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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

pursuant to Article 13 of Regulation (EU) 2022/1031 on the application of this Regulation and on the progress made in international negotiations, regarding access for Union economic operators to the public procurement or concession markets of third countries, undertaken under this Regulation

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') was published in the Official Journal of the European Union on 30 June 2022 and entered into force on 29 August 2022.

Article 13 of the IPI Regulation requires the European Commission ('the Commission') to submit, by 30 August 2025 and at least every two years thereafter, a report to the European Parliament and to the Council on the application of this Regulation and on the progress made in international negotiations, regarding access for Union economic operators to the public procurement or concession markets of third countries, undertaken under this Regulation. This report is to be made public by the Commission.

The IPI Regulation also mandates the Commission to establish certain tools to facilitate the application of the Regulation. The Commission has complied with these requirements and Section 1 outlines the corresponding measures taken. Since the entry into force of the IPI Regulation, the Commission has initiated and concluded one IPI investigation concerning measures and practices of the People's Republic of China ('the PRC') in the public procurement market for medical devices.[2] This first IPI investigation is presented in Section 2. Finally, Section 3 below provides the Commission's conclusions based on its experience with the application of the IPI Regulation up to the date of this report.

1. Tools to facilitate the application of the IPI Regulation

The Commission has made available to all relevant stakeholders a number of tools to facilitate the application of the IPI Regulation, in the form of operational guidelines, guidance, and two online tools: a complaint tool aimed for parties potentially affected by procurement restrictions abroad, and an explanatory tool aimed to facilitate the implementation of IPI measures by Union contracting authorities.

1.1. Commission guidelines to facilitate the application of the IPI Regulation by contracting authorities and contracting entities, and by economic operators

Article 12 of the IPI Regulation requires the Commission to issue operational guidelines to facilitate the application of the Regulation by contracting authorities and contracting entities, and by economic operators, within six months from its entry into force. The Commission has complied with this requirement by publishing such guidelines on 21 February 2023 ('the Guidelines').[3]

The Guidelines provide guidance to contracting authorities and contracting entities in determining the origin of the economic operators, goods and services. For economic operators, the criterion is the place of constitution, and the Guidelines provide an explanation of the notion

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1 OJ L 173, 30.6.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/1031/oj.

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/2024/2343), OJ C, C/2024/2973, 24.4.2024, ELI: http://data.europa.eu/eli/C/2024/2973/ojhttp://data.europa.eu/eli/C/2024/2973/oj.

3 Communication from the Commission 'Guidelines to facilitate the application of the IPI Regulation by contracting authorities and contracting entities and by economic operators' (2023/C 64/04), OJ C 64, p. 7, 21.2.2023, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023XC0221(02).

of 'substantial business operation', introduced to prevent circumvention of the IPI Regulation through the use of shell companies. In the case of goods, the origin is established in accordance with the non-preferential rules of origin under the Union Custom Code.[4] As for services, the origin is determined by that of the services supplier.

Finally, the Guidelines clarify the rules for the application of IPI measures by contracting authorities and contracting entities, including valuation rules to determine if the value of the contract is below or above the thresholds for the application of IPI measure(s) under Article 6 of the IPI Regulation. They set transparency requirements in the public procurement procedures to apply IPI measures (score adjustment measures and exclusions) and explain the rules regarding the application of IPI measures to specific contracts such as framework contracts.

1.2. The Online Complaint Tool

Article 5(1), second subparagraph, of the IPI Regulation requires the Commission to make an online tool available on its website for Union interested parties and Member States to formally submit a substantiated complaint, which can lead the Commission to initiate an investigation into an alleged third-country measure or practice. The Commission has complied with this obligation by making available an online complaint tool ('OCT').[5] The OCT contains mandatory fields such as the identity of the complainant, information about the complaint, factual description of the third-country measure and/or practice and optional fields (e.g. economic or systemic impact of the measure, bidding experience and actions already undertaken or planned). The Commission has introduced robust safeguards to ensure a very high standard of confidentiality and anonymity in the handling of complaints. To date, the Commission has not received any substantiated complaint via this dedicated OCT. At the same time, the Commission has received a number of informal complaints about public procurement barriers in third-countries via other channels.

1.3. Guidance for interested parties to provide information under Article 5(1) of the IPI Regulation

According to Article 5(1) of the IPI Regulation, the notice of initiation of and IPI investigation shall invite interested parties and Member States to provide relevant information to the Commission within a specified period of time. In order to inform interested parties about how to make themselves known, and to structure the collection of information from interested parties and Member States, the Commission has published a guidance for interested parties to provide information.[6]

1.4. The "Procurement4Buyers" online tool

Albeit not required by the IPI Regulation, the Commission has made publicly available on its website a procurement tool that, *inter alia*, informs contracting authorities and contracting entities when they must restrict the participation of foreign bidders in accordance with IPI measures. In order to quickly and reliably verify which third-country bidders have legally guaranteed access to bid for an intended procurement, procuring authorities and procuring

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4 Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

5 https://trade.ec.europa.eu/access-to-markets/en/contact-form?type=COMPL_IPI.

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

entities can use the "Procurement4Buyers" tool[7] that has been made available on DG Trade's "Acces2Markets" website. It suffices to indicate the identity of the procuring entity, the subject matter and estimated value of the intended procurement (CPV code[8]) and, where required, answer some follow-up questions. The tool will then provide the user with a positive list of countries whose bidders are entitled to participate in the procurement, as well as a negative list of countries whose companies are excluded from bidding. The latter list will reflect the outcomes of IPI decision making procedures.[9]

2. The IPI investigation concerning measures and practices of the PRC in the public procurement market for medical devices

On 24 April 2024, the Commission launched, on its own initiative, an investigation pursuant to Article 5(1) of the IPI Regulation concerning measures and 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. In accordance with Article 5(2) of the IPI Regulation, consultations with the PRC took place from 24 to 26 July 2024 in Beijing. The consultations did not lead to a satisfactory resolution of the procurement restrictions identified during the investigation.

On 14 January 2025, upon conclusion of its investigation and the consultations with the PRC, the Commission made publicly available a report pursuant to Article 5(4) of the IPI Regulation containing the findings of its investigation and a proposed course of action[10] ('the investigation report'). The Commission presented the investigation report to the European Parliament and to the Council, pursuant to Article 5(4) of the IPI Regulation, on 29 and 30 January 2025, respectively.

This investigation was particularly challenging due to the opaque nature of the Chinese public procurement market. Discrimination against foreign suppliers does not stem solely from legal provisions, but also from a plethora of administrative measures, internal guidelines, and instructions issued at various levels of government. A major difficulty was the collection of a large sample of procurement contracts from the PRC in a format that allowed a meaningful assessment of the existence of restrictive measures affecting Union companies in the accompanying documentation and tender conditions. These obstacles required the deployment of very substantive resources. Through extensive analytical effort and cooperation with stakeholders, the Commission was ultimately able to overcome these challenges and build a detailed picture of the systemic barriers in place.

In the investigation report, the Commission concluded that the PRC has established a comprehensive system that systematically favours domestic medical devices over foreign ones

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7 https://trade.ec.europa.eu/access-to-markets/en/contact-form?type=COMPL_IPI.

8 Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV), as amended (OJ L 340 16.12.2002, p. 1; ELI: http://data.europa.eu/eli/reg/2002/2195/2022-07-10http://data.europa.eu/eli/reg/2002/2195/2022-07-10).

9 https://webgate.ec.europa.eu/procurementbuyers/#/procumementlocation.

10 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 PRC in the public procurement market for medical devices, COM(2025) 5 and Commission Staff Working Document Factual findings of the IPI investigation on the procurement market for medical devices in the PRC 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 PRC in the public procurement market for medical devices, SWD(2025) 2 ('the SWD').

through legally binding provisions that require public entities to prefer domestic products whenever a local alternative is available, reinforced by burdensome approval procedures for imported goods and sector-specific measures and target quotas for hospitals to acquire domestic products. This comprehensive discriminatory system applies to all categories of medical devices and in the entire territory of the PRC, irrespective of the value of the procurement contracts concerned. In addition, the Commission found that the organisation of volume-based procurement in the PRC incentivizes suppliers to offer extremely low prices to win large contracts and *de facto* excludes profit-oriented companies that do not receive State subsidies. The Commission found evidence of discriminatory and exclusionary practices in 87% of the procurement contracts it managed to examine. The Commission concluded that these measures and practices result 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. Therefore, they constitute third-country measures or practices within the meaning of Article 2(1), point (i) of the IPI Regulation. Regarding the outcome of the consultations, the investigation report mentions that the Government of China ('GOC') claimed it would not open unilaterally its procurement market in relation to medical devices and did not propose specific corrective actions to remedy this serious and recurrent impairment of access.

On that basis, the Commission assessed the conditions laid down in Article 6 of the IPI Regulation in view of adopting an IPI measure as defined in Article 2(1), point (j) of the IPI Regulation. The Commission assessment focused on (i) the proportionality and adequacy of a possible IPI measure with regard to the identified measures and practices; (ii) the availability of alternative sources of supply; and (iii) the Union interest (the economic interest of the Union producers; the possible impact on Union contracting authorities and contracting entities, and the overall effects of the IPI measure on the Union economy).

Following this assessment, the Commission envisaged to impose an IPI measure in the form of exclusion of tenders submitted by all economic operators originating in the PRC for all public procurement procedures in the Union having as subject-matter the procurement of medical devices falling under the Common Procurement Vocabulary ('CPV codes 33100000-1 to 33199000-1 as defined in Regulation (EC) No 2195/2002[11]) and with an estimated value equal to or above EUR 5 000 000 net of VAT. This is the most comprehensive measure that the Union can impose in the medical devices sector under the framework of the IPI Regulation, which does not allow measures that would apply to procurement procedures with a lower estimated value. However, its scope remains narrower than that of the discriminatory measures and practices identified in the PRC. While the Chinese system applies broadly to all public procurement contracts, regardless of the value, the IPI measure only targets contracts with an estimated value above 5 million euro. Moreover, the IPI measure allows successful bidders to source up to 50% of the medical devices used in fulfilling contracts from the PRC, thereby still enabling a substantial presence of Chinese-origin medical devices in the Union procurement markets. These limitations are a direct consequence of the thresholds and conditions embedded in the IPI Regulation itself.

On 19 June 2025, the Commission adopted the IPI measure by means of a Commission Implementing Regulation (EU) 2025/1197 of 19 June 2025[12] in accordance with the

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[11] Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV), as amended (OJ L 340 16.12.2002, p. 1; ELI: http://data.europa.eu/eli/reg/2002/2195/2022-07-10http://data.europa.eu/eli/reg/2002/2195/2022-07-10).

[12] Commission Implementing Regulation (EU) 2025/1197 of 19 June 2025 imposing an International Procurement Instrument measure restricting the access of economic operators and medical devices originating in the PRC to the European Union public procurement market for medical devices pursuant to

examination procedure referred to in Article 11(2) of the IPI Regulation in the Trade Barriers Committee. The measure entered into force ten days following its publication in the Official Journal for a duration of 5 years. On 6 July 2025, the GOC adopted retaliatory measures regarding EU companies, goods and services.

Despite the efforts of the Commission to achieve improved market access for Union economic operators and Union-made medical devices to the PRC's public procurement market for medical devices, and numerous exchanges with the GOC, this IPI process has not yet resulted in the removal by the GOC of the identified measures and practices. The consultations with the GOC were however useful to better understand the restrictive measures and practices in the PRC and to identify the measures needed for their entire removal. The Commission remains committed to continued engagement with the GOC, which can continue until the identified measures and practices are removed. In this respect, Article 6(10) of the IPI Regulation provides for the possibility for the Commission to suspend or withdraw an IPI measure if the third country concerned takes satisfactory corrective actions to eliminate or remedy the impairment of access for Union economic operators, goods or services to public procurement or concession markets of that third country, thereby improving such access. The Commission will ensure close monitoring of the application of the IPI measure by EU contracting authorities and contracting entities including the exceptions to the application of the IPI measure. In this respect, the Commission reserves its faculty to request information from Member States in accordance with Article 13(1) of the IPI Regulation.

3. Insights drawn from the application of the IPI Regulation

During the period under review, the Commission has gathered information on alleged restrictive measures and practices in third countries using its own investigative resources and through contacts with the Union industry representatives in different sectors. The identified restrictions typically range from the exclusion of Union economic operators and/or goods and/or services from the procurement procedures to localisation requirements and domestic preferences such as offsets, often resulting in the *de facto* exclusion.

The Commission has gathered information which suggests that some of these measures and practices might strongly impair the Union industry access to third-country public procurement markets and result in lost opportunities for Union economic operators.

Despite the indication of this significant economic prejudice, the Union industry has not made use of the possibility to submit a formal IPI complaint in accordance with Article 5(1) of the IPI Regulation regarding any of the measures or practices identified. The only IPI investigation during the reporting period was thus launched *ex-officio*. The Commission considers that multiple factors may explain the absence of formal IPI complaints.

First, in public procurement markets, active economic operators (bidders) often have a strong dependency vis-à-vis the buyer (the public authority). Although the Commission has put in place a strict confidentiality policy based on the highest standards for the protection of confidential information in handling complaints, economic operators across different sectors and active in different third country markets report a fear of suffering targeted retaliation and adverse treatment from the third country concerned in case of submitting a formal complaint.

Regulation (EU) 2022/1031 of the European Parliament and of the Council. http://data.europa.eu/eli/reg_impl/2025/1197/oj.

Second, EU companies currently active in third countries procurement markets have, on some occasions, limited interest in closing the Union market to obtain leverage and engage in discussions with the country concerned. The assessment of the general interest when deciding on the initiation of an investigation needs to be well calibrated, taking into account the economic interest of all Union companies.

To support the effective use of the IPI Regulation, the Commission has developed tools and guidance to facilitate its application by stakeholders across all sectors, as appropriate.

The investigation concerning measures and practices of the PRC in the public procurement market for medical devices was based on solid evidence. It has nonetheless highlighted certain gaps with regard to the data available regarding international public procurement flows. These shortcomings concern the difficulty in accessing the public procurement contract data needed to assess the participation of Union bidders in the public procurement of third countries, as well as the impact of existing third-country procurement barriers against Union bidders. There are also certain data gaps in the Union procurement market that render the assessment of impact of potential IPI measure(s) in the Union rather difficult. For instance, the current data on public procurement contracts available in the Tender Electronic Daily ('TED') indicates the origin of the successful bidder but does not provide information regarding the origin of the goods and services procured. There is also limited information about the subcontracting to third-country operators and the ultimate ownership of successful bidders. Enriching the TED database with such information, in particular the origin of the goods and services procured, would facilitate both the conduct of IPI investigations and the implementation and ex-post monitoring of IPI measures.

4. Conclusions

In line with the legal requirements contained in the IPI Regulation, the Commission has put in place the tools necessary to facilitate the application of the IPI Regulation by economic operators and contracting authorities and entities. The report on the application of the IPI Regulation is also based on the Commission's experience of the only IPI investigation so far, concerning measures and practices of the PRC in the public procurement market for medical devices.

Regarding the longer-term outcome of this first investigation and the first IPI measures, it is premature to draw conclusions as to the extent to which the instrument has met the objective to open public procurement market in third countries. IPI measures serves as a leverage for the Union to obtain such opening. Indeed, although a satisfactory solution has not been found during the consultation process with the GOC, the Commission remains open for engagement even after the imposition of the IPI measure, which could be suspended or withdrawn if the identified measures and practices are removed by the PRC.

Finally, it is important to note that the Commission gathers extensive information on procurement barriers in third countries, but the decision to launch an investigation requires careful consideration, due to the inherent difficulties in navigating foreign procurement systems. These challenges include interpreting complex legal frameworks, identifying discriminatory practices that may not result from legal provisions but from administrative measures and practices, and understanding how such systems apply in practice. This often involves reviewing a large volume of procurement contracts, which are frequently not publicly available, or lack the necessary documentation for proper assessment. Close cooperation with industry on the ground is therefore essential. Maintaining open channels of communication,

and ensuring full confidentiality of exchanges, is critical, something the Commission has already secured and continues to prioritise.