

THE IMPACT OF THE NEW ITALIAN FOREIGN INVESTMENTS RULES ON THE PHARMA SECTOR

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Legal Briefings

Differently from certain sectors (such as energy, telecommunications and transportation) that have always been included in the scope of application of the Italian regime for foreign direct investments (“**FDI**”), the powers of the Italian Government on FDI in the pharmaceutical sector have only recently been introduced. Therefore, investors in this sector must commence to deal with it.

Foreign investments in certain strategic sectors are subject to the regime set out by Law Decree No. 21 of 15 March 2012, as subsequently amended in 2017 and 2019 (the “**Golden Power Decree**”). In particular, under the Golden Power Decree, certain transactions and corporate resolutions in the defence and national security sectors, as well as regarding networks, plants, assets and contractual relationships deemed strategic for the national interest in other sectors (ie communications, energy, transport and high-tech sectors) (collectively, the “**Strategic Sectors**”) must be notified to the Italian Government. The Italian Government can then request information, impose specific rules or conditions or exercise a veto in relation to the relevant transaction or corporate resolution (the “**Government Powers**”) under certain circumstances, which differ on the basis of the sectors involved, including a threat of serious damage to public interests relating to the continuity of supplies (“**Grounds for Intervention**”).

In order to face the impact on the Italian economy of the COVID-19 pandemic, under Law Decree of 8 April 2020, No. 23 (the “**Liquidity Decree**”)¹ the Government powers of intervention in respect of foreign investments have been extended to all sectors listed under Article 4 letter from a) to e) of Regulation (EU) 2019/452 (which include, *inter alia*: financial services, infrastructures and critical technologies, energy, transport, water and health, food security, access to sensitive information and personal data, artificial intelligence, robotics, semiconductors, cybersecurity, nanotechnology and biotechnology, collectively, the “**New Strategic Sectors**”)². Following the extension of the Governmental Powers on FDI, the President of the Council of Ministers enacted Decrees no. 179 and no. 180, detailing the scope of application of the Government Powers³.

With respect to the pharmaceutical and healthcare sectors, under Decree of the President of the Council of Ministers of 23 December 2020, no. 179 the FDI regime applies, at least, to the following assets and activities:

- critical technologies that aim to analyse data and use biological knowledge for health and diagnostics, prognostics, therapy, and related follow-up (Article 5 letter b));
- critical bioengineering technologies and nanotechnologies used in the pharmaceutical and medical devices sector, in the diagnostics, prognostics and therapy sector, as well as in the chemical and agri-food sectors (Article 5 letter c));
- economic activities of strategic importance in the healthcare sector, including economic activities relating to the procurement of medicines, devices and health equipment as well as the research and development activities related to them, through the management, use or exploitation of the infrastructures and technologies referred to in letters a) (ie critical technology for the supply, also remotely, of healthcare services), b) and c), or carried out by companies with an annual net turnover of not less than Euro 300 million and with an average annual number of employees of no less than 250 units (Article 5 letter d));
- data collected through the use of digital technologies (and related systems of integration and interconnection between them) related to the provision of healthcare, disease prevention and health promotion, even remotely, capable of acquiring, processing, recording, transmitting and decoding medical information and data (Article 6, paragraph 2, lett. c), no. 10);
- critical technologies in the biological field, including technologies whose purpose is to decode and use biological knowledge for the production of goods and services in the industrial and the environmental field (Article 9 letter i)).

A case-by-case assessment must be made on the basis of the relevant activity and company involved, given the detailed content of the decrees.

By virtue of Article 10-ter of Law of 18 December 2020, no. 176, the temporary regime under the Liquidity Decree has been extended until 30 June 2021. In particular, until that date, acquisitions of controlling interests by EU investors and acquisition by any non-EU investor of an interest equal or higher than 10% of the voting rights (provided that the investment value is at least equal or exceeds Euro 1 million), as well as any subsequent acquisition exceeding 15%, 20%, 25% and 50% will be subject to notification duties. After 30 June 2021, provided that the temporary regime is not extended, only acquisitions of controlling interests by non-EU investors will be subject to notification duties.

In sum, investors in the pharma and healthcare sector will have to be careful going forward at assessing the implications of the adoption of certain corporate resolutions and the transfer of assets or shares of companies operating in the sector in order to efficiently plan the timing and structure of any potential transaction and the possible existence of Grounds for Intervention.

¹ These measures follow the European Commission Guidelines of 25 March 2020 instructing Member States how apply the FDI rules in line with, but ahead of, the EU's FDI Regulation entering into force on October 2020.

² These assets are in addition to those already identified as strategic by applicable laws, ie Law Decree no. 21 of 15 March 2012, Decree of the President of the Council of Ministers no. 85 of 25 March 2014, Decree of the President of the Council of Ministers no. 108 of 6 June 2014.

³ In addition, those Decrees clarify that Governmental Powers are excluded (but notification has, nonetheless, to be carried out):

- a. if the safeguard of security and public order, including protection of the essential interests of the State in safeguarding the security and operation of networks and installations and of the continuity of supplies, is adequately guaranteed by specific sector regulations, including those stemming from a concession; and
- b. for the following intra-group transactions: mergers, demergers, acquisitions or transfers of shares, transfer of the company's headquarters in a country not belonging to the European Union, change of the company's purpose, winding up of the Company, amendments to the by-laws clauses adopted under Article 2351, paragraph 3 of the Italian Civil Code (ie providing for a limit of the voting rights in relation to the number of shares held by the same person) or pursuant to Article 3 paragraph 1 of Law Decree 332/1994 (pursuant to which companies operating in defence, transport, telecommunications, energy, and other public services and banks and the insurance undertakings, directly or indirectly controlled by the State, or by public authorities,

including local and regional and economic authorities, may introduce a limit to the share ownership), creation or transfer of property rights or intangible assets, adoption of restrictions affecting the use, including by reason of its subjection of the company to insolvency proceedings.

These exclusions do not apply if the relevant transaction may lead to a prejudice to the continuity of supply or a danger to security and public order. However, the practical implementation of this exclusion may be problematic due to an unclear and somehow contradictory provisions.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.



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