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Restrictions on medical devices of Chinese origin: the regional administrative court of Tuscany seeks clarification from the court of justice

By Order No. 2080 of 29 October 2026, the Regional Administrative Court of Tuscany, openly challenging the interpretation previously provided by ANAC on this point, asked the Court of Justice of the European Union to clarify whether, pursuant to and for the purposes of EU legislation on so-called 'IPI measures', a European economic operator may be excluded from a public tender procedure for having offered medical devices of Chinese origin accounting for more than 50 per cent of the contract value.

1. IPI measures: the regulatory framework

Regulation (EU) **No 2022/1031** allows the Commission, where a third country hinders European companies' access to its public procurement contracts, to adopt specific measures (so-called 'IPI' measures, an acronym for 'International Procurement Instrument'), to in turn restrict the access of undertakings, goods and services from that third country to EU public procurement procedures exceeding certain thresholds.

To achieve this, the Commission has, in principle, two tools at its disposal: imposing an adjustment to the scores of tenders submitted by economic operators from the third country, or their automatic exclusion from the tender (see Article 6). Furthermore, Regulation No 2022/1031 requires specific obligations to be included in the tender documents to be borne by the successful tenderer: to ensure, throughout the duration of the contract, that goods and services from the affected country do not exceed 50 per cent of the contract value; in the event of a breach, a penalty of between 10 per cent and 30 per cent of the total contract value is provided for.

Implementing Regulation (EU) No 2025/1197 constitutes the first application of the general framework set out in Regulation No 2022/1031, which is aimed at countering restrictions imposed by the Chinese medical devices market on European companies.

The Commission has therefore provided for the exclusion of tenders from economic operators originating in the People's Republic of China from all EU tenders for the supply of medical devices (CPV codes 33100000-1 to 33199000-1) with a value of 5 million euros or more. The Implementing Regulation also sets out the obligations incumbent on the successful tenderer, including, in particular, the payment of a penalty of between 10 per cent and 30 per cent of the total contract value where medical devices of Chinese origin account for more than 50 per cent of the contract value.

2. The proceedings before the Regional Administrative Court of Tuscany and the referral to the CJEU

Recently, ESTAR, acting as the central purchasing body for the Region of Tuscany, launched a tender procedure for the supply of medical devices, divided into various lots and with a total value of approximately 72 million euros. The procedure provided for the automatic exclusion of bids involving medical devices originating in the PRC where such devices accounted for more than 50 per cent of the economic value of the relevant lot, in explicit application of

Regulation No. 2025/1197 and in accordance with the guidance provided in ANAC Opinion No. 10 of 2026.

An economic operator, a company established in Italy and the exclusive distributor of medical devices originating in the PRC, subsequently challenged this clause before the Regional Administrative Court of Tuscany. After granting an interim injunction, the Regional Administrative Court stayed the proceedings and referred the matter to the CJEU.

3. The preliminary ruling and its significance

The Regional Administrative Court asks the Court of Justice to clarify whether it is permissible to exclude a tender from a European undertaking where Chinese medical devices account for more than 50 per cent of the contract value. The order for a preliminary ruling is accompanied by the observations of the Florentine panel, which questions the lawfulness of ESTAR's decision.

Specifically, the Regional Administrative Court emphasises various literal provisions of the legislation, concluding that the 50 per cent limit should only be relevant during the contract's execution phase and should not, from the outset, prevent participation in the tender.

It is particularly interesting that the Regional Administrative Court (TAR) has recognised and openly stated that the automatic exclusion from public tenders of EU companies offering Chinese products accounting for more than 50 per cent of their range would conflict with the principle of competition in the internal market, with the risk of creating oligopolies. Indeed, the Regional Administrative Court observes that SMEs distributing medical devices – which can remain competitive only by offering Chinese products – would effectively be excluded from the relevant market, as their only alternatives would be to source supplies at unsustainable costs or to 'scale down' by participating only in tenders worth less than 5 million euros (which, as such, fall outside the scope of the IPI measure).

4. Conclusions

The order for a preliminary ruling represents one of many turning points in the medical devices sector, which in recent years has been marked by numerous disputes – foremost among them the *payback* dispute – of central importance.

It is reasonable to expect that the CJEU's ruling will only be delivered in the coming months. In the meantime, the order for a preliminary ruling does not prevent other contracting authorities from following ANAC's guidance and, therefore, from including the contested clause in the *lex specialis* of future tenders. However, this will inevitably lead to further appeals, pending the Court of Justice's final ruling.

There is therefore a risk that this interpretative uncertainty will lead, at least in the medium term, to a slowdown in the procurement system of contracting authorities, with consequences for distributors and SMEs and, above all, for the efficiency of the National Health Service.

In this scenario, the economic operators concerned should carefully examine the lex specialis of tenders with a value of 5 million euros or more and promptly assess whether to challenge clauses similar to the one in dispute, including by referring to the order of the Regional Administrative Court of Tuscany. For contracting authorities, on the other hand, it might be prudent to limit themselves to stipulating the 50 per cent threshold as a binding obligation, backed by the penalty provided for in the Regulations, so as to reduce the risk of litigation.

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