Official Journal
of the European Union

EN
L series

2025/1197

20.6.2025

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 People's Republic of China to the European Union public procurement market for medical devices pursuant to Regulation (EU) 2022/1031 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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'), and in particular Article 6(1) and (6), letter b), thereof,

Whereas:

1. PROCEDURE

1.1. IPI investigation and consultations

(1) On 24 April 2024, the European Commission ('the Commission') initiated, on its own initiative, an investigation pursuant to Article 5(1) of the IPI Regulation concerning measures and practices of the People's Republic of China ('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. To this end, the Commission published a Notice of Initiation in the *Official Journal of the European Union* ([2]) ('the Notice of Initiation').

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

(3) 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 to eliminate or remedy the measures and practices included in the Notice of Initiation. The Commission also sent to the GOC a request for information in the form of a detailed questionnaire. The GOC did not reply to this questionnaire but engaged in consultations with the Commission, within the meaning of Article 5(2) of the IPI Regulation, which took place from 24 to 26 July 2024 in Beijing.

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

1.2. **Investigation report**

(4) 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 ([3]) ('the investigation report').

(5) In the investigation report, the Commission concluded that the measures and practices identified during the investigation ([4]) ('the identified measures and practices') exist, are applied across the entire territory of the PRC, and 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. Therefore, they constitute third-country measures or practices within the meaning of Article 2(1), point (i) of the IPI Regulation. The Commission also noted that the GOC did not propose any specific corrective action to remedy this serious and recurrent impairment of access.

(6) On that basis, the Commission proposed to assess 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.

(7) 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.

1.3. **Subsequent procedure**

1.3.1. *Public consultation on a possible IPI measure*

(8) On 19 February 2025, the Commission published a notice of public consultation ([5]), in which it sought the views of entities that may be potentially affected by a possible IPI measure pursuant to Article 6 of the IPI Regulation restricting the access of economic operators and medical devices originating in the PRC to the Union's public procurement market for medical devices ('the public consultation'). The Commission received submissions from several entities. Certain submissions related to potential supply issues concerning certain medical devices and budgetary implications for contracting authorities and contracting entities. Other submissions concerned the potential impact of the measures on economic operators manufacturing medical devices in the PRC, the determination of the origin of goods and economic operators as well as the determination of the value of the tenders. Certain entities requested clarification on how the 50 % thresholds referred to in Article 8(1) of the IPI Regulation would be established and the necessary evidence the concerned economic operators would need to provide. The Commission duly took into account the submissions received in its assessment.

1.3.2. *Information to Member States*

(9) As required by 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 of the European Parliament and of the Council ([6]).

([3]) 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 and 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 (SWD (2025) 2) ('the SWD').

([4]) See Section II of the investigation report and Sections 1 and 2 of the SWD (in particular recitals 1 to 49).

([5]) Public consultation in relation to possible measures restricting the access of economic operators and medical devices originating in the People's Republic of China to the EU public procurement market for medical devices pursuant to Article 6 of the International Procurement Instrument (OJ C, C/2025/1259, 19.2.2025, ELI: http://data.europa.eu/eli/C/2025/1259/oj).

([6]) 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, ELI: http://data.europa.eu/eli/reg/2015/1843/oj).

(10) Following the publication of the investigation report, the Trade Barriers Committee has also been updated on the assessment of the conditions laid down in Article 6 of the IPI Regulation in view of the possible adoption of an IPI measure as defined in Article 2(1), point (j) of the IPI Regulation.

(11) In the framework of the assessment of the condition laid down in Article 6(3), point (b) of the IPI Regulation about the 'availability of alternative sources of supply for the goods […] concerned, in order to avoid or minimise a significant negative impact on contracting authorities and contracting entities', the Commission consulted Member States in the Trade Barriers Committee to ascertain that there are no dependencies of Members States on medical devices originating in the PRC.

2. DETERMINATION OF THE IPI MEASURE

(12) In accordance with Article 6(1) of the IPI Regulation, where the Commission finds that a third-country measure or practice, within the meaning of Article 2(1), point (i) exists, it is to, if it considers it to be in the interest of the Union, adopt an IPI measure by means of an implementing act. Article 6(2) of the IPI Regulation specifies that an IPI measure is not to be adopted where the Commission concludes that it is not in the Union's interest to adopt such a measure.

(13) Pursuant to Article 6(3) of the IPI Regulation, an IPI measure is to be determined in light of available information and on the basis of two criteria: (i) its proportionality with regard to the third-country measure or practice; and (ii) the availability of alternative sources of supply for the goods and services concerned, in order to avoid or minimise a significant negative impact on contracting authorities and contracting entities. In conformity with Article 6(8) of the IPI Regulation, the Commission is to specify the scope of application of the IPI measure, including the sectors or categories of goods, the specific categories of economic operators, as well as of contracting authorities or contracting entities and the specific thresholds to which the IPI measure applies and, where appropriate, the percentage values of a score adjustment applicable.

(14) Pursuant to Article 6(6) of the IPI Regulation, the Commission may decide, within the scope of the IPI measure, to restrict the access of economic operators, goods or services originating in a third country to public procurement procedures in the Union by requiring contracting authorities or contracting entities to: either impose a score adjustment on tenders submitted by economic operators originating in that third country; or exclude tenders submitted by such economic operators. In this regard, pursuant to Article 6(9) of the IPI Regulation, when determining the IPI measure based on these two options, the Commission is to opt for the kind of measure that would be proportionate and most effectively remedy the level of impairment of access for Union economic operators, goods or services to the third-country public procurement or concession markets.

(15) In view of the above, it is necessary, first, to identify an IPI measure the scope of which is proportionate to the identified measures and practices, and to select the appropriate form of measure, from the two available options set out in Article 6(6) of the IPI Regulation, that would be proportionate and most effectively remedy the level of impairment of access created by the identified measures and practices; second, to assess the existence of alternative sources of supply should such IPI measure be imposed; and third, to evaluate whether the imposition of that IPI measure would be in the Union interest.

2.1. **Proportionality and adequacy of a possible IPI measure with regard to the identified measures and practices**

2.1.1. *The identified measures and practices*

(16) In the investigation report, the Commission presented two essential findings regarding the identified measures and practices.

(17) First, the Commission found that, through such measures and practices, the GOC has put in place an overarching system of generally applicable preferences for the procurement of domestic medical devices which significantly impairs the access of Union operators and Union-made medical devices to the public procurement market of the

PRC ([7]). The central feature of this system is a legally binding obligation imposed on contracting entities to procure domestic medical devices whenever they are in competition with imported ones and constitute a reasonable alternative. The discriminatory nature of this general obligation is strengthened by burdensome approval procedures ([8]) for the procurement of imported medical devices, which significantly constrain the ability of contracting entities to procure imported medical devices. Furthermore, within this framework, preference is given to imported medical devices that are associated with the transfer of technology to domestic companies ([9]). The system is further reinforced by sector specific measures ([10]), which are set in the form of instructions by the GOC to public hospitals to achieve specific domestic procurement targets for several categories of medical devices calling for the full exclusion of imported medical devices in 137 categories. Finally, high-performance medical devices are identified in the Made in China 2025 Strategy ([11]), resulting in the instruction to county hospitals to reach very high targets for the share of procurement of domestically produced high-end medical devices, i.e. 70 % by 2025 and 95 % by 2030, which would de facto reduce to near zero the scope for access of imported products to a significant part of the Chinese public procurement market.

(18) The Commission has proved that this overarching system of generally applicable preferences for the procurement of domestic medical devices applies in the whole territory of the PRC and affects all medical devices categories.

(19) The Commission has established, through the analysis of a sufficiently representative sample of public procurement procedures in the PRC ([12]), that 87 % of the public tenders for medical devices contain explicit and/or implicit prohibitions to procure imported medical devices or discriminatory requirements affecting such procurement ([13]). The examination of those tenders showed that the prohibitions and discriminations apply irrespective of the value of the contract. As established in the staff working document accompanying the investigation report, the fact that the purchase of imported medical devices may be allowed in a tender procedure does not necessarily mean that imported medical devices are not subject to discrimination, for instance through technology transfer requirements ([14]). Furthermore, even in the cases where the procurement of imported medical devices is authorised, the sectorial targets referred to in recital 17 for domestic procurement create a significant advantage for those suppliers and medical devices originating in the PRC. Therefore, the Commission has established that the overarching system of generally applicable preferences for the procurement of domestic medical devices in the PRC, which consists in laws and implementing measures of general application, affects the entire public procurement

([7]) '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' (see Section V of the investigation report for further details).

([8]) 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 for the procurement of imported goods. 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 (see Section 2.1.2 of the SWD, recitals 19 to 27 for further details).

([9]) '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' (see recital 20 of the SWD).

([10]) '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' (see recital 28 of the SWD).

([11]) 'The "Made in China 2025 technology roadmap for key areas" (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' (see recital 6 of the SWD).

([12]) The sample is composed of the 35 504 tenders that contained in a publicly available format the minimum documents that allow to determine the eligibility criteria and other conditions of participation for prospective bidders and could thus be usefully examined for the purpose of the investigation (see Section 2.3, recital 51 of the SWD).

([13]) See Section V of the investigation report, p. 10 and Section 2.3.1, recital 54 of the SWD.

([14]) '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"' (see Section 2.3, recital 55 of the SWD).

market for medical devices in the PRC irrespective of the value of the procurement contract. Thus the Commission concluded in its investigation report 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.

(20) Second, the Commission found that the volume-based procurement of medical devices as implemented by the GOC also significantly and recurrently impairs the access of Union operators and Union-made medical devices to the public procurement market of the PRC ([15]). Indeed, the set-up of this volume-based procurement leads suppliers to submit extremely low bids to meet the selection criteria and win contracts, resulting in significant price reductions, which, in the long run, are unsustainable for profit-oriented companies that cannot rely on State support. The restrictive effect of this volume-based procurement system may be further enhanced by State support to producers with manufacturing and R & D activities in the PRC, particularly when this support is specifically linked to winning volume-based procurement tenders. The investigation report established that 'the specific set-up 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' ([16]) and concluded that 'the practical set-up 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' ([17]).

2.1.2. *Proportionality of a possible IPI measure*

(21) The overarching system of generally applicable preferences for the procurement of domestic medical devices in the PRC affects the totality of medical devices originating in the Union without any threshold and irrespective of whether they are offered by Union bidders, domestic bidders or other foreign bidders. In addition, this system contains burdensome approval procedures for the procurement of imported medical devices and the imposition of sector-specific targets for the procurement of medical devices originating in the PRC. As explained in recitals 17 to 19 above, the Commission concluded in its investigation report that the implementation of this system has resulted 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. Indeed, the Commission has established that 87 % of the public tenders for medical devices contain explicit and/or implicit prohibitions to procure imported medical devices or discriminatory requirements affecting such procurement ([18]), thus leading to the closure of the public procurement market for medical devices in the PRC to a large extent.

(22) Pursuant to Article 6(4) of the IPI Regulation, an IPI measure can only apply to public procurement procedures with an estimated value equal to or above EUR 5 000 000 net of VAT for goods. Therefore, the exclusion of all economic operators originating in the PRC from all Union procurement procedures with a value equal or above EUR 5 000 000 net of VAT concerning all categories of medical devices would be the most comprehensive possible IPI measure that the Commission may adopt in this sector pursuant to the IPI Regulation ([19]). The Commission examined whether such IPI measure would be proportionate with regard to the identified measures and practices.

(23) According to the data included in Tenders Electronic Daily ('TED') ([20]), with respect to medical devices, procurement procedures with an estimated value equal to or above EUR 5 000 000 net of VAT represent around 59 % of the total Union procurement market of medical devices. In addition, pursuant to Articles 6(8) and 8(1) of the IPI Regulation, any IPI measure could only affect the supply of medical devices originating in the PRC at the maximum level of 50 % of the total value of the contract, irrespective of the origin of the bidder. Moreover, unlike the system implemented by

([15]) See Section V of the investigation report.
([16]) See Section V of the investigation report, p. 11.
([17]) See footnote 16.
([18]) See footnote 13.
([19]) Since the IPI Regulation does not restrict the possible scope of an IPI measure to the sector investigated in the third country concerned, the Commission is allowed in this case to adopt an IPI measure covering other sectors or a combination of sectors including medical devices. The Commission has nonetheless determined to confine the IPI measure solely to the medical-devices sector, given that there is a significant volume of imports into the Union of medical devices originating in the PRC (more than EUR 6 billion, see recital 40). The Commission considers that such a targeted measure will wield sufficient leverage in an area of strategic interest to the PRC.
([20]) https://ted.europa.eu/en/.

the PRC, an IPI measure, would not require additional restrictive features, such as burdensome approval procedures for the procurement of medical devices from the PRC or the imposition of sector-specific targets for the procurement of medical devices originating in the Union.

(24) Considering all the elements set out in recitals 17 to 23, the scope and potential exclusionary effect of the most comprehensive possible IPI measure in the medical devices sector would in any case be narrower than the scope and established exclusionary effect of the overarching system of generally applicable preferences for the procurement of domestic medical devices put in place by the PRC.

(25) The gap between the effect of the most comprehensive possible IPI measure that may be adopted in this sector pursuant to the IPI Regulation and the effects of the identified measures and practices, are further increased by the restrictive effect of the measures and practices related to volume-based procurement in the PRC. Therefore, it is appropriate to include in the scope of the most comprehensive possible IPI measure also the procurement in the Union of those goods which are subject to volume-based procurement when procured in China.

(26) In view of the above, an IPI measure including in its scope: (i) all Union procurement procedures concerning all categories of medical devices; (ii) organised by all Union contracting authorities and contracting entities; (iii) with a value equal or above EUR 5 000 000 net of VAT ([21]); and (iv) affecting all economic operators originating in the PRC, can be considered proportionate with regard to the identified measures and practices put in place and implemented by the GOC.

(27) For the purposes of application of any IPI measure, the origin of the economic operators and goods would have to be determined in accordance with Article 3 of the IPI Regulation as further clarified by the Commission in its 'Guidelines to facilitate the application of the IPI Regulation by contracting authorities and contracting entities and by economic operators' ('the Guidelines') ([22]). The Guidelines also provide clarifications on the obligations upon successful tenderers.

2.1.3. *Form of an IPI measure that would be proportionate and would most effectively remedy the level of impairment of access identified*

(28) As set out in recital 14, the two possible forms of an IPI measure are either a score adjustment on tenders submitted by economic operators originating in the PRC or exclusion of tenders submitted by such economic operators.

(29) As referred to in recital 20, the Commision concluded in the investigation report 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' ([23]). The Commission also established that the identified measures and practices mostly result in the exclusion of economic operators and goods in the medical devices sector originating in foreign countries, including those from the Union ([24]) thus leading to a siginificant closure of the public procurement market for medical devices in the PRC.

([21]) The relevant estimated values of the contracts should be calculated in accordance with Article 5 of Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65, ELI: http://data.europa.eu/eli/dir/2014/24/oj).

([22]) Communication from the Commission – 'Guidelines to facilitate the application of the IPI Regulation by contracting authorities and contracting entities and by economic operators' (OJ C 64, 21.2.2023, p. 7).

([23]) See Section VI of the investigation report.

([24]) See Section V of the investigation report and Section 2.3 of the SWD, where the Commission has established that 87 % of the public tenders for medical devices contain explicit and/or implicit prohibitions to procure imported medical devices or discriminatory requirements affecting such procurement.

(30) Given the extent of the discriminatory and exclusionary features of the identified measures and practices, as well as the significant exclusion of Union economic operators and goods to which they lead, imposing a score adjustment on tenders submitted by economic operators originating in the PRC ([25]), would only have a limited effect and in any event, it would not effectively remedy the level of impairment of access identified. Indeed, pursuant to Article 6(7) and (8) of the IPI Regulation, this form of IPI measure could only affect the evaluation and ranking of the tenders to a certain extent (up to 50 %) for tender procedures that are based on the best price-quality-ratio, and possibly up to 100 % for tenders based only on prices. Therefore, an IPI measure in the form of a score adjustment would include variations in the extent to which economic operators and medical devices originating in the PRC could be excluded from the Union public procurement market, as it would not allow contracting authorities and contracting entities to systemically exclude operators originating in the PRC. Thus, it would not remedy the impairment of access for Union economic operators and medical devices consisting in the identified exclusion of Union medical devices and Union economic operators in the PRC.

(31) Therefore, an IPI measure in the form of a score adjustment would not be the form of measure that would most effectively remedy the identified level of impairment of access, as required by Article 6(9) of the IPI Regulation.

(32) The Commission considers that an IPI measure in the form of exclusion of tenders submitted by economic operators originating in the PRC ([26]) would be more appropriate in this case. It would be proportionate and would most effectively remedy the identified impairment of access as it would achieve, to the largest possible extent, the exclusionary effects of the identified measures and practices.

2.1.4. *Conclusion on the IPI measure*

(33) In view of the above, an IPI measure in the form of exclusion of tenders within the meaning of Article 6(6), letter (b), of the IPI Regulation submitted by economic operators originating in the PRC and including in its scope: (i) all Union procurement procedures concerning all categories of medical devices; (ii) organised by all Union contracting authorities and contracting entities; (iii) with a value equal or above EUR 5 000 000 net of VAT; and (iv) affecting all economic operators originating in the PRC, to be adequate and proportionate with regard to the identified measures and practices put in place and implemented by the PRC, and would most effectively remedy the level of impairment of access identified.

2.2. **Availability of alternative sources of supply**

(34) An IPI measure excluding tenders submitted by economic operators originating in the PRC would have no impact on the sources of supply available for procurement procedures with an estimated value below EUR 5 000 000 net of VAT, as pursuant to Article 6(4) of the IPI Regulation, these procurement procedures would be excluded from the scope of application of any IPI measure. Around 96 % of all Union procurement procedures for medical devices registered in TED for the years 2017 to 2022 ([27]) include values below this threshold and represent around 41 % of the aggregated value of all procurement procedures registered. This means that Union contracting authorities and contracting entities would suffer no negative effects in most of the procurement procedures they would organise following the imposition of the possible IPI measure in the medical devices sector, and that almost half of their expenses on medical devices would remain unaffected by that IPI measure.

(35) For procurement procedures with values equal or above the threshold of EUR 5 000 000 net of VAT, it could be argued that an IPI measure excluding tenders submitted by all economic operators originating in the PRC may in theory reduce the overall choice of medical devices available and have an impact on their prices. However, such potential negative effects would be mitigated by several factors.

(36) First, bidders originating outside the PRC would still be able to submit tenders including medical devices originating in the PRC, provided that the proportion of medical devices supplied originating in the PRC would not represent a value above 50 % of the total value of the contract ([28]). Hence, medical devices originating in the PRC would still be offered in Union procurement procedures.

([25]) Pursuant to Article 6(6), point (a) of the IPI Regulation.
([26]) Pursuant to Article 6(6), point (b) of the IPI Regulation.
([27]) The last year for which the Commission has comprehensive data in TED.
([28]) In accordance with Article 8(1) of the IPI Regulation.

(37) Second, in the cases where only bidders originating in the PRC would be able to meet the tender requirements or would be the only ones able to offer specific medical devices necessary for overriding reasons relating to the public interest, the exceptions provided by Article 9(1) of the IPI Regulation would still allow Union contracting authorities and contracting entities not to apply the IPI measure, thus preventing any reduction in the availability of sources of supply in those situations.

(38) Third, the information that the Commission received from Member States following its request for identification of possible dependencies on medical devices originating in the PRC in their procurement procedures, referred to in recital 11, does not provide any indication that such dependencies exist in any category of medical devices.

(39) Fourth, the Commission established that there are sufficient alternative sources of supply. The Union has a significant trade surplus with the rest of the world in the medical device sector, estimated at over EUR 19 billion in 2023 ([29]), which suggests that exports could be redirected to the Union market in response to a potentially reduced supply of Chinese medical devices. Furthermore, the volume of medical devices affected by the IPI measure could also be replaced by either increased production of medical devices in the Union or increased volume of imports from other third countries, such as the United Kingdom, Switzerland, the United States and Japan ([30]).

(40) The Union imported around EUR 6,2 billion worth of medical devices from the PRC in 2023. The same year, it exported over EUR 69 billion worth of medical devices to the rest of the world. Therefore, at an aggregate level, Union manufacturers of medical devices have a net production capacity already available that is more than tenfold the level of Union imports of medical devices from the PRC. In addition, the Union also imported over EUR 49 billion worth of medical devices from other trading partners than the PRC, indicating that the Union already disposes of diversified sources of supply.

(41) Moreover, not all Union imports of medical devices originating in the PRC would fall within the scope of the IPI measure. Publicly available data from the Union industry show that public procurement accounts for only 50 % to 70 % of the total Union market for medical devices. If it is assumed that public procurement of medical devices originating in the PRC would account for a similar share (i.e. between EUR 3 and 4,5 billion), combined with the fact that 41 % of the Union public procurement procedures for medical devices would not be subject to the IPI measure ([31]), the value of medical devices originating in the PRC that would potentially need to be procured from alternative sources of supply, would be much smaller than the total value of Union imports of medical devices from the PRC.

(42) In addition, the Commission's detailed analysis of availability of supply for all product categories of medical devices (at six-digit HS code level for all medical devices) using the parameters described above, suggests that Union manufacturers of medical devices have the necessary capacity to ensure alternative sources of supply. In particular, Union manufacturers would only need to redirect 3 % to 4 % of their current exports to substitute all medical devices imported from the PRC potentially excluded from Union procurement procedures. On the basis of this analysis, the Commission determined that the Union contracting authorities and contracting entities would have a large variety of alternative sources of supply (which include both Union and imported medical devices) for all categories of medical devices to replace the medical devices originating in the PRC that would be impacted by the IPI measure. In conclusion, the adoption of the IPI measure determined in recital 33 would not create shortages or significantly reduce the supply of medical devices for Union contracting authorities and contracting entities as the Union would still dispose of alternative sources of supply, which would be sufficient to address the public procurement demand.

([29]) *Source*: Eurostat (https://ec.europa.eu/eurostat/web/main/home).

([30]) According to the latest Eurostat trade statistics on the sourcing of medical devices, the Union has imported EUR 49 billion of medical devices from third countries other than the PRC as indicated in recital 40.

([31]) As they would fall below the EUR 5 000 000 net of VAT threshold set in Article 6(4) of the IPI Regulation.

2.3. **Union interest**

(43) Article 6(2) of the IPI Regulation requires that the determination as to whether it is in the Union's interest to adopt an IPI measure is be based on an appreciation of all the various interests taken as a whole, including the interests of the Union's economic operators.

(44) In addition, recital 20 of the IPI Regulation clarifies that the Commission should weigh the consequences of adopting an IPI measure against its impact on the Union's broader interests, giving special consideration to the general objective of achieving reciprocity by opening the third-country market at stake and improving market access opportunities for Union economic operators. The objective of limiting any unnecessary administrative burden for contracting authorities and contracting entities as well as economic operators should also be taken into account.

(45) On this basis, it is appropriate to assess in the present case, first, the economic interest of the Union producers; second, the possible impact on Union contracting authorities and contracting entities, and third, the overall effects of the IPI measure on the Union economy. Then, the Commission would need to weigh the consequences of the IPI measure against the broader interests of the Union, taking into consideration the general objective of achieving reciprocity by opening the PRC's public procurement market of medical devices and improving market access opportunities for Union economic operators in that market.

2.3.1. *Interest of Union economic operators*

(46) As referred to in recital 39, the Union has a significant trade surplus with the rest of the world in the medical devices sector, which demonstrates that the Union's manufacturers hold a strong global competitive position in this sector and have a significant production base. The value of the PRC's procurement market for medical devices can be estimated at approximately EUR 128 billion ([32]). The removal of the discriminatory barriers in this market would offer considerable growth opportunities for Union economic operators. The adoption of the IPI measure would create leverage to convince the GOC to remove the discriminatory barriers, thereby establishing a more level playing field in a large international market that will be in the advantage of Union economic operators.

(47) Moreover, the Commission has not identified significant negative effects of the IPI measure for Union economic operators.

(48) Indeed, it should be recalled that the analysis of the data available in TED shows that the overall value of Union procurement procedures with an estimated value equal to or above EUR 5 000 000 net of VAT for medical devices, and thus within the scope of the IPI measure, would correspond to around 59 % of the aggregated value of all procurement procedures for medical devices reported in this database for the years 2017 to 2022. As public procurement accounts for 50 % to 70 % of the total Union consumption of medical devices, and there is no reason to consider that the share between public and private procurement would be different for the medical devices originating in the PRC, it can be estimated that, under a conservative scenario, the exclusion of economic operators originating in the PRC from the procurement procedures covered by the IPI measure, coupled with the obligation on successful bidders not to offer, for the duration of the contract, a proportion of medical devices originating in the PRC of a value above 50 % of the total value of the contract, could reduce imports of medical devices originating in the PRC by 15 %–20 % annually ([33]). That would represent between EUR 1 billion and EUR 1,2 billion annually, out of the EUR 6,2 billion of total imports of medical devices originating in the PRC ([34]).

([32]) For 2023, the total Chinese market for medical devices was estimated at EUR 160 billion. While there is no available data on the precise total value of the public procurement market, public hospitals accounted for 83,5 % of the total patient visits nationwide during the same year; this provides a strong indication that the share of the public procurement market in the value of the medical devices market may be estimated at around 80 %, i.e. EUR 128 billion.

([33]) The conservative estimation is based on the following parameters: (i) the value of Union imports of medical devices originating in the PRC (EUR 6,2 billion); (ii) the share of public spending in the Union market of medical devices (ranging between 50 %–70 %); (iii) the estimated share of public procurement procedures for medical devices above the threshold for the application of the IPI measure in total procurement (around 59 %); and (iv) the 50 % origin requirement for the maximum value of medical devices in any procurement procedure above the threshold for the application of the IPI measure.

([34]) The size of the new market opportunities expected for Union manufacturers can only be estimated based on official trade statistics, due to the lack of direct, firm-level data on the overall value of medical devices originating in the PRC that are destined for public procurement in the Union.

(49) Considering the strong global competitive position of Union manufacturers and the presence in the Union market of medical devices from other major exporting countries, if contracting authorities and contracting entities could not procure medical devices originating in the PRC in a specific case due to the IPI measure, they could procure medical devices made either in the Union or originating in other third countries instead. Based on the industry estimates concerning the size of the Union medical devices' market and the value of imported medical devices from third countries, the current market share of Union medical devices of the total Union consumption of medical devices is estimated at approximately 60 %. Assuming that the market share of the medical devices originating in the PRC potentially affected by the IPI measure (i.e. EUR 1-1,2 billion) would be allocated between Union medical devices and medical devices imported from other third countries in proportion to the current market shares, the Union medical devices producers could potentially capture around 60 % of the procurement volume that would have originated in the PRC in the absence of the IPI measure.

(50) It could be expected that these new opportunities in the Union procurement market subject to the IPI measure would be available to all producers of medical devices in the Union. According to publicly available data from Union industry associations, there are over 30 000 Union firms, around 90 % of which being small and medium-sized enterprises ([35]).

(51) The Commission has also assessed the impact of the IPI measure on certain Union importers of medical devices sourcing such products in the PRC, including Union economic operators manufacturing medical devices in the PRC and importing them into the Union, as they could face a reduction in their sales of medical devices originating in the PRC, following the imposition of the IPI measure. In this respect, the Commission has considered the comments of entities that submitted inputs following the public consultation on the possible IPI measure and concluded that the potential negative impact of the IPI measure on such operators would still be limited. First, around 96 % of all Union procurement procedures of medical devices would fall outside the scope of the IPI measure, representing approximately 41 % of the total Union medical devices procurement value. Second, these importers would still be able to sell 50 % of their volume of medical devices imported from the PRC affected by the IPI measure in accordance with Article 8(1), letter (b), of the IPI Regulation. Considering that public procurement for medical devices accounts for 50 % to 70 % of the total Union market for medical devices, it can be estimated that the Union importers concerned would be able to keep more than 80 % of their current import volume from the PRC ([36]). Finally, any such potential negative economic effects on importers of medical devices affected by the IPI measure would be offset by the broader Union interests, in particular the general objective to engage with the PRC to open its public procurement market for medical devices in a reciprocal way and to ensure a level playing field for all Union operators in the medical devices sector.

2.3.2. *Interest of Union contracting authorities and contracting entities*

(52) The Commission has carried out a thorough assessment of the availability of supply for all categories of medical devices in the event of a comprehensive IPI measure covering all categories and sub-categories of medical devices. As detailed in Section 2.2 above, the IPI measure is not expected to reduce the availability of supply of medical devices for Union contracting authorities and contracting entities, which was further confirmed by the results of the consultation of Member States in the Trade Barriers Committee on possible dependencies on medical devices originating in the PRC. In any event, as explained in recital 37, in cases where only bidders originating in the PRC would be able to meet the tender requirements or would be the only ones able to offer specific medical devices necessary for overriding reasons relating to the public interest, Union contracting authorities and contracting entities would be allowed not to apply the IPI measure in accordance with Article 9(1) of the IPI Regulation.

(53) In addition, since approximately 96 % of all Union procurement procedures would remain outside the scope of the IPI measure, the administrative burden for contracting entities could be expected to be low.

([35]) medtech-europe--facts-figures-2024.pdf.

([36]) The estimation is consistent with the expected reduction of the imports of medical devices originating in the PRC, which represents between EUR 1 billion and EUR 1,2 billion annually (see recital 48) and close to 20 % of the EUR 6,2 billion of total imports of medical devices originating in the PRC registered in 2023.

(54) The Commission assessed a possible adverse effect of restrictions regarding the procurement of medical devices originating in the PRC on public budgets. Based on currently available information, and considering that Member States have not communicated any expected significant budgetary impact, the Commission considers that the budgetary implications for contracting authorities and entities would remain limited. In addition, the Union medical devices market is very competitive with a wide range of alternative suppliers (both domestic and foreign). Considering this strong competition, the Commission estimates that despite the exclusion of economic operators originating in the PRC from a limited number of tenders, there would be sufficient offer of affordable medical devices on the Union market.

(55) As a result, the overall impact of the IPI measure on Union contracting authorities and contracting entities can be expected to remain limited.

2.3.3. *Interest of the Union economy*

(56) The identified measures and practices put in place and implemented by the PRC have caused significant harm to Union manufacturers of medical devices that account for approximately 700 000 jobs in the Union ([37]). The leverage that could be created by the IPI measure to remove the discriminatory barriers in the medical devices public procurement market in the PRC and remedy the serious and recurrent impairment of access from which Union economic operators suffer, could be beneficial, for Union manufacturers and thus for the creation of additional employment in the sector. Even in the case where these barriers would not be removed, the Commission has estimated that the expected substitution of imports from the PRC by medical devices manufactured in the Union would sustain the existing jobs in the sector and could potentially generate over 3 000 new Union jobs ([38]). Therefore, the current IPI measure is expected to have an aggregate positive impact on the overall Union industrial output.

2.3.4. *The Union's broader interests*

(57) By restricting access of economic operators originating in the PRC to the Union's procurement market, the IPI measure could serve as an incentive for the PRC to remove its restrictive and discriminatory measures and practices against Union economic operators and medical devices and thus open its procurement market in a reciprocal manner. Considering the potential reduction of imports from the PRC into the Union, following the imposition of the IPI measure, combined with the strategic importance of the medical devices sector for the PRC in its aim to become a leading exporter in this sector, the imposition of the IPI measure could create the necessary leverage to improve market access opportunities for Union economic operators and goods in the sector. The expected leverage stemming from the IPI measure would also be in line with the Union's broader interests to promote open and fair public procurement markets while supporting the competitiveness of the Union's industries.

(58) The Commission considers that these broad interests would not be outweighed by the limited negative consequence of the IPI measure identified, notably in view of its expected positive impact on the Union's medical device industry, which can partially offset the serious and recurrent impairment of access of Union operators in the PRC medical devices market.

(59) In light of the above, the Commission considers that it is in the interest of the Union to impose this IPI measure.

([37]) medtech-europe--facts-figures-2024.pdf.

([38]) This estimation is based on the assumption made in recital 49 that 'the Union medical devices producers could potentially capture around 60 % of the procurement volume that would have originated in the PRC in the absence of the IPI measure' (i.e. 60 % of EUR 1-1,2 billion) and the productivity per employee in the Union estimated at EUR 177 000 in 2024 (*source*: medtech-europe--facts-figures-2024.pdf).

3. **CONCLUSION**

(60) In view of the above considerations, in accordance with Article 6(1) of the IPI Regulation, the Commission should impose the IPI measure set out in recital 33.

(61) The IPI measure should apply in procedures concerning all categories of medical devices under the Common Procurement Vocabulary (CPV) codes 33100000-1 to 33199000-1 as defined in Regulation (EC) No 2195/2002 of the European Parliament and of the Council ([39]).

(62) To facilitate the implementation of the IPI measure by the Union contracting authorities and contracting entities, as well as economic operators, it is appropriate to allow a reasonable time period of 10 days between the day the IPI measure is published in the *Official Journal of the European Union* and the day of its entry into force.

(63) Pursuant to Article 11(1) of the IPI Regulation, the Commission has been assisted by the Trade Barriers Committee in the adoption of the IPI measure, which is a committee within the meaning of Article 3 of Regulation (EU) No 182/2011 of the European Parliament and of the Council ([40]).

(64) The IPI measure provided for in this Regulation is in accordance with the opinion of the Trade Barriers Committee,

HAS ADOPTED THIS REGULATION:

Article 1

1. An International Procurement Instrument measure ('IPI measure') in the form of exclusion of tenders within the meaning of Article 6(6), letter b) of Regulation (EU) 2022/1031 submitted by all economic operators originating in the People's Republic of China is imposed in all public procurement procedures in the Union having as subject matter the procurement of medical devices falling under CPV codes 33100000-1 to 33199000-1 as defined in Regulation (EC) No 2195/2002 and with an estimated value equal to or above EUR 5 000 000 net of VAT.

2. The IPI measure referred to in paragraph 1 shall apply to all Union contracting authorities and contracting entities, without prejudice to Article 7 of Regulation (EU) 2022/1031.

Article 2

1. Union contracting authorities and contracting entities as well as successful tenderers shall comply with the requirements laid down in Article 8 of Regulation (EU) 2022/1031 with respect to public procurement procedures falling withing the scope of the IPI measure referred to in paragraph 1 of Article 1.

([39]) Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV) (OJ L 340, 16.12.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/2195/oj).

([40]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

2. Union contracting authorities and contracting entities shall:

(a) determine the origin of the economic operators and medical devices that may be covered by the IPI measure in accordance with the criteria set out in Article 3 of Regulation (EU) 2022/1031 and Article 60 of Regulation (EU) No 952/2013 of the European Parliament and of the Council ([41]), respectively;

(b) calculate the relevant estimated values of the contracts in accordance with Article 5 of Directive 2014/24/EU.

Article 3

This Regulation shall enter into force on the tenth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 June 2025.

For the Commission
The President
Ursula VON DER LEYEN

([41]) 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, ELI: http://data.europa.eu/eli/reg/2013/952/oj).