

# HealthCare: news & business opportunities

ITALY





SECTORS	ABSTRACT	REFERENCES
<b>Medical devices</b>	<ul style="list-style-type: none"><li>• The Italian legislator provided for a simplified procedure to produce, import and market surgical masks for medical use and personal protective equipment (PPE) without CE marking. Therefore:<ul style="list-style-type: none"><li>- conformity assessment by notified bodies is not required, by way of derogation from Directive 93/42/EC and EU Regulation no. 425/2016;</li><li>- compliance with ISO technical standards and grant of a favourable opinion from the Italian National Institute of Health (ISS) or INAIL are sufficient.</li></ul></li><li>• CE marked products continue to be subject to EU legislation. However, payment of duties and VAT is suspended for the import of medical devices (<i>e.g.</i> ventilators) and PPE (<i>e.g.</i> FFP2 and FFP3 masks) and any other means to contrast the Covid-19 outbreak, with the authorisation of the Customs Agency.</li></ul>	<ul style="list-style-type: none"><li>• <i>D.L. 18/2020, articles 15 -16</i></li><li>• <i>Italian Customs Agency, Determination of April 3, 2020</i></li></ul>
<b>Pharma</b>	<ul style="list-style-type: none"><li>• The Italian National Health Agency (AIFA) has taken various initiatives within the framework of the national legislation previously in force and the emergency one:<ul style="list-style-type: none"><li>- the immediate authorization of <b>off-label use</b> of specific medicinal products (as an exception to the ordinary regulation of off-label drugs)</li><li>- a simplified, accelerated and centralized procedure to authorize <b>clinical trials</b> and compassionate use of specific medicines</li></ul></li></ul> <p><u>Medicines involved:</u></p> <ul style="list-style-type: none"><li>✓ Plaquenil (Sanofi)/ Cloriquine (Bayer)</li><li>✓ Kaletra (AbbVie - generics Mylan)</li><li>✓ Rezolsta (Janssen-Cilag)</li><li>✓ Remdevisir (Gilead Sciences)</li><li>✓ Tocilizumab (Roche)</li><li>✓ Avigan (Fujifilm Toyama Chemical)</li><li>✓ Gamifant / Kineret (Sobi)</li><li>✓ Kevzara (Sanofi)</li></ul>	<ul style="list-style-type: none"><li>• <i>D.L. 18/2020, article 17</i></li><li>• <i>Circular of the Ministry of Health of April 3, 2020</i></li></ul>



	<ul style="list-style-type: none"><li>• The Scientific Committee appointed in Italy to manage the Covid 19 emergency gave a first partially negative indication about the widespread use of <b>serological tests</b>, considering that they need further evidence on their performance and operational usefulness. This is due, in particular, to the fact that the detection of antibodies may not be specific to SARS-CoV2 infection and the detection of antibodies does not exclude the possibility of an early stage or asymptomatic infection and related risk of contagiousness of the individual. In addition, if these tests lack the CE marking as self-testing devices, they could not be used by those who do not have the qualification/competence to do so. These indications were published after some Regions (in particular Veneto) expressed their intention to proceed independently with serological tests.</li><li>• Some hospitals (Pavia, Mantova) have started a clinical trial regarding plasma transfusion treatment from individuals recovered from Covid 19.</li></ul>	
<b>Public Procurement</b>	<ul style="list-style-type: none"><li>• In order to deploy the resources available to hospitals, <b>tender procedures have been launched for the supply of large quantities of medical devices and appliances</b>. These procedures are of considerable value, accelerated (as an exception to ordinary rules of law), centralized (managed by a single entity, Consip S.p.A., a subsidiary of the Ministry of Economic Affairs), the most important ones being structured in a special way, providing that all bidding companies become contractors through the signing of a Framework Agreement and are called to provide the offered products according to a ranking based on the price offered until the hospitals' needs are fully met. <u>Products involved in framework agreements:</u><ul style="list-style-type: none"><li>✓ masks and medical devices (allocation € 132,341,599.50)</li><li>✓ humidifiers, crash carts, CPAP helmets, NIV helmets (allocation € 49,186,500.00)</li><li>✓ personal protective equipment and electromedical equipment, (allocation € 253,260,871.80)</li><li>✓ supply of medical devices for intensive and sub-intensive care (allocation € 184,875,000.00)</li></ul></li></ul>	<ul style="list-style-type: none"><li>• <i>DPCM no. 666/2020</i></li><li>• <i>orders of the Department Head of Civil Protection No 630/2020 and No 639/2020</i></li></ul>



<b>Disinfectants and Sanitization</b>	<ul style="list-style-type: none"><li>• Through agreements between the Government and the trade unions, anti-infection security measures have been introduced providing, in particular, for daily cleaning service and periodic sanitization of the workplace. Sanitization refers to interventions (with the use of common hospital disinfectants, such as sodium hypochlorite (0.1% -0.5%), ethanol (62-71%) or hydrogen peroxide (0.5%)) aimed at eliminating any bacteria and contaminants that cannot be removed by standard cleaning.</li><li>• The health emergency has led to a serious shortage of epidermal disinfection products (both for common use and in health sector). Several companies operating in the alcoholic beverages sector have converted part of their activities into the production of ethyl alcohol-based disinfectant and sanitizing liquids and gels (Campari Group, in collaboration with the Intercos / Ramazzotti Cosmetic Group, Pernod Ricard Group, Disaronno, Illva Saronno Group) and donated these products to various public entities.</li></ul>	<ul style="list-style-type: none"><li>• <i>Joint regulatory protocol for measures to combat and contain the spread of the Covid-19 virus in the workplace.</i></li></ul>
<b>Home Health Care</b>	<ul style="list-style-type: none"><li>• In order to limit the movement of people, the <b>transmit from doctor to patient of the reference codes for medical prescriptions</b> necessary for the purchase of certain drugs, whose cost is borne by the National Health System, has been temporarily allowed (via e-mail, SMS or telephone).</li><li>• Various <b>services of medicines home delivery</b>, free of charge for certain sections of the population, have become widespread.</li><li>• In order to reduce the influx of people into hospitals, the regional health authorities have organised, in cooperation with certain pharmaceutical companies and specialised and certified transport companies, the <b>home delivery of hospital medicines</b> (these medicines are not available in ordinary pharmacies and are used by chronically ill patients with pre-established treatment plans).</li><li>• Various forms of <b>telemedicine and remote medical advice</b> (particularly in patient monitoring) have become widespread, with similar services also being offered by insurance companies. In the home treatment of the disease, the use of <b>pulse oximeters</b> is becoming common, making it possible to qualify the severity of the disease and the need for hospitalization.</li></ul>	<ul style="list-style-type: none"><li>• <i>Order of the Department Head of Civil Protection n. 651/2020</i></li><li>• <i>Regional measures and agreements</i></li></ul>