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CHINA AND SWITZERLAND: THE FTA AND MEDICAL DEVICES

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Introduction

This article outlines the implications of the new Free Trade Agreement (FTA) between China and Switzerland in relation to the trade in medical devices. There will be a special focus on the impact on tariffs, the applicable rules of origin, and the reduction of technical barriers to trade.

The FTA was signed on 6 July 2013, and is expected to enter into force in the second half of 2014.[1] The agreement's general aim is to improve mutual market access for goods and services. The agreement is also to enhance legal security for the protection of intellectual property and bilateral economic exchange. It shall further contribute to sustainable development, and deepen bilateral cooperation between the parties. [2]

For goods in particular, such as medical devices, the FTA widely reduces and eliminates tariffs. It includes a set of rules of origin, so as to determine whether or not a product falls under its protection. It specifies provisions for trade facilitation and a set of trade remedies in case of threat of serious damage to either party's domestic market. It also includes regulations on technical barriers to trade (TBT), plus sanitary and phytosanitary (SPS) measures.[3]

Tariff Reductions

General

The FTA specifies that the parties are to eliminate or reduce customs duties imposed on the importation of products originating from either party.[4] This does not include equivalents to internal taxes, anti-dumping or countervailing duties or fees and charges of any kind imposed in connection with the importation commensurate with the cost of services rendered.[5]

Customs duties for most industrial products exported from Switzerland to China are to be gradually adjusted over time (depending on the product in 0-, 5-, 10-, 12- and 15-year periods), whereas industrial products exported from China to Switzerland are instantly freed of customs duties. The explanation for this difference is China's claim to have a specific need for adjustment given the sometimes substantially higher level of tariffs than Switzerland.[6]

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[1] According to information provided by the Swiss State Secretariat for Economic Affairs (SECO) (22.8.2013)

[2] Factsheet FTA CH-China, p. 1

[3] Factsheet FTA CH-China, p. 1

[4] FTA art. 2.3.2.

[5] FTA art. 2.3.1.(a), (b), (c), the terms are consistent with the GATT (General Agreement on Tariffs and Trade) 1994 and the relevant rules therein (paragraph 2 Art. III, Art. VI and Art. VIII) apply to (a), (b), (c), respectively.

[6] Factsheet FTA CH-China, p. 2

The schedules for tariff reductions for particular products are set out in the FTA's Annex I and its Appendixes I (for China) and II (for Switzerland).

China Adjustment Specifics (Appendix I to Annex I)
The periodical reduction rates for tariffs on products entering into China are to be applied to the "most-favoured nation" rate applied on 1 January 2010, included in the charts of the Appendixes as the "base rate".[7] The most-favored nation rate means the lowest customs duties rates granted to any other trade partner by China. Upon entry into force of the FTA, there will be an instant drop of these rates of customs duties for all goods to a new "preferential rate", with the exception of those goods that have no preference. The preferential rate is an exclusive rate granted under the FTA by China to Switzerland. There will be another drop of this preferential rate on 1 January of the following year and from then on annually on this date. [8]

Switzerland Adjustment Specifics (Appendix II to Annex I)
As mentioned above, in contrast to China, there is no gradual adjustment of customs duties on products entering into Switzerland. All customs duties will *instantly*, as categorized in Appendix II, either be classified under:

1. Category A (Completely freed);
2. Categories B1, B3 and C (Be partially dismantled); or
3. Category D (Will have no preference at all); upon entering into the agreement.

In contrast to the customs duties and reductions imposed by China, those specified by Switzerland aren't defined as percentages but as absolute sums in CHF.[9]

Medical Devices
According to the World Health Organisation (WHO), the definition of a medical device is as follows: any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of; diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.[10]

[7] FTA art. 2.4.1.
[8] Appendix I to Annex I of the FTA, A. explanatory notes
[9] Appendix II to Annex I of the FTA, A. explanatory notes

Appendixes I and II to Annex I list a number of categories of products that fit the WHO definition. [11]

China (Appendix I to Annex I)

Appendix I for China includes 28 categories of products that can be qualified as medical devices. The description includes instruments and appliances used in medical, surgical, dental and veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments. Of the listed categories, 12 are immediately freed from customs duties (Category A), nine are gradually freed over five years (Category B) and seven will be freed after the completion of 10 years (Category C1). Most of these are subject to a base rate of four percent under the most-favoured nation rate of 1 January 2010, which will be eliminated for all of these products at the end of the respective transitional period. None are subject to only partial dismantling of the tariff rate.[12]

Switzerland (Appendix II to Annex I)

Appendix II for Switzerland lists 13 categories of products that can be qualified as medical devices. They all fall into Category A, which means customs duties are all eliminated upon entry into force of the FTA.[13]

Rules of Origin

As the FTA only grants preference to products originating in either Switzerland or China,[14] it includes a set of rules of origin.[15]

Originating products must alternatively fulfill one of the following requirements:

1. They must be wholly obtained in a party; or
2. They must be produced in a party exclusively using originating materials of one or both parties; or
3. Where non-originating materials are used in the production process, the non-originating materials must undergo a substantial transformation in a party.[16]

In the last case, a certain relation of the value of non-originating materials used and the value of the ex-works price of the product must be maintained. This relation is called "VNM%".[17]

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[11] They are coded with the ciphers 9018 and following, for the first four digits of the tariff line code number in both Appendixes I and II to Annex I.

[12] Appendix I to Annex I of the FTA, A. explanatory notes and p. 522-524

[13] Appendix I to Annex II of the FTA, A. explanatory notes and p. 384-385. In contrast to China, Appendix II for Switzerland doesn't include an overhead title. It does however follow the same coding starting with the digits 9018 and above

[14] FTA art. 1.2

[15] FTA art. 3.1

[16] FTA art. 3.2 (a), (c)

[17] FTA art. 3.2 (b) icw art. 3.4.3

Annex II lists product-specific rules for products to have preference under the FTA. These are applicable to products of either party. Annex II refers to the International Convention on the Harmonized Commodity Description and Coding System in which medical devices are classified under Chapter 90. The only product-specific rule in Annex II for this chapter is the VNM%.[18] The specified VNM% for medical products is 55 percent. The value of non-originating materials used in the production process of medical devices can not exceed 55 percent of the value of the ex-works price, in order for it to have preference under the FTA.

Trade Facilitation

Chapter 4 of the FTA includes a set of rules on trade facilitation and customs procedures. It commits the parties to implement customs procedures in compliance with international standards and to make the laws and regulations relevant for the movement of goods available to the public. The parties also agree to base customs controls on objective risk analyses and to issue binding information on tariffs and country of origin to economic operators.[19]

Trade Remedies

Chapter 5 of the FTA lists a set of trade remedies that includes anti-dumping measures, subsidies and countervailing measures. For these the FTA refers to the relevant WTO provisions.[20] In addition to the WTO provisions, the FTA sets forth that the parties have to consult each other with a view to finding an acceptable solution before making use of the measures provided in Chapter 5 of the agreement.[21]

The FTA, under certain conditions, also allows for the application of bilateral safeguard measures. Notably, if tariff concessions of the FTA lead to a new level of imports that could cause serious damage to a domestic industry, tariff concessions may be temporarily suspended.[22]

Reductions of Technical Barriers to Trade (TBT)

A big technical barrier to trade with China for medical devices is the costly and long process for products to be approved by the authorities in order for them to be sold.

[18] Annex II of the FTA, p. 1 icw p. 16 and FTA art. 4.9
[19] Factsheet FTA CH-China, p. 3
[20] Factsheet FTA CH-China, p. 3
[21] Factsheet FTA CH-China, p. 3
[22] FTA art. 3.1

New and Incorporated Regulations

Chapter 6 of the FTA addresses technical barriers to trade (TBT). Its objective is to facilitate bilateral trade and access to respective markets for goods falling under the scope of the chapter.[23] Furthermore, the parties shall strengthen their technical cooperation in various areas, in view of increasing the mutual understanding of their respective systems.[24]

The FTA incorporates the existing WTO Agreement on Technical Barriers to Trade (WTO TBT Agreement), mutatis mutandis,[25] and includes rules that go further than the TBT Agreement, e.g. it specifically names standards issued by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunication Union (ITU) and the Codex Alimentarius Commission that are to be considered relevant for goods traded under the FTA.[26]

Along with the FTA there are several side agreements concerning TBT, such as the Agreement on Cooperation in the Area of TBT and SPS, and the Agreement on Cooperation in the Area of Certification and Accreditation.[27]

Keypoints

The WTO TBT Agreement expresses that the parties are to ensure that conformity assessment results of other members are recognized, provided there is confidence that the procedures are equivalent, even if different.[28] In coherence the FTA stipulates that the parties are to promote the accreditation of conformity assessment bodies on the basis of relevant standards and guides of the ISO and IEC, and to encourage the mutual acceptance of conformity assessment results of such accredited bodies.[29]

The side agreements on certification and accreditation and TBT and SPS further mean the parties are to cooperate on compulsory and voluntary certification schemes and accreditation,[30] to promote communication and cooperation between the respective competent authorities and certification and accreditation bodies of the two parties[31] and for these bodies to carry out cooperation activities under the side agreements.[32]

[23] FTA art. 6.1.(a)
[24] FTA art. 6.5
[25] FTA art. 6.2
[26] FTA art. 6.4 icw TBT Agreement art. 2.4
[27] SPS meaning Sanitary and phytosanitary measures in the sense of FTA chapter 7
[28] TBT Agreement art. 6.1
[29] FTA art. 6.5.(d) and (e)
[30] Agreement on Cooperation in the Area of Certification and Accreditation (CaA Side agreement) art. 1 and Annex III to Agreement on Cooperation in the Area of TBT and SPS (TBT SPS Side agreement) art. 1
[31] CaA Side agreement art. 2 and Annex III to TBT SPS Side agreement art. 2
[32] CaA Side agreement art. 3 and Annex III to TBT SPS Side agreement art. 3

In order for these cooperation schemes to reach their determined affect, the FTA also establishes a Sub-Committee on Technical Barriers to Trade under the Joint Committee that specifically monitors the implementations of the rules concerning TBT.[33]

According to the SECO, the extent of the practical implications of this new set of rules and its facilitations for certification and accreditation of products can't yet be determined. An improvement of the current situation, however, is anticipated.[34]

Summary

Concludingly the FTA will bring notable trade advantages for both parties. Tariffs will be widely eliminated or reduced on both sides, especially for medical devices. Tariffs on products being imported into Switzerland are instantly upon entry into force of the FTA eliminated, and tariffs on products being imported into China are also eliminated, albeit over a five- to 10-year transition period.

The rules of origin of the FTA specify where non-originating materials are used in the production process, these must undergo a substantial transformation. For medical devices, their value in relation to the ex works price of the product must be no more than 55 percent (VNM%).

As for the reduction of non-tariff barriers, the certification and accreditation process for medical products is expected to improve by the establishment of a set of rules to further the cooperation and communication between the parties. Such rules shall, amongst others, include the promotion of accreditation of conformity assessment bodies and the recognition of their results, the adoption of four international standards and the introduction of a sub committee on TBT.

[33] FTA art. 6.7 and Agreement on Cooperation in the Area of Certification and Accreditation art. 5
[44] According to Information provided by SECO (22.8.2013)

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