The Trade Agreements Act, 19 USC §§ 2501, et seq. implements the World Trade Organization Government Procurement Agreement (WTO GPA) and other international trade agreements in the United States by applying these agreements to certain government contracts. The TAA is intended to remove barriers to government procurement of foreign-sourced items, and it incentivizes countries to become signatories to the WTO GPA and free trade agreements using a carrot and a stick. The TAA waives Buy American Act preferences for eligible items in acquisitions subject to these agreements. At the same time, it prohibits procurement of end items that are not U.S.-made or designated country end items, such as items made in India and China, through contracts subject to the WTO GPA, unless offers of eligible items are not received or are insufficient to fill the agency’s needs. The TAA is implemented through the country of origin representations and certifications made by companies responding to a federal contract solicitation that contains the clauses proscribed by FAR Subpart 25.11.

Most pharmaceutical products are acquired by the federal government using the Federal Supply Schedule (FSS) contracts administered by the Department of Veterans Affairs under a delegation of authority from the General Services Administration, and the standing solicitation for Schedule 65 contracts (pharmaceutical supplies) is subject to the WTO GPA. Companies seeking to offer products for sale under FSS contracts must determine the country of origin of end items to be acquired under the contract and certify that they are U.S. or designated country end items. Because India and China are primary manufacturing sources of pharmaceutical agents, and country of origin of most drugs is determined by the place of manufacture of the drug’s active ingredient, the TAA limitation on procurement sources heavily impacts Schedule 65 contracts. This article explores potential solutions for the VA to acquire drugs manufactured in non-TAA countries.

Applicability of TAA to Pharmaceutical Supply Contracts

The Trade Agreements Act is not an embargo that prohibits the government from buying products from non-TAA countries under any circumstance. Separately, laws and regulations prohibit contracting with certain sources, such as entities in Cuba, Iran, and Sudan. Rather, the restriction on items from non-TAA countries is a procurement contract requirement that applies to supply and service contracts with a value equal to or exceeding $202,000. For IDIQ contracts, like Federal Supply Schedule contracts, the TAA applies if the estimated value equals

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1 FAR Part 25 sets forth the list of countries that qualify as designated countries.
2 FAR 25.403(c). Some contracts may have values that subject them to free trade agreements with certain countries but not the WTO GPA, in which case the restriction does not apply.
3 See FAR Subpart 25.7
4 The WTO GPA also applies to service contracts valued at or exceeding $202,000 and construction contracts valued at or exceeding $7,777,000.
or exceeds the threshold amount. Because the standing solicitation for Schedule 65 contracts contains the TAA clause, all prospective Schedule holders must certify the products in their offers are TAA-compliant, and the VA has included a field in its pharmaceutical pricing spreadsheets for contractors to identify the drug’s country of origin. If a product is not a U.S. or designated country end item, the VA may not include it in the awarded contract.5

The TAA similarly applies to the VA’s national “committed use” contracts, which are usually competed, single award requirements contracts, and its supply contracts with wholesalers (referred to as prime vendors).6 It also applies to the pharmaceutical and medical supply contracts that the Department of Defense awards to prime vendors under DoD’s Distribution and Pricing Agreement (DAPA) program;7 however, it does not apply to rebate agreements required by the Tricare Retail Pharmacy Program regulation.8 As discussed below, the contracting agency is responsible for determining whether a product is unavailable from TAA countries. Accordingly, the VA and DoD make their own non-availability determinations for their own contracts.

Determining Country of Origin

Under the TAA, the test for determining country of origin – where a product is wholly made or has been substantially transformed - is based on Customs rulings for determining duties


6 When the VA orders a drug under an FSS contract indirectly through its prime vendor, the prime contract is the FSS contract and the prime vendor provides distribution services; however, when the VA orders a drug that is not available on an FSS contract from the prime vendor, the prime contract is the prime vendor contract and the contract price is the price offered by the prime vendor.

7 DoD awards contracts to prime vendors in which the contractor agrees to deliver items ordered by DoD at a price that is established between DoD and the manufacturer of the item pursuant to an FSS contract or a DAPA, even if the price exceeds the amount the prime vendor paid when it acquired the item. Unlike the FSS, DAPAs are not procurement contracts and do not obligate the manufacturers to deliver supplies directly or through a prime vendor. When an item is not ordered from the prime vendor under an FSS contract, to ensure that DoD is invoiced at the manufacturer’s DAPA price, and that the prime vendor receives a chargeback credit from the manufacturer, the agency requires that manufacturers enter into collateral chargeback agreements with the prime vendor, as well as pricing agreements with DoD, as a condition of their products being included in the DAPA program. For manufacturers of covered drugs, this three-way contracting arrangement is a “depot contracting system” subject to price caps under 38 U.S.C. §8126. Pursuant to a memorandum of agreement between DoD and the VA, DoD cancelled its DAPA for pharmaceuticals and agreed to order drugs and biological products under manufacturers’ FSS contracts, directly or through its pharmaceutical prime vendor. Recently, however, DoD has indicated a willingness to enter into pricing agreements with manufacturers of pharmaceuticals unavailable on the FSS due to TAA restrictions.

8 DoD’s Tricare retail pharmacy program contracts with a pharmacy benefit manager to reimburse retail pharmacies for drugs they procured through commercial channels and dispensed to Tricare beneficiaries. By regulation, the program mandates manufacturers of covered drugs provide rebates to DoD on these prescription transactions. DoD is not procuring dispensed drugs when it pays these pharmacy benefits. Further, legislation that subjected this pharmacy benefit program to the procurement ceiling price in 38 USC §8126 did not subject rebate transactions to procurement source limitations. Accordingly, VA has advised that rebates provided to the Tricare retail pharmacy program apply to covered drugs that are excluded from the FSS because of TAA rules.
and tariffs. These rulings have established, generally, that, for pharmaceutical products, the country of origin is the country in which the active pharmaceutical chemical ingredient (API) is made. Customs rulings have not considered the dosing of API and the processing required by the FDA to sell the bulk chemical substance as an approved drug to be sufficient to transform the API into a wholly different article – the approved drug. Instead, Customs applies the same analysis that would apply to duties paid on any chemical. Unless the chemical formula and name is changed or the API undergoes a process that changes its properties and characteristics, or is combined with other active agents, the API is not considered substantially transformed into a different article, even if it cannot be sold for human consumption in bulk form. Accordingly, the site of manufacture of the API usually determines the country of origin for TAA purposes.

Unavailability Determinations

Any agency can exempt an article from the TAA prohibition against procurement of non-TAA country end items if the contracting officer determines that a particular item is not available in quantities sufficient to meet the agency’s needs. Accordingly, DoD has conducted market research, determined that offers of TAA-compliant end products were not available for particular multiple source drugs, and exempted them from TAA requirements for a period of time. These actions have allowed DoD to place orders for non-TAA compliant drugs under DoD’s supply contracts at the awarded contract price. DoD has also indicated a willingness to enter into pricing agreements with manufacturers of single source drugs delisted from the FSS. If DoD establishes a DAPA covering pharmaceutical items unavailable for purchase under the FSS, and determines items are unavailable from TAA countries, it could place orders under its pharmaceutical prime vendor contract for the drugs priced pursuant to the DAPA, assuming the manufacturer is willing to abide by the DAPA program requirements, or for drugs priced by the prime vendor. The VA can make similar unavailability determinations for acquisitions under its own contracts, and under the FSS if GSA were to delegate that authority.

VA’s Sourcing Problem

The TAA has created a dilemma for the VA, because of procurement policies. As discussed, China and India are primary manufacturing sources for pharmaceutical chemicals, but drug products with API made in these countries are unavailable for purchase under the FSS. If there is only one source for a drug and its API is made in India or China, or all manufacturers of a particular multiple-source drug acquire the API in non-TAA countries, applying Customs’ country of origin test can mean no product is available for procurement under the FSS. Other times, a brand drug made in a TAA-compliant country may be available for purchase under the FSS, but not a cheaper generic version made in India or China. Thus, a determination of non-availability by the VA for purposes of exempting a drug from the TAA’s procurement

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9 The VA relies on rulings and guidance of the U.S. Customs and Border Protection interpreting country of origin under section 304 of the Tariff Act of 1930, as amended, 19 U.S.C. §1304. Section 134.1(b) of Customs Regulations defines "country of origin" as: “the country of manufacture, production or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the ‘country of origin’ within the meaning of this part.”


11 Although DoD has a prime vendor contract covering pharmaceutical products, it does not currently maintain a Pharmaceutical DAPA.
restrictions is appropriate in many instances. The problem is that GSA establishes FSS contracting policy and GSA policy prohibits contracting officers from making non-availability determinations for FSS contracts. Thus, making such determinations for pharmaceuticals offered in Schedule 65 contracts would contradict GSA policy.

Compounding this problem is that VA sourcing rules require the agency to follow a hierarchy in which the FSS takes precedence over regionally awarded or locally awarded contracts and open market purchases.\(^\text{12}\) In order to procure a drug through a regional, local or open market contract, an ordering office must determine the item that will meet its needs is not available on a Schedule 65 contract, and obtain a waiver.\(^\text{13}\) Although FSS contracts do not take precedence over national contracts, and the VA can procure drugs unavailable on the FSS under its national prime vendor supply contract, the contract prices offered the VA by the prime vendor are generally limited to prices for generic drugs, which the prime vendor acquires at a discount. Thus, in order to acquire brand drug products manufactured in India and China, the VA must award a national contract to a single contractor that offers the product at a contract price or waive the FSS requirement.

Another problem for the VA is that the agency may be unable to acquire a particular drug from its manufacturer if the drug is unavailable under the manufacturer’s FSS contract. The Veterans Health Care Act, 38 USC §8126, requires manufacturers to offer covered drugs for sale to the VA through the FSS program as a condition of Medicaid payment. If the VA does not add the product to the FSS contract, the manufacturer has still met its obligation. Further, the VA lacks statutory leverage to obtain offers of contract pricing outside the FSS program. Because covered drugs are subject to a ceiling price when purchased through a depot contracting system, for some drugs, particularly low-cost authorized generics, where the statutory discount coupled with the prime vendor fee can make sales unprofitable, there may be little reason for a manufacturer to offer them for sale under a VA contract. Nevertheless, if the VA entertained acquisition strategies that would permit it to make TAA non-availability determinations for its own contracts, or avoid the TAA altogether, it can be expected that some manufacturers of covered drugs would voluntarily offer contract prices to get the VA’s business.

**Potential Procurement Solutions**

The FSS program is a convenient and efficient means for an agency to acquire medical supplies as it need not estimate its requirements, conduct a competition, and negotiate terms before placing an order. It would be very burdensome for an agency to follow such a process every time a medical facility needed to acquire pharmaceuticals. Moreover, access to multiple sources under the Schedules program helps assure product availability as well as competitive pricing. From a manufacturer’s perspective, the FSS acquisition process is advantageous given the volume of orders placed by treatment facilities, and the ease of administering a single

\(^\text{12}\) VA interprets the hierarchy in FAR Part 8 as requiring the agency to use national committed use contracts first to acquire drugs, then Schedule 65 contracts with BPAs, then Schedule 65 contracts without BPAs, then regionally awarded and locally awarded contracts for items not on national contracts or Schedule 65 contracts, then open market purchases. See VA Directive 7408.1 Appendix A (June 9, 2005).

\(^\text{13}\) VA Directive 7408.1, Requesting Waivers from the Requirement to Use VA Federal Supply Schedules (June 9, 2005).
contract used by all federal government customers. The ideal solution is for Customs to reconsider its view regarding the transformation of bulk pharmaceutical chemicals into FDA approved products. Short of that, the VA should be able to exercise discretion to determine drug products from non-TAA countries may be acquired under the FSS, which is effectively what the agency is doing by continuing to list products made in these countries. However, if GSA does not change its position, legislative authority to waive the TAA in Schedule 65 contracts may be necessary. In the meantime, the FSS is not the only contract vehicle for procuring pharmaceuticals even if it is the most convenient one. If products with a non-TAA country of origin are unavailable under FSS contracts, there are alternatives for user agencies.

First, the TAA does not apply to contracts under the “micro purchasing” threshold of $3,000 and the simplified acquisition threshold of $150,000. Under the FAR micro purchasing rules, government facilities are permitted to place small orders under $3,000 with a wholesaler or a manufacturer without soliciting competitive quotations.\(^{14}\) Individual purchase order contracts above $3,000 but under $150,000 are subject to competition rules, but the rules are more limited and the award process less burdensome than for acquisitions above the threshold.\(^{15}\) Agency facilities can place open market orders up to the simplified acquisition threshold if they post notices of their requirements and evaluation criteria sufficient for potential suppliers to develop price quotes, solicit price quotes orally, and award individual purchase order contracts based on the posted criteria. Thus, while non-competed orders placed with a wholesaler, as well as those placed directly with a manufacturer, should be limited to micro purchases, open market orders up to $150,000 can be processed with minimal competition requirements.

If the VA contemplates repeat orders under the simplified acquisition threshold, it could enter into basic ordering agreements or stand-alone blanket purchase agreements, which are collections of terms that apply to contracts created by the placement and acceptance of orders.\(^{16}\) Just recently, the ASBCA reiterated precedent that a BPA is not a procurement contract but is simply a framework for future contracts that arise when an order is placed under the BPA and accepted.\(^{17}\) Accordingly, a purchase order contract incorporating BPA terms might require some level of competition, but it would not be subject to the TAA if the value fell below the $202,000 contract value triggering application of the TAA. The downside to a BPA strategy to avoid the TAA is that the manufacturer’s obligations would extend only to accepted orders, and purchase orders could not exceed $202,000.

Alternatively, the VA could determine that a single source drug is unavailable from TAA countries and award a contract for the drug with a value exceeding $202,000 without competition. Where only one manufacturer’s drug is approved for a particular indication, the VA could also award a national contract to that vendor. This solution seems to be one the VA is pursuing to access brand drugs. As with all “sole source” awards, the VA would have to justify its action and negotiate contract terms. To permit procurement under existing FSS contracts, the VA is seeking authority to issue a blanket determination of unavailability for all single source brand drugs. Either strategy would facilitate acquisition of unique drugs and help the VA meet

\(^{14}\) FAR 13.202(2).
\(^{15}\) See generally FAR Part 13.
\(^{16}\) BPAs that are modifications to FSS contracts are subject to the terms and conditions of the FSS contracts.
\(^{17}\) Hewlett-Packard Co., ASBCA No. 57940, 57491 (July 9, 2013).
its patients’ needs, but has limited utility. A sole source requirements contract is problematic if there is a generic equivalent to the brand drug in the marketplace, unless the generic version is not approved for every indication. Moreover, despite the VA’s previously stated desire to apply a determination of unavailability to all covered drugs under the VHCA, for multiple source drugs, a determination that ignores available sources or applies selectively would be vulnerable to challenge. Absent legislative authority to exempt all covered drugs from the TAA, where there are generic sources, it may be necessary for the agency to conduct non-availability determinations on a drug-by-drug basis, and apply that determination to acquisitions of the drug from any source under all VA contracts that exceed the TAA threshold. Moreover, the VA’s ability to acquire non-TAA compliant multiple source drugs would continue to be limited to those for which the prime vendor established a contract price.

As it is likely that the number of pharmaceutical chemicals sourced in India and China will not decrease, and that the TAA status of these countries will not change in the near future, the most viable near term solution for the VA for many pharmaceuticals may be adoption of a depot contracting system similar to DoD’s DAPA program, and issuance of non-availability determinations on a drug-by-drug basis applicable to the prime vendor contract. However, no solution is as good as a statutory waiver of the TAA for covered drugs offered for sale under FSS contracts, because manufacturers of covered drugs are not compelled by the terms of the VHCA to enter into any contractual arrangements with the VA other than FSS contracts.