Council of the European Union

Brussels, 15 January 2025
(OR. en)

5377/25
ADD 1

POLCOM 1
COMER 3
MAP 1
MI 26

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	14 January 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2025) 2 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Factual findings of the IPI investigation on the procurement market for medical devices in the People's Republic of China *Accompanying the document* REPORT FROM THE COMMISSION pursuant to Article 5(4) of Regulation (EU) 2022/1031 on the investigation under the International Procurement Instrument concerning measures and practices of the People's Republic of China in the public procurement market for medical devices

Delegations will find attached document SWD(2025) 2 final .

Encl.: SWD(2025) 2 final

EUROPEAN
COMMISSION

Brussels, 14.1.2025
SWD(2025) 2 final

COMMISSION STAFF WORKING DOCUMENT

Factual findings of the IPI investigation on the procurement market for medical devices in the People's Republic of China

Accompanying the document

REPORT FROM THE COMMISSION

pursuant to Article 5(4) of Regulation (EU) 2022/1031 on the investigation under the International Procurement Instrument concerning measures and practices of the People's Republic of China in the public procurement market for medical devices

{COM(2025) 5 final}

1. Alleged measures and practices in the Notice of Initiation

(1) In the Notice of Initiation[1], the Commission identified the following alleged measures and practices implemented by the PRC at both central and local level, and applying to all public entities procuring medical devices, including State-owned enterprises such as public hospitals:

1.1. Measures and practices favouring the procurement of domestic medical devices and services, by means of, inter alia:

- Article 10 of the Government Procurement Law of the PRC ('GPL')[2], which implements the 'Buy China' policy and provides that *"government entities shall procure domestic goods, services and works, except: (a) when the goods, services and works are not available within the territory of the People's Republic of China or are not available under reasonable commercial terms; (b) when the goods, services and works procured are intended for use outside China; and (c) when otherwise specified by other laws and regulations"*. 'Buy local' initiatives implemented by local authorities also favour locally manufactured goods;
- the requirement in the *'Made in China 2025'* Strategy[3] ('MIC 2025') that that hospitals' procurement of domestically produced mid and high-end medical devices should reach 50 % by 2020 and 70 % by 2025;
- the requirement in the '*Notice on Examination and Guidance Criteria for Government Procurement of Imported Products'* No 551 ('Document 551') of 2021[4] that local authorities increase the domestic procurement rate of 315 products, out of which 178 are medical devices (for 137 of them imposing a requirement to procure 100 % domestic products);
- the requirement in the '*Notice on Deepening the Reform of the Medical and Health System'*[5] Guo Ban Fa [2015] No. 34 that public hospitals have to give priority to domestic medical devices and its encouragement to purchase domestic high-value medical devices under a centralised procurement.

1.2. Measures and practices restricting the procurement of imported medical devices

---

1 Notice of initiation of an investigation pursuant to the International Procurement Instrument concerning measures and practices of the People's Republic of China in the public procurement market for medical devices, (C/2024/2973), 24.4.2024

2 The Government Procurement Law of the People's Republic of China, Order of the President of the People's Republic of China No.68 of 29 June 2002

3 *'Notice of the State Council on Issuing the "Made in China (2025)"'* No.28 [2005] of the State Council, available at: https://www.gov.cn/zhengce/content/2015-05/19/content_9784.htm (accessed on 23 September 2024)

4 *'Notice on Issuing "Guiding Audit Standards for Government Procurement of Imported Products"'* (2021 Edition), Document Issued by Department of Treasury, Ministry of Finance and No. 2 Department of Equipment Industry, Ministry of Industry and Information Technology, Treasury Note [2021] No. 551, available at: https://aimg8.dlssyht.cn/u/2074671/ueditor/file/1038/2074671/1629090344664695.pdf / https://www.cgwenjian.com/view/industry/20211011000184101?zt_id_from=54 (accessed on 23 September 2024)

5 '*Notice of the General Office of the State Council on Printing and Distributing the Summary of the Work in 2014 and the Key Work Tasks in 2015 on Deepening the Reform of the Medical and Health System'* Guo Ban Fa [2015] No. 34

– the *'Administrative Measures for the Procurement of Imported Goods'* (the 'Administrative Measures')[6], which lay down more stringent rules for the procurement of imported products compared to the procurement of domestic ones such as (i) a rigorous application-evaluation-approval procedure for the procurement of imported products, with an objective to verify whether available domestic products exist and should be procured instead of the imported ones; (ii) a mandatory clause on safeguarding national interests and social public interests to be included specifically in the contracts concerning procurement of imported goods with possibility of termination of the contract on this ground and (iii) explicit provisions on using offsets in government procurement of imported products, such as granting priority to the procurement of imported products from suppliers who have transferred technology to Chinese enterprises.

1.3. Imposing conditions in its centralised procurement of medical devices leading to abnormally low bids that cannot be sustained by profit-oriented companies

2. Findings of the investigation

(2) During the investigation, the Commission gathered further information with respect to the alleged measures and practices and their implementation and identified additional ones.

(3) In the sense of Article 2(1)(i) of the IPI Regulation, a measure or practice means any legislative, regulatory or administrative measure, procedure or practice, or combination thereof, adopted or maintained by public authorities or individual contracting authorities or contracting entities at any level.

(4) The investigation confirmed the existence and application of the measures mentioned in the Notice of Initiation and the Commission identified additional ones. The investigation showed that the measures and practices favouring the procurement of domestic medical devices and those restricting the procurement of imported medical devices, referred to in the Notice of Initiation, are two interlinked elements of a 'Buy China' policy implemented by the GOC, which sets a generally applicable preference for the procurement of domestic medical devices to the detriment of imported ones. Therefore, the Commission decided to examine these two types of measures and practices jointly, and the centralised volume-based procurement separately.

2.1. The 'Buy China' policy

2.1.1. Policy measures encouraging the domestic medical devices industry

[6] *'Circular of the Ministry of Finance on Issuing the Measures for the Administration of Government Procurement of Imported Products'* Caiku [2007] No. 119, available at: https://www.gov.cn/zwgk/2008-01/15/content_858659.htm (accessed on 23 September 2024)

(5) The Commission found that in the PRC the manufacturing of medical devices, particularly the high-end segment, is a strategic sector, which is encouraged and supported through various policy tools, notably public procurement., The implementation of this policy through public procurement is aimed to directly favour domestic medical devices to the detriment of imported ones.

(6) High-performance medical devices are one of the ten core industries identified in the MIC 2025[7], a national strategic and industrial plan aimed to shift Chinese industry to higher value-added manufacturing and make China a global manufacturing powerhouse for ten industries. The *'Made in China 2025 technology roadmap for key areas'*[8] (the 'MIC Roadmap'), which specifies goals for each industry identified in the MIC 2025, sets specific targets for the share of domestically produced high-end medical devices procured by county hospitals, which should reach 50 % by 2020, 70 % by 2025, and 95 % by 2030.

(7) Since 2010, the PRC has put in place a sector-specific five-year plan for medical devices. The latest, the *'14th Five-Year Plan for the Medical Equipment Industry Development'*[9] ('14th FYP'), encourages the development of high-end medical devices through various support tools, including public procurement[10], with an objective to replace imported products by domestic supply[11].

(8) The *'National Medium- and Long-Term Science and Technology Development Plan (2006-2020)'* [12] lists advanced medical equipment and biomedical materials among the *"focus areas and their priority themes"* for development[13] and identifies various policy tools for such development, through the implementation of *'fiscal and taxation policies*

---

7 (VI) 10. *"(...) Improve the innovation ability and industrialization level of medical apparatus and give priority to developing high-performance diagnostic equipment including image documentation equipment and medical robot, high-value medical consumables including fully degradable intravascular stent, and wearable and remote diagnostic mobile medical products. Realize breakthrough and application of biological 3D printing technology, induced pluripotent stem cell technology and other new technologies."*

8 https://www.gov.cn/xinwen/2015-09/29/content_2940676.htm (accessed on 23 September 2023), https://www.cae.cn/cae/html/files/2015-10/29/20151029105822561730637.pdf (accessed on 23 September 2023) and http://www.qbj.gov.cn/qbjq/uploadfiles/ecyq/20190328102628112 69.pdf (accessed on 23 September 2024)

9 Notice on printing and distributing the "14th Five-Year Plan" for the development of the medical equipment industry Ministry of Industry and Information Technology Liangui [2021] No. 208, available at: https://www.gov.cn/zhengce/zhengceku/2021-12/28/content_5664991.htm (accessed on 23 September 2024)

10 The 14th FYP instructs to "*further strengthen the government procurement management and support the medical equipment industry development"*.

11 In particular, the 14th FYP provides that *"local governments, industrial funds and social resources will be guided to support the breakthroughs of medical-industry collaboration in developing medical equipment, key parts and basic materials, and financial investment in the transformation and industrialization of breakthroughs"*.

12 Outline of the National Medium- and Long-Term Science and Technology Development Plan (2006-2020) State Council No. 9 of 2006, available at: https://www.gov.cn/gongbao/content/2006/content_240244.htm (accessed on 24 September 2024)

13 In Point III.8 (51)

to encourage enterprise technological innovation'[14]; the strengthening of the *'digestion, absorption and re-innovation of imported technologies'*[15], and the implementation of *'government procurement that promotes indigenous innovation'*[16]; therefore, government procurement is used as a tool to promote domestic products and brands developed in the PRC.

(9) The *'Notice of the State Council on the Issuance and Implementation of Several Supporting Policies of the 'Outline of the National Medium- and Long-Term Science and Technology Development Plan (2006-2020)'*, Guo Fa [2006] No. 6[17] refers in point (25) to "*an examination system for the purchase of foreign products"* under which *"the purchaser shall give priority to the purchase of domestic products in accordance with the provisions of the* [GPL]*"* and *"when purchasing foreign products, adhere to the principle of facilitating indigenous innovation of enterprises or digestion and absorption of core technologies, and give priority to the purchase of products that transfer technology"*. Point (30) of this Notice states that *"the advanced equipment and products formed by digestion, absorption and re-innovation shall be included in the scope of government procurement"*.

(10) The *'Notice on Deepening the Reform of the Medical and Health System'* Guo Ban Fa [2015] No. 34[18] provides, under the heading *'key tasks for deepening the reform of the medical and health system in 2015'* that public hospitals *"give priority to the use of domestic medical equipment and instruments"* and *"encourage the purchase of domestic high-value medical consumables"*.

(11) The *'Guiding Opinions of the General Office of the State Council on Promoting the Healthy Development of the Medical and Pharmaceutical Industry'* Guo Ban Fa [2016] No. 11[19] calls for strengthening the fiscal and financial support to the medical devices domestic sector through *"financial support methods (...) incentives and guidance, capital injection, application demonstration subsidies, etc."*, and for "*improving government procurement mechanisms"* by *"strictly implementing the provisions of the [GPL]*". In this respect, the guiding opinions stipulate that *"if domestic drugs and*

---

[14] i.e. *"implement the State's preferential tax policies on promoting technological innovation, accelerating the transformation of scientific and technological achievements and equipment upgrading, actively encourage and support enterprises to develop new products, new processes and technologies"*.

[15] e.g. *"improve and adjust the national industrial technology policy, and strengthen the digestion, absorption and re-innovation of imported technologies. Through adjusting the structure and focus of government investment, special funds will be set up to support the digestion, absorption and re-innovation of imported technologies, and support the research and development of major technical equipment and key common technologies of major industries"*.

[16] *"Establish a coordination mechanism for government procurement of indigenous innovative products. For important high-tech equipment and products with indigenous intellectual property rights developed by domestic enterprises, the government implements the first-purchase policy. Provide policy support for enterprises to purchase domestic high-tech equipment. Support the formation of technical standards through government procurement"*.

[17] Circular of the State Council on Printing and Distributing Several Supporting Policies for the Implementation of the Outline of the National Medium- and Long-Term Science and Technology Development Plan (2006-2020), Guo Fa [2006] No. 6, available at: https://www.gov.cn/gongbao/content/2006/content_240246.htm (accessed on 23 September 2024)

[18] *'Notice of the General Office of the State Council on Printing and Distributing the Summary of the Work in 2014 and the Key Work Tasks in 2015 on Deepening the Reform of the Medical and Health System'* Guo Ban Fa [2015] No. 34, available at: https://www.gov.cn/zhengce/content/2015-05/09/content_9716.htm (accessed on 23 September 2024)

[19] https://www.gov.cn/zhengce/content/2016-03/11/content_5052267.htm (accessed on 23 September 2024)

medical devices can meet the requirements, government procurement projects must purchase domestic products in principle, and gradually improve the level of domestic equipment allocation in public medical institutions".

(12) The *'Guiding Opinions on Expanding Investment in Strategic Emerging Industries and Cultivating Strengthened New Growth Points and Growth Poles'* NDRC High Technology (2020) Document No. 1409[20] lists high-end medical equipment and medical robots in the key industrial investment areas under *"high-end equipment manufacturing industry"* and thus entitle such equipment and robots to benefit from fiscal and financial support. The document encourages local governments *"to set up special funding plans for strategic emerging industries"* and urges *"financial institutions to innovate and develop financial products and services adapted to the characteristics of strategic emerging industries"* and *"increase support for core enterprises in the production chain".*

(13) The Commission also found that the China Medical Equipment Association (the 'Association') produces regularly a *'Selection Catalogue of Excellent Domestic Medical Equipment Products'* (the 'Catalogue')[21] under the direction of the National Health Commission of the PRC[22] (the 'NHC'), which is the main regulator of the healthcare system in China. The selection process is intended to identify advanced, competitive, and high-quality domestic medical equipment for inclusion in the Catalogue. The scope of selection is *"*[d]*omestic independent brand products"*[23]. The Catalogue is intended as a reference for healthcare institutions across China in deciding which medical equipment to use.

(14) The Commission also found references to the Catalogue in several policy documents[24] released by the NHC and the Ministry of Science and Technology of the PRC ('MST')

---

[20] https://www.ndrc.gov.cn/xxgk/zcfb/tz/202009/t20200925_1239582.html (accessed on 23 September 2024)

[21] See Chinese Medical Equipment Association, *Announcement on the Selection of Excellent Domestic Medical Equipment Products*, 2014, http://www.nhc.gov.cn/ewebeditor/uploadfile/2014/05/20140526114014171.pdf. To date, there have been ten batches of products selected for inclusion in the Catalogue:
Third batch available at: https://mt.sohu.com/20170318/n483796226.shtml;
Sixth batch available at: https://www.cn-healthcare.com/articlewm/20200524/content-1115974.html;
Seventh batch available at: https://www.cn-healthcare.com/articlewm/20210621/content-1234071.html;
Eighth batch available at: https://www.cn-healthcare.com/articlewm/20221010/content-1447444.html;
Tenth batch, available at: https://finance.sina.com.cn/roll/2024-09-21/doc-incpxsme9898809.shtml (all accessed on 4 November 2024)

[22] In 2014, China's former National Health and Family Planning Commission (the predecessor of the NHC) charged the Association with the selection of "excellent domestic medical equipment products". See in this respect the *Announcement on the Selection of Excellent Domestic Medical Equipment Products*, 2014, http://www.nhc.gov.cn/ewebeditor/uploadfile/2014/05/20140526114014171.pdf.

[23] See Chinese Medical Equipment Association, Announcement on the Selection of Excellent Domestic Medical Equipment Products, 2014:
http://www.nhc.gov.cn/ewebeditor/uploadfile/2014/05/20140526114014171.pdf.

[24] Response to Proposal No. 3987 of the Third Session of the 12th National People's Congress, Response to Proposal No. 4808 at the Third Session of the 12th National People's Congress, Response to Proposal No. 7401 of the Third Session of the 12th National People's Congress and Response to Proposal No. 1047 (Category of Science and Technology No. 051) of the Third Session of the 12th National Committee of the Chinese People's Political Consultative Conference; Response to Proposal No. 0624 (Commercial and

that present the Catalogue as a tool for promoting the use and procurement of domestic medical devices by medical and healthcare institutions in accordance with the GPL as a key to promote the objective of strengthening China's medical device industry.

(15) The Association is a national, non-profit social organization registered with the Ministry of Civil Affairs for the medical equipment industry.[25] However, it is subject to the control, or at least strong influence, of the State and can therefore be considered as a quasi-governmental organization. The *Measures for Comprehensive Supervision of Industry Associations and Chambers of Commerce* provide for oversight by the Chinese Communist Party of the PRC over all industry associations.[26] This is also reflected in the Association's Constitution, which provides that it *"shall adhere to the overall leadership of the Communist Party of China, and establish the organization of the Communist Party of China in accordance with the provisions of the Constitution of the Communist Party of China"*. In practice, a Party-linked organization embedded within the Association[27] is involved in all major decisions, which, *e.g.*, include the appointment and removal of the executive director and oversight over changes to the Association's Constitution. Therefore, the Catalogue released by the Association can be considered as a policy tool to steer public procurement of medical devices toward Chinese producers.

2.1.2. Legal measures related to the 'Buy China' policy regarding public procurement of medical devices

(16) The government procurement of medical devices in the PRC is governed by the GPL and its implementing measures.

(17) Article 10 of GPL provides that: *"*[t]*he government shall procure domestic goods, construction and services, except in one of the following situations: (1) where the goods, construction or services needed are not available within the territory of the* [PRC] *or, though available, cannot be acquired on reasonable commercial terms; (2) where the items to be procured are for use abroad; and (3) where otherwise provided for by other laws and administrative regulations"*.

Tourism No. 035) of the Fifth Session of the Twelfth CPPCC [China's National People's Congress and the Chinese People's Political Consultative Conference] National Committee; Response to Proposal No. 0692 (Medical and Sports No. 079) of the Fifth Session of the 12th National Committee of the Chinese People's Political Consultative Conference; Reply to Proposal No. 6103 of the First Session of the 13th National People's Congress and Reply to Proposal No. 4505 (Medical and Sports Class No. 636) of the Third Session of the 13th National Committee of the Chinese People's Political Consultative Conference. -While not legally binding, these policy documents were issued by the NHC and MST in response to proposals from CPPCC calling for the strengthening and prioritization of the domestic medical device industry. Notably, they suggest that both the NHC and the MST view the Catalogue as key to promoting the objective of strengthening China's medical device industry.

[25] The website of the Association cannot be accessed outside of China; however, the Commission has received insight into the information available on that website.

[26] See National Development and Reform Commission, *Measures for Comprehensive Supervision of Industry Associations and Chambers of Commerce*, 2016, available at: https://www.gov.cn/xinwen/2016-12/29/content_5154008.htm (accessed on 4 November 2024).

[27] The Chinese Communist Party is embedded in the Association through the Organization for Party Building Work, which acts as the Central and State Organs Working Committee, *i.e.,* a local agency of the Central Committee of the Communist Party. The Organization for Party Building Work is involved in all major decisions made by the Association.

(18) This provision imposes an obligation on procuring entities to purchase domestic goods, except in the three exceptional circumstances specifically listed.

(19) When domestic goods are not available or cannot be acquired on reasonable commercial terms in the PRC, the procurement of imported goods is subject to a specific assessment and approval procedure laid down in the Administrative Measures, which implement the GPL with respect to the procurement of imported goods[28]. Indeed, Article 4 of the Administrative Measures first recalls that *"in case of government procurement, domestic goods shall be purchased"* and then, when the procurement of imported goods is *"really necessary"*, requires a specific approval to authorise such procurement. The approval, granted by the local financial departments, is based on the assessment by an expert group of whether there are goods produced in the PRC with technical specifications and functional use comparable to those of the imported goods.

(20) Article 5 of the Administrative Measures lays down the principle that purchasing imported goods should be "*conducive to indigenous innovation or digestion and absorption of core technologies by domestic enterprises"* and requires to "*give priority to purchasing goods that transfer technology"* or *"provide training services and other compensation trade measures*". Pursuant to Article 15, this priority must be specified in the procurement documents for the purchase of the imported goods.

(21) According to Articles 8 to 13 of the Administrative Measures, in order to purchase an imported good, the procuring entity must submit several documents for approval by the competent finance departments: i.e. a standard application form stating the reasons for an exemption to the prohibition resulting from Article 10 of the GPL; a copy of legal or policy documents encouraging the purchase of the imported good in question (if any); an opinion of the relevant sectoral authority at municipal level or above; and the evaluation report from an expert panel.

(22) The Administrative Measures are implemented and clarified by the *'Notice of the General Office of the Ministry of Finance on Issues Concerning the Administration of Government Procurement of Imported Goods Cai Ban Ku [2008] No. 248* ('Notice No 248') [29].

(23) Point 5 of Notice No 248 clarifies that, before procuring imported goods, the purchaser must obtain the approval of the financial department. If the procurement of imported goods is approved, it shall be clearly stipulated in the procurement documents. This provision further lays down that if the procurement is carried out without the prior approval, the procurement documents shall clearly indicate that imported goods are not allowed to participate. Finally, if the procurement documents do not indicate whether imported goods are allowed to participate or not, it will be deemed that they are not allowed.

---

[28] The *'Administrative Measures for the Procurement of Imported Goods'* are formulated in accordance with the GPL and other laws and regulations, in order to implement the Notice of the State Council on the Implementation of Several Supporting Policies of the Outline of the National Medium- and Long-Term Science and Technology Development Plan (2006-2020), promote the implementation of the government procurement policy of independent innovation and regulate the government procurement of imported products.

[29] http://www.da.gov.cn/daczj/0500/202109/52b4c4ac10a6434bb97336b080b05fe5.shtml (accessed on 23 September 2024)

(24) Various provincial governments have introduced local measures implementing the Administrative Measures, some of which set additional and/or more stringent requirements. For instance, some provincial measures require to carry out a public consultation of applications for approval of the procurement of imported goods with a view to identifying domestic substitutes and objections from domestic manufacturers.[30] The Commission has identified the following provincial measures that are publicly available: the *'Anhui Province (2022) Notice on Regulating Relevant Matters concerning Public Health Institutions' Government Procurement of Imported Products'* (Anhui Caigou [2022] No 365)[31]; the *'Notice of the Guangdong Provincial Department of Finance on Regulating the Examination and Approval of Provincial Single-Source Procurement Methods and the Approval and Management of Imported Products'* Yue Cai Procurement [2020] No. 13, the *'Notice of the Guangdong Provincial Department of Finance on Optimizing the Management of Government Procurement of Imported Products'* Yuecai Procurement [2021] No. 1[32]; the '*Notice of the Sichuan Provincial Department of Finance on Standardizing the Examination of Government Procurement of Imported Products'* (Chuan Cai Cai [2012] No. 15)[33]; and the *'Circular of the Zhejiang Provincial Department of Finance on Further Strengthening the Administration of Government Procurement of Imported Products'* Zhejiang Cai Cai Jian [2010] No. 51[34].

(25) Certain local governments such as the Provinces of Guangdong, Sichuan, and Zhejiang, have issued annual lists[35] of a limited number of medical devices reviewed by expert groups and deemed suitable for importation and thus subject to less stringent approval procedures. For instance, the Sichuan Province (2021) Provincial Government Procurement Import Products List for 2021-2022 contained only 59 categories of medical devices for which the procurement of imported goods was authorised[36]. These lists are updated annually or every two years, and the number of imported goods allowed to be procured has been progressively reducing. Any specific good listed may be removed once a suitable domestic substitute has been identified. For instance, the Zhejiang provincial list for imported medical equipment contained 232 products for 2018-2019[37], 215 products for 2019-2020[38] and 195 products for 2021-2022[39]. The list of medical devices allowed to be imported released by the Guangdong Provincial Health

---

30 For instance, https://www.sohu.com/a/475280349_121123889

31 https://www.ahtba.org.cn/site/news/detail/925c9835-9de7-4ee1-8538-30ec2826a188 (accessed on 22 August 2024)

32 https://cgzx.scnu.edu.cn/portalwebController.do?goArticleDetail&id=8a78b89d88800c9b01888e9915ca2169 (accessed on 22 August 2024)

33 https://info.cecbid.org.cn/detail/203104630.html (accessed on 8 July 2024)

34 https://czj.hangzhou.gov.cn/art/2010/12/14/art_1655734_40941519.html (accessed on 22 August 2024)

35 Guangdong Provincial Health Commission (2021) Announcement of the List of Imported Products for Provincial Health Institutions, available at: https://wsjkw.gd.gov.cn/zwgk_gsgg/content/post_3233250.html (accessed on 22 August 2024); Sichuan Province (2021) Provincial Government Procurement Import Product List for 2021-2022, available at: https://www.innomd.org/article/6094a5a423ce965474205667 (accessed on 22 August 2024) and Notice of the Zhejiang Provincial Department of Finance on Announcing the 2021-2022 Unified Demonstration List of Imported Products Purchased by the Provincial Government (Medical Equipment), available at: https://www.sohu.com/a/449491228_120057163 (accessed on 22 August 2024)

36 See https://www.innomd.org/article/6094a5a423ce965474205667

37 https://xxgk.hznu.edu.cn/c/2018-12-11/2102197.shtml

38 https://www.linhai.gov.cn/art/2019/12/25/art_1514544_42277885.html (accessed on 25 October 2024)

39 https://xxgk.hznu.edu.cn/c/2021-05-10/2542476.shtml (accessed on 25 October 2024)

Commission saw a decreased from 132 to 46 between 2019 and 2021[40]. The authorities of some Chinese provinces have issued statements stressing that, in principle, imported medical devices are not allowed to be procured and supporting the procurement of domestic ones.[41]

(26) The Commission also found that, in 2020, the Health Commission of Guangdong Province published an official Letter [2020] No 9[42] in which it supports the allocation of domestic branded medical equipment in hospitals and more specifically, encourages hospitals to purchase medical equipment from Chinese brands.

(27) In addition, the *'Circular of the Ministry of Health on Printing and Distributing the Measures for the Administration of Medical Equipment in Medical and Health Institutions',* Wei Gui Cai Fa [2011] No. 24[43] contains references specific to the procurement of medical devices. In this respect, Article 22 underlines that *"where it is necessary to purchase imported medical equipment, the approval procedures for the procurement of imported equipment shall be strictly performed in accordance with the relevant provisions of the State"*. As explained in recital (19), the approval procedures are laid down in the Administrative measures and their local implementing measures.

(28) Finally, Document 551 lays down requirements on all local authorities to increase the procurement of domestic goods for 178 categories of medical devices. The target share of domestic medical devices varies between 25 % and 100 %, with a 100% target for 137 categories of medical devices.

2.2. Centralised volume-based procurement

(29) The volume-based procurement of medical devices is based on the acquisition of very large quantities of products subject to strong competition at national or provincial level to obtain lower prices. There are three forms of volume-based procurement: city-level or cross-cities alliance procurement; provincial-level procurement and cross-provinces alliance procurement. Various legal documents set up the organisation and management of volume-based procurement of medical devices.

(30) To achieve lower prices, the entity organising the tender establishes a reference (or ceiling) price, which appears to be too low, and maximum price margins for bid selection forcing bidders to bid either below the reference or ceiling price or at price close to the (still unknow) lowest price offered. The parameters for the determination of the reference price are not clearly established. The bidders compete only on price (i.e. the lowest offers win) and the contract is awarded to a group of bidders guaranteeing the requested quantities at the lowest price, according to the parameters established in the tender. Therefore, in volume-based procurement, the level of the reference price and the

[40] https://m.innomd.org/article/60b837db23ce965474ffae9d; https://www.cn-healthcare.com/articlewm/20210323/content-1202052.html

[41] e.g.: https://m.innomd.org/article/60b837db23ce965474ffae9d (accessed on 23 September 2024)

[42] Letter of the Guangdong Provincial Health Committee on Proposal No. 20200567 of the Third Session of the CPPCC 12th Guangdong Provincial Committee [2020] No 9 of 24 March 2020, available at https://wsjkw.gd.gov.cn/gkmlpt/content/3/3055/post_3055444.html#2532 (accessed on 29 October 2024)

[43] https://www.gov.cn/gongbao/content/2011/content_1960690.htm (accessed on 23 September 2024)

price margins for acceptable bids are determinant to frame the competition among bidders.

(31) At the time of the investigation, with respect to medical devices, the PRC has organised volume-based procurement only for medical consumables.

(32) The Commission has identified the following measures governing the centralized procurement of medical devices, and in particular medical consumables, in the PRC: the *'Notice of the Ministry of Health on Further Strengthening the Management of Centralized Procurement of Medical Devices'* Wei Gui Cai Fa [2007] No. 208[44] which aims to standardise and promote the centralised procurement of medical devices; the *'Notice of the reform plan to manage high-value medical consumables'* Guo Ban Fa [2019] No. 37 ('Notice [2019] No. 37')[45]; the '*Guiding Opinions on Carrying out the Centralized Procurement and Use of High-value Medical Consumables Organized by the State'*[46] and the *'Guideline on Implementing the National Centralized Volume-based Procurement and Use of High-value Medical Consumables'* Medical Insurance Fa [2021] No. 31 ('Guideline [2021] No. 31')[47].

(33) In addition, during the consultations, the PRC clarified certain legal bases of volume-based procurement for medical consumables : (i) the *'Pilot Program for the Centralized Procurement and Use of Drugs Organized by the State'* of the State Council Fa [2019] No. 2[48]; (ii) the *'State Council on promoting the centralized procurement of drugs Views on the development of a normalized system'* Guo Ban Fa [2021] No. 2[49] and (iii) the *'Notice of the Office of the National Medical Security Administration on Strengthening Regional Coordination and Improving the Quality and Expansion of Centralized Pharmaceutical Procurement in 2024'* Medical Insurance Office [2024] No. 8[50].

(34) Notice [2019] No. 37 has for an objective to inter alia "*comprehensively and deeply control high-value medical consumables"* and *"improve the price formation mechanism and reduce the inflated prices of high-value medical consumables*". This notice calls for improving the methods for centralized volume-based procurement of high-value medical consumables *"with large clinical usage, higher procurement amount, more mature clinical use, and production by multiple enterprises"* and encourages medical

---

44 https://www.gov.cn/zwgk/2007-06/29/content_666514.htm (accessed on 23 September 2024)

45 https://www.gov.cn/zhengce/content/2019-07/31/content_5417518.htm (accessed on 24 September 2024)

46 Eight departments including the National Health Insurance Administration issued the *"Guiding Opinions on Carrying out the Centralized Procurement and Use of High-value Medical Consumables Organized by the State",* available at*:* https://www.nhsa.gov.cn/art/2021/6/4/art_14_5209.html (accessed on 24 September 2024)

47 The National Health Insurance Administration, the National Development and Reform Commission, the Ministry of Industry and Information Technology, the Ministry of Finance, the National Health Commission, the State Administration for Market Regulation, the State Food and Drug Administration, and the Logistics Support Department of the Central Military Commission have issued guidance on the centralized procurement and use of high-value medical consumables organized by the state - https://www.nhsa.gov.cn/art/2021/6/4/art_37_5208.html (accessed on 24 September 2024)

48 https://www.gov.cn/zhengce/content/2019-01/17/content_5358604.htm accessed on 24 September 2024)

49 https://www.gov.cn/gongbao/content/2021/content_5585228.htm (accessed on 24 September 2024)

50 https://www.gov.cn/zhengce/zhengceku/202405/content_6952505.htm (accessed on 24 September 2024)

institutions to *"jointly carry out volume negotiation and procurement, and actively explore cross-provincial alliance procurement"*. A general objective of the notice, which applies to all the measures covered by it, including the organisation of volume-based procurement, is to *"support domestic high-value medical consumables with indigenous intellectual property rights to enhance their core competitiveness"*. Although the PRC claimed during the consultations that this notice is not applied and that all the consumables subject to volume-based procurement receive equal treatment, it did not provide any evidence to substantiate this claim. On the contrary, the invitations to bid and the procurement documents for national volume-based procurement explicitly refer to this notice[51].

(35) The Medical Insurance Letter [2022] No. 136 of the National Medical Security Administration[52] clearly mentions in point 2 *'On increasing support for domestic medical devices'* that centralized volume-based procurement is *"objectively supporting domestic high-quality enterprises of the same quality but lower cost to win the competition",* while point 3 sets as an objective to *"provide for the development of domestic high-quality enterprises"*.

(36) The volume-based tenders for the procurement of medical consumables cover a major proportion of the overall procurement volume of the concerned products, for some of them more than 95 % of the annual demand. According to Guideline [2021] No. 31, the purchase volume determined according to the indications of demand submitted by medical institutions, combined with factors such as the volume used in the previous year, clinical use status and medical technology progress. The Guideline provides that all public medical institutions shall participate in this system for high-value medical consumables[53], which is further confirmed in the announcements and procurement documents of volume-based procurement procedures mentioned in recital (34) that also refer to this Guideline. Furthermore, Guideline [2021] No. 31 specifies the rules for bidding and selection in volume-based procurement of high-value medical consumables. According to these rules, similar high-value medical consumables with similar therapeutic purposes, clinical efficacy, and product quality are grouped and subject to a price-only competition. It is specified that *"[if] more than one enterprise is selected, the*

---

[51] *Joint Procurement Office National Organization Coronary Stent Centralized Procurement Document (GH-HD2020-1)*: https://hc.tjmpc.cn:10128/upload/202010/16/202010161537489949.pdf; *Announcement on the Centralized Procurement of Intraocular Lens and Sports Medicine Medical Consumables (No. 1* https://hc.tjmpc.cn:10128/public/show14416.html; *Announcement on the Centralized Procurement of Artificial Joints by the State*: https://hc.tjmpc.cn:10128/public/show14367.html, *Announcement on Continued Procurement upon Expiration of Centralized Procurement Agreement for Artificial Joints (No. 1)*: https://hc.tjmpc.cn:10128/public/show14430.html; *National Organization of Artificial Joints Centralized Procurement Document (GH-HD20211*: https://hc.tjmpc.cn:10128/upload/202108/23/202108231724279599.pdf; *National Organization of Orthopaedic Spine Consumables Centralized Procurement Document (GH-HD2022-1)*: https://hc.tjmpc.cn:10128/upload/202209/07/202209072042181898.pdf.

[52] The National Medical Security Administration's response to the Fifth Session of the 13th National People's Congress Response to recommendation No. 8427, available at: http://www.nhsa.gov.cn/art/2022/9/1/art_110_8940.html

[53] Point II (5) of the Guideline.

price difference between different enterprises should be reasonably controlled". At the end of the procedure, a list of selected bidders is established with the corresponding purchase volume.

(37) The Commission established that the production of medical devices in the PRC is subsidised through various tools and programs, which is particularly relevant for the understanding of how the PRC's system of centralized volume-based procurement works in practice, as it usually has an impact on the incentives or ability of bidders to offer particularly low prices.

(38) Medical devices are mentioned in various policy documents and catalogues of the PRC listing 'encouraged' industries and products, including the 12th Five-Year Plan for the Medical Device Technology Industry (2011-2015)[54], the MIC 2025[55], the *'Guiding Catalogue for Industry Restructuring* (2019 Version'[56] as well as 2024 edition[57]), the *'Industry 'Four Basics' Development Catalogue (2016 edition)'*[58], the *'Guiding Catalogue of Key Products and Services for Strategic Emerging Industries (2016 Edition)*[59] and the *'Intelligent Manufacturing Development Plan (2016-2020)'*[60], which is based on the MIC 2025[61].

---

[54] https://most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/gfxwj/gfxwj2011/201201/t20120118_92017.html (accessed on 11 October 2024)

[55] For more details, see Commission staff working document on significant distortions in the economy of the people's republic of China for the purposes of trade defence investigations, page 70, https://ec.europa.eu/transparency/documents-register/detail?ref=SWD(2024)91&lang=en

[56] https://www.gov.cn/zhengce/2021-12/27/content_5713262.htm (accessed on 15 October 2024). This version contains a list of medical devices in the "encouragement" category: *"new medical diagnostic equipment and reagents, digital medical imaging equipment, artificial intelligence-assisted medical equipment, high-end radiotherapy equipment, electronic endoscopy, surgical robot and other high-end surgical equipment, new stents, prostheses and other high-end implant intervention equipment and materials and additive manufacturing technology development and application, critical illness life support equipment, mobile and remote diagnostic equipment, new genetic, protein and cell diagnostic equipment"* and also *"intelligent medical, medical imaging-assisted diagnostic system", "medical rehabilitation robots"* and *"medical fine ceramic materials and components"* mentioned in other parts of the document.

[57] https://www.ndrc.gov.cn/xxgk/zcfb/fzggwl/202312/t20231229_1362999.html In the 2024 edition: medical core technology breakthroughs and applications, innovative development of high-end medical devices, medical electronics, medical imaging aided diagnosis systems and medical robots.

[58] In the category *'X. Biomedicine and high-performance medical devices'*. The catalogue aims at, inter alia, Guiding financial institutions, credit guarantee industries, and insurance industries to make full use of a variety of financial means to support enterprises engaged in research and development, production, and use of products and technologies listed in the catalogue - https://www.waizi.org.cn/doc/24372.html

[59] Point 4.2 'Biomedical Engineering Industry', Sub-points 4.2.1. 'Medical imaging equipment and services', 4.2.2. 'Advanced therapeutic equipment and services' and 4.2.3. 'Medical examination inspection instruments and services'.
Available at: https://www.ndrc.gov.cn/xxgk/zcfb/gg/201702/t20170204_961174.html (accessed on 24 September 2024)

[60] High-performance medical equipment is also mentioned among the key areas for intelligent transformation https://www.gov.cn/xinwen/2016-12/08/content_5145162.htm (accessed on 24 September 2024)

[61] The Commission has found out in the above-mentioned anti-subsidy investigations that industries "encouraged" through MIC 2025 are eligible to considerable funding via dedicated State funds, such as the National Integrated Circuit fund, the Advanced Manufacturing Fund and the Emerging Industries Investment Fund.

(39) In addition, several categories of medical devices[62] are 'listed in the *'2016 Catalogue of High-tech Fields Supported by the State'*[63] and thus their domestic producers[64] are entitled to a reduction of the income tax rate to 15 % instead of 25% pursuant to Articles 25 and 28 of the Law on Enterprise Income Tax ('EIT Law')[65]. Moreover, pursuant to Article 30(1) of the EIT Law, as implemented by Article 95 of the Implementation Rules for the EIT[66], R&D expenses incurred by these producers to develop new technologies, new products and new techniques, are subject, under certain conditions, to an additional 100% or 200% deduction, on top of the deduction of actual expenses.

(40) The Commission has also identified a non-exhaustive list of government support programs through which municipal and provincial governments[67] provide subsidies to medical device manufacturers to encourage the development and manufacturing of products within their jurisdictions, including medical devices subject to volume-based procurement.

(41) Beijing offers subsidies to the medical device industry in various forms through the '*Administrative Measures for the Beijing High-end Industries Development Fund'*[68]. Moreover, the Beijing Economy and Technology Development District (Zone) has put in place a programme supporting the manufacturing and R&D activities of certain

---

62 Medical instruments, equipment and medical specific software (i.e. medical imaging diagnostic technology; first aid and rehabilitation technology; new electrophysiological testing and surveillance technology; medical testing technology and new equipment; new software for medical specialized networks; medical detection and ray measurement testing technology).

63 https://kj.quanzhou.gov.cn/wsbs/xgxz/201703/t20170322_431820.htm (last accessed on 15 October 2024) According to Article 93 of the Implementation Rules for the Enterprise Income Tax Law (Implementing Regulations of the Enterprise Income Tax Law of the People's Republic of China (Revised in 2019) - Order of the State Council of the People's Republic of China No. 714) read together with Circular of the Ministry of Science and Technology, Ministry of Finance and the State Administration of Taxation on revising and issuing Administrative Measures for the Recognition of High-Tech Enterprises (No. 32 of 2016); Circular of the Ministry of Science and Technology, the Ministry of Finance and the State Administration of Taxation on Revising and Issuing the Guidelines for the Administration of Accreditation of High-tech Enterprises, (No. 195 of 2016) and Announcement of the State Administration of Taxation on the Application of Preferential Income Tax Policies to High-tech Enterprises (Announcement No. 24 of 2017)

64 Considered high and new technology enterprises' ('HNTE')

65 Order No 23 of the President of the People's Republic of China

66 As well as Announcement of the State Administration of Taxation on Issues concerning the Attribution Scope of the Weighted Pre-tax Deduction of R&D Expenses (Announcement No 40 of 2017) and Announcement of the Ministry of Finance and State Administration of Taxation on Further Improving the Policies Regarding Weighted Pre-tax Deduction of R&D Expenses (Announcement No 7 of 2023)

67 Beijing, Shanghai, Shenzhen, Guangzhou, and Suzhou are the Chinese cities with the largest medical device industries – see in this respect https://www.thepaper.cn/newsDetail_forward_26681704

68 *'Notice of the Beijing Municipal Bureau of Economy and Information Technology and the Beijing Municipal Bureau of Finance on Printing and Distributing the Measures for the Management of Funds for the Development of High-tech Industries in Beijing'* Jingjing Xinfa [2021] No. 84, available at: https://www.beijing.gov.cn/zhengce/zhengcefagui/202109/t20210925_2501587.html (accessed on 29 October 2024). The 2022, 2023, and 2024 Implementation Guidelines for the Beijing High-end Industries Development Fund each offer grants for various medical device projects, available at: https://www.beijing.gov.cn/fuwu/lqfw/gggs/202202/t20220208_2606216.html, https://www.beijing.gov.cn/zhengce/zhengcefagui/202302/t20230227_2924581.html and https://jxj.beijing.gov.cn/jxdt/tzgg/202401/t20240119_3541288.html (accessed on 29 October 2024).

medical devices in the zone[69]. This programme also specifically supports the manufacturing of products subject to centralised volume-based procurement - enterprises are encouraged to participate in the centralized procurement of medical devices in the State and Beijing, and can receive a refund of the total bid price for such products that have been manufactured for the first time in the zone, with a maximum refund for a single variety of up to 3 million CNY. Finally, the Zhongguancun National Independent Innovation Demonstration Zone and some Beijing districts have issued support programs for the medical devices industry to provide grants supporting the development of advanced industries, including medical devices innovation.

(42) The General Office of the Shanghai Municipal People's Government has also put in place several programs[70] to provide financial support to medical devices companies located in Shanghai in the form of grants, loan interest subsidised, refund on R&D expenses etc. In addition, the China (Shanghai) Free Trade Zone Lingang New Area issued *Several Measures on the Cluster Development of the Biomedical Industry*[71] that provides a variety of cash grants to the medical device industry.

(43) The *Shenzhen Development and Reform Commission on the Issuance of Several Measures to Promote the High-Quality Development of Biomedical Industry Clusters in Shenzhen Municipality,* Shen Fa Gai Gui [2022] No. 10[72] contains measures providing financial support to enterprises engaged in production and R&D activities in the

---

[69] The programme is established through two documents called 'Several Measures on Promoting High-Quality Development of Pharmaceutical and Health Industry', Jingji Guan Fa [2023] No. 5 [https://www.ncsti.gov.cn/zcfg/zcwj/202303/t20230301_109733.html (accessed on 28 October 2024)] and *'Several Measures for Promoting the High-quality Development of the Intelligent Manufacturing Industry for High-end Medical Equipment*' [https://kfqgw.beijing.gov.cn/zwgkkfq/2024zcwj/202405/t20240510_3670133.html (accessed on 29 October 2024)]. The support measures concern the following medical devices: medical imaging equipment, implantable interventional instruments and consumables, genetic testing and synthesis equipment, surgical treatment and life support equipment and other instruments and equipment, in vitro diagnostic reagents and products, biomedical materials, surgical robots, intelligent software and other medical devices.

[70] '*Opinions on Promoting the High-Quality Development of the City's Biomedical Industry'*, available at https://www.shanghai.gov.cn/2021hfbgwg/20210519/2d51b319d0af457dab381045d8cd4b02.html (accessed on 28 October 2024); '*Several Measures on Promoting the Development of the High-end Manufacturing Industry',* available at: https://www.ssme.sh.gov.cn/public/news!loadNewsDetail.do?id=2c91c28d83647d700183c5a963422229 (accessed on 29 October 2024); '*Several Opinions on Supporting the Innovation and Development of the Biomedical Industry Chain',* available at: https://service.shanghai.gov.cn/XingZhengWenDangKuJyh/XZGFDetails.aspx?docid=240912111721j3leumMZXJEiChWtVv5 (accessed on 29 October 2024); '*Several Policy Measures to Accelerate the Creation of a Global Hub for Biomedical R&D, Economic Development and Industrialization',* available at: https://www.ssme.sh.gov.cn/public/news!loadNewsDetail.do?id=2c91c28d848a2c89018498e17ec604ab (accessed on 29 October 2024); '*Several Policies on Promoting the Development of Shanghai's Biomedical Industry',* available at: https://www.lexiscn.com/law/content.php?provider_id=1&isEnglish=N&origin_id=1373930&eng=0&keyword=5Yy755aX5Zmo5qKwLOacgOmrmCzlhYM%3D&t_kw=&prid=7e9aa2d5-a3a0-4307-b3f3-9ff23d940fa7&crid=ae1443e3-d67c-4405-a393-f3dd55203317 (accessed on 29 October 2024) and '*Several Policies on Promoting the Development of Shanghai's Biomedical Industry (2014 Version)'*, available at: https://www.shanghai.gov.cn/nw31831/20200820/0001-31831_40018.html (accessed on 29 October 2024)

[71] Available at: https://www.lingang.gov.cn/html/website/lg/index/government/file/1819074381640433666.html (accessed on 29 October 2024)

[72] https://www.sz.gov.cn/zfgb/2023/gb1273/content/post_10403843.html (accessed on 28 October 2024)

municipality to promote the development of high-end medical devices industry clusters[73]. The programme also encourages local enterprises to participate in the national centralised volume-based procurement by subsidising winning medical devices with a grant with a maximum funding for each individual class of medical devices up to 3 million CNY and for single enterprises up to 5 million CNY annually. Other programs also support the development of core technologies for the medical devices sector and provide subsidies in the form of refunds of R&D and investment costs[74].

(44) In Guangdong province, the *Several Policies and Measures to Promote the High-Quality Development of the Biomedical Industry in Guangzhou, Sui Fu Ban Gui [2024] No 1*[75] provide various cash grants[76] to companies producing and developing innovative high-end medical devices. Furthermore, the *Several Measures to Promote the Development of Biomedical Innovation* [2020] No. 86[77] also provide cash grants and other forms of support to the medical devices industry.

(45) Shandong Province has issued an *Action Plan for Leading Innovative Drugs and High-end Medical Devices (2020-2022)* Lu Ke Zi [2020] No. 33[78] to support the medical devices industry in the province. The city of Qingdao provides additional support, such as grants for local production, refund of R&D expenses and subsidies on investment costs[79].

---

[73] The measures support high-end medical imaging, in vitro diagnosis, life monitoring and life support, high-end implant intervention, emergency treatment, tumor radiotherapy, medical endoscopy, genetic testing, optical equipment, DNA synthesizer, intelligent rehabilitation aids and health management and other instruments and equipment, various reagents and products required for disease screening and precision drug analysis, high-end implantable interventional products such as stent valves, ventricular assist devices, intraocular lenses, orthopaedic devices, degradable materials, tissue and organ induction regeneration and repair materials, new oral materials, biomedical materials such as high-value domestic replacement consumables, surgical robots, intelligent software and other artificial intelligence information technology applications in medical equipment scenarios, etc. in the form of 40 % refund of the actual investment in research and development, with a maximum of between 3 and 5 million CNY for the first approval of specific medical devices produced locally, and up to 10 million CNY for newly built or renovated manufacturing plants. High-end medical devices, approved and sold in the US, Japan and the EU can receive up to 10 million CNY for a single enterprise per year if they conduct research and development and industrialisation locally.

[74] The '*Notice on Organizing and Implementing a Special Support Plan for Major Public Service Platforms and Core Technology Research in the Biomedical Industry':* https://www.samd.org.cn/home/newsDetail?id=2884&typeId=440 (accessed on 29 October 2024) and '*Several Measures to Promote the Cluster Development of the Biomedical Industry in Shenzhen'.*

[75] https://www.gz.gov.cn/zwgk/fggw/sfbgtwj/content/post_9451070.html (accessed on 28 October 2024)

[76] *"The city and district will jointly give talent rewards, R&D and industrialization incentives, investment shares, discount loans and other full-chain support, with a maximum support amount of 5 billion yuan and a support period of up to 5 years".*

[77] https://gdii.gd.gov.cn/gkmlpt/content/2/2967/post_2967541.html#2891 (accessed on 29 October 2024)

[78] http://kjt.shandong.gov.cn/art/2020/5/22/art_103585_9129786.html (accessed on 30 October 2024)

[79] *Several Policies on Further Supporting the High-quality Development of the Biomedical Industry of Qingdao* [2023] No. 12, available at: http://www.qingdao.gov.cn/zwgk/zdgk/fgwj/zcwj/szfgw/202312/t20231208_7705269.shtml (accessed on 30 October 2024); *Detailed Implementation Rules on Several Policies for Further Supporting the High-quality Development of the Biomedical Industry of Qingdao,* [2024] No. 14, available at http://www.qingdao.gov.cn/zwgk/xxgk/gyxx/gkml/gwfg_533/202403/t20240315_7911768.shtml (accessed on 30 October 2024); and *Several Policies on the Development of the Qingdao Biomedicine and Medical Device Industry Park* [2023] No. 17, available at:

(46) The Commission found that one of the major Chinese manufacturers of medical devices, Jiangsu Yuyue Medical Equipment & Supply Co., Ltd, has received a range of subsidies through various support programs in Jiangsu province[80]. In particular, the *Implementation Measures for Promoting the Development of the Medical Devices and Biomedical Industry*[81] provide financial support for the manufacturing and development of medical devices in the Suzhou National High-Tech Industrial Development Zone.

(47) The Commission also identified the following subsidy programs in other provinces of the PRC: *Notice of the General Office of Chongqing Municipal People's Government on Triggering Several Measures to Accelerate the Development of Biomedical Industry in Chongqing Municipality, Yu Fu Ban [2022] No. 12*[82]; *Industrial policy for high-quality development of biomedicine in the Tianjin Economic and Technological Development*

---

http://www.qingdao.gov.cn/zwgk/xxgk/gyxx/gkml/gwfg_533/202403/t20240315_7911768.shtml (accessed on 30 October 2024)

80 http://www.cninfo.com.cn/new/disclosure/detail?plate=szse&orgId=9900004462&stockCode=002223&announcementId=1216658782&announcementTime=2023-04-28 (accessed on 30 October 2024)
2018 Zhenjiang Science and Technology Innovation Fund (Major Science and Technology Special Project), the A*nnual Allocations for the 2017 and 2018 Municipal Major Science and Technology Special Projects, Filing of the Medical Ventilator Mechanical Products Construction Project of Yuwell Medical Equipment Co., Ltd, 2020 Central Government Subsidy for the Construction of an Emergency Material Support System, Measures for the Administration of Special Funds for the Transformation of Scientific and Technological Achievements (Trial),* available at https://jsstyj.jiangsu.gov.cn/art/2020/6/5/art_78433_9198419.html (accessed on 30 October 2024); *Measures for the Administration of Special Funds to Transform and Upgrade the Industrial and Information Technology Industries* Su Cai Gui [2020] No. 29, available at: https://www.js.gov.cn/art/2020/12/22/art_64797_9611822.html (accessed on 30 October 2024) - in this respect see also the *Announcement on the Third Batch of 2021 Projects of the Special Funds for Transformation and Upgrading of Industrial and Information Industry. (2021)* https://gxt.jiangsu.gov.cn/art/2021/11/22/art_6281_10121293.html (accessed on 30 October 2024) which lists Jiangsu Yuwell's Intelligent Manufacturing Demonstration Factory Project for High-end Medical Equipment in the third batch supported by this fund – and *Measures on the Administration of Special Funds for the Development of Strategic Emerging Industries* Su Cai Gui [2022] No. 10, available at https://czt.jiangsu.gov.cn/art/2022/12/30/art_77684_10716017.html (accessed on 30 October 2024) - in this respect, see also *Jiangsu Development & Reform Commission. (2022). Announcement on 2022 Projects of Provincial Special Funds for the Development of Strategic Emerging Industries,* available at*:* https://fzggw.jiangsu.gov.cn/art/2022/6/16/art_284_10495496.html listing Jiangsu Yuyue Medical Equipment Co., Ltd. high-performance diagnosis and treatment equipment project for respiratory critical diseases as one of the projects supported by this fund.

81 http://kcb.ideatob.com/pc/sadmin/upload/2020-06-01/202006012140233966.pdf (accessed on 30 October 2024)

82 The program aims at financially supporting the industrialization and R&D of innovative medical devices, the development of overseas markets and the construction of advanced manufacturing platforms in terms of digital, intelligent and green production technologies, available at: https://www.cq.gov.cn/zwgk/zfxxgkzl/fdzdgknr/zdmsxx/yl/zyzc/202203/t20220311_10496287.html (accessed on 28 October 2024)

Zone[83] and *Several Measures to Promote the High-Quality Development of Dongguan Songshan Lake Biomedical Industry*[84].

(48) According to a report published by the Mercator Institute for China Studies ('MERICS') in November 2023 titled *'Investigating State support for China's medical technology companies'*[85], a sample of 122 Chinese companies manufacturing medical devices have seen their government support[86] increase five-fold between 2017 and 2022 [from 5 billion CNY to 20 - 27 billion CNY (655 million EUR to 2,8 – 3,8 billion EUR)][87]. In addition, medical technology received about 10 % of all public spending on research and development (40 billion CNY, or 5,6 billion EUR) in 2022. This report also finds that Chinese companies manufacturing medical devices receive more subsidies relative to their size than those active in other sectors (subsidies as a share of revenue) [88]. The report finally shows that the tax benefits for the 122 companies in the sample have increased six-fold between 2017 and 2022 and reached 11,4 billion CNY (1,6 billion EUR), representing an average benefit of 93,8 million CNY [13,3 million EUR] per company, which is worth 2,6 % of their average revenue[89].

(49) Based on their publicly available annual reports, seven of the largest Chinese manufacturers of medical devices[90] have received approximately 2 billion CNY direct grants for the years 2022 and 2023, and approximately 1,3 billion CNY in the form of VAT refunds for the sale of software. All these companies have enjoyed the preferential EIT rate of 15% and the additional deduction of R&D expenses, which resulted in an estimated combined amount of 11,5 billion CNY EIT savings and an estimated R&D savings of approximately 240 - 400 million CNY for the two years.

2.3. The application of the measures and practices

2.3.1. The application of the measures and practices related to the "Buy China" policy

[83] The Economic Development Zone actively encourages and supports the development of high-end innovative medical devices and gives up to 15 million CNY of financial incentives to enterprises that have obtained relevant qualifications or industrialisation, available at: https://www.teda.gov.cn/contents/13/24313.html (accessed on 28 October 2024)

[84] This program provides for a maximum subsidy between 1 million CNY and 3,2 million CNY for the registration of specific medical devices, with additional 500,000 CNY for innovative medical devices, available at: http://www.imd-cfda.com/ueditor/php/upload/file/20211220/1639985477974932.pdf (accessed on 30 October 2024)

[85] Available at https://merics.org/en/report/investigating-state-support-chinas-medical-technology-companies

[86] Including direct subsidies, tax benefits, below-market borrowing and below-market equity

[87] See on pages 24 and 25.

[88] See page 27 of the report. As a result, State support directed to China's medical devices companies was estimated at around 28% of their net profit, or 77% of their R&D expenses. This is consistent with the OECD findings that the PCR provides significantly more state support than other advanced economies, with data between 2005 and 2019 showing the same forms of support amounted to approximately 4.45% of revenue for firms in China on average in 13 sectors, compared to just 0.69% of revenue for firms in OECD countries.

[89] See on page 28.

[90] Namely Qingdao Haier Biomedical Co., Ltd., Lepu (Beijing) Medical Instruments Co., Ltd., Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shandong Shinva Medical Instrument Co., Ltd., Shanghai United Imaging Healthcare Co., Ltd., Beijing Wandong Medical Technology Co., Ltd. and Jiangsu Yuwell Medical Equipment & Supply Co., Ltd.

(50) The Commission investigated the actual procurement practices for medical devices prevalent in the PRC in available procurement portals.[91] The investigation was hampered by the fact that the PRC does not publish systematically online the essential documents needed to understand the eligibility of foreign bidders and the tender requirements, particularly for those conducted at subcentral level. It is also worth noting in this respect that a recent empirical study found that the overall level of transparency in public procurement in China is well below the one found in the European Union. The study used a procurement-specific transparency index (with values between 0 and 1, where 0 is "completely opaque" and 1 "fully transparent") and estimated that the PRC scored only 0.6, well below the scores achieved in the EU Member States, all ranking above 0.9.[92]

(51) The Commission managed to accede publicly available information for a set of over 380 000 procurement tenders on medical devices conducted between January 2017 and 31 May 2024. However, publicly available information about tender procedures in the PRC has proved to be limited and spread among multiple sources and not all published tenders contain the necessary minimum information. In particular, the Commission found that only 35 504 of these tenders contained the minimum documents that allow to determine the eligibility criteria and other conditions of participation for prospective bidders that could be usefully examined for the purpose of the investigation (hereinafter 'the first sample').

(52) The analysis of the tender documents contained in this first sample allowed the Commission to examine (i) the nature of the tender requirements which restrict the procurement of imported medical devices and (ii) their prevalence across product categories and the Chinese territory.

(53) The analysis of the first sample shows a systematic use of various restrictions. Explicit restrictions include explicit prohibitions of the procurement of imported medical devices and other requirements that *de facto* impair the access to such procurement for foreign economic operators and goods and create a significant competitive disadvantage for imported medical devices, e.g. the requirement to produce in China, or to use Chinese

---

[91] https://search.ccgp.gov.cn/bxsearch; http://www.ccgp-beijing.gov.cn/; https://www.zfcg.sh.gov.cn/; https://gdgpo.czt.gd.gov.cn/; http://zfcg.szggzy.com:8081/; http://www.ccgp-henan.gov.cn/; http://www.ccgp-hebei.gov.cn/; http://tjgpc.zwfwb.tj.gov.cn/web_index1.do; http://www.ccgp-jiangsu.gov.cn/; https://zfcg.czt.zj.gov.cn/; http://www.ccgp-yunnan.gov.cn/; http://www.ccgp-sichuan.gov.cn/; http://www.ccgp-chongqing.gov.cn/; https://www.ccgp-anhui.com.cn/default; http://www.ccgp-fujian.gov.cn/; http://jycg.hubei.gov.cn/; http://www.ccgp-hunan.gov.cn/; http://www.ccgp-jiangxi.gov.cn/; http://www.ccgp-xinjiang.gov.cn/; http://www.ccgp-xizang.gov.cn/; http://www.ccgp-guangxi.gov.cn/; http://www.ccgp-guizhou.gov.cn/; http://www.ccgp-heilongj.gov.cn/; http://www.ccgp-jilin.gov.cn/; http://www.ccgp-liaoning.gov.cn/portalindex; https://www.ccgp-hainan.gov.cn/zhuzhan/; http://www.ccgp-neimenggu.gov.cn/; https://www.ccgp-shaanxi.gov.cn/; http://www.ccgp-shanxi.gov.cn/; http://www.ccgp-shandong.gov.cn/; https://www.ccgp-gansu.gov.cn/; https://www.ccgp-ningxia.gov.cn/public/NXGPP NEW/dynamic/index.jsp

[92] Sangeeta Khorana, Santiago Caram, Nripendra P. Rana, "Measuring public procurement transparency with an index: Exploring the role of e-GP systems and institutions", Government Information Quarterly, Volume 41, Issue 3, 2024 (https://www.sciencedirect.com/science/article/pii/S0740624X24000443).

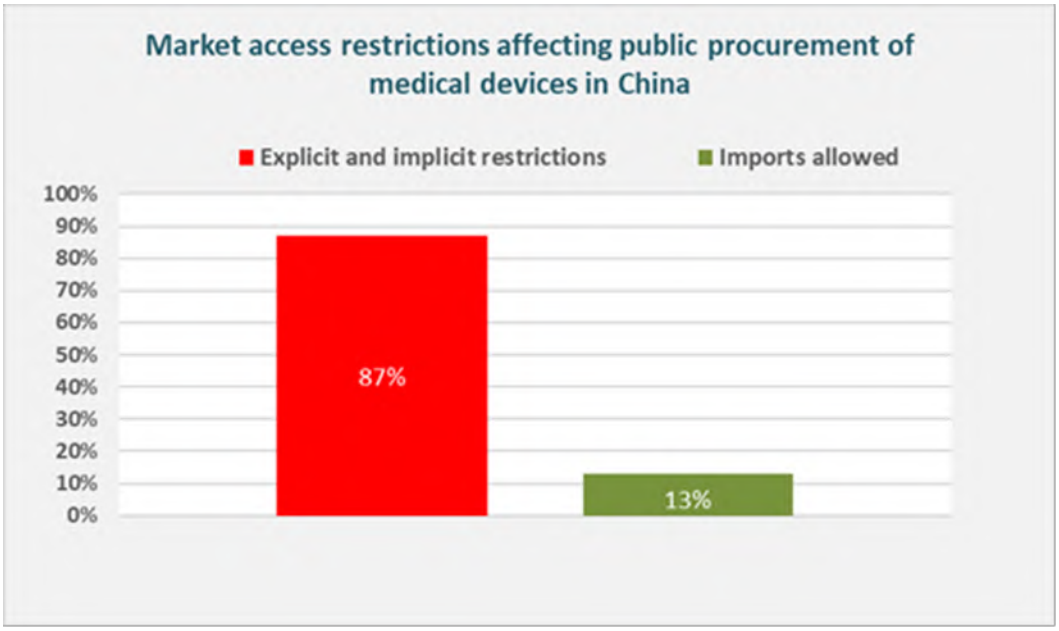
materials and components, the requirement to transfer technology to Chinese companies or to achieve some degree of domestic performance in terms of sales, investment, or research and development activities). Implicit restrictions include cases where the tenders do not contain explicit prohibition of imported medical devices or other discriminatory requirements, but *de facto* lead to the exclusion of imported medical devices. They follow from the application of Notice No 248, which provides that where the tender documents do not clearly specify that imported medical devices are allowed, it shall be deemed that they are not allowed[93] and thus prohibited to be procured. Therefore, the absence of explicit prohibition of imported medical devices or other discriminatory requirements cannot be interpreted as an indication that imported medical devices are allowed to participate in the tenders concerned.

(54) Overall, the Commission found that 87% of public procurement tenders of the first sample contained explicit or implicit restrictions affecting the procurement of imported medical devices (see Figure 1).

(55) In addition, it is important to underline that the fact that the purchase of imported medical devices is allowed in a tender procedure and that the relevant documents do not contain explicit discriminatory requirements does not necessarily mean that imported medical devices are not subject to discrimination. In fact, discrimination affects the procurement of imported medical devices even if such procurement is approved, to the extent that Article 5 of the Administrative Measures instructs procuring entities to *"give priority to purchasing products that transfer technology (...), provide training services and other compensation trade measures"*.

Figure 1. Access to the public procurement markets of medical devices in PRC

[93] See some examples in this respect: *'Competitive negotiation of medical equipment procurement project of Qixian People's Hospital in Shanxi Province'*, point 6 "*If the above content is not specifically marked as "imported products", domestic products must be purchased"*, available at http://www.ccgp.gov.cn/cggg/dfgg/jzxcs/202205/t20220530_17988891.htm (accessed on 29 October 2024); *'The First People's Hospital of Jinzhong City anesthesia breathing circuit disinfection system and other medical equipment purchase projects public bidding announcement', "If the words "imported products" are not specifically marked in the above table, domestic products must be purchased"*, available at: http://www.ccgp.gov.cn/cggg/dfgg/gkzb/202304/t20230417_19718341.htm (accessed on 29 October 2024); *'Public bidding announcement for the purchase of medical equipment in Fenyang Hospital of Traditional Chinese Medicine'* Note: 1. *"All bidding contents are purchased from domestic products unless specifically marked as "imported products"*, available at: http://www.ccgp.gov.cn/cggg/dfgg/gkzb/202403/t20240308_21611160.htm (accessed on 29 October 2024) and *'Heilongjiang Neng'an Technology Co., Ltd., Suihua Maternal and Child Health Hospital Procurement of Financial and Medical Electronic Bill Project Transaction Announcement*', available at: https://www.ccgp.gov.cn/cggg/dfgg/cjgg/202307/t20230728_20394036.htm (accessed on 28 October 2024) Point 26. *'Purchasing policy'* specifies that *"Procurement shall be of domestic goods; if goods cannot be obtained domestically or not on reasonable commercial terms, imported products may be procured after approval in accordance with the prescribed procedures (in the absence of special requirements in the announcement or documents, domestic goods are to be procured)."*

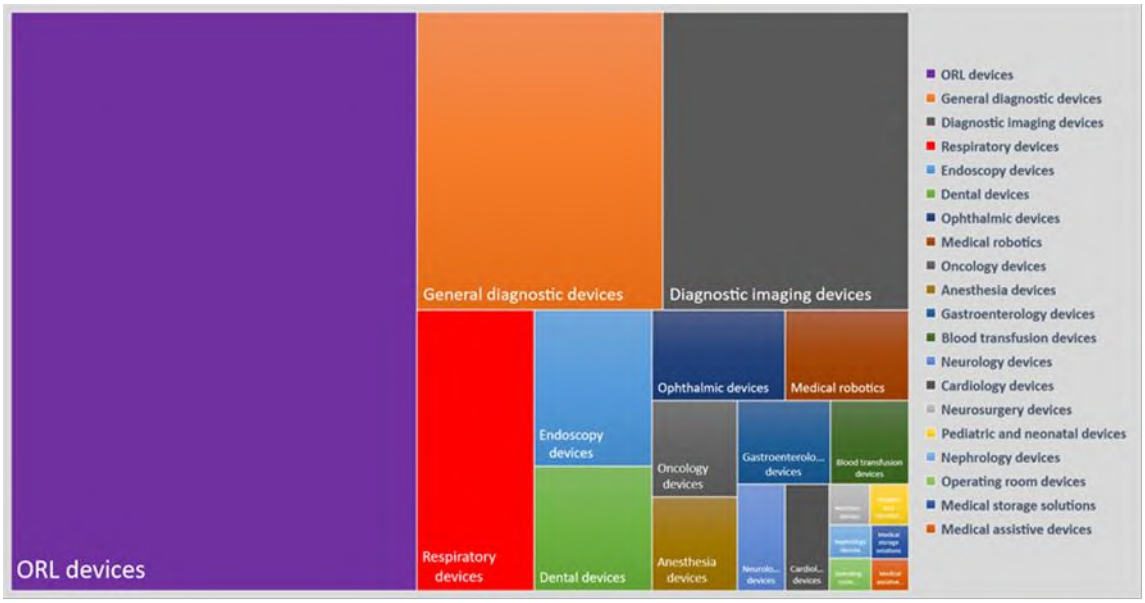


Source: Commission finding, based on tender information publicly available from Chinese public procurement portals.

(56) The examination of the sample also clearly indicates that the inclusion of explicit prohibition of imported medical devices or other discriminatory requirements is found for all product categories identified in the Notice of Initiation in a systemic and recurrent manner. However, they are particularly prevalent in tenders concerning certain categories of medical devices. Figure 2 shows a selection of such medical device categories and the share of tenders in the sample subject to explicit prohibitive or discriminatory requirements.

Figure 2. Types of medical devices mainly affected by Chinese prohibitive or discriminatory requirements

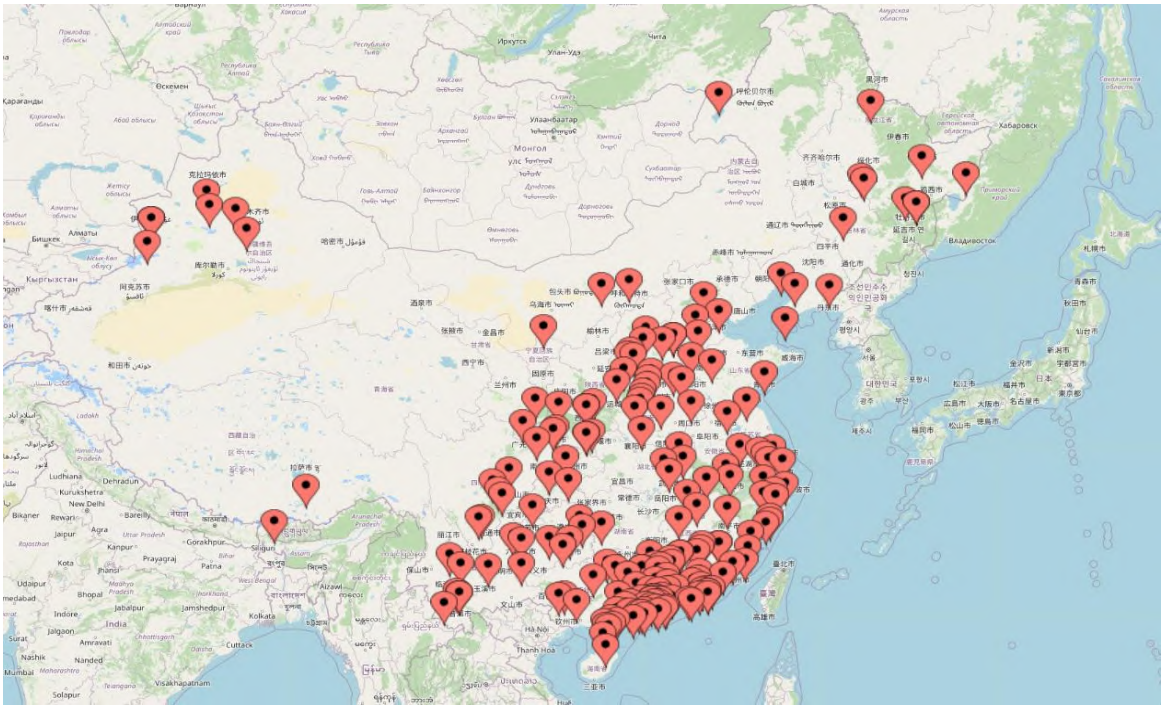
(based on the total number of tenders publicly available)



Source: Based on tender information publicly available from Chinese public procurement portals.

(57) In addition to the systemic and recurrent nature of prohibitive or discriminatory requirements across all medical devices categories, the sample also indicates a very widespread application of such requirements across all Chinese provinces, except the autonomous province of Tibet. Figure 3 offers a snapshot of the widespread geographical nature of these requirements found in tenders of the sample organised in more than 300 cities across the Chinese territory.

Figure 3. Geographical incidence of explicit prohibitive or discriminatory requirements affecting medical devices in China



Source: Based on tender information publicly available from Chinese public procurement portals.

(58) In addition, the Commission conducted an in-depth examination of a second separate sample of publicly available tenders for the years 2022, 2023 and half-2024, focusing only on tenders with explicit discriminatory requirements concerning imported medical devices. The Commission found explicit prohibitions of purchase of imported medical devices in 36 % of the discriminatory tenders concerned in 2022, which decreased to 43 % in 2023 and 53 % in the first half of 2024. This indicates a sustained increase of the explicit prohibition of imported medical devices among the tenders at stake.

(59) With respect to Document 551, a study by L.E.K. Consulting *'Hospital Priorities 2023 China Edition: Strategic Implications for Medtech Companies'*[94] completed in August 2023 shows that public hospitals in the PRC have already largely implemented the targets laid down in Document 551, as explained in recital (28), and are committed to further implement them, even beyond the products listed therein. In fact, while in 2022

[94] https://www.lek.com/sites/default/files/PDFs/china-hospital-priorities-2023-medtech.pdf

only 16 % of the respondent public hospitals stated that they had already implemented Document 551, this percentage increased to 60 % in 2023. In 2023, 33 % of respondent public hospitals declared that they will implement Document 551 in the next six months and only 6 % stated that they will do so beyond the next six months. In 2023, 35 % of the respondent public hospitals declared that they would implement Document 551 on both the medical devices on the list and those beyond the list, compared to 13 % in 2022. Finally, the study shows that the proportion of hospitals restricting the use of imported medical devices has increased 13-fold since Document 551 has been released. In this respect, the proportion of the response *"no restrictions on the use of imported products"* decreased from 36 % in 2020 to 11 % in 2023.

(60) The Commission also found tenders in which medical devices listed the Catalogue of the China Medical Equipment Association were awarded additional points during the bid evaluation process[95] or where the technical specifications require that products are listed in that Catalogue.[96]

2.3.2. The application of volume-based procurement

(61) Up to the end of the investigation period, the Commission found that the PRC has organised national volume-based procurement for five categories of high-end medical consumables: coronary stents, artificial joints, interocular lens and sports medicine medical consumables, orthopaedic spine consumables and cochlear implants and peripheral vascular stents. In addition, the Commission found that volume-based procurement tenders were also conducted at provincial level for various medical consumables such as pacemakers, balloon dilatation catheters, trauma fixation products, artificial joins, coronary stents, artificial bones, orthopaedic consumables etc.[97]. The PRC is planning to expand the use of volume-based procurement to other categories of medical devices in the near future.

---

[95] See in this respect: https://www.ccgp.gov.cn/cggg/dfgg/gzgg/202208/t20220817_18477897.htm (accessed on 4 November 2024) - if the procured goods are selected in the Catalogue of Excellent Domestic Medical Equipment Products, 2 points are awarded upon presentation of a copy of the certificate issued by the China Medical Equipment Association, and https://www.ccgp.gov.cn/cggg/dfgg/gzgg/202112/t20211229_17462399.htm (accessed on 4 November 2024) - if the procured products are shortlisted for the Excellent Domestic Medical Equipment Product Catalogue issued by the China Medical Equipment Association in 2019, 1 point is awarded. It should be noted that evaluation criteria and scoring information are not always included in public procurement announcements.

[96] See in this respect: https://www.ccgp.gov.cn/cggg/dfgg/gkzb/202210/t20221010_18788060.htm (accessed on 4 November 2024) - one of the specification requirements for anaesthesia machine is *"Certification: Passed CFDA and CE certification, and was selected in the Excellent Domestic Medical Equipment Product Selection Catalogue"* and https://www.ccgp.gov.cn/cggg/dfgg/xjgg/202212/t20221215_19238161.htm (accessed on 4 November 2024) – the product specifications for anaesthesia monitor contain the following requirement: *"4.3 The product model has been selected into the excellent domestic medical equipment product catalogue"* (with respect to this product, the tender announcement also specifies that the procurement of imported goods is not allowed)

[97] e.g., in Anhui, Hubei, Shandong, Shanxi, Fujian, Jiangsu, Qinghai, Shanghai, Zhejiang, Hunan, Henan, and cross-province alliance: Guangdong 7-povinces alliance, Guizhou-Chongqing-Hainan Alliance, Beijing-Tianjin-Hubei Alliance and Inner Mongolia 8-provinces alliance, Henan 12 provinces alliance, Beijing

(62) The Commission examined the publicly available documents and results of the national volume-base procurement procedures for coronary stents, artificial joints, interocular lens and sports medicine medical consumables, and orthopaedic spine consumables.

(63) In all these cases, the contracting authorities first announced the tenders[98], subsequently published the procurement documents[99] and, finally, published the results[100]. In the tender announcements, medical institutions were invited to declare their needs, and interested bidders to disclose their maximum annual supply capacity for the Chinese market. Bidders were then placed in two bidding groups, named "A unit" and "B unit"[101], and competition took place within each unit. Bidders in each unit could only offer one price per product category. The announcements specified also a maximum number of finalists. The bidders were shortlisted based on price, from the lowest to the highest. According to the tender announcements, the bidding price of shortlisted bidders should not be higher than a so-called *"highest effective declaration price"* (which is a maximum reference or ceiling price that could be offered by bidders). This highest effective declaration price was then set in the subsequent procurement documents. The final selection of shortlisted bidders in unit A required that the *"price difference* [between the selected bidders' offered prices] *is controlled within a reasonable range"* within the same product category and between different product categories (as explained in recitals (64) to (66) below, the procurement documents require that to be selected a bidder should offer a price equal or inferior to a certain amount of times the lowest bidding price received for the same product). Bidders in unit B could only be selected if the *"price difference* [between the selected bidders' offered prices] *is controlled within a reasonable range"* and the bidding price was not higher than the highest winning price in unit A. Bidders not selected under these rules could still be selected in a second or third round, pursuant to other rules which were not explained in the announcement but in the procurement documents. However, the declared objective of this second selection round was to *"promote the selection of more enterprises with prices lower than a certain level*". The procurement documents further clarified the above elements and included more precise information about the price selection mechanism and different procedural steps.

(64) As an illustration, in the first coronary stent volume-based tender organized in 2020, the procurement documents required a price to be selected equal or inferior to 1,8 times the

---

[98] See for instance: https://hc.tjmpc.cn:10128/public/show14394.html; https://hc.tjmpc.cn:10128/public/show14416.html and https://hc.tjmpc.cn:10128/public/show14430.html.

[99] See for instance, *Joint Procurement Office National Organization Coronary Stent Centralized Procurement Document (GH-HD2020-1)*: https://hc.tjmpc.cn:10128/upload/202010/16/202010161537489949.pdf; *National Organization of Artificial Joints Centralized Procurement Document (GH-HD20211)*: https://hc.tjmpc.cn:10128/upload/202108/23/202108231724279599.pdf; and *National Organization of Orthopaedic Spine Consumables Centralized Procurement Document (GH-HD2022-1)*: https://hc.tjmpc.cn:10128/upload/202209/07/202209072042181898.pdf.

[100] See for instance, https://hc.tjmpc.cn:10128/public/show12356.html for coronary stents; and https://hc.tjmpc.cn:10128/public/show14378.html for artificial joints.

[101] Unit A includes only suppliers that can potentially supply the entire country or can cumulatively cover 85% of the total demand. Unit B includes the remaining bidders.

lowest bidding price received for the same product, or, if higher than 1,8 times, a price below 2 850 CNY (i.e. the "highest effective declaration price"). In the second coronary stent tender organized in 2022, the "highest effective declaration price" was even lower, set at 848 CNY.

(65) In the first volume-based tender for artificial joints organized in 2021[102], the "highest effective declared price" was as follows: 19 000 CNY for a ceramic hip joint product system, 18 000 CNY for a ceramic-polyethylene hip joint product system, 16 000 CNY for an alloy-polyethylene hip joint product system and 19 000 CNY for a knee joint product system. The price of selected products had to be equal or inferior to 1,5 times the lowest bidding price for the same product, or, if higher than 1,5 times, a price below 50 % of the "highest effective declaration price".

(66) In the 2024 volume-based tender for artificial joints[103], the "highest effective declared price" for each product system was lower even than in 2021: 7 588 CNY for a ceramic hip joint product system, 6 761 CNY for a ceramic-polyethylene hip joint product system, 5 615 CNY for an alloy-polyethylene hip joint product system and 5 162 CNY for a knee product system. According to the procurement document, the price for selected products had to be equal or inferior to 1,2 times the lowest bidding price, or if higher than 1,2 times, below the "highest effective declared price".

(67) Therefore, the volume-based tenders resulted in a significant price decrease[104]. The average price reduction was, up to 95% for coronary stents, 82 % for artificial joints, 84 % for orthopaedic spine consumables, and 70 % for interocular lens and sports medicine medical consumables.

(68) The Commission found information about some of the largest Chinese manufacturers of medical devices, which have received financial support as explained in recital (49), have won in volume-based tenders that have led to significant price decreases.

(69) In 2021, Lepu (Beijing) Medical Instruments Co., Ltd. won a bid for a volume-based procurement contract in Shanghai for providing coronary drug-eluting balloons ('DEBs')[105] Under the contract, it provided 244 DEBs at a cost of 11,497 CNY per unit,

[102] https://hc.tjmpc.cn:10128/upload/202108/23/202108231724279599.pdf

[103] https://www.nhsa.gov.cn/module/download/downfile.jsp?classid=0&filename=b7cee42cfccc4c8a8a947ee4891606a0.pdf

[104] https://veranex.com/2023/01/17/the-new-normal-for-market-access-in-china-volume-based-procurement/; http://www.qinghai.gov.cn/zwgk/system/2021/01/08/010373900.shtml; https://www.cmdi.org.cn/zx_4/xyzl/202101/t20210124_279695.html; http://ybj.gxzf.gov.cn/xwdt/bjdt/t7916501.shtml; https://www.stdaily.com/index/kejixinwen/202405/0dde2a7e253c45b78d9cad9472631cb1.shtml, and https://govt.chinadaily.com.cn/s/202405/31/WS6659a3b2498ed2d7b7eaef3f/centralized-procurement-of-artificial-joints-boosts-healthcare-accessibility-in-china.html (accessed on 5 November 2024)

[105] Wall Street Knowledge. (2021). *'Another product has been included in the centralized procurement! Lepu's price has been reduced by more than 60%, and it has won the bid. Will it be okay this time?'*, available at https://new.qq.com/rain/a/20210608A0BS9T00?web_channel=wap&openApp=false&suid=&media_id= (accessed on 30 October 2024)

a discount of approximately 40 % off the market price of 18,700 CNY per unit[106]. In 2020, the purchase volume of Lepu's DEBs in Shanghai was zero[107] and under a previous volume-based procurement contract in Guangdong, Lepu only provided seven DEBs[108].

(70) In 2019, MicroPort Scientific Corporation won the bid for its PTCA balloon dilatation catheter in the Jiangsu Province second round of volume-based procurement for three types of high-value medical consumables.[109] According to the article, the negotiations involved more than 300 models in three categories such as ophthalmic artificial crystals, blood vessels intervention ball sacs, orthopaedic artificial hip joints, for an annual purchase amount is about 1 billion CNY[110]. The average price reduction was 74,37 % (with a maximum of 81,05 %) for vascular intervention balloons; 47,20 % for orthopaedic artificial hip joints (with a maximum of 76,70 %) and 26,89 % (with a maximum of 38 %) for ophthalmic artificial crystals[111].

(71) In January 2024, Shandong Shinva Medical Instrument Co., Ltd. reported that it had won the bid for all products in the centralized procurement of medical consumables for all products in the centralized procurement of haemodialysis medical consumables in 22 provinces.[112]

(72) Finally, Jiangsu Yuwell Medical Equipment & Supply Co., Ltd. was among the winners in the 2021 volume-based procurement of two types of medical consumables: disposable abdominal puncture devices and disposable blood glucose test strips in Nanjing[113]. The negotiation resulted in an average reduction of 67,42 % for the two types of medical consumables (with the highest decrease of 91,23 %).

3. Consultations with the GOC

(73) The Commission held consultations with representatives of the Ministry of Finance, the Ministry of Commerce, the Ministry of Science and Technology, the Ministry of Industry and Information Technology, the National Healthcare Security Administration, the National Health Commission, and the National Medical Products Administration of the PRC.

---

[106] Id.
[107] Id.
[108] Id.
[109] Cailian. (2019), *'Jiangsu Province announced the results of the centralized procurement of three types of high-value medical consumables, with enterprises such as MicroPort and Aikang winning the bid'*, available at: https://m.jiemian.com/article/3557611.html (accessed on 30 October 2024).
[110] Id.
[111] Id.
[112] Jiemian News. (2024). Shinva: All products won the bid in the centralized volume-based procurement work of the inter-provincial alliance of medical consumables for hemodialysis in 22 provinces, available at: https://www.jiemian.com/article/10727110.html (accessed on 30 October 2024)
[113] CN-Healthcare. (2021). *'The maximum price reduction is 91.23%, and the results of consumables negotiations have been announced: Abbott, CR Care, Yuyue...'*, available at: https://www.cn-healthcare.com/articlewm/20210107/content-1178362.html (accessed on 30 October 2024)

(74) During these consultations, the Commission referred to the alleged measures and practices, as identified in the Notice of Initiation and during the investigation and asked specific questions about their application and implementation in the Chinese procurement market for medical devices. More specifically, the Commission asked for detailed information about the implementation, in this market, of the explicit preference for domestic products embedded in Article 10 of the GPL, and about the conditions for the authorisation of the procurement of imported medical devices, notably in accordance with the Administrative Measures and its various implementing acts[114]. The Commission also asked questions about the specific targets for the share of domestic goods in the procurement of medical devices resulting from the MIC 2025, the '*Made in China 2025 technology roadmap for key areas'*, and the *Notice on Issuing 'Guiding Audit Standards for Government Procurement of Imported Products'*. The Commission reviewed the various instruments by means of which the PRC supports the development of the Chinese industrial base in the sector of medical devices, including the various calls for the use of public procurement procedures to favour[115] and to foster the transfer of technology from foreign bidders to Chinese industries under the Administrative Measures*'*. Finally, the Commission asked questions about the functioning of the system of volume-based procurement and in particular, the establishment of the 'reference price' in such procedures.

(75) The GOC did not contest the existence of these measures and practices and did not deny that they create a preference in public procurement procedures for medical devices manufactured in the PRC and that they impose specific procedures for the procurement of imported medical devices. In this regard, the GOC admitted that, under its 'Buy China' policy, only domestic products must be procured unless they are not available in China. With respect to the targets imposed in Document 551, the GOC claimed that this document had been issued to counter the preference of many Chinese hospitals for imported products, which put domestic medical devices at a disadvantage. Although the GOC did not deny the existence of the above discriminatory measures and provisions in the Chinese legal framework, it claimed they were not implemented in practice in a discriminatory manner, in particular Articles 5 and 15 of the Administrative Measures, which impose technology transfer requirements, and Article 18, which provides for a mandatory clause on safeguarding national interests. However, the GOC could not provide a convincing explanation why such measures and provisions still exist in the Chinese legal framework and are mentioned in recent tender documents.

[114] Including the *'Notice of the General Office of the Ministry of Finance on Issues Concerning the Administration of Government Procurement of Imported Products'* and the provincial implementing acts referred to in Section 3.3.1 above)

[115] Such as the *'Notice on Deepening the Reform of the Medical and Health System'* or the *'Guiding Opinions on Expanding Investment in Strategic Emerging Industries and Cultivating Strengthened New Growth Points and Growth Poles'*

(76) The GOC stressed, instead, that, since the PRC had not taken any international commitments on public procurement, the alleged measures and practices were legitimate, and claimed that EU companies have *de facto* access to the Chinese procurement market for medical devices, as the PRC imports a significant number of medical devices (in particular high-end products) and companies owned by EU shareholders and established in the PRC ('foreign-invested companies') can participate without discrimination with respect to their "domestic products" (which need to be manufactured in the PRC).

(77) The GOC underlined in this respect that it is committed to eliminate any discriminatory measures against foreign-invested companies and pledged to define the notion of 'domestic product' so that the foreign ownership of the foreign-invested companies does not play an undue role in the appreciation of contracting authorities as to whether a procured good is domestic or not. However, it has not taken any corrective action nor specific commitments to this end.

(78) As for the system of volume-based procurement, the GOC explained that it had decided to organise this system for certain high-end medical consumables because their prices in the Chinese market were inflated above international prices, and that it selected the products covered based on the need for big volumes and the existence of strong competition with many large producers. It claimed that no domestic preference was applicable in this system (as price was the only criteria) and explained that 'reference prices' were based on historic market data, without providing further details. When asked how companies could offer such low prices and remain profitable, the GOC stated that it is up to companies to decide whether to participate under such conditions.

(79) At the end of the consultations, the Commission and the GOC explored possible solutions to the Union concerns set out in the Notice of Initiation and explained by the Commission. The GOC claimed that the future accession of the PRC to the Government Procurement Agreement ('GPA') could solve such concerns and stressed that it was not in a position to open the procurement market of the PRC unilaterally outside the framework of an international agreement on government procurement.

(80) On 30 August 2024, the GOC sent a Note Verbale to the Commission conveying a request to terminate the investigation and to negotiate instead a comprehensive agreement aimed to open the government procurement market of both sides bilaterally. The Commission replied by Note verbale of 7 October 2024 and explained the reasons why it had decided to continue the investigation. The Commission recalled that the objective of the investigation is not the negotiation of a comprehensive agreement on government procurement, but to achieve reciprocity and ensure a level playing field, which requires the elimination of the discriminatory barriers identified.