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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

{SWD(2025) 2 final}

I. INTRODUCTION

On 24 April 2024, the European Commission (the 'Commission') launched, on its own initiative, an investigation pursuant to Article 5(1) of Regulation (EU) 2022/1031[1] (the 'IPI Regulation') concerning measures and practices of the People's Republic of China ('PRC') resulting in a serious and recurrent impairment of access of Union economic operators, goods and services to the PRC's public procurement market for medical devices (hereinafter the 'alleged measures and practices'). To launch the investigation, it published a Notice of Initiation in the Official Journal of the European Union (the 'Notice of Initiation').[2]

In the Notice of Initiation, in accordance with Article 5(2) of the IPI Regulation, the Commission invited the Government of China ('GOC') to submit its views, provide relevant information and engage in consultations with the Commission to eliminate or remedy the alleged measures and practices. On the same day, the Commission also sent a Note Verbale to the GOC including a request for information in the form of a detailed questionnaire to be replied within 30 days. The GOC did not reply to this questionnaire but agreed, with a Note Verbale it sent on 27 May 2024, to engage in consultations with the Commission. The Commission held consultations with the GOC within the meaning of Article 5(2) of the IPI Regulation from 24 to 26 July 2024 in Beijing.

In the Notice of Initiation, the Commission also invited Member States and interested parties within the meaning of Article 2(1)(h) of the IPI Regulation to participate in the investigation and provide relevant information. The Commission has received input from several interested parties. Pursuant to Article 5(2) of the IPI Regulation, the Commission has regularly informed Member States on the progress of the investigation and consultations within the Trade Barriers Committee established by Article 7 of Regulation (EU) 2015/1843[3].

Pursuant to Article 5(3) of the IPI Regulation, the Commission must conclude the investigation and consultations within nine months after the date of their initiation. Article 5(4) of the IPI Regulation requires that, upon conclusion of the investigation and the consultations, the Commission shall make publicly available a report setting out the main findings of the investigation and a proposed course of action that it shall present to the European Parliament and to the Council.

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1 Regulation (EU) 2022/1031 of the European Parliament and of the Council of 23 June 2022 on the access of third-country economic operators, goods and services to the Union's public procurement and concession markets and procedures supporting negotiations on access of Union economic operators, goods and services to the public procurement and concession markets of third countries (International Procurement Instrument – IPI), OJ L 173, 30.6.2022, p. 9.

2 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), OJ C, 24.4.2024.

3 Regulation (EU) 2015/1843 of the European Parliament and of the Council of 6 October 2015 laying down Union procedures in the field of the common commercial policy in order to ensure the exercise of the Union's rights under international trade rules, in particular those established under the auspices of the World Trade Organisation, OJ L 272, 16.10.2015, p. 1.

II. SCOPE OF THE INVESTIGATION AND ALLEGED MEASURES AND PRACTICES

The Notice of Initiation contains an indicative list of the categories of medical devices affected by the alleged measures and practices in its annex.

In the Notice of Initiation, the Commission identified the following categories of alleged measures and practices: (i) measures and practices favouring the procurement of domestic medical devices; (ii) measures and practices restricting the procurement of imported goods, including medical devices and (iii) imposing conditions in the PRC's centralised procurement of medical devices leading to abnormally low bids that cannot be sustained by profit-oriented companies.

The scope of the investigation covers measures and practices in public procurement procedures relevant to all medical devices. 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.

The Commission considered the legal and factual framework existing in the PRC and the information available until November 2024.

More details with respect to the alleged measures and practices are provided in the accompanying Commission Staff Working Document ('SWD').

III. FINDINGS OF THE INVESTIGATION

The investigation confirmed the existence and application of the measures and practices 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.

1. The 'Buy China' policy

1.1. Policy measures encouraging the domestic medical devices industry

The Commission found that the medical devices industry in the PRC, in particular its high-end segment, is considered as strategic and encouraged through various policy tools, notably public procurement.

High-performance medical devices are one of the ten core industries identified in the '*Made in China 2025'* Strategy ('MIC 2025')[4] and the '*Made in China 2025 technology roadmap for key areas'*[5] ('MIC Roadmap'), which specifies goals for each industry identified in the MIC 2025, and 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.

The *'14th Five-Year Plan for the Medical Equipment Industry Development'*[6] (the '14th FYP'), encourages the development of high-end medical devices through public procurement[7] among various support tools, with an objective to replace imported products by domestic supply[8]. Furthermore, various policy and legal documents lay down instructions for the priority purchase of domestic products, such as the *'National Medium- and Long-Term Science and Technology Development Plan (2006-2020)'* [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[10], the *'Notice on Deepening the Reform of the Medical and Health System'* Guo Ban Fa [2015] No. 34[11], *'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[12] and *'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[13].

The Commission also found that the China Medical Equipment Association (the 'Association') produces regularly a *'Selection Catalogue of Excellent Domestic Medical*

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4 Notice of the State Council on Issuing the "Made in China (2025)" No.28 [2005] of the State Council: https://www.gov.cn/zhengce/content/2015-05/19/content_9784.htm

5 https://www.gov.cn/xinwen/2015-09/29/content_2940676.htm https://www.cae.cn/cae/html/files/2015-10/29/20151029105822561730637.pdf and http://www.qbj.gov.cn/qbjq/uploadfiles/ecyq/2019032810262811269.pdf

6 Notice of the ten departments 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: https://www.gov.cn/zhengce/zhengceku/2021-12/28/content_5664991.htm

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

8 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"*.

9 Outline of the National Medium- and Long-Term Science and Technology Development Plan (2006-2020) State Council No. 9 of 2006: https://www.gov.cn/gongbao/content/2006/content_240244.htm

10 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: https://www.gov.cn/gongbao/content/2006/content_240246.htm

11 *'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: https://www.gov.cn/zhengce/content/2015-05/09/content_9716.htm

12 https://www.gov.cn/zhengce/content/2016-03/11/content_5052267.htm

13 https://www.ndrc.gov.cn/xxgk/zcfb/tz/202009/t20200925_1239582.html

Equipment Products' (the 'Catalogue')[14] under the direction of the National Health Commission of the PRC[15] (the 'NHC'). The scope of selection is *"*[d]*omestic independent brand products"*. Several policy documents[16] 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 Government Procurement Law of China[17] ('GPL') as a key to promote the objective of strengthening China's medical device industry. The Commission also established that the Association is subject to the control, or at least strong influence, of the State and can therefore be considered as a quasi-governmental organization.

Section 2.1.1. of the accompanying SWD contains more details regarding the above-described policy measures.

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

The main piece of legislation is Article 10 of the GPL, which is implemented through other measures at central and provincial level. Article 10 of the GPL provides for a generally applicable preference for the procurement of domestic goods and services, including medical devices, that leads to the discrimination against imported goods. The *'Administrative Measures for the Procurement of Imported Goods'* (the 'Administrative Measures')[18], which are "*formulated* […] *in accordance with the GPL*", govern the procurement of imported goods. The Administrative Measures recall the principle laid down in Article 10 of the GPL that *"in case of government procurement, domestic products shall be purchased"* and provide for a specific and cumbersome approval procedure for the procurement of imported products when it is *"really necessary"*. The Administrative Measures also give priority to imported products that transfer technology to Chinese companies. Various provincial governments have introduced local measures implementing the Administrative Measures, some of them setting additional and/or more stringent requirements. In addition, as further explained in the Section 2.1.2. of the SWD, certain local governments have issued and regularly updated annual lists of imported medical devices, for which the approval procedure for procurement is simplified. The investigation indicates that the number of medical devices included in these lists has been progressively reduced.

Furthermore, the Commission established that the *'Notice on Issuing 'Guiding Audit Standards for Government Procurement of Imported Products' (2021 Edition)'* ('Document

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[14] 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.

[15] 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".

[16] See recital 14 of the SWD for more information.

[17] Order of the President of the People's Republic of China No.68 of 29 June 2002

[18] *'Circular of the Ministry of Finance on Issuing the Measures for the Administration of Government Procurement of Imported Products'* Caiku [2007] No. 119: https://www.gov.cn/zwgk/2008-01/15/content_858659.htm

551')[19], which lays a requirement on all local authorities to increase the procurement of domestic products for 178 categories of medical devices, is applied across the territory of the PRC. Public hospitals have committed to go even beyond the target shares of domestic products contained therein[20], which vary between 25 % and 100 % depending on the category, with a 100 % target for 137 categories.

Finally, Article 22 of 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[21] recalls the rules governing the procurement of imported medical devices[22], which are laid down in the Administrative Measures and its implementing measures.

Section 2.1.2. of the SWD provides a comprehensive overview of these legal measures.

1.3. The application of the measures and practices related to the 'Buy China' policy

To confirm the magnitude of the issues described above, the Commission investigated the actual procurement practices for medical devices prevalent in the PRC in several procurement portals[23]. 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, only 35 504 of these tenders contained, in an accessible form, information about eligibility criteria and other conditions of participation for prospective bidders (hereinafter 'the sample'). This shows that the Chinese procurement procedures suffer from a serious lack of transparency as the vast majority of published tenders do not contain essential documents and information in an accessible form. The assessment of the sample indicates clearly the systemic and recurrent nature of measures and practices entailing discrimination on several accounts: (a) restrictions of procurement of imported goods are applied by Chinese contracting authorities in all medical devices categories; (b) procurement restrictions are found in all Chinese provinces (except Tibet) and in over 300 cities across China, and (c), there is a prohibition of imported medical devices and several other forms of direct and indirect discrimination in 87 % of the tenders in the publicly available sample[24]. The Commission conducted an in-depth analysis of a second separate sample[25] focusing only on tenders with explicit prohibitions and discriminatory requirements, where it found explicit prohibitions of imported medical devices in 36 % of the tenders concerned in 2022, which

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[19] Notice on Issuing *"Guiding Audit Standards for Government Procurement of Imported Products"* (2021 Edition), Treasury Note [2021] No. 551: https://aimg8.dlssyht.cn/u/2074671/ueditor/file/1038/2074671/1629090344664695.pdf/https://www.cgwenjian.com/view/industry/20211011000018410 1?zt_id_from=54

[20] See the study by L.E.K. Consulting 'Hospital Priorities 2023 China Edition: Strategic Implications for Medtech Companies': https://www.lek.com/sites/default/files/PDFs/china-hospital-priorities-2023-medtech.pdf

[21] https://www.gov.cn/gongbao/content/2011/content_1960690.htm

[22] This provision states 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".*

[23] See footnote 91 in the SWD.

[24] See recitals (51) – (57) of the SWD.

[25] See recital 58 of the SWD.

increased 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.

With respect to the target share of domestic products set by Document 551, a study by L.E.K. Consulting *'Hospital Priorities 2023 China Edition: Strategic Implications for Medtech Companies'*[26] completed in August 2023 shows that public hospitals in the PRC have already largely implemented the targets laid down in Document 551 and are committed to further implement them, even beyond the products listed therein.

The Commission also found tenders in which medical devices listed in the Catalogue of the Association were awarded additional points during the bid evaluation process or where the technical specifications require that products are listed in that Catalogue.

2. Centralised volume-based procurement

2.1. Measures governing volume-based procurement

The Commission identified the applicable legal framework and the underlying principles governing centralised volume-based procurement. The accompanying SWD provides details in this respect.

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. To achieve lower prices, the entity organising the tender sets a maximum number of finalists, establishes a maximum reference (or ceiling) price[27] and maximum price margins for bid selection, as explained in recitals (63) to (66) of the SWD. This forces bidders to offer the lowest possible price, as the selection criteria impose a maximum deviation from the lowest bidding price, and in any case the price offered must be below the reference price. The parameters for the calculation of the reference price are not published. In subsequent volume-based tenders for the same medical devices, the reference price was set at even lower levels. 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. Therefore, in volume-based procurement, the level of the reference price and in particular, the price margins for acceptable bids are determinant to limit the competition among bidders.

Certain measures governing volume-based procurement specifically refer to the aim of supporting domestic products. In this respect, the *'Notice of the reform plan to manage high-value medical consumables'* Guo Ban Fa [2019] No. 37[28] has as a general objective, which applies also to the organisation of volume-based procurement of medical consumables, to *"support domestic high-value medical consumables with indigenous intellectual property rights to enhance their core competitiveness".* In addition, the Medical Insurance Letter

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[26] See footnote 21
[27] Called "highest effective declaration price".
[28] https://www.gov.cn/zhengce/content/2019-07/31/content_5417518.htm

[2022] No. 136 of the National Medical Security Administration[29] states that centralised volume-based procurement is *"objectively supporting domestic high-quality enterprises of the same quality but lower cost to win the competition"*.

2.2. The application of volume-based procurement

The Commission established that, at the time of the investigation, the PRC has organised national volume-based procurement procedures for five categories of high-end medical consumables[30] and several others at provincial level.[31]

These tenders resulted in a significant price decrease. For instance, the average price reduction in the volume-based procurement of artificial joints was 82 %[32], while the national volume-based procurement tender for coronary stents conducted in November 2020 led to a price decrease of more than 90 %.[33] The Commission also found that some of the largest Chinese manufacturers of medical devices, which have benefitted from financial support have won volume-based tenders that have resulted in significant price reductions as explained in recitals (68) to (72) of the SWD.

Section 2.3. of the accompanying SWD contains more details about the application of the measures and practices.

IV. CONSULTATIONS WITH THE GOC

The Commission discussed with the GOC all the alleged measures and practices and their application and implementation in the PRC's procurement market for medical devices. The GOC did not contest the existence of the alleged measures and practices, that they create a preference in public procurement contracts for medical devices manufactured in the PRC and impose specific procedures for the procurement of imported medical devices. However, it claimed, without providing convincing arguments or proof, that some of these measures are not implemented in practice. At the end of the consultations, the Commission and the GOC explored possible solutions. The GOC claimed that the future accession of the PRC to the Government Procurement Agreement ('GPA')[34] could solve the Union's concerns, while stressing that it would not open unilaterally its procurement market in relation to medical devices and proposing instead the negotiation of a comprehensive bilateral agreement

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

[30] coronary stents, artificial joints, intraocular lens and sports medicine medical consumables, orthopaedic spine consumables and cochlear implants and peripheral vascular stents.

[31] for various medical devices such as pacemakers, balloon dilatation catheters and trauma fixation products

[32] https://govt.chinadaily.com.cn/s/202405/31/WS6659a3b2498ed2d7b7eaef3f/centralized-procurement-of-artificial-joints-boosts-healthcare-accessibility-in-china.html

[33] 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

[34] https://www.wto.org/english/docs_e/legal_e/rev-gpr-94_01_e.pdf

between the European Union and the PRC on government procurement. On 30 August 2024, the PRC sent a Note Verbale conveying a request to terminate the investigation and to negotiate instead such bilateral agreement. The Commission replied by Note Verbale of 7 October 2024 explaining the reasons why it could not terminate the IPI investigation on these grounds[35]. Section 3 of the accompanying SWD contains further information regarding the consultations with the GOC.

V. ASSESSMENT OF THE MEASURES AND PRACTICES IDENTIFIED IN THE COURSE OF THE INVESTIGATION

The investigation has confirmed that the measures and practices described in Section III above and further explained in Section 2 of the SWD exist and that they are applied by procuring authorities and entities in the PRC. They are jointly referred here below as 'the measures and practices' unless a specific measure is individually referred to.

The analysis of the measures and practices under investigation shows that through such measures and practices, the PRC has put in place a multilayered overarching system of generally applicable preferences for the procurement of domestic medical devices that has led to a systematic discrimination against imported medical devices and foreign economic operators, implementing a comprehensive 'Buy China' policy.

The cornerstone of this overarching system is Article 10 of the GPL, which is at the core of the 'Buy China' policy implemented by the GOC. This provision creates a legally binding obligation for contracting entities to procure domestic medical devices instead of imported ones whenever both types of medical devices are in competition and the domestic medical devices constitute a reasonable alternative. The discriminatory nature of this general obligation is reinforced by the burdensome approval procedure for the procurement of imported goods, including medical devices, laid down in the Administrative Measures, which significantly constrains the ability of contracting entities to procure imported medical devices. The need to obtain, to this end, a specific approval by the local financial departments, based on the assessment by an expert group of the technical specifications and functional use of the imported goods at stake to ascertain that there are no domestic alternatives, is, by itself, a significant deterrent for contracting entities to procure imported goods. Indeed, they need to conduct an additional and cumbersome process of uncertain outcome on top of the regular organisation of the tender procedure. The restriction is further reinforced by the various provincial measures setting up additional approval procedures for the procurement of imported medical devices.

The Administrative Measures and the corresponding provincial measures significantly restrict the procurement of imported goods, in particular medical devices, and thus the access of Union economic operators offering imported medical devices, even where such medical

[35] 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.

devices are allowed to participate in procurement tenders, as they create a preference for those imported goods linked to the transfer of technology to domestic companies. This significantly impairs the participation of potential Union bidders who do not want to share their technology with possible competitors.

Regarding medical devices, the multilayered system of domestic preferences is further articulated, and reinforced, through two main sector-specific measures. The first measure is 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[36], which underlines the obligation to strictly perform the approval procedures for the procurement of imported medical devices in accordance with the relevant provisions of the State. The second measure is 'Document 551', which imposes very high targets for the procurement of domestic medical devices and calls for the full exclusion of imported medical devices in 137 categories. These targets create a strong deterrent for contracting authorities to procure imported medical devices even in the cases where such procurement is approved, as the more tenders are won by bidders offering imported medical devices the more difficult for the contracting authority to meet the relevant targets. While Document 551 has been issued in the form of *"guiding audit standards"*, the targets set therein are established by the GOC in clear terms, with no indication that they are not required to be attained by public hospitals, which ultimately depend for their funding and organisation on the State or sub-central levels of government. Furthermore, as explained in Section III. 1.3. above and in more details in recital (59) of the SWD, public hospitals have a strong commitment to reach and even go beyond these targets. Therefore, it can be concluded that the targets are not just a form of encouragement to fully autonomous contracting entities that could just decide to ignore them. They constitute, instead, a form of instruction to contracting entities to achieve specific results, and hence significantly restrict the ability of bidders offering imported medical devices to participate in public tenders.

In addition, the inclusion of high-performance medical devices within the list of 'encouraged' products identified in the MIC 2025 has resulted in the instruction to county hospitals to reach very high targets for the share of procurement of domestically produced high-end medical devices, 70 % by 2025 and 95 % by 2030 in the MIC Roadmap, which *de facto* would reduce to near zero the scope for access of imported products to a significant part of the Chinese public procurement market.

The overarching system of generally applicable preferences applies in the whole territory of the PRC. Indeed, the analysis of the sample of tenders referred to in Section III. 1.3 above and in Section 2.3.1. of the SWD shows that requirements restricting the procurement of imported medical devices are widespread in the Chinese procurement market and affect all medical devices categories.

[36] https://www.gov.cn/gongbao/content/2011/content_1960690.htm

Due to the significant lack of transparency of the public procurement market in the PRC, the Commission has been only able to gather a subset of publicly available tenders including, in an accessible format, the relevant tender requirements. However, the sample of tenders examined by the Commission is sufficiently representative to illustrate the extent to which contracting authorities have restricted the procurement of imported medical devices, as there is no reason to consider that the tender requirements in the untransparent tenders would be less restrictive than in those were such requirements are publicly accessible. Both, explicit and implicit prohibitions and discriminatory requirements are found in 87 % of the tenders examined, and the presence of explicit prohibitions has increased over the years, consistent with the declared objective of the GOC to substitute imported medical devices by domestic medical devices throughout the whole procurement market of the PRC.

The overarching system of generally applicable preferences for the procurement of domestic medical devices described above significantly impairs the access of Union operators and Union-made medical devices to the public procurement market of the PRC. Its systemic and permanent nature, resulting from the fact that the domestic preferences are embedded in laws of general application and in implementing measures and guidelines, either of general application or specific to medical devices, allows to conclude that this impairment is serious and recurrent within the meaning of Article 2.1(i) of the IPI Regulation.

The volume-based procurement of medical devices put in place by the GOC leads suppliers to offer extremely low bids to meet the selection criteria within the established price margins and potentially win a contract, which has resulted in significant price reductions as explained in Section III. 2.2. above and in Section 2.3.2. of the SWD. Despite the fact that a number of foreign companies may also be among the winners in the recently organised volume-based tenders, although in a much smaller proportion than Chinese companies, offering extremely low prices is not sustainable in the long run for profit-oriented companies that cannot rely on State support.

The restrictive effect of the conditions under which volume-based procurement is conducted may further be enhanced by the elaborated system of transfer of resources put in place by the PRC in favour of Chinese medical devices companies, as explained in Section 2.2. of the SWD.

The support specifically linked to volume-based procurement and granted to winners of relevant tenders with manufacturing and R&D activities in the PRC, reinforces the *de facto* discriminatory effect of volume-based procurement for foreign operators and imported medical devices, as it creates a strong incentive for domestic companies to win the tenders by offering abnormally low prices. More generally, the financial support received by domestic companies makes it possible for them to meet the selection criteria by offering very low prices. This results in price cuts of more than 90 % in certain volume-based tenders, leading to the *de facto* exclusion of companies that cannot receive financial support.

Consequently, the specific setup of volume-based procurement in the PRC puts imported medical devices and foreign economic operators at a significant disadvantage and leads to *de facto* discrimination and restriction or even exclusion of foreign operators importing medical devices, as well as imported medical devices competing in these volume-based tenders.

This finding has to be considered in the light of the fact that volume-based procurement is conducted for a variety of high-end consumables, covering a major proportion of the total consumption of the concerned consumables in the PRC, and that there is an intention to include further categories of medical devices in the future. The *de facto* induced limitations to participate in such procurement procedures therefore deprives bidders from almost all business opportunities in the product categories concerned by volume-based procurement. As a result, the practical setup of volume-based procurement of medical devices in the PRC significantly and recurrently impairs the access of Union operators and Union-made medical devices to the public procurement market of the PRC within the meaning of Article 2.1(i) of the IPI Regulation.

VI. CONCLUSION AND PROPOSED COURSE OF ACTION

On the basis of the investigation and consultations with the GOC pursuant to Article 5 of the IPI Regulation, the Commission has reached the conclusion that the measures and practices identified in the course of the investigation, put in place by the PRC with respect to the procurement of medical devices, exist and are applied across the entire territory of the PRC. They affect all categories of medical devices in a way that results in a serious and recurrent impairment of access of Union economic operators and Union-made medical devices to the public procurement market for medical devices in the PRC.

The PRC has not proposed any specific corrective action to remedy this serious and recurrent impairment of access.

On the basis of the above findings, the Commission will assess the conditions laid down in Article 6 of the IPI Regulation in view of adopting one or more IPI measures within the meaning of Article 2(1)(j) of the IPI Regulation.