Strategic Purchasing in the Health Sector and Trade Law Implications

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On the eve of the UHC 2030 conference in Tokyo in December 2017, the World Health Organization (WHO) and the World Bank released their report on the status of health care in the world.[1] The report found that "at least half the world's population still lacks access to essential health services. Futhermore, some 800 million people spend more than 10 percent of their household budget on health care, and almost 100 million people are pushed into extreme poverty each year because of out-of-pocket health expenses."[2] Anna Marriott, health policy adviser for the international aid agency Oxfam, said the report was a "damning indictment" of governments' efforts on health. This situation is not unique to any one country or types of health system; it happens in predominantly private health care systems such as in the United States, in publicly delivered health care systems such as in Canada and the United Kingdom, and in mixed systems common in many countries in the world. Some of the challenge arises in countries with smaller populations where public and private providers lack significant leverage in purchasing goods and services due to their limited scale. For every country, the ever-expanding range of new treatments and medicines resulting from scientific advancements has made it impossible for many countries to offer these given limits on technical, scientific, professional, and financial resources. Yet, since the responsibility for the health of the population lies primarily with the government, a lot of attention has been focused on how governments meet this obligation.

The push to improve health outcomes and conditions and meet global health mandates such as those of universal health coverage (UHC) and the sustainable development goals while controlling costs is not unique to any one country; indeed, all are struggling to find ways to deliver high-quality care at affordable prices no matter the type of health care system.[3] Just in the last year, a tremendous amount of high-profile attention has been directed at how to solve the dilemma of quality care that is affordable at global health events such as the UHC Summit in Tokyo and the spring 2017 meeting "Strategic Purchasing for UHC: Unlocking the Potential," which was organized by the WHO's Department of Health Systems Governance and Financing.[4] The market has driven a number of changes to theoretically aid in meeting these goals, such as international standards for "medical education … [and] hospital accreditation," the spread of "principles and technologies of Western scientific medicine," and the opening of health systems to "foreign direct investment and joint

ventures" with Western counterparts.[5] Among the goals, challenges, and solutions, strategic purchasing of health services by governments, the topic of this article, has gained momentum.

Despite the utility proven by the experience in the commercial sector, to date only mere nods to the legal implications of the mechanics of strategic purchasing are found in the published literature on the topic of UHC and strategic purchasing. Though there are many legal issues that may be reviewed on strategic purchasing, in this article, the focus is on the main international trade law aspects that are likely to be encountered with the strategic purchasing of health services by governments. Strategic purchasing can include product purchasing, but since much has been written about the cross border purchasing of medical products, this aspect of strategic purchasing will not be covered in this piece. We provide an introduction to how international law guides cross-border strategic sourcing of health services by governments, and we explore topics worthy of further consideration.

What Is Strategic Purchasing?

In the commercial sector, strategic sourcing first appeared during the late 1980s as Fortune 500 companies expanded their markets around the world based on three "fundamental philosophies that drive the strategic elements and also the infrastructure required" to support it. These are: (1) shifting focus to the "total delivered value, not the purchase price"; (2) working in collaboration with suppliers; and (3) emphasizing profitability "rather than cost savings." The result is the development of longstanding relationships with suppliers and "economies of scale."[6] Inherent in all of this is a determination of priorities, improved negotiating, and reduction of the total supply cost.[7]

The health care world took up strategic purchasing more than 30 years after the business community but is doing so based on the same principles.[8] The global health community mirrors the commercial approach, acknowledging that the strategic purchase of health care services "applies equally to the purchase of health system inputs … such as trained personnel, diagnostic equipment, and vehicles." This means technological development, major equipment acquisition, and training of personnel all become subject to review under the principles of strategic purchasing to ensure efficiency and value. Whether acquisition of health system inputs is done by government or by private agencies (i.e., private insurers, providers, or households), the government has a role in "using its regulatory and persuasive influence to ensure that these purchases improve, rather than worsen, the efficiency of the input mix." Added to this requirement for efficiency or effectiveness is "value for money … obtained," which also translates to "good prices."[9] This makes good sense because no matter the type of service provided, at the end of the day, the purchase of health services is a commercial transaction.

Strategic purchasing of health care is dynamic because it is also a process that shifts the emphasis from one transaction at the lowest price point to "a continuous search for the best ways to maximize health system performance by deciding which interventions should be purchased, how, and from whom." This involves "actively choosing interventions in order to achieve the best performance, both for individuals and the population as a whole."[10]

Building Capacity

The phrase "strategic purchasing" has become synonymous with strategic sourcing or procurement and, when the transaction is across borders, with global sourcing or cross-border purchasing. Strategic purchasing is more than public procurement and can include the direct purchase of health care services for one or a few patients who are sent abroad for treatment. However, medical tourism is not included in our article since that sector is patient-initiated rather than provider-initiated, but it does include telemedicine. Strategic procurement of health services implicates a number of different regulatory schemes at any one time and telemedicine is an example. This is the situation in the European Union where it was determined that there is a close association between information transfer and the absence of common standards or norms for medical liability.[11]

A factor that distinguishes strategic procurement from regular or passive procurement is that cost savings is not the singular factor in procurement decision-making. Instead, purchasers can take into consideration quality-based factors such as technical merit, accessibility, environmental characteristics, and other non-cost dimensions. In Europe, this shift has led to important changes to European procurement directives, which now make the so-called "most economically advantageous tender" mandatory.[12] In the health sector, this transformation of public procurement into strategic procurement has led to the emergence of a "value-based" agenda that features a focus on patients, health services integration, and a shift in emphasis from volume of services provided to improved patient outcomes rather than cost alone. Health technologies assessment as required by the Affordable Care Act is an example of this value-based approach to maximize value for patients and payers.

Some countries have even formed or joined group purchasing organizations or formed fully or semi-autonomous national purchasing entities to consolidate capacity and build in the variety of expertise needed to address the wide variety of products and services health systems need. Private and public health care systems purchase not only clinical services but also banking and treasury services; information technology services; mobile, voice, and data services; recruitment services; and external legal services, among many others. Having the requisite technical capacity in the procurement team is critical to success.

By creating a strategic procurement process, other significant goals can be aligned. Some of these are improved inventory management; reduced contract administration expenses and internal contract review and compliance; streamlined (re)ordering and payment processes, such as creating a single point-of-contact office; increased leverage for future cost escalations; more efficient use of framework contracts; improved quality of services; and increased customer satisfaction. Strategic partners can also provide expertise in data collection and analysis, develop systemwide guidelines, and provide personnel training. To address the problem of scale, some hospitals have joined with other regional and national health care systems. In the United States, for example, where private health care predominates, more than 600 hospitals were acquired or merged over the six years from 2007 to 2013, according to the American Hospital Association and the Center for Healthcare Economics and Policy. With strategic procurement, both buyers and sellers of services have the opportunity to be strategic.

International Trade Law Reduces Barriers to Strategic Purchasing

Strategic purchasing of services across borders necessarily implicates international trade law. Absent attention to this topic, government health policies may unintentionally thwart their best

intentions. The roots of the main international legal frameworks for strategic purchasing of health services are contained in the 1947 and 1994 General Agreement on Tariffs and Trade (GATT), which forms the heart of the World Trade Organization (WTO), and the General Agreement on Trade in Services (GATS).[13] The four main principles governing international trade are set forth in the GATT, apply to government transactions and how governments regulate private actors, and have found applicability in the arenas of trade in services, financial transactions, information flows, and other areas that impact cross-border trade.[14] Thus, when a government is seeking to supply health care services from foreign providers by implementation of a strategic purchase regimen, the rules apply absent an exception.

GATS extends to over 160 different sectors, which include medical and dental services, the services of nurses and midwives, hospital services, and other human health services.[15] It pertains to trade in services that include "the supply of a service … from the territory of one member" into another member's territory, a service supplied to a "service consumer" of another member, a service supplied "through a commercial presence" in another member's territory, or even one supplied by a "service supplier" of a member providing a service to "natural persons of a member in the territory of" another member.[16] According to the WTO, less than 50 WTO members have undertaken any commitments in one of the four health service subsectors, and most of those concern hospital services. These four subsectors are telemedicine (called Mode 1), foreign patients entering domestic territory (Mode 2), foreign company establishing domestic subsidiaries or branches for services (Mode 3), and movement of natural persons (Mode 4).[17]

GATS is directed at "measures by members," which means primarily actions taken by "central, regional, or local governments" and delegated authorities.[18] But as GATS excludes "services supplied in the exercise of governmental authority" there is a question whether a government purchasing health services is doing so to fulfill its governmental authority. Nonetheless, GATS applies to government policy or regulation of all other services.[19] If the experience with the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration[20] that created additional measures to suspend intellectual property protections on medicine are any guide, it is likely that this argument will be made to justify actions that would otherwise be in violation of GATS.[21] While at present there are no rumblings to do the same for health services, in response to the global pressure to create universal health, such as was seen in Tokyo at UHC 2030, a similar push may occur in the realm of health services. If so, private companies engaging in strategic purchasing may need to take additional steps to protect themselves.

There are other potentially important protections under GATS. Accordingly, WTO member states commit to providing market access to services and "service suppliers"[22] while doing so on terms that are "no less favorable" than those provided under a schedule or commitment.[23] Governments are to accord national treatment, or the same treatment, to "services and service suppliers of any other member" as it does to those of its own country.[24] When it comes to commitments for market access, governments are specifically prohibited from limiting certain things. These prohibitions include limits on the following: the number of service suppliers, the total value of service transactions or assets, the total number of service operations or quantity of service output, the total number of "natural persons that may be employed," the types of legal entities or joint ventures that may engage in providing services, and foreign capital participation.[25]

Cross-border purchasing of health care services involves professional and nonprofessional staffing; thus, training and licensing or accreditation of personnel become important considerations. Article VI.4 of the GATS speaks directly to "qualification requirements" and "licensing requirements" because it prohibits these from becoming "unnecessary barriers to trade in services." Thus, for example, a diagnostic service delivered by electronic means could not be forced to have its radiologist doctors be licensed in the country where the patient is located. GATS instructs the Council for Trade in Services to "develop any necessary disciplines" to ensure that licensing and associated criteria does not restrict the supply of the service.[26] Concurrently, member states, in the course of recognizing the education or experience prerequisites for licenses or certifications of service providers, cannot do so in a manner to discriminate between countries and service providers or services from those countries.[27]

GATS is designed to eliminate hindrances to the cross-border provisioning of services in several other areas. Many member states are developing economies in which more monopolies might be found than in developed economies. Even in the case of monopolies that supply a service, the monopoly is not allowed to hinder trade in services, which GATS Article VIII.1 makes clear. Other areas include the elimination of "certain business practices," as set out in Article IX.1, and the implementation of emergency safeguards on the basis of nondiscrimination, as explained in Article X. Payments "for current transactions" and international transfers are not to be restricted, as per Article XI.1.

Another body of international trade law, the Government Procurement Agreement (GPA) holds the dual promise of building countries' capacity for strategic procurement while eliminating barriers to the same. It does so by requiring governments to apply principles of international trade to all their procurement actions whether these are for goods or services. At this point in time, only about 47 member states of the WTO have signed onto the agreement while another 10 are in the process of acceding to the GPA.[28] Of note, Article IV of the GPA applies the principle of nondiscrimination to government procurement actions. Article X requires the governing authorities to "prepare, adopt, or apply" technical specifications and conformity assessment procedures so as not to have either the "purpose or the effect of creating unnecessary obstacles to international trade." Perhaps of greatest note are the provisions of Article XVIII (entitled "Domestic Review Procedures") that make the policies and actions of governments available for judicial review in domestic forums.[29]

Exceptions to Trade Law

Just as in the GATT, with the GATS there are two recurring themes: nondiscrimination and equal treatment of services and service providers from other member states. However, those themes are not without some limitations. GATT XX(b) is the foundation for the public health exception that grants space to countries to protect health as was done with the Doha Declaration. GATS Article XIV allows measures to "protect public morals or to maintain public order," to protect life of humans or animals or plants, to prevent deceptive or fraudulent practices, to promote safety, and to protect the privacy of individuals. In addition to the public health exceptions most likely to be in play with procurement of health services, GATS limits the imposition and collection of taxes so these cannot result in different treatment unless such is to ensure the "equitable or effec-

tive imposition or collection of direct taxes" to include avoidance of double taxation as previously determined by international agreements.[30] GATS Article XIV *bis* allows certain exemptions for security purposes. Subsidies are allowed of certain service industries under Article XV, but these must avoid trade distortion. Finally, restrictions on trade in services are allowable under Article XII to safeguard a country's balance of payments, but these must not discriminate against member states.

Dispute Resolution

In the health services industry, as in others, a number of options present themselves should issues arise as to contract interpretation, compliance, or enforcement. Private international law mechanisms of contract can specify how and where disputes are to be handled, such as by arbitration under the UNCITRAL Arbitration Rules. Coupled with the U.N. Convention on the Recognition and Enforcement of Foreign Arbitral Awards (also known as the "New York Convention"), which makes arbitral decisions enforceable around the globe, there are options to manage disputes if questions of sovereign immunity are also managed. This leads to a very important consideration—the resolution of disputes or, perhaps more accurately, how governments may be brought to comply with international trade laws. Companies have come to understand the power of an entire industry in advancing interests through national trade representatives. The U.S. pharmaceutical industry is an example in this regard. Using § 301 of the Trade Act of 1974, the pharmaceutical industry annually petitions the president through the Office of the U.S. Trade Representative to remove trade barriers from foreign governments by specifying the obstacles and recommending solutions.[31]

The trade regime is also unique in that it has a dispute resolution system binding on governments. GATT Article XXIII authorizes use of the procedures more fully set out in the document known as Rules and Procedures Governing the Settlement of Disputes.[32] GATS has a system as well that allows the Council of Trade in Services to resolve disputes[33] concerning the provisioning of cross-border services to include handling consultations between members on business practices,[34] complaints concerning restrictions on transfers and payments,[35] and as mentioned earlier on licensing and certification issues of personnel or professionals.

Where Do We Go From Here?

Strategic procurement is a viable solution to solve the challenge of providing access to care with some amount of cost control and of ensuring other factors important to health systems such as quality and efficiency. Though the health sector may have only begun to utilize strategic purchasing recently, it is already undergoing a paradigm shift to understand these transactions as commercial in nature. The international trade system provides further guidance and requirements, as well as limits to how governments can regulate and engage in these transactions. That system also provides a number of measures that are designed to protect the sellers of services so as to create a level playing field. But when the subject is health, the very same system has measures, such as Article XX of GATT, that allow governments to prioritize public health above trade. It remains to be seen how the public health exceptions and the exclusion for services supplied in the exercise of governmental authority will play out as strategic purchasing for UHC ramps up across the globe. Nonetheless, it can be anticipated that for those in the business of health care services, there will be opportunities to expand through strategic procurement as UHC is adopted in more countries. ⊙

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Endnotes

[1]World Health Org. & Int'l Bank for Reconstruction & Dev., Tracking Universal Health Coverage: 2017 Global Monitoring Report (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

[2]*Id.* at 1.

[3]Sustainable development goal 3.8 seeks to provide all people with access to high-quality, integrated, "people-centered" health services that include promotive, preventive, curative, rehabilitative, and palliative health services, as well as safe, effective, quality, and affordable essential medicines and vaccines.

[4]This goal, as reiterated in the Tokyo Declaration, is to protect people from financial hardship when they access services. Gov't of Japan et al., *Tokyo Declaration on Universal Health Coverage*, Universal Health Coverage Forum 2017 (Dec. 12-15, 2017), *available at* http://www.who.int/mediacentre/events/2017/uhc-forum-2017/en.

[5]Globalization is defined as "the increased interconnectedness and interdependence of people and countries, (WHO, 2014a)." Carol Holtz, Global Health Care: Issues and Policies (2016).

[6]Sathit Parniangtong, Strategic Management: Strategic Sourcing 6-7 (2016).

[7]*Id.*

[8]Loraine Hawkins, Senior Consultant, World Health Org., System Perspective and Scheme Needs: What are the Governance Issues and How to Assess Governance for Strategic Purchasing, Presented at Strategic Purchasing for UHC: Unlocking the Potential (Apr. 26, 2017). *See also* Ayako Honda, Univ. of Cape Town, Strengthening Governance in Purchasing Markets—Challenges When Multiple

Funding Flows Exist, Presented at Strategic Purchasing for UHC: Unlocking the Potential (Apr. 26, 2017).

[9]World Health Org., The World Health Report 2000: Health Systems: Improving Performance xvii (2000) [hereinafter WHO Health Report 2000], http://www.who.int/whr/2000/en/whr00_en.pdf.

[10]WHO articulated three principles of strategic procurement for its own operations. These are risk mitigation, cost effectiveness, and the emplacement of a strategic procurement capability, which it termed as focusing "on strengthening operational capability, effectively managing suppliers, optimizing the supply chain, comprehensive quality assurance, and reinforcing the procurement foundation (such as structure, process, system tools, skills, and knowledge)." WHO Health Report 2000, at 97. The third pillar is a properly constructed and operating strategic procurement capability that must be in place to effectuate strategic sourcing. World Health Org., WHO Procurement Strategy 12 (Apr. 27, 2015), http://www.who.int/about/resources_planning/WHO_Procurement_Strategy_April2015.pdf.

[11]Vera Lucia Raposo, *Telemedicine: The Legal Framework (or the Lack of It) in Europe*, 12 GMS Health Tech. Assessment (2016).

[12]*See, e.g.*, Directive 2014/25/EU, of the European Parliament and of the Council of 26 February 2014 Concerning Procurement by Entities Operating in the Water, Energy, Transport and Postal Service Sectors and Repealing Directive 2004/17/EC, 2014 O.J. (L 94/244); *and* Directive 2014/24/EU, of the European Parliament and of the Council of 26 February 2014 on Public Procurement and Repealing Directive 2004/18/EC, 2014 O.J. (L 94/65).

[13]*See WHO Legal Texts*, World Trade Org., https://www.wto.org/english/docs_e/legal_e/legal_e.htm (last visited Jan. 8, 2018).

[14]These principles are: (1) according equal treatment to the goods or products of another country that is a signatory (or contracting party) to the GATT (art. I, Most Favored Nation Treatment); (2) treatment no less favorable than that provided under applicable concession agreements, which are caps on tariffs (art. II, Schedules of Concessions); (3) treatment of products, which means treating foreign products the same as domestic products (art. III, National Treatment on Internal Taxation and Regulation); and (4) elimination of quantitative restrictions (arts. XI and XIII).

[15]*Services: GATS: The General Agreement on Trade in Services (GATS): Objectives, Coverage and Disciplines*, World Trade Org., https://www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm (last visited Jan. 8, 2018).

[16]General Agreement on Trade in Services [GATS] art. I.2.

[17]*Services: Sector by Sector: Health and Social Services*, World Trade Org., https://www.wto.org/english/tratop_e/serv_e/health_social_e/health_social_e.htm (last visited Jan. 8, 2018).

[18]GATS art. I.3(a).

[19]GATS arts. I.3(b) & XIII.1.

[20]World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/W/2 (Nov. 14, 2001), http://www.who.int/medicines/areas/policy/tripshealth.pdf.

[21]*Id.*

[22]*Supra* note 17.

[23]GATS arts. XVI.1 & II.

[24]GATS art. XVII.1.

[25]GATS art. XVI.2.

[26]*Id.*

[27]GATS arts. VII.1 & VII.3.

[28]*Agreement on Government Procurement: Parties, Observers and Accessions*, World Trade Org., https://www.wto.org/english/tratop_e/gproc_e/memobs_e.htm(last visited Jan. 8, 2018).

[29]*Revised Agreement on Government Procurement*, World Trade Org., https://www.wto.org/english/docs_e/legal_e/rev-gpr-94_01_e.htm (last visited Jan. 8, 2018).

[30]GATS art. XIV.

[31]Pharma. Res. & Manufacturers of Am. (PhRMA), Special 301 Submission 2017 (2017), http://phrma-docs.phrma.org/files/dmfile/PhRMA-2017-Special-301-Submission.pdf.

[32]World Trade Org., GATT Annex 2: Understanding on Rules and Procedures Governing the Settlement of Disputes (1997), https://www.wto.org/english/docs_e/legal_e/28-dsu.pdf.

[33]GATS art. VIII.3.

[34]GATS art. IX.2.

[35]GATS art. XI.