C/2024/2973

24.4.2024

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)

The European Commission ('the Commission') has decided on its own initiative to initiate, pursuant to Article 5(1) of 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) [1] ('the IPI Regulation'), an investigation into alleged 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').

An indicative list of the categories of medical devices affected by these measures and practices is contained in the annex to this notice.

1. Description of the measures and practices of the PRC

The alleged measures and practices, implemented by the PRC at both central and local level, and applying to all entities procuring medical devices, including State-owned enterprises such as public hospitals, consist of:

a) 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'), 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 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 of 2021 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*' [2] 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 method.

b) Restricting the procurement of imported goods, including medical devices, particularly by means of the '*Administrative Measures for the Procurement of Imported Goods*' [3] 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

[1] OJ L 173, 30.6.2022, p. 9.

[2] '*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

[3] Circular of the Ministry of Finance on Issuing the Measures for the Administration of Government Procurement of Imported Products Caiku [2007] No. 119

who have transferred technology to Chinese enterprises.

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

The Commission reserves the right to investigate other relevant measures or practices of the 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 of which it learns in the course of the investigation.

2. **Commission's preliminary assessment of the measures and practices of the PRC**

The above import restrictive measures and practices put at a significant and systemic disadvantage Union economic operators, goods and services as they systematically favour the procurement of domestic products to the detriment of imported ones or make the participation of Union economic operators in procurement subject to discriminatory procedures. By preventing the procurement of imported medical devices unless, inter alia, the devices to be procured *'are not available within the territory of the People's Republic of China'*, such import restrictions and practices deprive Union producers of medical devices of all or significant business opportunities in the procurement market of the PRC. This negative impact is further reinforced by the setting of domestic procurement targets for contracting authorities. Moreover, even when access to such market is granted, it is often subject to conditions that deprive Union producers of a fair chance to participate, such as the obligation to give access to their technologies. Finally, the practices within the framework of the centralized procurement of medical devices lead bidders to submit abnormally low bids that cannot be sustained by profit-oriented companies ([4]). In addition, publicly available documents indicate that centralized procurement is used to support domestic companies ([5]). This practice creates unfair competition in the procurement market for medical devices in the PRC and results in a *de facto* exclusion of foreign suppliers.

The above measures and practices are either laid down in legislative, regulatory or administrative acts of general application or applied in practice on a regular basis, thus having a recurrent effect.

Therefore, the Commission's preliminary assessment is that the above measures and practices result in a *de jure* and *de facto* serious and recurrent impairment of access of Union economic operators, goods and services to the public procurement market for medical devices in the PRC.

3. **Procedure**

Based on the above preliminary assessment, the Commission hereby initiates an investigation pursuant to Article 5(1) of the IPI Regulation.

The investigation will determine whether the alleged measures and practices in the PRC exist and result in a serious and recurrent impairment of access of Union economic operators, goods and services to the public procurement market for medical devices in the PRC.

In accordance with Article 5(2) of the IPI Regulation, the Government of China ('GOC') is invited to submit its views and to provide relevant information with respect to the alleged measures and practices. The GOC is also invited to enter into consultations with the Commission in order to eliminate or remedy the alleged measures and practices.

([4]) As an example, in the case of coronary stents and artificial knee joints, the centralized procurement led to an average price reduction of 93 % and 82 % respectively.

([5]) Medical Insurance Letter [2022] No. 136, 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 (accessed on 18 March 2024), Point 2 *'On increasing support for domestic medical devices'* clearly mentions that centralised volume-based procurement is *'objectively supporting domestic high-quality enterprises of the same quality but lower cost to win the competition'*. Point 3 of the document sets as an objective to *'provide for the development of domestic high-quality enterprises'*. According to this document, in the coronary stent centralised procurement, 6 of the 8 selected companies were domestic-funded companies, and in the artificial knee joins centralised procurement 30 out of 44 were domestic-funded.

Member States and interested parties within the meaning of Article 2(1)(h) of the IPI Regulation are invited to participate in the investigation and provide relevant information, within 30 calendar days from the date of this Notice, as to the existence and effects of the measures and practices of the PRC as well as to the Union interest in the adoption of IPI measures. For this purpose, they are invited to make use of the online guidance document for submission of information included in the Access to Markets portal available at:

https://trade.ec.europa.eu/access-to-markets/en/form-assets/IPI_interested_parties_guidance.pdf

4. **Instructions for making written submissions and correspondence**

All written submissions, including the information requested in this Notice, and correspondence provided by the PRC, Member States and interested parties for which confidential treatment is requested shall be labelled 'Sensitive' ([6]). Parties submitting information in the course of this investigation are invited to provide a non-confidential summary of such information that could be used by the Commission during the investigation.

Information submitted to the Commission for the purpose of IPI investigations shall be free from copyrights. Interested parties, before submitting to the Commission information and/or data, which is subject to third party copyrights, must request specific permission to the copyright holder explicitly allowing the Commission to use the information and data for the purpose of this IPI investigation.

All submissions and requests should be made by email to
TRADE-EU-INTERNATIONAL-PROCUREMENT-INSTRUMENT@ec.europa.eu

Commission address for correspondence:
European Commission
Directorate-General for Trade
Directorate E/Unit E4
Office: CHAR 05/052
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

5. **Schedule of the investigation**

Pursuant to Article 5(3) of the IPI Regulation, the investigation shall be concluded within nine months from the date of the publication of this Notice. In justified cases, the Commission may extend this period by five months by publishing a notice in the *Official Journal of the European Union*.

In accordance with Article 5(2) of the IPI Regulation, the Commission shall regularly inform Member States on the progress of the investigation and consultations within the Trade Barriers Committee established by Article 7 of Regulation (EU) 2015/1843 ([7]).

In accordance with Article 5(4) of the IPI Regulation, upon conclusion of the investigation and consultations, the Commission shall make publicly available a report setting out the main findings of the investigation and proposed course of action. The Commission shall present that report to the European Parliament and to the Council.

6. **Extension to time limits specified in this Notice**

Extensions to time limits provided for in this Notice should only be requested in exceptional circumstances and will only be granted if duly justified upon good cause being showed.

([6]) A 'Sensitive' document is a document protected pursuant to Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council (OJ L 145, 31.5.2001, p. 43).

([7]) 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 Organization (OJ L 272, 16.10.2015, p. 1).

7. **Processing of personal data**

Any personal data collected in this investigation will be treated in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council ([8]).

([8]) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

ANNEX

Product category	HS code ([1])
Instruments and appliances used in medical, surgical, dental or veterinary sciences,	901811, 901812, 901813, 901814, 901819, 901820, 901831, 901832, 901839, 901841, 901849, 901850 and 901890
Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus	901910 and 901920
Orthopaedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability	902110, 902121, 902129, 902131, 902139, 902140, 902150 and 902190
Apparatus based on the use of X-rays or of alpha, beta, gamma or other ionising radiations, whether or not for medical, surgical, dental or veterinary uses, including radiography or radiotherapy apparatus, X-ray tubes and other X-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like	902212, 902213, 902214, 902219, 902221, 902229, 902230 and 902290
Medical, surgical, dental or veterinary furniture	940210 and 940290
Medical, surgical or laboratory sterilisers	841920
Carriages for disabled persons, whether or not motorised or otherwise mechanically propelled	871310 and 871390
Wadding, gauze, bandages and similar articles (for example, dressings, adhesive plasters, poultices), impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.	300510 and 300590
Consumables and materials for medical use	300630, 300640, 300650, 300691, 370110, 370210 and 401512

([1]) HS Nomenclature 2022 edition.