INTERNATIONAL TRADE ADMINISTRATION

Trans-Pacific Partnership

Opportunities for the U.S. Health Products Sector

U.S. Health Products Exporters Currently Face Barriers in New TPP Markets**

$8.6 Billion in U.S. Health Products Exports to New TPP Markets in 2015

Health Products Exports Face Tariffs in New TPP Markets Up to **30%**

Red Tape, Border Delays, and Customs Inefficiencies **Increase Costs** and Impede the Flow of U.S. Exports Throughout the Region

The Health Products Sector includes products such as pharmaceuticals, medical supplies, and medical devices

Key Market Access Benefits

Japan will eliminate import taxes on **100%** of U.S. health products exports **immediately**

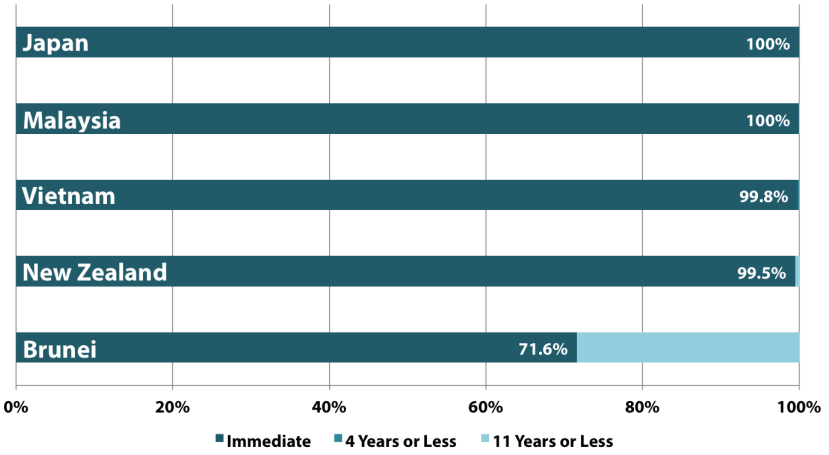
Malaysia will eliminate import taxes on **100%** of U.S. health products exports **immediately**

Vietnam will eliminate import taxes on **99.8%** of U.S. health products exports **immediately**

New Zealand will eliminate import taxes on **99.5%** of U.S. health products exports **immediately**

99.9% of U.S. Health Products Exports to New TPP Markets will Enjoy Duty-Free Access Immediately

Share of Exports by Tariff Elimination Basket



* **TPP Countries:** Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam

** **New TPP Countries:** Countries with which the United States currently does not have preferential market access – Brunei, Japan, Malaysia, New Zealand, and Vietnam

Importance of the U.S. Health Products Sector

657,000 U.S. Health Product Workers in 2015

Accounted for **5%** of Total U.S. Manufacturing Production in 2014

$95.3 Billion in U.S. Health Products Exports to the World in 2015

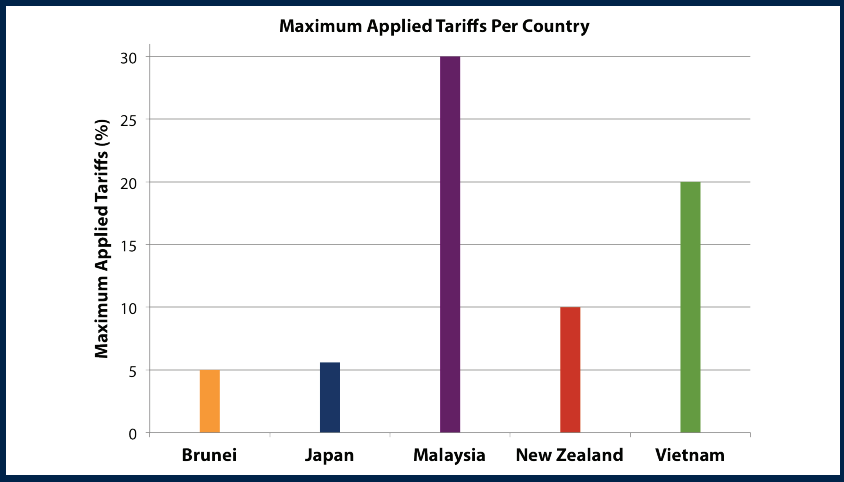
U.S. Health Products Exports to the World Grew by **18%** between 2009 – 2015

25% of Total U.S. Health Products Exports to the World in 2015 Went to the TPP Region

New TPP Partners are Significant Markets for U.S. Health Product Exports

Japan	$7.9 Billion
Malaysia	$313 Million
Vietnam	$207 Million
New Zealand	$180 Million
Brunei	$6 Million

U.S. Health Product Exports Currently Face High Barriers in New TPP Markets . . .



. . . Which Will be Eliminated Under TPP

Opportunities for Selected Health Products

Pharmaceuticals

The United States exports $4.0 billion in pharmaceutical products to the new TPP markets annually. Yet, those exports currently face barriers in the region, such as tariffs as high as 10% in Vietnam. Under TPP, all tariffs on pharmaceutical products will be eliminated immediately. In addition, TPP's Technical Barriers to Trade (TBT) chapter and annex remove further barriers to U.S. pharmaceutical exports by requiring TPP countries to promote transparent and open practices when regulating pharmaceuticals products.

Medical Devices

The United States exports $5.0 billion in medical devices to the new TPP markets annually. Currently, the United States faces tariffs as high as 30% on certain medical devices in Malaysia. Under TPP, the tariffs on 99.9% of U.S. exports of medical devices will be eliminated immediately, helping to make U.S. products more competitive in the region.

Remanufacturing

TPP contains additional benefits for America's competitive remanufacturers of medical devices. Remanufactured medical devices such as imaging equipment, often cost 50%-75% less than original equipment, yet are manufactured to the same standards. This makes them attractive investments for hospitals and facilities in the TPP region. TPP ensures that U.S. remanufactured medical devices are not unfairly hindered in TPP markets by requiring that remanufactured devices be afforded the exact same treatment as original equipment.

TPP Commitments Will Make it Easier to Sell More Made-in-America Products

Saves Time

- **Customs Procedures:** TPP provides for transparent and predictable customs regulations to facilitate the quick release of goods, and promotes regional supply chains. This includes special features to support small business exporters, including extra facilitations to speed express delivery.
- **Rules of Origin:** TPP provides common rules of origin to ensure that TPP benefits go to the United States and other TPP countries, not China or other non-members.
- **Digital Economy:** TPP is the most ambitious and advanced digital trade agreement the United States has ever concluded. TPP establishes requirements that support a single, global Internet, including ensuring a free flow of data across borders. TPP also provides for non-discriminatory treatment of digital products transmitted electronically, and commits TPP countries not to impose customs duties on digital products.

Reduces Costs

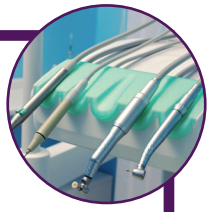
- **Investment**: TPP ensures that U.S. investors have the same kinds of protections in TPP markets that the United States already provides investors here at home, such as due process, non-discrimination, and just compensation in the event of expropriation.
- **Technical Barriers to Trade (TBT):** TPP enhances transparency, reduces unnecessary testing and certification costs, and promotes greater openness as standards are developed. This will enable U.S. exporters to ship more specialized, high-value manufactured goods to the region. TPP includes special TBT annexes on medical devices, pharmaceuticals, and proprietary formulas which provide specific guidelines that regulatory bodies in each partner country should undertake in the development of technical regulations and conformity assessment procedures.

Promotes Fairness

- **Intellectual Property Rights:** TPP establishes strong and balanced protections for patents, trademarks, copyrights, and trade secrets, as well as robust enforcement that will protect innovation and the 40 million American jobs that are directly or indirectly tied to innovation. TPP goes beyond past trade agreements to require partner countries to criminalize the theft, including cyber theft, of trade secrets. It contains copyright provisions that respect the rights of creators and establish clear protection of works, and facilitate the development of new business models for distributing creative content. Enhanced protection and enforcement tools for patents and trademarks will give medical device exporters greater assurances that their innovations and brands are secure in TPP markets. Innovative and generic pharmaceuticals will benefit from clearly defined commitments to protect pharmaceutical patents and clinical trial and test data. TPP rules will ensure that pharmaceutical patent holders have greater opportunities to recoup research and investment costs in new drugs.
- **Government Procurement:** TPP guarantees new market access to government procurement markets in TPP countries and ensures fair, transparent, and non-discriminatory rules for covered procurement.
- **Regulatory Coherence:** TPP establishes new principles for procedures and mechanisms to plan, implement, and review regulations. The partner countries have also agreed to a set of good regulatory practices, including the use of regulatory impact assessments and regulators' assessments of the economic costs and benefits of the regulation.

Want to learn about the tariff for your specific product in the TPP? Visit the FTA Tariff Tool at http://www.export.gov/fta/ftatarifftool/

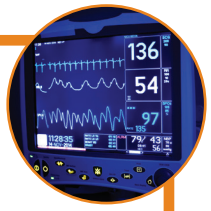
TPP Implementation Offers New Opportunities for U.S. Exporters



Market Opportunity Spotlight

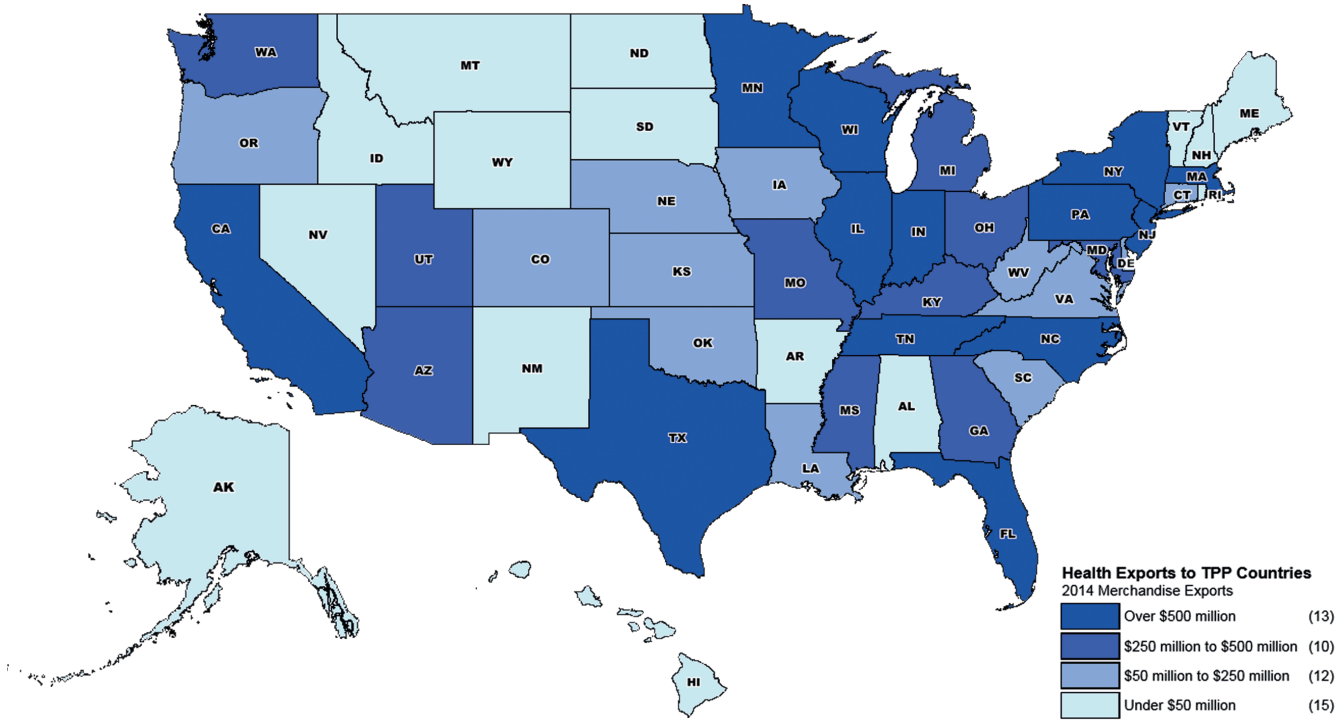
Malaysia –Dental Equipment

One of the major needs in Malaysia is one-stop dental trauma centers, as most of the dental clinics only provide basic dental care. The Malaysian public dental health division has recognized this need and has made it a priority over the next five years. At the same time, many of Malaysia's older dental schools are in the midst of expanding, upgrading, and refurbishing facilities. As a result, there will be increased demand for new equipment, such as dental chairs, X-ray and 3D imaging equipment, dental compressors and generators, dental laboratory equipment, clinical computer systems, and simulators. The United States is a leading supplier of orthodontics products in Malaysia and stands to benefit from this increased demand, especially as tariffs and other market access barriers are eliminated under TPP.



Market Opportunity Spotlight

Brunei and Vietnam – Medical Device Regulatory Coherence

TPP provides a unique opportunity to improve medical device regulation in TPP member countries, potentially leading to greater U.S. exports. For example, neither Brunei nor Vietnam has a medical device regulatory regime currently in place. Vietnam has issued government "circulars" to manage the importation of medical devices, but these "circulars" are not consistent with international best practices for regulating the sector. Under TPP, the two countries committed to using transparent, non-discriminatory rules to develop technical regulations; using internationally developed medical device guidance documents when writing those regulations; and aligning these regulations with those found in other countries. In 2014, the United States exported nearly $76 million in medical devices to Vietnam, and $8 million in medical devices to Brunei; market opportunities in both countries should increase significantly once each country adopts an internationally consistent medical device regulatory regime, allowing both countries to provide more life-enhancing and life-extending medical technologies for their citizens.

Health Products Companies Across the United States Export to the TPP Region