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China and Switzerland: the FTA and Medical Devices

The medical devices industry is an innovative and fast-growing market, and equally so in China. This article outlines the implications of the recent Free Trade Agreement (FTA) between China and Switzerland (the parties) in relation to the trade in medical devices. There is a special focus on the impact of tariff reductions, applicable rules of origin, and the removal of technical barriers to trade.

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Contents

Introduction

[Rz 1] The medical devices industry is an innovative and fast-growing market, and equally so in China. This article outlines the implications of the recent Free Trade Agreement (FTA) between China and Switzerland (the parties) in relation to the trade in medical devices. There is a special focus on the impact of tariff reductions, applicable rules of origin, and the removal of technical barriers to trade.

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

Tariff Reductions

I. Overview

1. General

[Rz 3] For goods in particular, such as medical devices, the FTA widely reduces and eliminates current tariffs. The FTA specifies that the parties are to eliminate or reduce customs duties imposed on the importation of products originating from either party.[2] This does not include equivalents to internal taxes, anti-dumping or countervailing duties or fees and charges of any kind imposed

1 Factsheet FTA CH-China, p. 1.

2 FTA art. 2.3.2.

in connection with the importation commensurate with the cost of services rendered.[3]

[Rz 4] 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 the country imposes (for example in the watch, machine and chemical/pharmaceutical industries).[4]

[Rz 5] The schedules for tariff reductions for particular products are set out in Annex I and its Appendixes I (for China) and II (for Switzerland) of the FTA.

2. China Adjustment Specifics (Appendix I to Annex I)

[Rz 6] The periodical reduction rates for tariffs on products entering into China are to be applied to the «most-favored nation» rate applied on 1 January 2010, included in the charts of the Appendixes as the «base rate».[5] 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.[6]

3. Switzerland Adjustment Specifics (Appendix II to Annex I)

[Rz 7] 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 (no preference under the FTA); upon entering into the agreement.

[Rz 8] In contrast to the customs duties and reductions imposed by China, those specified by Switzerland are not specified as percentages but rather as absolute sums in Swiss Francs (CHF).[7]

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3 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 of art. III, art. VI and art. VIII) apply to (a), (b), (c), respectively.

4 On average 8.7% in China compared to 2.4% in Switzerland. Botschaft zur Genehmigung des Freihandelsabkommens zwischen der Schweiz und China sowie des Abkommens zwischen der Schweiz und China über die Zusammenarbeit in Arbeits- und Beschäftigungsfragenvom 4. September 2013 (Botschaft, only available in German and French), p. 8183; Factsheet FTA CH-China, p. 2 and 3.

5 FTA art. 2.4.1.

6 Appendix I to Annex I of the FTA, A. explanatory notes.

7 Appendix II to Annex I of the FTA, A. explanatory notes.

II. Medical Devices

1. General Definition

[Rz 9] The FTA as well as the appendices do not contain a definition of medical devices. For a definition we therefore have to rely on other sources. The World Health Organization's (WHO) official definition of a medical device is as follows: any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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 medical purpose(s) 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 by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.[8]

2. Tariffs Regarding Medical Devices

[Rz 10] To find out which products can be defined as medical devices under the FTA, one has to consult the schedules of concessions in Appendixes 1-2 to Annex 1. Those schedules are primarily based on the Harmonized Commodity Description and Coding System as of 2007.[9] The Harmonized System (HS) is an internationally recognized nomenclature for the classification of products and allows participating countries to classify traded goods on a common basis for customs purposes. At the international level, the HS employs a six-digit code system.[10] Medical devices are generally listed under tariff numbers with the first four digits beginning with 9018 through 9022, but there are also further tariff numbers referring to medical devices.[11] Each specific product must therefore first be checked for their corresponding number and the relative tariffs.[12]

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8 http://www.who.int/medical_devices/full_deffinition/en/http://www.who.int/medical_devices/full_deffinition/en/; also see WHO Medical Device Regulations, Global overview and guiding principles 2003.

9 http:/www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs_convention.aspx.

10 http://unstats.un.org/unsd/tradekb/Knowledgebase/Harmonized-Commodity-Description-and-Coding-Systems-HS.

11 For example medical, surgical, dental or veterinary furniture under tariff number 9402 or machinery, plant or laboratory equipment, whether or not electrically heated under tariff number 8419, further also 3005, 3006, 3407, 3808, 3821, 3822, 4014, 4015, 5208, 6210, 6307, 7015, 7017, 7324, 7418, 7615, 8423, 8539, 8705, 8713, 9001, 9004, 9011, 9012, 9025, 9027, 9619 etc. For specific information regarding the tariff numbers consult www.tares.ch for Switzerland.

12 The Oberzolldirektion, Zentrale OZD Tarif of Switzerland will not give out an advance ruling with regard to the tariff schedules of the FTA until the FTA is in force (according to information provided on 23 April 2014). To get an overview of the applicable tariff numbers, the China Medical Devices Review, January 2014, contains a list of China's imports and exports of medical devices 2013, showing each commodity with the relevant HS code.

[Rz 11] For the purpose of this article and for simplicity in showing the definitions that apply in China and Switzerland, our considerations below will focus on tariff numbers 9018 through 9022 only.

3. Definition Applying in China (Appendix I to Annex I)

[Rz 12] Within tariff numbers 9018 through 9022, at least 50 categories of products 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, some are immediately free from customs duties (Category A), others are gradually released over a period of five years (Category B) or will be released after a period of 10 years (Category C1) and at least one (tariff number 90211000, «orthopaedic or fracture appliances») will be reduced by 60 percent within 10 years (Category C2, non-linear).

4. Switzerland (Appendix II to Annex I)

[Rz 13] Appendix II for Switzerland lists at least 19 categories of products in tariff numbers 9018 through 9022 that can be qualified as medical devices. The description also includes instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus, and sight-testing instruments. They all fall into Category A, which means customs duties are all eliminated upon entry into force of the FTA.[13]

III. Rules of Origin

[Rz 14] As the FTA only grants preference to products originating in either Switzerland or China,[14] it includes an FTA-specific set of rules of origin that the medical devices must fulfill.[15]

[Rz 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]

[Rz 16] With regard to the last requirement, Annex II lists product-specific rules for products of either party with regard to the grade of substantial transformation in order to have preference under the FTA. 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] The

[13] Appendix II to Annex I of the FTA, A. explanatory notes and p. 384-386. In contrast to China, Appendix II for Switzerland does include overhead titles. It also follows 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.

[17] FTA art. 3.2 (b) icw art. 3.4.3; VNM% = VNM/ex-works price x 100.

specified VNM% for medical products is 55 percent, i.e. the maximum value of non-originating materials used in the production process of medical devices cannot exceed 55 percent of the value of the ex-works price[18], in order for it to enjoy preferential treatment under the FTA.

IV. Further Issues

[Rz 17] When dealing with medical devices under the FTA, additional mechanisms and the respective regulations shall help facilitate trade between the parties.

1. Trade Facilitation

[Rz 18] 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 (note that the latter is already an existing WTO requirement). 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, i.e. companies.[19]

2. Trade Remedies

[Rz 19] Chapter 5 of the FTA lists a set of trade remedies that includes anti-dumping measures, subsidies and countervailing duties. 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 dispute resolution measures provided in Chapter 5 of the agreement.[21]

[Rz 20] 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, or threaten to cause, serious damage to a domestic industry, tariff concessions may be temporarily suspended.[22]

3. Removal of Technical Barriers to Trade (TBT)

a. New and Incorporated Regulations

[Rz 21] A substantial technical barrier to trade with China for medical devices (besides tariffs) has historically been what is perceived as a costly and lengthy approval process. Chapter 6 of the FTA addresses such technical barriers to trade (TBT). Its objective is to facilitate bilateral trade

[18] «Ex-works price» meaning the price paid for the product ex-works to the producer located in a party in whose undertaking the last working or processing is carried out, provided that the price includes the value of all the materials used, wage and any other cost, and profit minus any internal taxes returned or repaid when the product obtained is exported; FTA art. 3.1 (g).

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

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

[21] FTA art. 5.3.2.

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

and access to respective markets for goods falling under the scope of the chapter.[23] In addition and related to this, the parties agree to strengthen their technical cooperation in various areas, in view of increasing the mutual understanding of their respective systems.[24]

[Rz 22] The FTA incorporates the existing WTO Agreement on Technical Barriers to Trade (WTO TBT Agreement[25]), mutatis mutandis,[26] 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 Codex Alimentarius Commission (CAC), that are to be considered relevant for goods traded under the FTA.[27]

[Rz 23] Along with the FTA there are several side agreements concerning TBT, such as the Agreement on Cooperation in the Area of TBT and Sanitary and Phytosanitary Measures (SPS), and the Agreement on Cooperation in the Area of Certification and Accreditation.[28]

b. Keypoints

[Rz 24] 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.[29] 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.[30]

[Rz 25] The side agreements on certification and accreditation and TBT and SPS further mean the parties are to:

1. Cooperate on compulsory and voluntary certification schemes and accreditation;[31]
2. Promote communication and cooperation between the respective competent authorities and certification and accreditation bodies of the two parties;[32] and
3. Carry out cooperation activities under these agreements.[33]

[Rz 26] 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.[34]

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23 FTA art. 6.1 (a).

24 FTA art. 6.5.

25 http://www.wto.org/english/res_e/booksp_e/analytic_index_e/tbt_01_e.htm.

26 FTA art. 6.2.

27 FTA art. 6.4 icw TBT Agreement art. 2.4.

28 SPS meaning Sanitary and phytosanitary measures in the sense of FTA chapter 7; Botschaft, p. 8191; agreements: http://www.seco.admin.ch/themen/00513/00515/01330/05115/index.html?lang=de.

29 TBT Agreement art. 6.1.

30 FTA art. 6.5 (d) and (e).

31 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.

32 CaA Side agreement art. 2 and Annex III to TBT SPS Side agreement art. 2.

33 CaA Side agreement art. 3 and Annex III to TBT SPS Side agreement art. 3.

34 FTA art. 6.7 and CaA Side agreement art. 5.

[Rz 27] At this stage, and with the FTA not yet in force, it is difficult to foresee what changes the agreement will bring. 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 cannot yet be determined. An improvement of the current situation, however, is anticipated.[35]

Expected Effects of the FTA on the Trading of Medical Devices

[Rz 28] In general, the FTA is expected to bring notable trade advantages for both parties. Although both will suffer a loss of revenues from custom duties, the positive effects of the agreement lie in the improved access for goods and services as part of the export activities of both countries.[36] In 2013, medical and technical equipment imports from Switzerland to China amounted to USD 1.2 billion, and exports from China to Switzerland reached USD 163.5 million.[37] According to the Joint Feasibility Study on a China-Switzerland Free Trade Agreement, the bilateral trade volume will increase by 49.18 percent, China's exports to Switzerland will increase by 28 percent (about USD 1.15 billion) and imports from Switzerland to China will increase by 63 percent (about USD 4.06 billion).[38] The tariff savings for exports from Switzerland to China are, following expiration of the transitional periods, estimated at over CHF 200 million per year.[39]

[Rz 29] With regard to the situation in China, Liu Mingli, an associate researcher on European economic issues at the China Institute of Contemporary International Relations, Institute of Europe[40], stated in a «Sounds of Economy» radio interview last year[41] that «in general, Swiss products are very popular and competitive in China...with considerable demand on medical equipment like nuclear magnetic resonance or electromagnetic pulse equipment...but currently the prices tend to be high...with the new FTA and the thus resulting substantial tariff reductions in force, it is expected that the prices will be reduced and the demand for medical devices and the import trading thereof thus increased.» Liu further mentioned that the FTA will become a crucial part of China's strategy of building a sound and healthy «free trade network» for China and that China expects benefits through the easier access to Swiss markets. He added that although Switzerland is not big, it is one of the world's most developed countries, has a stable economy, plays a key role in Europe, and has huge potential for Chinese enterprises and products.

[Rz 30] Apart from a wide reduction to the outright elimination of tariffs, the practical implications of the FTA have yet to be proven. 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 cooperation and communication between the parties. Such rules shall, amongst others, include the promotion of accreditation of conformity assessment bodies and the

35 According to Information provided by SECO on 22 August 2013.

36 See with regard to Switzerland, Botschaft, p. 8209 and 8210.

37 http://www.worldsrichestcountries.com/; http://www.tagesanzeiger.ch/wirtschaft/konjunktur/Die-Schweiz-als-chinesischer-Brueckenkopf/story/17414300.

38 Joint Feasibility Study on a China-Switzerland Free Trade Agreement, Beijing, 9th August 2010, p. 84.

39 This amount saved in tariffs depends on the future usage of the rules of origin and the scope of the imported preferential goods; Botschaft, p. 8210.

40 http://www.cicir.ac.cn/english/.

41 The interview was later summarized by Chinese Radio Network, http://finance.cnr.cn/jjpl/201305/t20130524_512665639.shtml.

recognition of their results, the adoption of international standards, and the introduction of a sub committee on TBT.

[Rz 31] However, Swiss medical device manufacturers and exporters must keep in mind that the Chinese healthcare system will not significantly change because of the FTA. There have been three major issues of concern to medtech companies in the Chinese market: product registration, market access and tender bidding processes.

[Rz 32] Regarding the registration process, the China Food and Drug Administration (CFDA)[42] has been preoccupied with past compliance scandals and what is by market actors perceived to be an untransparent and inconsistent evaluation process of medical device products. These evaluations often depend on the individual government official handling the specific request.[43] While the U.S. and Europe have a consistent and transparent regulatory process managed by highly competent bodies, substantial work remains to be done in China in that area.

[Rz 33] A large majority of medical device companies from outside China are using intermediaries to access the domestic healthcare market. One of the prevailing reasons is that doctors and hospital equipment departments often tie the purchase of products to advantages and other considerations provided to them by the seller, i.e. the next intermediary. Foreign companies are thus encouraged to use intermediaries.

[Rz 34] A commonly heard argument is that it is normal to engage intermediaries because China is such a large country. However, most foreign companies would rather prefer to go directly into the healthcare market in large cities such as Beijing, Shanghai and Guangzhou; intermediaries are preferred to be used only in the western provinces. The reason is that in larger cities with more robust purchasing power, the companies may exploit the full margin by directly moving in the market as sellers. In the less attractive western cities with diminished economic clout, intermediaries can be engaged. As soon as a territory becomes economically stronger, a direct sales force can be employed as is the case in the development of most developed markets. The high margins charged by intermediaries, particularly for high-value implantables (dental, orthopedic products, stents, etc.) are often surprisingly high in the eyes of European or U.S. executives (up to over half of the hospital price). Therefore, the profits which can be realized by foreign companies using intermediaries are on the lower side compared to other markets with direct access.

[Rz 35] There are a few examples of foreign companies attempting to enter the healthcare market without intermediaries, but this has more often than not resulted in a discontinuation of this business model after realizing that there were not sufficient opportunities to maintain viability. It is important to mention that the bulk of business in China is in the public sector while private hospitals play a minor role, at least for the time being.

[Rz 36] Finally, another hurdle is the tender bidding process. Tender bidding processes are common in healthcare markets. In China, however, this process seems to be less transparent with a similar situation to the one described above regarding product registration.

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42 http://eng.sfda.gov.cn/WS03/CL0755/.

43 While the rules regarding the length of product registration are quite strict (with registration periods of 30, 60 or 90 days according to the «Measures for Administration of Medical Devices Registration», http://www.sda.gov.cn/WS01/CL0053/25844.html), practical experience shows that those periods are seldom met, with some registrations taking up to two-and-a-half years.

Summary

[Rz 37] In conclusion, the FTA will bring notable trade advantages for both parties. Tariffs will be widely eliminated or at least reduced on both sides, especially for medical devices. With regard to tariff numbers 9018 to 9022, which we focused on for the purpose of this article, tariffs on products being imported into Switzerland will be instantly eliminated upon entry into force of the FTA, and tariffs on products being imported into China will also be eliminated or reduced, albeit over a five- to ten-year transition period. This is arguably a somewhat long time horizon, which might not have an immediate commercial impact in many cases.

[Rz 38] The rules of origin of the FTA specify that 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%).

[Rz 39] Concerning the reduction of non-tariff barriers, it has yet come into effect to what extent the new FTA will have regarding practical implications. Within the territory of China, several issues such as product registration, market access and tender bidding still need to be improved in order for both parties to fully profit from the new FTA.

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