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Not a U.S.-Fits-All-Proposition: Four Key Considerations When Building the Compliance Framework to Go Global with Patient Support—Part I of II

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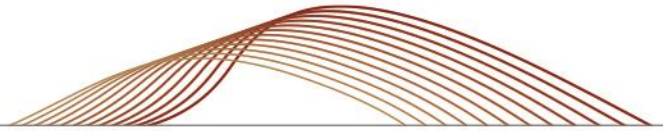
Within the U.S., patient support programs ("PSPs") have drawn increased regulator scrutiny, consistent with their growing importance in the healthcare sector, where it is increasingly being said, and quite appropriately so, that "the patient is the new healthcare provider." As such, many companies have begun developing compliance programs for PSPs structured entirely on practices, regulations, and enforcement in the U.S. Yet as global healthcare spend continues to increase, multi-national companies throughout the industry are likewise increasing investment in PSPs and other patient support, such as interactions with or funding of patient assistance organizations or other charitable organizations helping patients (together, "Patient Support") outside of the U.S. All too often, however, this increased global investment has not been met with a corresponding globalization of patient support compliance efforts—leaving many companies ill-prepared to mitigate risk or face global regulator scrutiny as they go global with Patient Support. This two-part series considers the growth of global patient support, and the global patient support compliance framework required to mitigate the corresponding compliance risks.

Growing Global Patient Support Programs Counsel Development of a Global Patient Support Compliance Framework

Investment in Patient Support outside the U.S. has grown substantially in recent years, driven, in part, by increasing use of complex therapies such as specialty drugs. The percentage of total healthcare spend on specialty drugs, for example, has more than doubled since 2007, with total share of healthcare spend increasing from 42% in 2018 to an estimated ~50% in most developing countries by 2023.[1] As specialty drugs continue to edge towards dominance of the global healthcare market, a parallel need has arisen for programs and efforts to support patients in accessing and managing them.

To help understand the purpose and objectives of Patient Support, one can look to various industry groups' definitions of the term PSP—all aimed at improving the quality of the patient experience via focus on patient health, appropriate data collection, improving quality use of medications, therapies, or devices, and/or improving patient adherence to treatments. As examples, the Association of the British Pharmaceutical Industry ("ABPI") has defined PSPs by reference to their data-collection function, as an "organised data collection system (ODCS) where a marketing authorisation holder



receives and collects information relating to the use of its medicinal products", while also describing it as a program "that aim[s] to help patients . . . better manage disease outcome[s], understand their conditions and/or provide advice on managing disease."[2] Innovative Medicines Canada ("IMC"), as another example, defines PSPs with a more direct focus on patient benefits, as "programs offered by Member companies for the benefit of patients . . . [that] aim at increasing or facilitating patient understanding of a disease and/or treatment, bettering patient outcomes as well as possibly improving patient adherence to treatment."[3]

To achieve these goals, global PSPs may offer patients and/or HCPs a wide array of services, such as reimbursement support, patient access services, nurse educator programs, or transportation services, and companies may engage in other patient support efforts outside of the PSP such as funding to or interactions with patient assistance organizations providing similar services or support. The features of any given Patient Support effort, however, will vary greatly across companies, products, devices or therapies, diseases, and markets. Companies, providers, and charitable organizations—all potential Patient Support providers—typically design their Patient Support in view of four core variables or characteristics: (1) the nature of the product, therapy, or device at issue (e.g., tablet vs. injectable), (2) the underlying condition or disease (e.g., rare vs. ultra-rare), (3) legal or industry code confines, and (4) the expected challenges faced by a patient in accessing the therapy or product. As examples, a patient who is living in a market with minimal, if any, obstacles to access and reimbursement, such as the United Kingdom ("U.K.") or France, may only need outpatient adherence and disease management support. However, in markets where access is challenging, either administratively in a market like Brazil where patients often need the judicialization process to receive product, or logistically as in more rural markets in Africa or Asia, patients may need significant assistance in navigating insurance or regulatory hurdles or in having the transport or distribution assistance necessary to overcome challenges to diagnosis or treatment. And then there are the therapies requiring specialty diagnostics, precise timing, and/or with complex therapeutic cycles where patients may—in some markets—need support ranging from identification of and transport to centers of excellence to solutions as simple as a mechanism for telling time.

Despite this breadth of possible support, because Patient Support offerings invariably provide something of value to patients or HCPs, they naturally generate concern that the offering was provided in whole or in part to influence decision-making or sales. In the U.S., this concern has led to numerous federal investigations and litigation premised on the theory that PSP offerings constitute illegal inducements under the federal Anti-Kickback Statute ("AKS"),[4] state analogues to the AKS, or the Federal Beneficiary Inducements Act,[5] i.e., remuneration offered to induce prescriptions reimbursable by government programs. Part of the concern is that these programs may also steer patients to more expensive drugs in lieu of more affordable, equally effective products, which, in turn, drives up costs for government payers. For example, in September 2018, the California Department of Insurance intervened in a whistleblower case against AbbVie Pharmaceuticals by filing a complaint alleging, in part, that AbbVie's nursing and reimbursement support services for Humira have resulted in illegal kickbacks to prescribing HCPs and $1.3 billion in tainted claims to California insurers.[6] The Department alleges that AbbVie offered the services, consisting of prior authorization support, patient education and counseling, and similar services, to prescribing HCPs in order to add value to their practice or save them substantial time and resources that they otherwise would have had to expend. The complaint further alleges that the nurses engaged in improper promotional practices by engaging in so-called "white-coat marketing," presenting unbalanced information to patients, and promoting Humira off-label. If the state prevails, AbbVie faces penalties in the billions of dollars. AbbVie is also

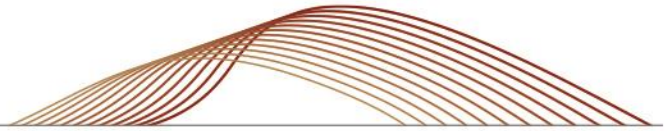
currently litigating similar claims in a federal district court case under the federal AKS and False Claims Act, which involves the same whistleblower.[7]

While not perfect analogues to the AKS, many countries and industry codes have restrictions on transfers of value and/or prohibit improper inducement or interference with treatment decisions that—particularly when paired with global and domestic corruption laws such as the Foreign Corrupt Practices Act in the U.S.,[8] the U.K. Bribery Act,[9] and Brazil's Clean Companies Act[10]—present similar (if not heightened) multi-regulator enforcement exposure to global Patient Support efforts. Beyond the context of improper influence or transfers of value, a number of industry codes and a range of specific and non-specific regulatory provisions, variant across markets, reach the operation of Patient Support offerings, governing issues ranging from data privacy, to the collection and use of patient data, to reporting and/or pre-approval obligations.[11]

Combine the diversity of access, reimbursement, and logistical challenges with variant legal, regulatory and industry standards, and the threat of multi-regulator anti-corruption and other exposures, and one quickly recognizes that compliance structures built to manage U.S. Patient Support under U.S. legal regimes fall far short. Indeed, from raids and public investigations of patient assistance organizations in Brazil, to internal investigations into Patient Support in Asia—involving allegations of inappropriate benefits to HCPs, off-market resale of free goods, and misuse of patient data—to violation of disclosure and transparency requirements in Europe, the importance of establishing a global Patient Support compliance framework has never been more clearly underscored.

While a global Patient Support compliance framework must certainly be flexible in order to accommodate the diversity of Patient Support efforts and legal and industry requirements, the task of creating such a framework is not impossible. As its most basic component, the global framework—documented in policies, procedures, work instructions, FAQs, and other guidance consistent with the company's governance structure for guiding documents—should clearly outline the initiation, review, and approval process for any potential Patient Support effort, mandating the necessary documentation, any relevant approval flows/value thresholds, and core considerations in creating and/or approving Patient Support. And of course, the framework should outline, or by reference to other company policies address, core compliance risks and related requirements for items such as interactions with patients, engaging HCPs and government officials, and managing personal data.

In constructing this global framework, companies should consider and address four core components: First, the framework must account for the variant legal regimes and industry codes applicable to the company's Patient Support. Second, the company's proper purpose for engaging in Patient Support should be clearly stated, while improper purposes should be articulated and forbidden. Third, the framework should mandate controls relating to the collection, storage, and use of patient data, and should include appropriate consideration of, and mechanisms for, adverse event reporting. Fourth, the framework should anticipate the circumstances under which it may be appropriate (or mandated) that a third party be utilized to execute a Patient Support effort, and any particular requirements for the selection, diligence, contracting, training, and/or monitoring of those third parties. Relatedly, the framework should delineate both the efforts required, and persons or functions responsible, for ongoing oversight and monitoring of the Patient Support. This first component—variant legal regimes and industry codes—is discussed below, while the remaining core components are discussed in Part II of this series.



Understand and Integrate Applicable Law and Industry Codes

All too often, companies have "global" compliance guidance that are merely find-replace versions of their U.S. counterparts. Though problematic in many contexts, this approach is particularly ill fit for Patient Support efforts, as many countries, regions, and industry groups have regulations that directly address (and often restrict) these programs. As examples, Canada, the U.K., the European Union (the "E.U."), and Australia have industry codes specifically addressing PSPs and, in some cases, patient safety and data requirements or interactions with HCPs and patients in connection with PSPs. Beyond PSP-specific provisions, a number of jurisdictions have laws and/or industry codes that—though general in scope—also impact the permissible structure and/or execution of Patient Support, as they define and restrict promotional activities, and/or place restrictions and/or reporting obligations on activities such as interactions with HCPs and/or patients. For instance, numerous markets have laws or codes with reporting requirements that could capture transfers of value made to HCPs in connection with Patient Support, such as the French Sunshine Law,[12] the Medicines Australia Code of Conduct[13] and the Privacy Act of 1988,[14] and the Japan Pharmaceutical Manufacturers Association's Transparency Guideline for the Relation Between Corporate Activities and Medical Institutions.[15] In addition to industry-specific laws and codes, Patient Support efforts may be touched by more general regulations such as anti-bribery and anti-corruption laws.

Beyond these requirements and restrictions, an understanding of applicable law and regulation more broadly is required. For example, understanding items such as the particulars of market and patient access, whether the relevant players are public or private, and what diagnostics, treatments, therapies, and services are reimbursed is critical to understanding what might constitute a transfer of value to an HCP or patient in a particular market or Patient Support effort.

While developing guidance tailored to the idiosyncrasies of law and code in each potential market is impossible, companies should both survey their markets to identify and integrate applicable themes, concepts, and requirements, and ensure that the global framework includes appropriate and timely moments certain in the process where applicable requirements are to be identified and considered. This step in the process—*pre-program approval*—is particularly crucial where Patient Support considerations or approvals are above-market and decision-makers may, unawares, run afoul of market-specific restrictions, pre-approval or notice requirements, and/or transparency reporting obligations.

Conclusion

In the realm of patient support a "one size fits all" approach—particularly where applying a U.S.-centric focus—is unlikely to result in tailored, effective risk mitigation of Patient Support efforts, and may leave companies exposed to, among other things, local law and industry code violations from the inception of an ex-U.S. Patient Support effort. As Patient Support continues to be an area of both global investment across the industry and increasing regulator focus, companies should develop a global compliance framework tailored to their Patient Support strategy and global footprint, and sufficiently flexible to cover the variant programs and efforts in their ex-U.S. Patient Support portfolio. In this first of a two-part series, we have explored the first of four core considerations in developing the global compliance framework for patient support. In Part II, we will address the remaining core considerations.

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[1] IQVIA INSTITUTE, THE GLOBAL USE OF MEDICINE IN 2019 AND OUTLOOK TO 2023, FORECASTS AND AREAS TO WATCH (Jan. 2019); IQVIA Institute, 2018 AND BEYOND: OUTLOOK AND TURNING POINTS (Mar. 2018).

[2] ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY (ABPI), GUIDANCE NOTES FOR PATIENT SAFETY AND PHARMACOVIGILANCE IN PATIENT SUPPORT PROGRAMMES (Mar. 2018).

[3] INNOVATIVE MEDICINES CANADA (IMC), CODE OF ETHICAL PRACTICES (2018).

[4] 42 U.S.C. § 1320a-7b.

[5] 42 U.S.C. § 1320a-7a.

[6] Complaint, *The State of California, et al. v. AbbVie, Inc. et al.*, No. RG18893169 (Cal. Super. Ct., Sep. 1, 2018). The case was subsequently removed to District Court, *The State of California, et al. v. AbbVie, Inc.*, No. 3:2018cv06392 (N.D. Cal., Oct. 19, 2019).

[7] Complaint, *U.S. ex. rel. Zuarez v. AbbVie*, 1:15-cv-08928 (N.D. Ill., Feb. 2, 2018).

[8] 15 U.S.C. § 78dd-1.

[9] Bribery Act, 2010 (U.K.).

[10] Law No. 12,846, (2014).

[11] *See, e.g.*, Regulation (EU) no. 2016/679 (regulates the collection, use, and storage of personal data of individuals within the European Union and European Economic Area); Personal Information Protection and Electronic Documents Act (2000) (governs the processing of personal information, including patient information, in Canada, and including restricting the purposes for which patient data may be used); Amended Act on the Protection of Personal Information (2017) (tightens patient data protection in Japan, bringing the approach more in line with European standards, imposing similar controls); Law No. 2011-2012 of 29 December 2011 (the "French Sunshine Act," which imposes reporting obligations on companies that give benefits to healthcare providers); MEDICINES AUSTRALIA, CODE OF CONDUCT, EDITION 18 (Jun. 17, 2014, as amended, Jun. 11, 2015) and the Privacy Act, 1988 (Aus.) (requiring the reporting of transfers of value to healthcare professionals in Australia); European Federation of Pharmaceutical Industries and Associations (EFPIA) HCP/HCO Disclosure Code (2014) (requiring the disclosure of transfers of value from pharmaceutical companies to HCPs and healthcare organizations); Law No. 93-121 of 27 January 1993 (the "French Anti-Gift Law" or "French DMOS Law" (regulating the provision of benefits to HCPs from health care companies and providing prior authorization procedures for programs and agreements).

[12] Law No. 2011-2012 of 29 December 2011.

[13] Medicines Australia, *supra*, note 9.

[14] Privacy Act, 1988 (Aus.).

[15] JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION'S TRANSPARENCY GUIDELINE FOR THE RELATION BETWEEN CORPORATE ACTIVITIES AND MEDICAL INSTITUTIONS, (Jan. 2011).