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COVID-19 Impact on the Italian Healthcare Sector

April 17, 2020

As part of its overall response to the coronavirus disease 2019 (COVID-19) outbreak, the Italian government introduced a number of measures specifically impacting the healthcare sector.

A brief summary of the main provisions affecting the healthcare sector is set forth below.

Healthcare Sector as an Essential Service

In order to ensure the continued operation of the sector as a whole during the emergency period, on March 22, 2020, the government issued Decree 76 of 2020 (Decree 76/2020) establishing a general lockdown of industrial activities, which, however, did not involve services deemed essential for the country, such as the healthcare sector.

Annex 1 to Decree 76/2020, in fact, lists specific activities that do not fall within the perimeter of the lockdown, including the manufacture of basic pharmaceutical products and pharmaceutical preparations, as well as medical and dental instruments, devices and supplies. Moreover, Article 1, letter f) of Annex 1 expressly specifies that the manufacturing, transportation, commercialization and delivery of medicines, sanitary technology and medical-surgical devices are allowed to continue during the lockdown period, as activities that are functional to coping with the emergency.

Financial Measures Aimed at Expanding or Reconverting Business Activities for the Production and Supply of Medical Devices and Personal Protective Equipment (Article 5 of Decree 18/2020)

Under Decree 18 of March 17, 2020 (Decree 18/2020), the Italian government introduced financial measures specifically regarding investment projects aimed at expanding or reconverting business activities for the production and supply of medical devices and personal protective equipment. These financial measures also cover investments related to medical devices and equipment not necessarily bearing the official *Conformité Européenne* (CE) marking, indicating they have successfully passed conformity testing standards set at the EU level.

The government allocated €50 million for the year 2020 for such financial measures aimed at expanding or reconverting business activities for the production and supply of medical devices and personal protective equipment. These financial support measures have been approved by the European Commission under applicable state aid rules.

Decree 18/2020 gives power to a special government commissioner to establish by means of ordinances how to spend the allocated amount. The first ordinance was issued by the commissioner on March 23, 2020.

The March 23 ordinance empowers Invitalia (the Italian National Agency for Attracting Investment and Business Development) to finance investment projects through non-repayable grants and operating grants, as well as subsidized loans, for companies manufacturing and supplying medical devices, such as masks, respirators and other protective devices.

Financing may take the form of low-interest or zero-interest loans, to cover up to 75% of the relevant investment project, repayable over eight years. The maximum possible financing is €800,000, and initial subsidized loans may be converted into non-repayable loans in variable percentages depending on the speed of implementation of the relevant project. Financing under this scheme has been available since March 26, 2020, through an online application process on the Invitalia website.

Derogation From Usual Production and Import Authorization Provisions for Surgical Masks and Personal Protective Equipment (Article 15 of Decree 18/2020)

Decree 18/2020 allows manufacturers and importers to place surgical masks and personal protective equipment on the Italian market through a fast-track authorization procedure and in derogation from the usual stricter authorization regime.

The decree provides for a simplified procedure, which allows producers or importers to place medical devices on the market through a self-certification system.

Manufacturers and importers of surgical masks and the relevant commercialization entities must send a form of self-certification, along with other useful product identification or verification materials, for validation to the National Institute of Health (*Istituto Superiore di Sanità*) (NSI) and to the National Institute for Insurance against Accidents at Work (*Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro*) (INAIL), an Italian statutory body regulated by the Ministry of Labour and Social Policies. Under their own responsibility, manufacturers and importers must certify that the technical characteristics of the devices and equipment comply with all safety requirements of current Italian legislation.

NIS and INAIL have three days to decide whether the devices comply with the regulations in force. If the results of the assessment show that the products do not comply with Italian regulations, the relevant producer must immediately cease production and the importer cannot place them on the market.

The aim of the legislation is to make it easier for companies to restructure their production to meet growing demand by streamlining the authorization procedures necessary for placing medical devices on the market.

Requisition From Any Public or Private Entity of Medical and Surgical Devices Necessary to Deal With the Health Emergency (Article 6 of Decree 18/2020)

Decree 18/2020 allows the government to forcibly requisition, from any public or private entity, medical and surgical devices, as well as movable property of any kind, necessary to deal with the health emergency or to ensure the supply of facilities and equipment to health companies or hospitals located in the national territory, as well as to furnish specialized beds for hospitalization wards of patients affected by COVID-19.

A requisition cannot last more than six months or beyond the end date of the state of emergency. Upon taking possession of requisitioned goods, the administration must make a cash payment to the owner by way of compensation.

Strengthening of Military Health Services and for the Purchase of Medical Devices and Healthcare Equipment (Article 9 of Decree 18/2020)

Under Decree 18/2020, the government authorized expenditure of €34.6 million during 2020 for strengthening military health services and for purchasing medical devices and healthcare equipment aimed at the management of urgent cases and biocontainment.

Authorization to Access All Data From Experimental Studies and Compassionate Uses Concerning COVID-19 Patients (Article 17 of Decree 18/2020)

Decree 18/2020 introduced a simplified procedure, limited only to the period of the state of emergency, for the collection and processing of health data of patients suffering from COVID-19.

In order to improve the capacity for coordination and analysis of scientific data, the government authorized *Agenzia Italiana del Farmaco* (AIFA), the Italian Drugs Agency, to access all data from experimental studies and compassionate uses concerning COVID-19 patients.

The decree provides that all study protocol data may be evaluated on a preliminary basis by the Technical Scientific Committee (CTS) of AIFA.

During the period of the state of emergency, the ethics committee of the National Institute for Infectious Diseases of the Lazzaro Spallanzani Hospital in Rome is the only national ethics committee authorized to evaluate clinical trials of medicinal products for human and medical devices for patients with COVID-19.

Off-label Use of Drugs to Fight COVID-19 (Article 17 of Decree 18/2020)

According to Decree 18/2020, AIFA has been entrusted with the evaluation of clinical trials of drugs to be used in the treatment of COVID-19. AIFA has adopted a simplified procedure for clinical trials and continuously updates the information on their status. AIFA also provides daily updates on the off-label use of drugs outside clinical trials in the treatment of COVID-19 patients.

EU Suspension of Customs Duties and VAT on Medical Supplies

In a related move, on April 3, 2020, the European Commission, following requests from member states, published Decision EU 491/2020, which granted exemptions from import duties and VAT on the importation of goods needed to combat the effects of COVID-19.

These exemptions are backdated to January 30, 2020, the date the World Health Organization declared the COVID-19 outbreak a public health emergency, and for a six-month period (namely, until July 31, 2020).

The goods that benefit from this exemption include COVID-19 test kits, personal protective equipment, such as surgical masks, protective suits and gloves, and ventilators. To qualify for the exemption, the goods must meet the following requirements:

1. They must be distributed free of charge or made available to persons affected by, at risk from, or involved in combating the outbreak of the disease
2. After they have been imported, the goods may not be used, lent, hired out or transferred for purposes other than those giving rise to the exemption, unless the VAT and tariff duties are paid
3. The medical disposals must be imported for release for free circulation by, or on behalf of, state organizations, including public bodies and other bodies governed by public law, and organizations approved by the competent authorities in member states

Extension of Golden Powers Regulations to Include Healthcare Industry

On April 9, 2020, the Italian government issued Decree No. 23 of 2020 (Decree 23/2020), in order to further mitigate the effects of the ongoing COVID-19 emergency on the national economy. In addition to a wide range of measures covering a number of sectors, Decree 23/2020 extended the scope of investment screening-related regulations, known as golden powers regulations, aimed at safeguarding the ownership of national companies during this period of high uncertainty caused by the COVID-19 spread. The investment screening powers of the Italian government now extend the definition of strategic industries in relation to which these powers can be exercised to include not only defense, telecommunications and infrastructure, but now also the healthcare and biotechnologies industry.

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