care professionals, de-identified information, and personal details publicly posted on social media platforms can be considered personal information, making the collection and use of that information subject to privacy laws.

Companies must balance a commercial desire to collect as much personal information as possible, in case it is useful or valuable in the future, with the privacy obligations and risks associated with having that information. Data security threats abound, not just from criminal hacking, but also from employee error and theft.

Life sciences companies must actively seek ways to protect personal information and other confidential or proprietary data in order to prevent breaches and mitigate their liability. Proactively addressing cybersecurity vulnerabilities may be even more important for connected device manufacturers where exploitation of a vulnerability could have significant consequences for patient safety.

2

Biologics

Biologics are costly to produce and a number of significant blockbusters are nearing the end of their patent term protection. As companies work toward development and promotion of less costly alternatives, biosimilars (previously called subsequent entry biologics or SEBs in Canada) have garnered a great deal of attention in Canada and throughout the world, especially in terms of whether such drugs can be substituted for the reference-based biologic and on issues of interchangeability.

A biosimilar is a biologic drug that enters the market subsequent to a version previously authorized in Canada and with demonstrated similarity to a reference-based biologic drug. A biosimilar relies in part on prior information regarding safety and efficacy that is deemed relevant due to the demonstration of similarity to the reference-based biologic drug, and which influences the amount and type of original data required.

Biologic sales continue to increase as there is a greater global focus on improving health-care access and reducing the cost of care, which presents growth opportunities for biosimilars. We can expect greater focus on issues applicable to biosimilars with regard to their regulatory approval, market entry, use and pricing terms. At the same time, biologics generally can be expected to take on a greater market share and drive industry growth.

3

Drug Pricing and Market Access

Canada is seeing greater attention focused on drug prices and pricing strategies by various stakeholders, including preferred listing agreements with private insurers and provincial tendering. Canada's Patented Medicine Prices Review Board (PMPRB) is currently undertaking an extensive review of its policies and guidelines on how to protect consumers from "excessively priced" patented medicines. Some areas being considered as part of PMPRB's consumer protection mandate include screening based on the potential for abuse of statutory monopoly and minimizing the price gap between public payers, private payers and cash customers.

As drug manufacturers strive to improve market access and sales, broaden distribution channels, and convince insurers to cover their drugs and list them as preferred medications, they are facing increased pressure to lower their prices. Due to complicated drug pricing laws, pricing in one province can impact not just the pricing in other provinces but also pricing in international markets. Provincial laws governing pricing and commercial arrangements in the life sciences sector vary widely among the provinces, and companies must ensure their pricing and commercial strategies and arrangements take into account not just the federal and provincial drug pricing laws in Canada, but also anti-trust laws.

Other strategies that pharmaceutical and medical device manufacturers are employing to increase their revenue streams include:

- Technology licensing and R&D and co-development collaborations to speed development or leverage the value of intellectual capital
- Outsourcing arrangements

- Product and business line acquisitions or divestitures to diversify, build on or consolidate core strengths
- Investments in, or strategic partnerships with, smaller biotech companies to enhance agility and replenish their product pipeline.

While pharmaceutical and medical device companies have actively pursued these types of activities for the last few years, we expect this trend to continue with life sciences companies relying more heavily on third-party partnerships to drive down prices and bring products to market faster and more cost-effectively.

4

Portfolio Swaps

Pharmaceutical and consumer health-care companies have been adapting to current market dynamics and looking at their geographical footprint to increase growth and synergies through portfolio swaps with other market players. Companies are becoming increasingly strategic when acquiring or selling product lines, and look for portfolio swaps to clarify their business, improve efficiency and increase profit.

Each company participating in the swap looks to sell a product line or portfolio that doesn't align with their current and future business plans to another industry player who in turn owns, and is willing to sell, a product line or portfolio that will give them growth or strength in an area in which they wish to expand. These transactions are viewed as a win-win situation for both buyer and seller, allowing each company to rationalize their businesses and achieve a sharpened focus on their high-performing or core therapeutic areas, and greater coverage of geographic markets internationally.

While we have already seen a high volume of M&A activity within the industry in the last few years, we expect the number of these transactions that will involve product or portfolio swaps between industry players will continue as life sciences companies look to be more strategic with their business.

5

Quebec Legislative Changes

Several legislative changes in Quebec are affecting the public health-care system as well as the practices of health-care professionals and their relationships with industry stakeholders. Some of these legislative amendments have resulted in a large-scale reorganization of the health-care system's management.

The legislation now clearly prohibits physicians in private practice who participate in the public health-care system from charging their patients for "accessory fees" for services, supplies, medications and equipment required to provide an insured health service, or to perform diagnostic tests related to such a service.

Other legislative amendments are impacting the commercial practices of pharmaceutical industry stakeholders. For example, the ceiling on professional allowances that generic drug manufacturers may pay to pharmacists has been lifted. The Minister of Health and Social Services may now enter into listing

agreements and proceed through a call for tenders to purchase certain medications from accredited manufacturers in order for the medication price to be included on the list of medications (the Quebec formulary). It may also issue calls for tenders for accredited wholesalers.

The minister will also have the power to suspend or terminate insurance coverage by the public insurance plan of a manufacturer's drug under various circumstances, including when a competitor drug is the object of a listing agreement. A drug manufacturer that has been accredited to have its drug included on the list of medications is also prohibited from entering into an exclusive agreement with an accredited wholesaler or intermediary for the supply in pharmacy of a medication included in the list of medications.

It is too early to determine the full impact that these amendments will have on the industry's commercial practices.

For further information, please contact Cheryl Satin, Alice Tseng, Marie-Hélène Constantin or any other member of our Life Sciences group.

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