

# U.S. Country Commercial Guides



## Italy 2020

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## Doing Business in Italy

### Market Overview

- Italy is the world's 8th largest economy with a GDP of \$2 trillion in 2019. Italy's GDP grew by 0.3% in 2019.
- Covid has had a tremendous impact on the Italian economy. The European Union Commission estimates that Italy's GDP will contract by 9.5% in 2020 as a result of the Covid pandemic and the lockdown imposed by the Italian Government. However, the Commission also estimates that Italy's GDP will bounce back by 6.5% in 2021 propelled by the return of many economic activities in the country starting in May 2020 and by expected public stimulus measures.
- In 2019 Italy was the 19th largest market for U.S. exports, which totaled approximately \$23.8 billion, and the 4th largest export market in the EU, following Germany, Netherlands and France. However, export values to the Netherlands (Rotterdam) and Belgium (Antwerp) are skewed by the 'Rotterdam Effect' where goods are valued at the port of entry, but then distributed throughout the EU.
- U.S. exports to Italy are concentrated in high-value sectors such as pharmaceutical products (17%), machinery (12%), and aircraft (7%).
- The United States remained by far Italy's largest non-EU export market with roughly a 9% share of all non-EU exports. In 2019, the United States was Italy's third largest destination for exports, with U.S. imports from Italy totaling \$57.2 billion, following Germany and France. The U.S. had a goods trade deficit with Italy valued at \$33.4 billion in 2019.
- In 2018 Italian foreign direct investment in the U.S. totaled \$38.6 billion, supporting 75,900 American jobs. Top industry sectors for Italian FDI include textiles, industrial equipment, consumer products automotive components, metals, and renewable energy.
- Italy's cumulative inward FDI investment is well below the EU average due largely to structural problems, which affect domestic as well as foreign investment. U.S. direct investment in Italy totaled \$30.70 billion in 2017, ranking Italy 8th in Europe, less than half of U.S. investment in France and one-fourth the size of U.S. FDI in Germany. U.S. investment in Italy is concentrated in manufacturing, computer services and software, and energy, with significant industrial relationships in the aerospace and automotive sectors.
- The current Italian government was formed in September 2019, when the anti-establishment Five Star Movement and the center-left establishment Democratic Party formed a coalition government with two minor parties. Giuseppe Conte serves as Prime Minister and Sergio Mattarella serves as President.
- Italy has a population of approximately 60 million. Industrial activity is concentrated in the north from Turin in the west through Milan to Venice in the east. This is one of the most industrialized and prosperous areas in the world and accounts for more than 50% of Italy's national income. By contrast, Italy's southern region, or "Mezzogiorno" is less developed.
- Small and medium-sized enterprises (SMEs) -many of them family-owned -comprise 99% of Italian businesses and produce 68% of Italy's GDP.
- Italy's SME sector has a higher proportion of firms employing fewer than ten people than the EU average. These companies contribute nearly half of total employment and one-third of value to the economy.
- Italy ranks 58 out of 190 countries in the World Bank Doing Business Report, and though its index score is gradually improving, it ranks 51 out of 176 countries in Transparency International's Corruption Perception Index.

### Market Challenges

- Italy's growth lags below the EU average although domestic consumption appears to be slowly rebounding. The Italian GDP grew marginally in 2019 and unemployment remains well above the EU average, particularly youth unemployment which is at 33%, the highest level across the Eurozone.
- Italy is a mature and sophisticated manufacturing market. U.S. entrants face strong competition from local and other EU companies in all market segments.
- Italy's regulatory environment is complex and at times lacks the transparency, clarity, efficiency and certainty found in other developed economies.
- Products that involve health, safety, or environmental concerns are likely to be highly regulated. While EU-wide regulations often apply, Italian laws may go beyond the basic EU requirements.

- Italian consumers are increasingly embracing digital services and the market is becoming more sophisticated. The digital evolution and growing internet penetration rates are fueled by investment in infrastructure from the Italian Government and key operators. Nevertheless, Italy still lags behind in fixed broadband and many SMEs lack funds to upgrade infrastructure. In Italy only 19% of SMEs have connection speeds of 100 Mbit/s.
- E-commerce in Italy is developing rapidly and has registered annual double-digit growth since 2014. Although the Italian digital economy lags behind other major European countries, e-commerce is poised to continue its upward trend with Business-to-Consumer (B2C), Business-to-Business (B2B), and Consumer-to-Consumer (C2C) transactions all posting solid growth.

## Market Opportunities

- U.S. firms enjoy opportunities in sectors where new regulations or programs (often imposed or initiated at the EU level) are creating demand; new products/services with little or no domestic competition; and where U.S. products offer clear technological, design, or price advantages.
- Best prospects for U.S. exports to Italy include: Advanced Manufacturing, Airport and Ground Support Equipment, Automotive Components, Biotechnology, Cosmetics and Toiletries, Cybersecurity, Medical Devices and Technologies, Pet Products, Safety and Security Equipment, Smart Grid Technologies and Travel and Tourism.
- Key U.S. exports to Italy include pharmaceutical products, industrial machinery and machine tools, electrical appliances, automobiles and auto parts, food and wine, and travel/tourism services.
- Pharmaceuticals ranks first among manufacturing sectors for U.S. investments. In 2015 U.S. biopharmaceutical companies had an annual turnover of 6 billion euro (20% of the total industry).
- The agricultural sector makes up a significant portion of U.S.-Italy trade. In 2019, U.S. agricultural, forest and fish exports to Italy were \$1.2 billion and U.S. imports from Italy were \$5.2 billion. Being a net agricultural importer, most raw materials and ingredients are imported, as Italy's economic strength is in the processing and the manufacturing of goods, primarily in small and medium-sized family-owned firms. Italy exports mainly consumer products to the United States, while the United States exports mostly bulk commodities to Italy.
- Italy announced plans to invest \$232 billion (196.5 billion euros) in transportation infrastructure investments over the next 15 years as part of its effort to kickstart its economy. It also announced measures to streamline public procurement to speed up government spending. Approved projects so far include \$134 billion for rail, \$64 billion of roads, 24.5 billion for mass transit, 5.5 billion for ports and 4 billion for airports.
- Italy hosts major trade shows that attract buyers from throughout Europe and beyond. The Commercial Service offers on-site support for U.S. exporters at most of the major international shows, or by request. The 2020 trade show calendar has largely been cancelled due to Covid concerns. Some shows are proceeding virtually while others are moving to dates in 2021.
- The U.S. Department of Commerce actively promotes investment in the United States through our [SelectUSA](#) program. In Italy we have extensively promoted opportunities to invest in the U.S. to Italian businesses, trade associations and multipliers. The Italian delegation to the Select USA Investment Summit in Washington DC has consistently been among the largest worldwide.

## Market Entry Strategy

- The cultivation and maintenance of personal relationships are a vital part of doing business in Italy. Finding the right Italian agent, distributor, or business partner is therefore essential. It is usually not effective to rely on agents or distributors located in neighboring markets, despite the existence of the EU common market.
- The ideal candidate should already have a network of relationships that will open doors in the market and solid understanding of local business practices and regulations. For technical products, the potential partner should have the ability to provide Italian customers with after-sales service.
- Patience is essential as it may take two to three times longer than expected to make relationships, establish a market presence or set up a business.
- The U.S. Commercial Service has offices in the U.S. Embassy in Rome and the U.S. Consulate in Milan to help U.S. exporters enter the market. Our industry and market experts help U.S. firms connect with key individuals and organizations through customized solutions including one-to-one meetings, company promotion events targeting customers and partners, market insights and advice, and participation in U.S. Pavilions at leading trade exhibitions.

- The U.S. Commercial Service offers regional customized solutions throughout Europe as well as country-specific programs. We help connect U.S. companies to opportunities across Europe.

For more information visit [www.export.gov/italy](http://www.export.gov/italy).

## Leading Sectors for U.S. Exports and Investment

The U.S. Commercial Service office in Italy has identified the following best prospect sectors for U.S. exporters.

### Advanced Manufacturing

#### Overview

Italy is the second largest manufacturing country in Europe with an extraordinary know-how in strategic, diverse sectors such as machine tools, fashion items, food products, automotive and pharmaceuticals. Successful Italian manufacturers are generally very export driven and invest in advanced manufacturing technologies that improve production and reduce manufacturing inputs.

Unfortunately, Covid has had a tremendous impact on the Italian economy in general and in particular on manufacturing, which represents 16.6% of Italy's GDP in terms of value added. Latest quarterly data available show that in the 3-month period from February to April 2020 industrial production in Italy decreased 23.2% versus the previous three months, with production of pharmaceuticals being the only sector showing growth (+2%). During the same period industrial revenues also decreased by 23.9%. The hardest hit industries were manufacturing of transportation vehicles, textiles and clothing. The EU Commission estimates that, as a result of the Covid pandemic and the lockdown imposed by the Italian Government, Italy's GDP will contract by 9.5% in 2020. However, the Commission also estimates that the GDP of Italy will bounce back by 6.5% in 2021, because of the return to economic activities in the country from May 2020 on and the Government measures to sustain them.

In 2019 the advanced manufacturing solutions market in Italy (known to Italians as "Industria 4.0") was worth €3.9 billion (\$4.37 bn.), +22% versus 2018, having almost tripled in 4 years. Originally, a growth rate between 20 and 25% had been forecasted for 2020, in line with the one for 2019, but Covid has altered those predictions, which now vary greatly between the original, optimistic scenario and one that accounts for the market shrinking by 5 – 10%. Nevertheless, the common sentiment towards all things "Industria 4.0" in Italy remains positive and the reaction to Covid through mandated or encouraged "smart working" may have accelerated digital transformation, which is a key element of advanced manufacturing.

#### Leading Sub-Sectors

Industrial Internet of Things (I-IoT) solutions accounted for 60% of the Italian advanced manufacturing technologies market in 2019 and their adoption had been growing rapidly before Covid. Milan's Politecnico University hosts an Observatory on Advanced Manufacturing and Internet of Things and in 2019 it conducted a survey on 100 large companies and 525 SMEs located in Italy, in order to understand which I-IoT projects were being implemented and what were expectations for the future. The first result that emerged was a significant gap in terms of knowledge: 97% of large companies in 2019 stated that they were familiar with I-IoT solutions compared with only 39% of SMEs. The survey confirmed that the most common I-IoT applications were those for factory management, i.e. Smart Factory, specifically for real time control of production and for predictive and/or preventive maintenance, followed by logistical support, i.e. Smart Logistics, for the traceability of goods within warehouses and along the supply chain. In terms of value, the Smart Factory segment was worth €350 million (\$392 million) in 2019, +40% versus 2018, and the Smart Logistics segment was worth €525 million (\$588 million), +26% versus 2018. Smart Lifecycle applications, i.e. projects aimed at optimizing product development and updates, were also increasingly becoming common. Besides I-IoT other relevant segments of the advanced manufacturing technologies market in Italy include additive manufacturing (worth €85 million/\$95 million in 2019), advanced automation (worth €190 million/\$212.7 million), industrial analytics (€630 million/\$705.3 million), cloud manufacturing (€325 million/\$363.8 million) and advanced Human-Machine Interface (HMI) solutions (€55 million/\$61.57 million). Additionally, the training and consulting market for "Industry 4.0" projects in 2019 was

#### Opportunities

A key factor for the recent growth of the advanced manufacturing technologies market in Italy has been the government of Italy's advanced manufacturing incentives plan, formerly known as "Piano Nazionale Impresa 4.0" and now known as "Piano Transizione 4.0". The latest version of the plan was signed on May 26, 2020 by the Minister of Economic Development. It consists of €7 billion (\$7.83 billion) in tax credits for investments in capital

goods, R&D and worker training, and expands by more than 40% the range of companies able to access the incentives. To counter the effect of Covid, the Plan also provides incentives for companies to invest in adapting production lines so that distancing can be guaranteed. It is hoped that the new version of the Plan will make it easier for companies to invest in digitalization, as data from previous plans showed that only a minority of companies (13%) had taken advantage of the incentives for digitalization due to high costs. Below is a summary of the technologies eligible for incentives. Opportunities exist for U.S. firms that can provide these types of technologies to the Italian market:

- 1) Advanced Manufacturing Solutions: autonomous, cooperating industrial robots with numerous integrated sensors and standardized interfaces;
- 2) Additive Manufacturing: 3D printing, particularly for spare parts and prototypes; decentralized 3D facilities to reduce transport distances and inventory;
- 3) Augmented Reality: augmented reality for maintenance, logistics, and SOP; display of supporting information, e.g., through glasses;
- 4) Simulation: simulation of value networks; optimization based on real-time data from intelligent systems;
- 5) Horizontal/Vertical Integration: cross-company data integration based on data transfer standards; precondition for a fully automated value chain (from supplier to customer, from management to shop floor);
- 6) Industrial Internet: network of machines and products; multidirectional communication between networked objects
- 7) Cloud: management of huge data volumes in open systems; real-time communication for production systems;
- 8) Cyber-security: operation in networks and open systems; high level of networking between intelligent machines, products, and systems;
- 9) Big Data and Analytics: full evaluation of available data (e.g., from ERP, SCM, MES, CRM, and machine data); real-time decision-making support and optimization.

## Resources

Italian Ministry of Economic Development document outlining Advanced Manufacturing

Plan in English (*original overview but provides a good overview of the plan's scope and policies*):

[http://www.sviluppoeconomico.gov.it/images/stories/documenti/2017\\_01\\_16-Industria\\_40\\_English.pdf](http://www.sviluppoeconomico.gov.it/images/stories/documenti/2017_01_16-Industria_40_English.pdf)

World Manufacturing Forum (WMF): November 11 – 12 2020, Cernobbio. 2- day conference that seeks to raise awareness and identify cooperative solutions to global manufacturing challenges through discovery, dialogue, and sharing of best practices between government, manufacturing, and innovation leaders.

<https://www.worldmanufacturingforum.org/>

Hannover Fair: April 12-16, 2021, Hannover. The world's leading industrial technology show, with many Italian exhibitors and attendees.

<http://www.hannovermesse.de/home>

## U.S. Commercial Service Contact:

Federico Bevini, Commercial Specialist

U.S. Commercial Service, U.S. Consulate Milan

Tel: +39 026268 8520

E-mail: [federico.bevini@trade.gov](mailto:federico.bevini@trade.gov)

<http://www.export.gov/italy/>



## Medical Devices and Technology

### Overview

Unit: USD Millions

	2018	2019 (Estimated)	2020 (Estimated)	2021 (Estimated)
Total Local Production	7,815	7,932	7,773	8,006
Total Exports	4,290	4,354	4,266	4,551
Total Imports	6,348	6,443	6,314	6,503
Imports from the US	374	390	382	393
<b><u>Total Market Size</u></b>	9,873	10,021	9,821	9,958

*The above statistics are unofficial estimates. They are based on reports and statistics from: Assobiomedica, BMI, Espicom, U.S. Dept of Commerce Bureau of Census and Eurostat.*

Italy is a mature market for medical equipment, and its high per capita income and sophisticated healthcare system translate into demand for a broad range of cutting-edge medical equipment. The Italian market for medical equipment and supplies is the fourth largest in Europe following Germany, France and the UK with about 3,957 companies (including 42% distributors, 53% producers and 5% service providers) and a workforce of 76,400. The Covid pandemic has negatively affected the medical devices market in Italy. While there has been an increase in demand for personal protective equipment and ventilators, most other medical devices, have seen a decline. The medical device market, including dental and optical devices, was valued at approximately \$9.8 billion in 2018 with imports accounting for \$6.3 billion. The Italian government is the primary purchaser of medical equipment. Public hospitals account for over 75 percent of medical device sales, with the remaining 25 percent of sales to the private sector. Despite having a considerable local manufacturing industry, the domestic market for medical equipment is highly dependent on imports. Major suppliers include the Netherlands, Germany, Belgium, France, and the United States, which had a 5.4% share of Italian imports, valued at \$374 million in 2018. Major U.S. medical device imports to Italy include diagnostic imaging, dental, and patient aids.

After medical devices, consumable products represent 19.7% followed by diagnostic imaging (16.7%) and patient aids (15.2%).

Budgetary pressures and escalating costs are moving Italy towards value-based health care: new products need to provide better health outcomes in cost-effective ways. In fact, the public healthcare system is likely to develop value- and quality-based pricing models and request data and analytics for cost-effective evidence. Preventive care, remote monitoring and early identification of at-risk-patients are increasingly valued.

The manufacturing sector comprises 3,605 production plants, made up of a broad network of small and micro businesses and technological start-ups. Local production is strong in diagnostic imaging equipment, contrast media for imaging, cardiology equipment, sterilizers, implantable pacemakers, hospital furniture, anesthesia equipment, respiratory apparatus, dialysis equipment, and dental products ranging from instruments to dental chairs. The highest concentration of medical devices companies is in Northern Italy, primarily in the regions of Lombardy, Veneto, and Emilia Romagna, which is an important hub for major medical device companies.

Approximately 60 U.S. manufacturers of medical equipment employ 5,700 workers and generate \$2.7 billion domestic revenue in Italy. Some U.S. suppliers maintain wholly-owned subsidiaries and sell equipment imported from the United States or from manufacturing facilities in third countries. There are also a considerable number of U.S. companies represented by local importers and distributors. Since U.S. technology and standards are highly regarded and recognized, U.S. companies are positioned to maintain their excellent market position in the future.

## Leading Sub-Sectors

### Medical Devices

The Italian government allocated at the beginning of 2020, 235 million euro for basic diagnostic devices acquisition, as part of the Italian healthcare plan to improve the local assistance to patients and therefore reduce dependence on emergency rooms. The basic diagnostic devices may include ECG, spirometers, holders, dermatoscopes, ultrasound devices such as Eco FAST, as well as health IT devices and platforms.

### E-Health

The European e-Health market has an estimated value of \$20 billion with an annual growth of 3 percent. Considering that the demand for healthcare products and services will rise significantly in coming years, the information technology applied to the healthcare systems is a key enabler for delivering more effective and efficient health care. In Italy the ICT expenditure in healthcare in 2018 was \$1.6 billion corresponding to 1.4% of the total healthcare expenditures, less than many other developed countries which average 2.5-3%. Despite the 7% increase compared to 2017 expenditures the adoption of digital instruments in healthcare remains fragmented.

EHEALTH INVESTMENTS	2017	2018	2017/208 %
Healthcare Facilities	1,051	1,145	+9%
Regions	378	389	+3%
General Practitioners	86	89	+4%
Ministry of Health	19.7	19.9	+1%

Source: Milan Politecnico School of Management

### Opportunities

Opportunities for U.S. manufactured medical equipment exist in the following areas: home care equipment, remote monitoring equipment, endoscopes and diagnostic imaging equipment non-invasive and micro-surgery devices and equipment, anesthesiology equipment, EKG, stimulators and defibrillators, ophthalmic equipment, monitoring equipment, telemedicine equipment and services. The Italian market is receptive to high quality and technologically advanced diagnostics as well as therapeutic equipment and products.

With increasing attention on reforming and improving healthcare management, medical devices companies providing services and solutions as add-ons to their products will also find strong opportunities e.g.: services to identify the appropriate patients for the use of a device, training for nurses on new procedures and products, partnerships with hospitals to increase efficiency.

The Covid emergency has accelerated the digital and organizational transformation towards a connected care model. According to the Osservatorio Innovazione Digitale in Sanità, over half of the Italian healthcare institutes have introduced smartworking and 51% of general practitioners worked remotely. Attention has increased towards telemedicine and artificial intelligence, considered useful to increase the personalization of treatments. The digital tools that general practitioners felt most needed were the smartphone to communicate with patients and other doctors (indicated by 72%), the portable laptop (61%) and services to access applications and documents remotely via VPN (60%), followed by tools for sharing and archiving documents (51%), virtualization solutions for desktops and applications (48%), tablets (47%), and tools for call-conferences (41%). The electronic prescription system was finally completed allowing patients to get their medicines directly from the pharmacies. The Covid crisis highlighted the need for the transition towards a more connected and digital healthcare model.

### Regulations and Procurement

The Italian government issues regulations governing the procurement of medical equipment. Recently the healthcare procurement system was re-organized into 33 procurements centers. Most purchases are made by public tender and

are open to both domestic and foreign companies. Announcements of tenders on public procurements are available on the National Procurement Center, CONSIP ([www.consip.it](http://www.consip.it)).

It is unrealistic for a foreign firm to believe they can navigate the cumbersome bureaucratic procedure of public procurement without having a base in Italy or a strategic Italian partner. Companies wishing to participate in public tenders must first qualify by submitting adequate evidence of their business experience and professional expertise.

In April 2017, the European Commission adopted two new regulations on medical devices (MDR) which entered into force in May 2017. These replace the three previous directives: *Active Implantable Medical Devices Directive* (90/385/EEC), *Medical Devices Directive* (93/42/EEC) and *In Vitro Diagnostic Medical Device Directive* (98/79/EEC). The new rules were expected to enter into full force in spring 2020. On April 22, 2020, The EU Council passed amendments officially delaying the MDR by one year until May 2021. The date of application for the in vitro diagnostics regulation will not be impacted, thus being May 26, 2022.

All medical devices marketed in the EU must bear the CE mark to certify conformity with EU law. Information on the new regulations can be found on the European Commission website:

[https://ec.europa.eu/growth/sectors/medical-devices/new-regulations\\_en](https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en)

The designated competent authority for medical devices in Italy is the Directorate General of Medical Devices and Pharmaceutical Services at the Ministry of Health. New-to-market medical devices must be registered and have a unique identification number in the National Health System directory (*Repertorio*). U.S. companies should designate a third party in Italy to register their products with the Minister of Health. The online registration can be found on the Ministry of Health website:

[http://www.salute.gov.it/portale/temi/p2\\_6.jsp?lingua=italiano&id=395&area=dispositivi-medicina&menu=registrazione](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=395&area=dispositivi-medicina&menu=registrazione)

#### **Resources**

**MINISTERO DELLA SALUTE** (Ministry of Health)

[www.salute.gov.it](http://www.salute.gov.it)

**CONFINDUSTRIA DISPOSITIVI MEDICI** (Italian Association of Medical Equipment Manufacturers)

[www.confindustriadm.it](http://www.confindustriadm.it)

**AIOP** (Italian Associazione of Private Hospitals)

[www.aiop.it](http://www.aiop.it)

#### **U.S. Commercial Service Contact:**

Kira Migliorini, Healthcare Technologies Specialist

U.S. Commercial Service, U.S. Embassy Rome

Tel: +39 064674 2202

E-mail: [Kira.Migliorini@trade.gov](mailto:Kira.Migliorini@trade.gov)

<http://export.gov/italy>

## Airport and Ground Support Equipment

### Overview

In 2019, Italian airports handled over 193 million passengers, an increase of 4 percent over 2018. Airports with the greatest passenger movement include Rome Fiumicino (43.5 million), Milan Malpensa (28.8 million), Bergamo (13.9 million), Venice (11.6 million), Naples (10.9 million) and Catania (10.2 million). For the second year in a row, air cargo activity slightly decreased (-3.2 percent) with 1.1 million tons of cargo transiting through Italian airports. Airports with significant freight traffic include Milan Malpensa (558,481 tons), Rome Fiumicino (194,526 tons) and Bergamo (118,964 tons). In February 2017, FedEx opened an expanded European logistics hub at Malpensa airport's Cargo City, and Amazon inaugurated a logistics hub in the province of Bergamo, both indicative of the significance of these airport networks.

The growth trend in both passenger and cargo container movement was expected to continue until the Covid pandemic hit, bringing traffic to a complete halt and pushing the airline and consequently the aircraft ground support equipment market into a recession. For 2020, the European airport association estimates a contraction in revenues of around \$26 billion, 41 percent less than the scenario expected before the pandemic spread. In March 2020, Italy saw a decrease of 66.3 percent in flights and a drop-in passenger traffic of about 85 percent, with respect to March 2019. In June, passenger traffic declined by 99.8 percent. Based on previous years, passenger traffic in May 2020 should have been around 17.9 million, with an estimated peak of 21 million in August. In early June, Italy partially lifted travel restrictions to and from the 26 other members of the European Union, Schengen Area members and the UK.

The Italian airline market is fragmented with both full service and low-cost carriers. Alitalia – Società Aerea Italiana (Alitalia SAI S.p.A.) is Italy's flagship carrier. Other Italian-owned charter airlines and low-cost carriers include Mistral Air, Blue Panorama, Easy Jet, Ryanair, Air Dolomiti, Air Italy (formerly Meridiana) and TUIfly. In May 2017, then UAE-backed Alitalia began bankruptcy proceedings and continued to suffer financially since. As the pandemic hit, the Italian Government announced its intention to renationalize the airline which remains challenging in a post-Covid world. A revamped Alitalia is expected to have a smaller fleet, with a reduction from 113 planes to between 92 and 105. International routes will be a focus rather than the fiercely competitive European short-haul market. The government's Relaunch Italy Decree came to the aid of the national airlines (Alitalia, Neos and Air Dolomiti) providing contributions to encourage a restart. The association of lowcost airlines (AICALF) operating in Italy (Blue Air, EasyJet, Norwegian, Ryanair, Volotea and Vueling) have asked for equal treatment.

### Leading Sub-Sectors

European Union ([EU Regulation n. 1087](#)) published in October 2011 requires all explosive detection systems (EDS) to meet standard specifications by September 1, 2020. A number of Italian airports have yet to make the required investments, including Turin, Naples, Venice, Genoa, Bologna, Verona, Ancona, as well as airports in the Apuglia Region and islands of Sardinia and Sicily.

Best prospects include anti-intrusion systems, automated baggage handling systems (BHS), approach surveillance radars, sea rescue equipment, precision approach path indicators and radars, digital x-ray systems, fire detection and extinguishing equipment and a broad range of services related to airport and ground handling operations. For passengers and hand luggage, airports are also adopting the latest technologies in hand and window metal detectors (HMD and WMD), explosives trace detectors (ETD), explosive trace detection systems (ETDS) and liquid explosive detection (LAG) systems. Other strong prospects include primary explosive detection systems (PEDT) and EDS for cargo luggage, as well as multi-level systems with threat image projection software for mail and parcels. The U.S. industry is recognized for its technological leadership in advanced products and quality standards and is expected to maintain a competitive edge.

### Opportunities

The Italian Government has worked actively to revamp the industry, establishing an independent transport regulation authority in September 2013 responsible for regulating issues such as taxation and infrastructure plans at national airports, railways, roadways and ports. Significant regulatory developments followed including the introduction of a new airport fee scheme, putting an end to a decade-long policy paralysis. Approved in 2015, the government's national airport plan followed a review of the airport infrastructure with the objective of rationalizing spending and expansion strategies, as well as improving intermodal accessibility to strengthen competitiveness and increase economic growth. The plan identified 3 strategic airports for intercontinental connectivity (Rome Fiumicino, Milan Malpensa, Venice),

10 under the Trans-European Transport Network (TEN-T) framework (Turin, Bologna, Pisa, Florence, Naples, Bari, Lamezia Terme, Palermo, Catania and Cagliari), and the remaining 25 of “national interest”.

The Italian market should continue to expect increased medium- and long-term investments, both private and public, for airport expansion, upgrading of existing structures and purchase of new equipment and system. Some airport infrastructure investments have been completed, others are underway, and more should be announced in the coming years. Investments are a mix of public, private and EU funding. A list of Italian airports that have presented master plans and investment values can be found in [ENAC's website](#).

The Milan Airports management company Sea S.p.A. invested a total of \$1.5 billion in infrastructure upgrades to support increased traffic for the World Expo 2015. An important expansion project continues in the Rome Fiumicino Airport managed by Aeroporti di Roma (AdR) S.p.A. The project, which involves private investments of over \$14 billion, was officially presented in Dec. 2011 and will run through 2044. The development plan is divided in 2 parts: the first focuses on the expansion of the current territory; the second (awaiting authorization) is a long-term project to expand airside and landside infrastructure through the acquisition of land to the north. The “E” international terminal was inaugurated in Dec. 2016, adding 90,000 square meters, two boarding areas and a state-of-the-art commercial center. Mid-term developments include the creation of new terminals, baggage handling systems and rapid transit systems. The airport and transportation infrastructures will be integrated in the wider context of an intermodal mobility plan with high speed rail service to Florence, Bologna, Venice, Milan and Naples. The total investment by AdR, the City of Rome, ANAS (road infrastructure) and RFI (railways) is \$8.7 million of which \$4.8 million will be covered by TEN-T funding.

In order to be considered as a source for Italian government purchases, we recommend that U.S. firms be established locally or represented by an agent/distributor.

Invitations to bid are published in the official European and Italian gazettes. For contracts below the European Community thresholds, the use of e-procurement platforms is widely established and encouraged by legislation to ensure, among other, the principles of economy, fair competition and transparency.

## Resources

Assaeroporti (Italian Airports Association): <http://www.assaeroporti.it/>  
Ministry of Infrastructure and Transportation: <http://www.infrastrutturertrasporti.it>  
Aeroporti di Roma (AdR) S.p.A.: [www.adr.it](http://www.adr.it)  
AdR expansion project:  
<http://www.adr.it/web/aeroporti-di-roma-en-/azn-airport-expansion>  
Sea S.p.A.: <http://www.seamilano.eu/en>  
ENAC: [www.enac-italia.it](http://www.enac-italia.it)  
ENAV SpA: [www.enav.it](http://www.enav.it)  
Official Gazette: <http://www.gazzettaufficiale.it>  
Italian tax administration: <https://www.agenziaentrate.gov.it/portale/web/english>

U.S. Commercial Service Contact:  
Maria Calabria, Commercial Specialist  
U.S. Commercial Service, U.S. Embassy Rome  
Tel: +39 06 4674 2427  
E-mail: [maria.calabria@trade.gov](mailto:maria.calabria@trade.gov)  
[www.trade.gov/italy](http://www.trade.gov/italy)

## Renewable Energy

### Overview

2018 is the last full year for which renewables capacity and production data in Italy were available. That year, overall installed power from renewables exceeded 54 GW, i.e. about 45% of the 118 GW-strong Italian generation park. During 2018 1,162 MW of renewables capacity were installed, broken down as follows: wind: 511 MW; photovoltaics: 437 MW; hydroelectric: 140 MW; biomass: 74 MW. Total installed capacity in 2018 was over 250 MW higher than that installed in 2017 (+ 28%). In 2018 Italy was the only major EU country to reach its 2020 renewable quota targets, set at 17%, ranking third in Europe in renewable energy consumption, after Germany and France.

The quota of renewables over total energy consumption in Italy in 2018 was 17.8%, broken down as follows:

Quota of renewables on energy consumption - Italy vs. EU 28 countries - 2018		
	Italy	EU 28 Countries
Renewables/Total Energy Consumption	17.8%	18.0%
Renewables/Transportation	7.7%	8.1%
Renewables/Electrical power generation	33.9%	32.1%
Renewables/Thermal power	19.2%	19.7%

Source: GSE

2019 whole-year data on renewables still have to be confirmed. However, during a June 2020 seminar GSE, the Italian government-owned company responsible for the development of sustainability and the granting of incentives for renewables and energy efficiency, presented a few key provisional 2019 data: total production from renewables: 116 TWh; additional renewable power installed: 1.2 GW, mainly photovoltaic (+750 MW) and wind (+400 MW), compensating for a decrease in hydro. GSE also noted that in 2019 overall installed power from renewables in Italy amounted to 55.5 GW. Moreover, in 2019 18% of energy consumption (electrical, thermal and transportation) was satisfied by renewables.

Because of the Covid pandemic, which impacted energy production and consumption, it is estimated that any forecasts for renewable power generation in 2020 and 2021 will have to be revised down by about 10%, despite renewable energies being more resilient than fossil fuels. Even with continued cost reductions, renewables are not sheltered from future market uncertainty caused by Covid in terms of demand and availability of financing. However, Ernst & Young's May 2020 Renewable Energy Country Attractiveness Index observed that "Italy will keep playing a central role in this sector." This is confirmed by the strategic plans to bolster renewables prepared by **the Government during the last few years.**

### Leading Sub-Sectors

#### Sources of Import

The renewable technology showing the strongest growth rate (past and future) for Italy is photovoltaic (PV) solar production, with over 22 TWh produced in 2018 by photovoltaic systems and installations. According to the International Energy Agency's Snapshot of Global PV Markets, Italy is among the countries that now have enough PV capacity to theoretically produce more than 5% of their annual electricity demand with PV. In 2019 Italy installed around 0.6 GW new PV power and ranks sixth among world countries and second in Europe for total PV installed capacity (20.8GW). Italy's €5.4 billion (\$6 billion) renewable incentives program is expected to spur new growth in

large scale PV while also providing incentives for rooftop systems. In order to receive the incentives, plants whose power is below 1MW will need to be enrolled in specific registers and for plants above 1MW auctions will be used.

### **Opportunities**

The Integrated National Plan for Energy and Climate (PNIEC) describes Italy's strategy from 2021 to 2030 with regards to decarbonization, energy efficiency, self-consumption and distributed generation, energy security and consumption electrification. The Plan aims to bring the share of renewables of the final gross energy consumption to 30% by 2030. The Plan's installed power objectives for the various renewable sources in 2025 and 2030 are ambitious and challenging. With regards to electricity generation, the Plan expects power generated by renewables by 2030 to increase by 65% compared to its current total, with renewables scheduled to cover more than 55% of national electricity consumption (estimated at 337 TWh) in 2030. Specifically, the Plan places a strong emphasis on wind energy (set to reach in 2030 almost twice the amount of installed power in 2017) and photovoltaics (2.5 times the 2019 installed power). This means a total increase of installed power from renewable sources by 75%.

Leading global energy company ENEL, headquartered in Italy and with a growing presence in North America, has committed to a “complete decarbonization” by 2050, which includes an increase in the weight of renewable energy to 60GW by 2022. Already, renewables represent 64% of Enel's total power generation capacity. ENEL welcomes the opportunity to partner with innovative U.S. technology providers through its Innovation Hubs network (with hubs located in the USA as well).

An area of opportunity for U.S. companies is in integrated photovoltaics and energy storage along with sustainable (electric) mobility.

### **Resources**

GSE: <https://www.gse.it/en/>

PNIEC – Integrated National Energy and Climate Plan:

[https://www.mise.gov.it/images/stories/documenti/it\\_final\\_necp\\_main\\_en.pdf](https://www.mise.gov.it/images/stories/documenti/it_final_necp_main_en.pdf)

Ecomondo/KeyEnergy trade show, Rimini, November 3 – 6 2020: <https://en.ecomondo.com/>

Enel Innovation Hubs: <https://startup.enel.com/en/innovation-hub.html>

U.S. Commercial Service Contact:

Federico Bevini, Commercial Specialist  
U.S. Commercial Service, U.S. Consulate Milan  
Tel: +39 026268 8520  
E-mail: federico.bevini@trade.gov  
<http://www.export.gov/italy/>

## **Automotive sector**

### **Overview**

Automotive is a major industry sector for Italy. In 2019 the Italian automotive supply chain was formed by over 5,500 companies and employed 274,000 employees (direct and indirect); its turnover was \$118.5 billion, 11% of manufacturing turnover in Italy and 6.2% of Italian GDP.

In 2019, Italy was the fourth European market after Germany, the UK and France. Sales were stable (1.916 million compared to 1.91 million in 2018). Italy was in the first quarter of 2020, the 3rd largest European automotive market after Germany and France, with 347,000 new registered passenger vehicles, a 35.5% decrease compared to the same period in 2019. The market was sharply diminished by the Covid crisis and the ensuing economic downturn. However, the situation seems to be slowly improving, as 132,000 new passenger vehicles were registered in June 2020, 23.1% less than June 2019. Between January and June 2020, the reduction was 46% (594,000 units in 2020 compared to 1,083,000 in 2019). In 2019 the Italian vehicles production was 854,000 units (995,000 in 2018.)

Italy is also one of the largest European markets for motorcycles and mopeds; in 2019 the total amount of two – wheel vehicles registered (mopeds excluded) was 232,000 units, 5.7% more than in 2018. In the first five months of 2020 registrations were 67,000 units, 38.6% less than in the same period in 2019. Considering the total market (mopeds included), registrations were 73,000 units in 2020, 37.8% less than in the first five month in 2019.

### **Leading Sub-Sectors**

#### **The Italian automotive market**

In 2019 and in 2018, foreign brands captured about 75% of the Italian automotive market. Major foreign competitors, all manufacturing abroad, were PSA and VW, respectively with 14% and 8% of the market. Italian manufacturers registered a 26% market share. FCA is the only auto manufacturer producing significant volumes of cars and light commercial vehicles in Italy. FCA models are mostly manufactured in Italy; some of them are imported from abroad, including from North America. Jeep models are both imported from the United States, (and from North America), and manufactured locally in Melfi (Italy). In the framework of the current incentives to help the automotive sector, FCA was given a \$7.05 billion state-backed loan to help its Italian unit and the whole country's automotive market and supply chain to overcome the crisis. FCA is supposed to complete a merger with the French PSA Group by the first quarter of 2021. Ferrari, Lamborghini, and Maserati are also manufactured in Italy. In 2018, Ford sold 129,000 cars (6.8% of the Italian market) and saw a decrease in 2019 to 122,000 cars (6.4% of the Italian market). In May 2020 Ford Puma was the bestselling hybrid car in Italy with 1,200 units. Tesla increased its sales from 53 units in 2018 to 364 units in 2019. Tesla's market share reached 1.5% in Italy in March 2020 from 0.14% of market share in March 2019.

Italy has one of the largest car stocks in Europe (over 39.5 million units in 2019, or 1.4% more than 2018). Cars are, on average, 11 years old. Italy also had a stock of 100,000 buses and 6.9 million motorcycles in 2019.

#### **Alternative Fuel Vehicles**

Alternative fuel vehicles are a sizable share (21%) of the Italian car market primarily due to incentives to buy non-polluting or less polluting models. There are country-wide bonuses as well as some local, 'regional' incentives

Italy remains a strong market for both LPG and CNG vehicles. In the past FCA opted for developing technologies related to these vehicles, more recently focusing on hybrid and electric models.

The alternative fuel vehicles market is composed by both new and retrofitted used vehicles. It is hard to determine proportion of vehicles manufactured in Italy versus imported. Alternative fuel vehicles rely on a widespread distribution network, with thousands of LPG and CNG refilling stations.

#### **Automotive Components**

Italy is one of the major world manufacturers of automotive components and in 2019 the sector's balance was \$7.31 billion. The United States was Italy's 5<sup>th</sup> export market, worth \$1.48 billion. U.S. imports accounted for 3% of the total Italian imports or \$580 million, creating a U.S. deficit was \$900 million. U.S. automotive component manufacturers, including Exide, Federal Mogul and PPG, have a significant manufacturing presence in Italy where they manufacture parts used in vehicles that are produced locally and then exported.



## Opportunities

Italy is an interesting market for alternative fuels technologies. The U.S. has a competitive advantage in the use of alternative fuels, particularly in the public transportation sector. Besides that, the Italian market offers opportunities for U.S. companies active in the following subsectors:

- Diagnostic equipment needed to maintain gasoline engines converted to dual fuel (gasoline/LPG and gasoline/CNG).
- Refueling stations, including parts and components. The increasing number of LPG and CNG vehicles requires refueling stations allowing for self-service refueling (self-service is very rare in Italy and was prohibited until recently due to safety reasons.)
- Electric vehicles. The Italian market shows interest in electric cars and two and three-wheelers. Since 08/01/20, new, diversified, incentives between Euros 1.75k and 10k are available to buy new Euro 6, hybrid or electric vehicles. A price ceiling (Euros 40 or 50k + taxes) is applied.

## Resources

Trade shows:

- [Automotive Dealer Day](#): – Digital Edition: September 16<sup>th</sup> - 17<sup>th</sup>, 2020. Innovative mobility services.
- [Oil&nonoil - Fuel Storage & Transport](#): October 20<sup>th</sup> - 23<sup>rd</sup>, 2020, Verona, Italy. Italy's only event for all players in the liquid and gas fuel distribution industry.
- [MBE](#) (Motor Bike Expo): January 21<sup>st</sup> - 24<sup>th</sup>, 2021, Verona, Italy. It is the world's largest custom motorcycle event, a key point of reference for the biggest brands in the motorcycle market.
- [EICMA](#) – International Motorcycle and Accessories Exhibition: November 11<sup>th</sup> - 14<sup>th</sup> 2021 (November 9<sup>th</sup> - 10<sup>th</sup> reserved to press and trade), Milano – Rho Fiera, Italy. It is the most important trade fair event for the entire two – wheel sector in the world.
- [Autopromotec](#): May 25<sup>th</sup> - 28<sup>th</sup>, 2022, Bologna, Italy. The most specialized international exhibition of automotive equipment and aftermarket products.

Major Associations:

- [ACI](#) – Automobile Club of Italy
- [ACEA](#) – European Automobile Manufacturers Association
- [ANCMA](#) – Italian of Cycles, Motorcycles and Accessories
- [ANFIA](#) – Italian Association of the Automotive Industry
- [UNRAE](#) – Association of foreign car makers operating in Italy

U.S. Commercial Service Contact:

Mr. Andrea Rosa, Commercial Specialist  
U.S. Commercial Service, U.S. Consulate Milan  
Tel. +39/02/62688-523  
E-mail: [Andrea.Rosa@trade.gov](mailto:Andrea.Rosa@trade.gov)  
Website: [Export.gov/Italy](https://Export.gov/Italy)

## Biotechnology

### Overview

The importance of the biotech industry to growth and competitiveness in Europe is clear. Recognized as a Key Enabling Technology (KET) under Horizon 2020, <https://ec.europa.eu/programmes/horizon2020/en> the majority of innovative medicines as well as many diagnostic products are developed or manufactured using biotechnology. Globally, biotech medicines represent 20% of commercialized drugs, 40% of authorized drugs and 50% of drugs under development. In Italy there are already 110 biotech drugs available.

In recent years, the biotech industry in Italy has developed due to excellent academic and industrial research. Italian biotech companies totaled 696 in 2019. The turnover is over \$12.5 billion with an average annual increase of 5% between 2014 and 2018, while investments in R&D amounted to \$2.6 billion with about 4,526 employees in biotech research.

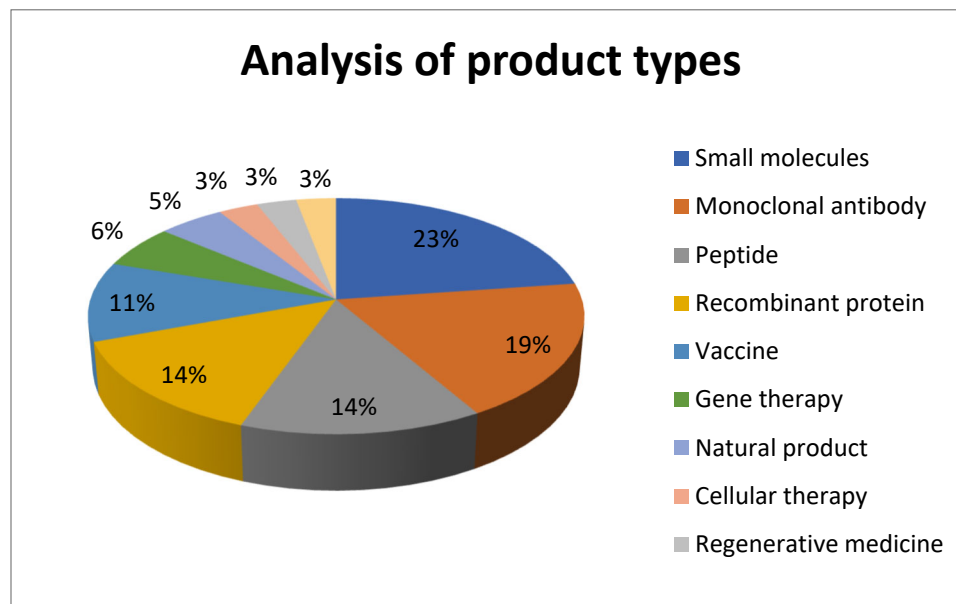
Companies in the life sciences biotech sector in Italy account for 344 of the total of 696 firms. Pharmaceutical and medical devices biotech firms (74%) are responsible for much of the turnover. There are approximately 100 laboratories (public research centers and university labs), 47 Scientific and Research Hospitals (IRCCS) and 200 companies. The development of this sector will provide strong opportunities for major U.S. biotech companies looking to partner in order to advance new treatments and product development.

According to the 2019 report and the Covid Survey by Centro Studi Assobiotec, the Italian biotech industry is particularly dynamic in the areas of precision medicine and advanced therapies, including genomics and proteomics (12% of companies). During the pandemic, Italian companies made an important contribution in research and production of solutions against the virus (57% of the sample) with particular reference to the area of diagnostics (44%) and therapeutic research (34%). 7% of companies were involved in a vaccine research.

The survey and report conclude that this industry needs a long-term national strategy with stable and certain rules to further develop and remain competitive. Currently, Italy relies on biotech drug imports primarily from the United States, Belgium and Germany.

### Leading Sub-Sectors

Italian biotech companies are primarily concentrated in the following areas: oncology, infectious diseases, inflammatory disease, neurological disease and cardiovascular diseases. Recent reemergence of infectious diseases and epidemic outbreaks have oriented investments towards vaccines and new drugs.



Centro Studi Assobiotec – ENEA Servizio Industria e Associazioni Imprenditoriali

Biopharmaceuticals account for 45% of the projects in the pipeline (discovery phase included), which includes monoclonal antibodies, recombinant proteins and advanced therapies (cellular, genetics and regenerative medicine).

Out of 375 projects, 131 are in the discovery phase, 171 are in the pre-clinical phase and 73 in clinical development:

- Discovery: 131
- Pre-clinical: 171
- Phase I: 33
- Phase II: 28
- Phase III: 12

Orphan drugs and advanced therapies represent areas of excellence and the Italian academic research sector has the highest number of scientific publications on orphan drugs, while the first ever approved product in advanced therapy in the Western world is a stem cell drug developed by an Italian biotech company.

14 products from Italian biotech companies have received at least one Orphan Drug Designation (ODD), while three products from Italian companies have obtained final market access:

- Defibrotide (Defitelio®): a life-saving drug for the treatment of the veno-occlusive hepatic disease;
- Safinamide (Xadago®): a therapy for Parkinsons disease; and
- Holoclar (Holoclar®): an advanced therapy for patients with corneal burns.

Most Italian biotech companies were created as start-ups or spin-offs from academia or industry. These biotech companies are primarily located in scientific parks or incubators (47%), universities or research labs (25%) or are independent (28%). The scientific parks are fundamental network centers for research, enterprise and capital, allowing very small companies to access the necessary resources to grow.

Regionally, Milan is the leading biotech area in Italy, housing approximately 35% of all biotech companies, including Newron and BioXell. Additionally, Lombardy is home to 12 universities, 26 institutes and centers of the National Research Council (CNR), of which 10 are in the biotechnology and health sciences sectors.

Small and medium-sized biotech companies in Italy are often the incubators of innovative products for the biopharmaceutical industry. There are a number of U.S. manufacturers of biotech products in the Italian healthcare market: Biogen, AbbVie, Amgen, Alexion, Bristol-Myers Squibb, Eli Lilly, Gilead, and Pfizer maintain wholly-owned subsidiaries in Italy.

## **Opportunities**

### **Human Technopole**

At the closure of the 2015 Milan Expo, Italy launched a project for building a new national cross-disciplinary research institute focused on life sciences, called *Human Technopole* (HT), offering strong opportunities for both U.S. and Italian companies. Its mission is to contribute to the development of personalized medicine in the treatment of cancer and neurodegenerative diseases. To this end the HT will use genomics, innovative algorithms for data analysis, multiscale methods in computational life sciences and advanced technologies for food and diagnostics. The new groundbreaking infrastructure will include seven research centers and four facilities). By fall 2020, the HT first wet laboratories called Incubator Labs will be ready. The development of the South Pavilion will be completed by spring 2021, while the North Pavilion, which will host research facilities – including the cryo-EM imaging facility – is due to be completed by summer 2020 with equipment installed by fall 2020. In February 2018, the coordinating committee appointed Scottish scientist Iain Mattaj as the HT Director General. To find more information visit <https://htechnopole.it/en>.

### **Government Incentives**

In recent years the Italian government has adopted a number of incentives to support innovation to foster economic growth:

- recognition of the status of “innovative” start-ups;
- introduction of a tax credit on research;
- preferential tax policy on revenue generated by intellectual property rights;
- and recognition of the status of “innovative” SMEs

## Venture capitals and business angels

Furthermore, a number of initiatives to finance new enterprises in Life Sciences have been recently launched, such as the venture capital fund Panakès ([www.panakes.it](http://www.panakes.it)) with 120 million euro dedicated to biomedical technologies and medical devices, the fund Principia III Health ([www.principiasgr.it](http://www.principiasgr.it)) with 206 million euro and the association of business angels, Italian Angels for Biotech – IAB ([www.italianab.it](http://www.italianab.it)), created by a group of entrepreneurs, managers and scientists to support ideas and talents in this sector.

However, with a total investment of 8.5 billion dollars, the Italian venture capital market remains significantly below levels in other major European countries.

## Partnering opportunities

The major networking event in Europe for U.S. companies is BIO-Europe. The largest conference serving the global biotechnology industry, it annually attracts leading dealmakers from biotech, pharma and finance along with the emerging companies. The conference features around 3,500 attendees and 19,200 one-to-one meetings. Upcoming conference in Munich, Germany October 26-28, 2020 (<http://www.ebdgroup.com/>).

The key Italian event to boost business, partnering and networking opportunities is “Meet in Italy for Life Sciences”, which will take place in Genoa on May 12-14, 2021. The last edition featured 300 participants and 1,400 one-to-one meetings: <https://meetitalylifesciences.eu>.

## Requirements

### Biopharmaceuticals

The main regulatory authority in Italy is the Ministry of Health. All products must be registered with the Ministry of Health’s pharmaceuticals committee, Commissione Unica del Farmaco (CUF). The regulatory body for pharmaceuticals is the AIFA (Italian Drug Agency). Market regulation is based on EU Directive 65/65/EEC, 75/318/EEC and 75/319/EEC. Despite the fact that the Italian has not implemented new measures impacting drug makers since 2014, issues such as the lengthy drug approval process and drug expenditures ceilings creates challenges for innovative pharmaceutical companies in the market.

### Biotech Medical Devices

In April 2017, the European Commission adopted two new Regulations on medical devices which entered into force in May 2017. These replace the existing three Directives: *Active Implantable Medical Devices Directive* (90/385/EEC), *Medical Devices Directive* (93/42/EEC) and *In Vitro Diagnostic Medical Device Directive* (98/79/EEC). The new rules were expected to entry into force in spring 2020. On April 22, 2020, The EU Council passed amendments officially delaying the MDR by one year until May 2021. The date of application for the In Vitro Diagnostics regulation will not be impacted, thus being May 26, 2022.

All medical devices marketed in the EU must bear the CE mark to certify conformity with EU law. Information on the new regulations can be found on the European Commission website:

[https://ec.europa.eu/growth/sectors/medical-devices/new-regulations\\_en](https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en)

The designated competent authority for medical devices in Italy is the Directorate General of Medical Devices and Pharmaceutical Services at the Ministry of Health. New-to-market medical devices must be registered and have a unique identification number in the National Health System directory (*Repertorio*). We recommend that U.S. companies designate a third party in Italy to register their products with the Minister of Health.

### Clinical trials

In Italy, clinical trials are regulated by the new EU [Regulation 536/2014](https://ec.europa.eu/health/human-use/clinical-trials/regulation_en) concerning the implementation of best practices in the conduct of clinical trials on medicinal products for human use. The new Regulation substitutes the EU Directive 2001/20/EC. The regulation will ensure that the rules for conducting clinical trials are identical throughout the EU. More information is available at [https://ec.europa.eu/health/human-use/clinical-trials/regulation\\_en](https://ec.europa.eu/health/human-use/clinical-trials/regulation_en).

For pharmaceuticals, the responsible authority is AIFA, while for medical devices the Italian Ministry of Health is the main point of contact.

## Resources

**Ministero Della Salute** (Ministry of Health)

[www.salute.gov.it](http://www.salute.gov.it)

**AIFA** (Italian Drug Agency)

[www.aifa.it](http://www.aifa.it)

**ASSOBIOTEC** (Italian Association of Biotechnology)

[www.assobiotec.it](http://www.assobiotec.it)

**Cluster ALISEI** (Advanced Life Sciences in Italy)

Association to promote and enhance innovation

[www.clusteralisei.it](http://www.clusteralisei.it)

**Farmindustria** (Italian Trade Association for Pharmaceuticals)

[www.farmindustria.it](http://www.farmindustria.it)

**Confindustria Dispositivi Medici** (Italian Trade Association for Medical Devices)

[www.confindustriadm.it](http://www.confindustriadm.it)

### **U.S. Commercial Service Contact:**

Kira Migliorini, Healthcare Technologies Specialist

U.S. Commercial Service, U.S. Embassy Rome

Tel: +39 064674 2204

E-mail: [Kira.Migliorini@trade.gov](mailto:Kira.Migliorini@trade.gov)

<http://export.gov/italy>

## Cybersecurity

### Overview

In 2019, the Italian cybersecurity market grew for the third consecutive year and was valued at \$1.5 billion, registering an increase of 11 percent compared to the previous year. The software segment was valued at just over \$450 million. Forecasts indicate a short-term growth rate of 7 percent over the 3-year period 2019-2022. The security and vulnerability management and network security categories continue to drive the sector, in some cases with growth rates of up to 10 percent. The integration of machine learning for the management of corporate vulnerabilities will support the growth of this sector in the medium- to long-term. Experts estimate that the security appliances segment will grow by 3 percent over the same period, while the services segment -- valued at just under \$675 million in 2019 -- should see an increase of about 2 percentage points.

According to the Italian Information Security Association (CLUSIT), in 2019 about 1,670 serious attacks were recorded, an increase of 7.6 percent compared to 2018, with a prevalence of threats related to cybercrime. The highest number of serious attacks is observed in the categories “Multiple Targets” (+29.9 percent), “Online Services/Cloud” (+91.5 percent) and “Healthcare” (+17 percent), followed by “Retail” (+28.2 percent), “Telecoms” (+54.5 percent) and “Security Industry” (+325 percent). An increasing number of cyberattacks are linked to the coronavirus emergency. The use of remote working arrangements, frequently with personal devices connected to home networks crowded with connected devices, is increasing vulnerabilities and risks for employees and companies. Cyber experts predict that cybercriminals will continue to use Covid in their campaigns in the foreseeable future.

A clear improvement in GDPR compliance was seen last year, although there are still a number of non-compliant companies. At the end of 2019, 55 percent of companies resulted compliant (compared to 24 percent at the end of 2018) resulting in a 45 percent increase in investments. Today, 61 percent of Italian companies have a Data Protection Officer.

Comparatively, Italy still lags behind other European countries in terms of cyber solutions in place. Large company investments primarily drive the Italian market for cybersecurity. The manufacturing sector makes the largest investments related to Industry 4.0 and to artificial intelligence (AI) technologies used by 45 percent of large companies with forecasts for continued growth. The financial/banking and utilities sectors are the main end-users of ICT security, followed by defense, national and local governments, manufacturing, transportation and telecommunications sectors. A recent market study published by IDC Italia indicates that by 2025, 25 percent of spending in security services will be destined to create and maintain a “trust framework”. Approximately 52 percent of security investments are in technological solutions, while the remainder is in services that show a growth trend.

More than 50 percent of small- and medium-sized enterprises (SME) continue to be unprepared to face increasing threats. One in 5 does not have a specific investment plan for information security or allocates resources only in case of need. Managers of small firms tend to show resistance in approving ICT security expenditures perceiving security as a cost rather than an investment. Sector analysts expect security spending by SMEs to grow given a slowly changing mindset to acknowledge cybersecurity as a core business requirement. Medium-size companies and (to a lesser extent) small companies are increasingly investing in ICT security, often choosing cloud security to take advantage of the most advanced solutions.

At the EU level, the Network and Information Systems (NIS) Directive took effect on June 26, 2018. The directive sets minimum baseline requirements to ensure better protection of critical infrastructures, outlines basic principles for Member States for common minimum capacity building and strategic cooperation, and directs operators of essential services (OES) and digital service providers (DSP) to ensure the application of basic common security requirements. The EU Cybersecurity Act entered into force on June 17, 2019. It aims to create a European framework for IT security certification of ICT products and digital services.

The Italian government considers cybersecurity a top priority and presented the first national cybersecurity framework in 2015, much of which derives from the U.S. NIST framework. Most provisions of the NIS Directive were already implemented through the national framework. Ministries with regulatory authority over OESs include the Economic Development, Infrastructures & Transportation, Economy & Finance and Health and Environment. The Security Intelligence Department (DIS) has been designated as the point of contact agency with the EU authorities.

## Leading Sub-Sectors

Top market drivers include increased IT security awareness and enforcement of new government measures, while challenges stem from the adoption of new technologies and new business organizational models requiring the implementation of security measures such as secure mobility and virtualization (digital transformation processes). Public administration investments are expected for the protection of digital identity and critical infrastructures.

U.S. technology is highly regarded, and strong opportunities exist for American companies offering innovative and sophisticated products and value-added services. Italy is a signatory of the Information Technology Agreement (ITA), a multilateral agreement that eliminates import duties on a large number of high technology products, including computers, telecommunication equipment, semiconductors, semiconductor manufacturing and testing equipment, software, scientific instruments, and many parts and accessories of these products. This applies also to products imported from the United States.

## Opportunities

Opportunities exist in the following areas:

Software: Mobile security; Cloud security; secure content management; identity and access management solutions, including solutions for controlling access to physical and virtual servers; security/vulnerability management solutions; strong authentication software solutions; Identity Relationship Management (IRM) for Internet of Things (IoT); endpoint solutions.

Hardware: Unified Threat Management (UTM) appliances; firewall/VPN appliances; intrusion detection/ prevention systems; secure content management appliances.

Services: Security management policy development; risk and vulnerability assessment; policy audit; policy enforcement consulting; management support consulting; managed security services; remote monitoring and management of security technologies.

## Public Sector

The implementation of EU legislation and actions stemming from the National Framework and the National Cybersecurity Plan are expected to facilitate the growth of this market. As part of its Digital Agenda, the Italian government is planning to make considerable investments in digital identity protection to increase the security levels of digital transactions and therefore the trust of consumers; to guarantee that online privacy and data laws are enforced to protect citizens' identities; and to activate warning systems to notify citizens when security breaches occur.

Public Administrations make their most relevant purchases through public tenders open to both domestic and foreign companies. Tender announcements are published in the EU's Tenders Electronic Daily (TED), <https://ted.europa.eu/TED/main/HomePage.do>. For information on public procurement in the EU, visit the U.S. Mission to the European Union website: <http://export.gov/europeanunion/>

## Resources

Security Intelligence Department (DIS) <https://www.sicurezza.gov.it/sisr.nsf/english/italian-national-cyber-strategy.html>

National Strategic Framework for Cybersecurity <http://www.cybersecurityframework.it/en>

Italian Cybersecurity Association (CLUSIT) <https://www.clusit.it/homee.htm>

Italian Association of Critical Infrastructures Experts (AIIC) <https://www.infrastrutturecritiche.it/>

La Sapienza University Research Center of Cyber Intelligence and Information Security (CIS) <http://www.cis.uniroma1.it/en>

Italian ICT Industries Association (Assinform) <http://www.assinform.com/>

Italian Digital Agenda (Agenzia per l'Italia Digitale) <https://www.agid.gov.it/en>

## Trade Events

Infosecurity Europe, London, June 8-10, 2021

<https://www.infosecurityeurope.com/>

U.S. Commercial Service Contact:  
Maria Calabria, Commercial Specialist  
U.S. Commercial Service, U.S. Embassy Rome  
Tel: +39 06 4674-2427  
E-mail: [maria.calabria@trade.gov](mailto:maria.calabria@trade.gov)  
<http://export.gov/italy>



## Travel and Tourism

### Overview

	2016	2017	2018	2019	2020
<b>Number of Italian Travelers to the US</b>	983,000	1,032,107	1,073,383	1,086,026	160,626 <sup>(p)</sup> Jan. to May
<b>% Change</b>	-5%	4.4%	4.0%	1.2%	-64.6%*
<b>Total Italian Travel &amp; Tourism Exports (Millions of USD)</b>	\$4,075	\$4,189	\$4,367	\$4,327	*
<b>% Change</b>	-5.8%	3%	4%	-1%	*

**Data Sources:** U.S. Department of Commerce, ITA, National Travel and Tourism Office (NTTO) from the International Travel to the U.S. (I-94) report.

(p) Preliminary 2020 I-94 visitor arrivals data will be revised during calendar year 2020. -- \*Data not yet available

Italy ranks as the 12<sup>th</sup> largest overall inbound market to the United States and the 4<sup>th</sup> in Europe after The United Kingdom, Germany, and France. In 2019, the market for Italian tourism to the United States continued to grow for the third year in a row reporting an increase of 1.2% compared to 2018 and 5.3% compared to 2017. In 2020, the Covid outbreak and the ensuing economic downturn sharply diminished the market. Preliminary data for January to May 2020 shows a decrease of 64.6%. Summer typically one of the peak travel periods, was hard-hit by the closure of U.S. Borders to travelers from Italy and the rest of the Schengen area to limit the Covid spread. As of publication, the sector is hoping to re-start activities in the second half of the year, especially during the holidays.

Despite the difficult time, the United States continues to be the preferred long-haul destination for Italians. Data from the U.S. Department of Commerce National Travel & Tourism Office (NTTO) shows that the primary ports of entry in 2019 were New York (39.4%) and Miami (15.5%). The four top states most visited by Italians were New York (46.6%), Florida (22.6%), California (18.8%) and Nevada (11%).

### Air Travel

Three U.S. carriers American Airlines, Delta and United, an Italian one, Alitalia, and others, offer daily non-stop service between the U.S. and Italy. Direct flights are offered from major Italian cities (Milan, Rome) and seasonally (Spring/Summer) also from Venice, Bologna and Naples. During Spring/Summer months, more than thirty non-stop flights connect Italy to the US, most of them with daily departures, for a total of over 180 direct flights each week.

### Accommodation

Most major U.S. hotel chains are represented in Italy: Best Western International, Hilton Worldwide, Hyatt, Marriott International, Starwood and Wyndham Hotel Group, thus making bookings in the US relatively easy for the Italian buyer.

### The profile of the Italian tourist:

In comparison to other countries, Italians look more for active and cultural trips, and are becoming less attracted to sea and sun. Holidays are almost always meant for discovering, not just relaxing.

- The outbound traveler is on average aged between 35 and 54
- Seniors represent an emerging and relevant traveler segment profile with high purchasing power and able to travel in any period of the year
- Italian travelers usually come from urban areas with a medium-high social and cultural profile
- They generally prefer organized tours with Italian speaking guides
- Italians consider security, quality of accommodation, and food as important elements
- Italians are traditionally lastminute bookers.

## Leading Sub-Sectors

**Tour Operators:** in Italy there are more than 280 Tour Operators, but only four exceed 100 million in annual revenues. Small/medium sized companies are the real engine driving the market, ensuring a greater flexibility and speed of response to travel agencies.

**Travel Agencies Networks:** around 8,500 travel agencies are currently working in Italy. Most of them (around 7,000) are associated to a travel network. The main 5 Italian networks are:

Welcome/Geo, Bluvacanze, Gattinoni Mondo di Vacanze, UVET, Robintour.

**Travel Agencies:** tour operators products account for only 54 percent of sales for travel agents; the remaining 46 percent is defined as “self-tour operating” with direct negotiations between the Italian travel agent and the inbound and/or hotel in the destination. The main market trends include vertical integration of the travel network and group trips organized by single travel agencies.

**OTA (Online Travel Agencies):** online booking is becoming more and more pervasive (from mass market websites to specialized portals or dedicated to specific targets).

## E-Commerce

The Italian tourism market continues to be dominated by the steady growth of e-commerce and mobile sales. Online travel continued to perform very well in 2019, driven by increased trust and habit of travelers. Mobile bookings also grew rapidly, as smartphones are widespread among Italian consumers. Direct booking through OTAs (Online Travel Agencies) is increasing with a total of 7 online travel agencies available (Expedia, TripAdvisor, Volagratis, Trivago, eDreams, Booking, SecretEscape). Travel related e-commerce in Italy represents 20% of the entire value of travel and tourism expenditures mainly for accommodation bookings, tour packages, and train and air tickets.

## Opportunities

Since January 2018, Brand USA, the nation's first public-private partnership to spearhead a globally coordinated marketing effort to promote the United States as a premier travel destination, named Hills Balfour as the new representation firm for the overall European market. To sharpen its Italian focus, Hills Balfour partnered with Milan-based [Interface Tourism Italy](#), a marketing, public relations, and representation agency that operates exclusively in travel and tourism.

## Resources

### Trade Shows

- **TTG Travel Experience:** October 14-16, 2020, Rimini, Italy <https://en.ttgexpo.it/>
- **BIT Milan – Brand USA Pavilion:** February 7-9, 2021, Milan Italy <http://bit.fieramilano.it/?lang=en>
- **Showcase USA-Italy:** March 6-9, 2021 (just before ITB in Berlin), Rome, Italy. Showcase USA-Italy is the only marketing event exclusively dedicated to promoting Italian tourism towards the United States. U.S. exhibitors can meet with high-quality Italian companies, focused on promoting tourism to the U.S. Our team will provide participants a complete and all-inclusive program of matchmaking appointments with Italian companies and media, logistical assistance, on-site business counseling and support, as well as a pre-event briefing. [www.export.gov/italy](http://www.export.gov/italy)

U.S. Department of Commerce, International Trade Administration, Office of Travel and Tourism Industries: <http://travel.trade.gov/>

Travel Trade & Destination Marketing Associations:

- U.S. Travel Association: <http://www.ustravel.org/>
- BrandUSA: <http://www.visittheusa.com> | <http://thebrandusa.com>
- Italian Tourism Agency: <http://www.enit.it>
- Visit USA Association Italy: <http://www.visitusaita.org/>

### U.S. Commercial Service Contacts:

Ms. Luisa Salomoni, Commercial Specialist  
U.S. Commercial Service, U.S. Consulate Milan  
Tel: +39 02 626 88 525

E-mail: [luisa.salomoni@trade.gov](mailto:luisa.salomoni@trade.gov) | Web: <http://export.gov/italy>

## Agricultural Sector

### Overview

The Foreign Agricultural Service (FAS) is part of the U.S. Department of Agriculture (USDA) and is U.S. agriculture's link to the constantly changing global marketplace. Italy is the third-largest economy in the euro-zone, with a GDP estimated at \$2.3 trillion and a per capita GDP of \$38,200. Being a net agricultural importer, most raw materials and ingredients are imported, as Italy's economic strength is in the processing and the manufacturing of goods, primarily in small and medium-sized family-owned firms. Italy exports mainly consumer products to the United States, while the United States exports mostly bulk commodities to Italy. In 2018, U.S. agricultural, forest, and fish exports to Italy were \$1.4 billion, while U.S. imports from Italy were \$5 billion.

#### Bilateral Ag Trade 2018

- In 2018, U.S. agricultural, forest, and fish exports to Italy were \$1.4 billion
- In 2018, U.S. agricultural, forest, and fish imports from Italy reached \$5 billion

U.S. leading exports to Italy	Italian leading exports to the U.S.
Soybeans: \$305.1 million	Wine and Beer: \$2.1 billion
Tree Nuts: \$282.6 million	Olive oil: \$572.9 million
Wheat: \$139.4 million	Cheese: \$324.4 million
Forest products: \$93.3 million	Snack foods: \$208.5 million
Fish products: \$76.3 million	Processed fruit and vegetables: \$160.4 million

Source: BICO

Agriculture is one of Italy's key economic sectors, accounting for around 2.1% of GDP. Italy's agriculture is typical of the northern and southern division found within the European Union (EU). The northern part of Italy produces primarily grains, soybeans, meat, and dairy products, while the south specializes in fruits, vegetables, olive oil, wine, and durum wheat. Even though much of its mountainous terrain is unsuitable for farming, approximately 4% of the population is employed in farming. Most farms are small, with the average size being eleven hectares. Italy has a diversified industrial economy with roughly the same total and per capita output as France or the United Kingdom. Italian industries, including the food-processing sector, rely heavily on imports of raw materials. Italy is one of the largest agricultural producers and food processors in the EU.

### Italian Food Importers and Retailers

Most imported food products enter the Italian market through brokers or specialized traders. Imported products from North America often enter Italy indirectly via the Netherlands' Port of Rotterdam or directly by air. Wholesalers are the main customers for fish and seafood products, as they purchase and distribute to numerous small restaurants and hotels. Most of the processed food and raw material sourcing decisions are made directly by the restaurant chef and/or hotel Food Purchasing Director. Restaurants, hotels, and catering companies tend to rely on importers, wholesalers, and food manufacturers, while trattorias and pizzerias purchase directly from large retail food outlets. While there are Category Associations for the Hotel and Food Service sectors, each establishment operates independently when it comes to sourcing decisions.

In Italy, the food retail and distribution sector is extremely fragmented and resistant to change. Consolidation remains low and traditional grocery stores continue to represent the majority share of the outlets, followed by open-air markets. In fact, the sector is one of the most fragmented and least saturated in Western Europe with fewer large retailers and many small local retail stores. Nonetheless, consolidation is slowly gaining momentum, with Italian and foreign operators starting to expand their network of stores, particularly in the south of the country.

## **Food and Agriculture Import Requirements**

To the extent that EU food laws have been harmonized, Italy's food laws and regulations follow EU rules. The main principle of the single market concept is to ensure that all food products, whether produced in the EU or imported from a third country, can move freely throughout the EU if they comply with uniform requirements. In Italy, food safety is the primary responsibility of the Italian Ministry of Health, while food production is the primary responsibility of the Italian Ministry of Agriculture. In some cases, other Italian Ministries may have responsibilities, such as the Ministry of Economic Development on standards, labeling and trade promotion, or the Ministry of Economy and Finance on customs and duties.

### **Leading Sub-Sectors**

#### **Italian Food Processing Ingredients Sector**

The Italian food processing industry continues to be highly fragmented, and depends almost entirely on imports of raw materials, many of which come from other EU countries. Italian consumers continue to prefer fresh products rather than canned or frozen. In Italy, the 10 leading food-processing companies account for around 40% of the sector's sales, and growth areas include chilled ready meals, frozen pizza, soups, and healthy foods.

#### **The Italian Hotel and Food Service Industry**

Every year more than 58.3 million tourists visit Italy, making it the world's fifth most attractive tourist destination. The Italian Hotel and Food Service Industry is a lucrative and growing sector, but it is also diverse and fragmented. Many small establishments dominate Italy, including bed and breakfasts, youth hostels, camping facilities, resorts, and rural tourism.

### **Opportunities**

U.S. bulk and intermediate commodities are used as ingredients or inputs for value-added Italian products that are re-exported. North American high-quality durum wheat, for example, is used to produce pasta. Opportunities exist for beer, food preparations, condiments and sauces, baked goods, snack foods, almonds, and gluten-free products. All sectors that have seen growth in recent years.

### **Resources**

Please refer to the FAS Rome webpage for information on U.S. agricultural genetics, bulk and processed commodities, food and beverage products, market intelligence, and market sector briefs to help U.S. firms better understand the Italian market: <https://it.usembassy.gov/embassy-consulates/rome/sections-offices/fas/>

Contacts for the Foreign Agricultural Service office, Rome:

Office of Agricultural Affairs

U.S. Embassy

Via Veneto 119A

00187 Rome, Italy

Tel.: +39-06-4674-2396

Fax: +39-06-4788-7008

E-mail: [agrome@fas.usda.gov](mailto:agrome@fas.usda.gov)

Website: <https://it.usembassy.gov/embassy-consulates/rome/sections-offices/fas/>

## Customs, Regulations and Standards

### Trade Barriers

For information on existing trade barriers, please see the National Trade [Estimate](#) Report on Foreign Trade Barriers published by USTR.

Information on agricultural trade barriers can be found at the following website: [Foreign Agricultural Service](#)

To report existing or new trade barriers and get assistance in removing them, contact either the [U.S. Mission to the European Union](#) or the [Trade Compliance Center](#).

For information on EU retaliatory tariffs on U.S. goods see the list on the Department of Commerce website.

### Import Tariffs

When products enter the EU, they need to be declared to customs according to their classification in the Combined Nomenclature (CN). All products entering the EU are classified under a **tariff code** that carries information on:

- duty rates and other levies on imports and exports
- any applicable protective measures (e.g. anti-dumping)
- external trade statistics
- import and export formalities and other non-tariff requirements.

The EU classification system consists of three integrated components. The [Harmonized System](#) (HS) which is a nomenclature developed by the [World Customs Organization \(WCO\)](#) comprising about 5,000 commodity groups, organized in a hierarchical structure by sections, chapters (2 digits), headings (4 digits) and subheadings (6 digits). The [Combined Nomenclature](#) (CN) which adds EU specific codes and information to become the EU's eight-digit coding system (in other words HS codes with further EU specific subdivisions). The CN both serves the EU's **common customs tariff** and provides [statistics for trade](#) inside the EU and between the EU and the rest of the world. The third component is the [Integrated Tariff \(TARIC\)](#) which provides information on **all trade policy and tariff measures** applicable to specific goods in the EU (e.g. temporary suspension of duties, antidumping duties, etc). It comprises the eight-digit code of the combined nomenclature plus two additional digits (TARIC subheadings).

The CN document is updated and published every year, and the latest version can be found on the [European Commission's website](#).

U.S. exporters should consult “The Integrated Tariff of the Community”, referred to as TARIC (Tarif Intégré de la Communauté), to identify the various rules which apply to specific products being imported into the customs territory of the EU.

The TARIC can be searched by country of origin, Harmonized System (HS) Code, and product description on the interactive website of the Directorate-General for Taxation and the Customs Union. The online TARIC is updated daily.

**Key Link:** [TARIC](#)

### Import Requirements and Documentation

#### *The Single Administrative Document*

The official model for written declarations to customs is the Single Administrative Document (SAD). This form describes goods and their movement around the world and is essential for trade outside the EU or trade of non-EU goods. Goods brought into the EU customs territory are, from the time of their entry, subject to customs supervision until customs formalities are completed. Goods are covered by a Summary Declaration which is filed once the items have been presented to customs officials. The customs authorities may, however, allow a period for filing the Declaration which cannot be extended beyond the first working day following the day on which the goods are presented to customs.

The Summary Declaration is filed by:

- the person who brought the goods into the customs territory of the Community or by any person who assumes responsibility for carriage of the goods following such entry; or
- the person in whose name the person referred to above acted.

The Summary Declaration can be made on a form provided by the customs authorities. However, customs authorities may also allow the use of any commercial or official document that contains the specific information required to identify the goods. The SAD serves as the EU importer's declaration. It encompasses both customs duties and VAT and is valid in all EU Member States. The declaration is made by whoever is clearing the goods, normally the importer of record or his/her agent.

European Free Trade Association (EFTA) countries including Norway, Iceland, Switzerland, and Liechtenstein also use the SAD. Information on import/export forms is contained in Commission Delegated Regulation (EU) No. [2015/2446](#).

More information on the SAD can be found at:

[Single Administration Document](#)

*The EU Customs Union and the Move to Use of an Electronic System*

The EU customs union, in place since 1968, is a pillar of the EU's single market and vital to the free flow of goods and services across member states. In 2013, the EU adopted [The Union Customs Code \(UCC\)](#) which is the main legal framework for ongoing actions to modernize EU customs. Its substantive provisions went into effect in May 2016. Its goals are to 1) provide a comprehensive framework for customs rules and procedures in the EU customs territory and 2) create a paperless and fully automated customs union system.

A comprehensive framework for customs rules and procedures is needed because while customs rules are the same across the EU, member states' customs authorities have not always applied them in a consistent manner regarding customs duties and clearance creating fragmentation and additional administrative burdens. The UCC forms the basis for structural and administrative changes to customs policy, procedures, and implementation.

In addition, the UCC mandates a move to an all-electronic customs system. The system consists of 17 separate but interconnected components and was originally due to be in place by the end of 2020. While some systems are currently in place or expected to be in place by the December 2020, due to the complexity of the tasks a number of components are lagging ([UCC Electronic Work Programme](#)) and timeframes have been extended for some provisions till 2022 and others till 2025 (see [Chapter 1 Article 278 UCC Consolidated Version](#)). F

### **Economic Operator Registration and Identification (EORI)**

Since July 1, 2009, all companies established outside of the EU are required to have an EORI number if they wish to lodge a customs declaration or an Entry/Exit Summary declaration. All U.S. companies should use this number for their customs clearances. An EORI number must be formally requested from the customs authorities of the specific member state to which the company first exports. Member state customs authorities may request additional documents to be submitted alongside a formal request for an EORI number. Once a company has received an EORI number, it can use it for exports to any of the 27 EU Member States. There is no single format for the EORI number. Once an operator holds an EORI number s/he can request the Authorized Economic Operator (AEO: see below under "MRA") status, which can give quicker access to certain simplified customs procedures.

More information about the EORI number can be found at [Economic Operator Identification and Registration](#)

U.S. – EU Customs Cooperation: Since 1997, the United States and the EU have had a Customs Mutual Assistance Agreement (CMAA) on customs cooperation for matters relating to the application of customs laws. For additional information, please see [Agreements with the United States](#)

In 2012 the United States and the EU signed a Decision recognizing the compatibility of AEO (Authorized Economic Operator) and C-TPAT (Customs-Trade Partnership Against Terrorism), thereby facilitating faster and more secure trade between U.S. and EU operators. The World Customs Organization (WCO) SAFE Framework of Standards provides the global standard for AEO. AEO certification is issued by a national customs authority and is recognized by all Member States' customs agencies. As of April 17, 2017, an AEO can consist of two different types of authorization: "customs simplification" or "security and safety." The former allows for an AEO to benefit from simplification related to customs legislation, while the latter allows for facilitation through security and safety procedures. Shipping to a trader with AEO status could facilitate an exporter's trade as its benefits include expedited processing of shipments, reduced theft/losses, reduced data requirements, lower inspection costs, and enhanced loyalty and recognition. Under the revised Union Customs Code, in order for an operator to make use of certain customs simplifications, the authorization of AEO becomes mandatory.

The United States and the EU recognize each other's security certified operators and will take the respective membership status of certified trusted traders favorably into account to the extent possible. The favorable treatment provided by the Decision will result in lower costs, simplified procedures and greater predictability for transatlantic business activities. It officially recognizes the compatibility of AEO and C-TPAT programs, thereby facilitating faster and more secure trade between U.S. and EU operators. The Decision was originally signed in May 2012 and was implemented in two phases. The first commenced in July 2012 with U.S. Customs and Border Protection (CBP) placing shipments coming from EU AEO members into a lower risk category. The second phase took place in early 2013, with the EU re-classifying shipments coming from C-TPAT members into a lower risk category. CBP identification numbers for foreign manufacturers (MID) are therefore recognized by customs authorities in the EU, as per Commission Delegated Regulation 2015/2446 (see above)

#### Environmental Regulations – Requirements and Documentation

A key EU priority is to ensure products marketed in the region are safe for the environment and human health. U.S. manufacturers exporting to the European Union need to ensure their products meet these requirements to enter the market.

#### **New Initiatives: European Green Deal & Circular Economy Action Plan II**

On 11 December 2019, Commission President Ursula von der Leyen presented the European Green Deal. The goal of this policy and legislative program is to transform Europe into a climate neutral society by 2050. The European Green Deal affects all aspects of the European economy including agriculture, construction, finance and manufacturing.

The Communication "A new Circular Economy Action Plan For a cleaner and more competitive Europe" (CEAP II) sets out Commission's product policy within the European Green Deal. The CEAP II succeeds the 2014 Communication "Towards a circular economy: A zero waste program for Europe" and implements the European Green Deal. When implementing the CEAP II, the European Commission will promote legislation and other measures that encourage a wholistic assessment of a product's environmental footprint at the design phase of development. One legislative instrument the European Commission is looking to achieve this objective is the EU Ecodesign Directive. It will also look at other instruments including the EU Ecolabel and REACH.

#### **Batteries**

The [EU Battery Directive](#) adopted in 2006 applies to all batteries and accumulators placed on the EU market. This includes automotive, industrial and portable batteries. The Directive seeks to protect the environment by restricting the sale of batteries and accumulators that contain mercury or cadmium (with an exemption for emergency and alarm systems, medical equipment and cordless power tools) and by promoting a high level of collection and recycling. It places the responsibility on producers to finance the costs associated with the collection, treatment, and recycling of used batteries and accumulators. The Directive also includes provisions on the labeling of batteries and their removability from equipment. The European Commission publishes a [FAQ](#) document to assist interested parties in

interpreting its provisions. The Directive was recently evaluated and [the report](#) was published in April 2019. A legislative proposal revising the EU Battery Directive is expected to be tabled in the fourth quarter of 2020 likely October. The revision will "notably encompass end-of-life and sustainability requirements".

### **Registration, Evaluation and Authorization and Restriction of Chemicals (REACH)**

REACH applies to all chemicals manufactured or imported into the EU in quantities exceeding one metric ton. The regulation entered into force in 2007 (Regulation 1907/2006) and touches virtually every industrial sector, from automobiles to textiles. REACH imposes a registration obligation on all entities affected by the one metric ton. The European Chemicals Agency (ECHA) is the agency responsible for receiving and ensuring the completeness of such registrations. U.S. companies without a presence in Europe need to rely on an EU-based partner, typically either an importer or a specialized 'Only Representative'. ECHA will issue a registration number to any company that submits a complete registration dossier.

In addition to the registration requirement, REACH allows the European Commission to monitor, restrict or prohibit the use of hazardous substances and products containing such substances. The 'Candidate List' of Substances of Very High Concern (SVHCs) identifies substances the European Commission intends to restrict or prohibit in the EU. Under certain conditions, companies must notify ECHA when they export products containing Candidate List substances. The 'Authorization List' identifies substances that require a company to obtain permission from the European Commission to import into the EU. Lastly, the 'Restriction List' contains a list of substances that are subject to specific controls within the EU. U.S. exporters can find each list below.

[Candidate List.](#)

[Authorization List](#)

[Restriction List](#)

### **Classification, Labelling and Packaging of Hazardous Substances (CLP)**

The CLP regulation (Regulation 1272/2008) implements the UN Global Harmonized System of classification, labelling and packaging of all hazardous substances. U.S. exporters must classify, label and package (including products containing such substances) hazardous substances according to the regulation's requirements. For certain hazardous substances, the European Commission will impose a common classification. Such a classification may affect EU demand for these substances. It may also trigger controls on product specific legislation. U.S. exporters can find the CLP regulation and the substances subject to common classification below.

[CLP Regulation](#)

### **[Waste Electrical and Electronic Equipment \(WEEE\) Directive](#)**

EU rules on WEEE, while not requiring specific customs or import paperwork, may entail a financial obligation for U.S. exporters. The Directive requires U.S. exporters to register relevant products with a national WEEE authority or arrange for this to be done by a local partner. It also requires manufacturers to inform the consumer that their product should be recycled by including the "crossed out wheellie-bin" symbol on the product or with the packaging. (See the section entitled "Mandatory Marks and Labels" for more information.) The WEEE Directive was revised on July 4, 2012 and the scope of products covered was expanded to include all electrical and electronic equipment. U.S. exporters seeking more information on the WEEE Directive should visit:

[Restriction on Hazardous Substances in Electrical and Electronic Equipment \(RoHS\)](#)

The ROHS Directive (Directive 2011/65/EU) imposes restrictions on the use of certain chemicals in electrical and electronic equipment. The directive applies to nearly all products that require power unless a specific exclusion or exemption applies. U.S. exporters certify a product meets the requirements of this legislation by affixing a "CE Mark" to their product. The U.S. exporter must retain a product file to support the CE Mark in the event of a control. (See



the section entitled “Mandatory Marks and Labels” for more information.). U.S. exporters seeking more information on the RoHS Directive should visit:

[ROHS 2](#)

### **EU Cosmetics Regulation**

The EU legislation harmonizing the regulation of cosmetic products has applied since July 11, 2013 (Regulation 1223/2009). The most controversial element of the regulation was the introduction of an EU-wide system for the notification of cosmetic products to the European Commission prior to their placement on the EU market. Only an EU-established entity may submit such a notification. Therefore U.S. exporters must either retain a “Responsible Person” to act on their behalf, rely on the entity responsible for the import of their product into the EU, or establish a presence in an EU Member State. U.S. exporters seeking more information on the marketing cosmetic products in the EU should see:

EU [Cosmetics](#) Regulation

### **Agricultural Documentation**

**Phytosanitary Certificates:** Phytosanitary certificates are required for most fresh fruits, vegetables, and other plant materials.

**Sanitary Certificates:** For commodities composed of animal products or by-products, EU countries require that shipments be accompanied by a certificate issued by the competent authority of the exporting country. This applies regardless of whether the product is for human consumption, for pharmaceutical use, or strictly for non-human use (e.g., veterinary biologicals, animal feeds, fertilizers, research). The vast majority of these certificates are uniform throughout the EU but the harmonization process is still ongoing. Most recently, certificates for a series of highly processed products including chondroitin sulphate, hyaluronic acid, hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids are being harmonized. Until harmonization is finalized, certain member state import requirements continue to apply. In addition to the legally required EU health certificates, a number of other certificates are used in international trade. These certificates, which may also be harmonized in EU legislation, certify origin for customs purposes and certain quality attributes. Up-to-date information on [Harmonized Import Requirements](#).

**Sanitary Certificates (Fisheries):** In April 2006, the European Union declared the U.S. seafood inspection system to be equivalent to the European one. Consequently, a specific public health certificate must accompany U.S. seafood shipments. The U.S. fishery product sanitary certificate is a combination of Commission Decision 2006/199/EC for the public health attestation and of Regulation 1012/2012 for the general template and animal health attestation. Unlike for fishery products, the U.S. shellfish sanitation system is not equivalent to that of the EU’s. The EU and the United States are currently negotiating a veterinary equivalency agreement on shellfish. In the meantime, the EU still has a ban in place (since July 1, 2010), that prohibits the import of U.S. bivalve mollusks, in whatever form, into EU territory. This ban does not apply to wild roe-off scallops.

The U.S. competent authority for issuing sanitary certificates for fishery and aquaculture products is the U.S. Department of Commerce, National Marine Fisheries Service (NOAA-NMFS).

In addition to sanitary certificates, all third countries wishing to export fishery products to the EU are requested to provide a catch certificate. This catch certificate certifies that the products in question have been caught legally.

For detailed information on import documentation for seafood, please contact the NOAA Fisheries office at the U.S. Mission to the EU ([stephane.vrignaud@trade.gov](mailto:stephane.vrignaud@trade.gov)) or visit the following [NOAA dedicated website](#).

## Labeling and Marking Requirements

### Summary

There is a broad array of EU legislation pertaining to the marking, labeling and packaging of products, with neither an “umbrella” law covering all goods nor any central directory containing information on marking, labeling and packaging requirements. This overview is meant to provide the reader with a general introduction to the multitude of marking, labeling and packaging requirements or marketing tools to be found in the EU.

### Introduction

The first step in investigating the marking, labeling and packaging legislation that might apply to a product entering the EU is to draw a distinction between what is mandatory and what is voluntary. Decisions related to mandatory marking, labeling and/or packaging requirements may sometimes be left to individual Member States. Furthermore, voluntary marks and/or labels are used as marketing tools in some EU Member States. This report is focused primarily on the mandatory marks and labels seen most often on consumer products and packaging, which are typically related to public safety, health and/or environmental concerns. It also includes a brief overview of a few mandatory packaging requirements, as well as more common voluntary marks and/or labels used in EU markets.

It is also important to distinguish between marks and labels. A mark is a symbol and/or pictogram that appears on a product or its respective packaging. These range in scope from signs of danger to indications of methods of proper recycling and disposal. The intention of such marks is to provide market surveillance authorities, importers, distributors and end-users with information concerning safety, health, energy efficiency and/or environmental issues relating to a product. Labels, on the other hand, appear in the form of written text or numerical statements, which may be required but are not necessarily universally recognizable. Labels typically indicate more specific information about a product, such as measurements, or an indication of materials that may be found in the product (such as in textiles or batteries).

Key Link: <https://www.trade.gov/knowledge-product/european-union-labelingmarking-requirements-0>

## U.S. Export Controls

The United States imposes export controls to protect national security interests and promote foreign policy objectives related to dual-use goods through implementation of the Export Administration Regulations (EAR). The Bureau of Industry and Security (BIS) is comprised of two elements: Export Administration (EA), which is responsible for processing license applications, counselling exporters, and drafting and publishing changes to the [Export Administration Regulations](#); and Export Enforcement (EE), which is responsible for the enforcement of the EAR. BIS works closely with U.S. embassies, foreign governments, industry, and trade associations to ensure that exports from the United States are secure and comply with the EAR. BIS officials conduct site visits, known as End-Use Checks (EUCs), globally with end-users, consignees, and/or other parties to transactions involving items subject to the EAR to verify compliance.

An EUC is an on-site verification of a non-U.S. party to a transaction to determine whether the party is a reliable recipient of U.S. items. EUCs are conducted as part of BIS’s licensing process, as well as its compliance program, to determine if items were exported in accordance with a valid BIS authorization or otherwise consistent with the EAR. Specifically, an EUC verifies the *bona fides* of transactions subject to the EAR, to include: confirming the legitimacy and reliability of the end use and end user; monitoring compliance with license conditions; and ensuring items are used, re-exported or transferred (in-country) in accordance with the EAR. These checks might be completed prior to the export of items pursuant to a BIS export license in the form of a Pre-License Check (PLC), or following an export from the U.S. during a Post-Shipment Verification (PSV).

BIS officials rely on EUCs to safeguard items subject to the EAR from diversion to unauthorized end uses/users. The verification of a foreign party’s reliability facilitates future trade, including pursuant to BIS license reviews. If BIS is

unable to verify the reliability of the company or is prevented from accomplishing an EUC, the company may receive, for example, more regulatory scrutiny during license application reviews or be designated on BIS's Unverified List or Entity List, as applicable.

BIS has developed a list of “red flags”, or warning signs, and compiled “[Know Your Customer](#)” guidance intended to aid exporters in identifying possible violations of the EAR. Both of these resources are publicly available, and their dissemination to industry members is highly encouraged to help promote EAR compliance.

BIS also provides a variety of training sessions to U.S. exporters throughout the year. These sessions range from one to two-day seminars that focus on the basics of exporting to coverage of more advanced, industry specific topics. Interested parties can check a [list of upcoming seminars and webinars](#) or reference BIS provided [online training](#).

BIS and the EAR regulate transactions involving the export of “dual-use” U.S. goods, services, and technologies. For advice and regulatory requirements, exporters should consult the other U.S. Government agencies which regulate more specialized items. For example, the U.S. Department of State's Directorate of Defense Trade Controls has authority over defense articles and services, or munitions. A list of other agencies involved in export control can be found on the [BIS website](#) or in Supplement No. 3 to Part 730 of the EAR.

The EAR is available on the [BIS website](#) and on the [e-CFR](#) (Electronic Code of Federal Regulations) and is updated as needed.

The [Consolidated Screening List](#) (CSL) is a list of parties for which the United States Government maintains restrictions on certain exports, reexports or transfers of items. The CSL consolidates eleven export screening lists of the Departments of Commerce, State and the Treasury into a single data feed as an aid to industry in conducting electronic screens of parties to regulated transactions. Exporters are encouraged to classify their items prior to export, as well as consult the CSL to determine if any parties to the transaction may be subject to specific license requirements.

### **Temporary Entry**

Specific information on the [ATA Carnet Customs](#) procedure used for temporary importation, transit and temporary admission of goods designed for specific purposes, duty-free and tax-free (such as professional equipment for presentations or trade fairs).

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States: [EU Member States' Country Commercial Guides](#)

### **Prohibited and Restricted Imports**

The Tarif Intégré de la Communauté (TARIC) is designed to show various rules applying to specific products being imported into the customs territory of the EU or, in some cases, when exported from it. To determine if a product is prohibited or subject to restriction, check the TARIC for the following codes:

- *CITES Convention on International Trade of Endangered Species*
- *PROHI Import Suspension*
- *RSTR Import Restriction*

For information on how to access the TARIC, see the Import Requirements and Documentation Section.

Key Link: [Taxation Customs and Tariffs](#)

### **Customs Regulations**

The following provides information on major regulatory efforts of the EC Taxation and Customs Union Directorate:

The Union Customs Code (UCC) was adopted in 2013 and its substantive provisions apply from 1 May 2016. It replaces the Community Customs Code (CCC). In addition to the UCC, the European Commission has published

delegated and implementing regulations on the actual procedural changes. These are included in Delegated Regulation (EU) 2015/2446, Delegated Regulation (EU) 2016/341 and the Implementing Regulation (EU) 2015/2447.

There are a number of changes in the revised customs policy which also require an integrated IT system from the customs authorities. In April 2016, the European Commission published an implementing decision (number: 2016/578) on the work program relating to the development and deployment of the electronic systems of the UCC. The EC continues to evaluate the timeline by which the EU-wide integration of the customs IT system can be implemented. The current deadline of December 2020 may be extended until 2025 ([draft proposal](#))

**Key Link:** [Homepage of Customs and Taxation Union Directorate \(TAXUD\) Website](#)

*Customs Valuation* – Most customs duties and value added tax (VAT) are expressed as a percentage of the value of goods being declared for importation. Thus, it is necessary to dispose of a standard set of rules for establishing the goods' value, which will then serve for calculating the customs duty.

Given the magnitude of EU imports every year, it is important that the value of such commerce is accurately measured for the purposes of:

- economic and commercial policy analysis;
- application of commercial policy measures;
- proper collection of import duties and taxes; and
- import and export statistics.

These objectives are met using a single instrument - the rules on customs value.

The EU applies an internationally accepted concept of '[customs value](#)'.

The value of imported goods is one of three 'elements of taxation' that provides the basis for assessment of the customs debt, which is the technical term for the amount of duty that has to be paid, the other ones being the origin of the goods and the customs tariff.

**Key Link:** [Customs Procedures](#)

## **Standards for Trade**

### **Overview**

Products tested and certified in the United States to U.S. regulations and standards are likely to have to be retested and re-certified to EU requirements as a result of the EU's different approach to the protection of the health and safety of consumers and the environment.

While harmonization of EU legislation can facilitate access to the EU Single Market, manufacturers should be aware that regulations (mandatory) and technical standards (voluntary) might also function as barriers to trade if U.S. standards are different from those of the European Union which is often the case. For more on how the EU standards and regulatory system functions as a barrier to trade see page 177 in the [National Trade Estimate](#).

In general, the harmonization of a number of EU standards has greatly simplified technical regulation in Europe. Prior to harmonization, each country in the EU developed its own standards through their national standards body creating differing and conflicting standards, laws, and conformity assessment procedures. Thus, it became necessary to create a new, integrated, European system of standardization. The new system provided for three EU standards bodies to create standards on a Europe-wide level: (1) The European Committee for Standardization (CEN); (2) the European Committee for Electrotechnical Standardization (CENELEC); and (3) The European Telecommunications Standards Institute (ETSI). CEN/CENELEC activities are in the electrotechnical and other sectors, while ETSI specializes in telecommunications. CEN and CENELEC's principal members are member state national standards bodies. ETSI's membership has a broader range of interested parties. These three are the only recognized bodies from which a

Harmonized European Standard (EN) can come. When the development of a European Harmonized Standard begins in one of these organizations, development of a national standard must stop. Harmonized Standards are standards that support European legislation. They (1) have been mandated by the European Commission, (2) have been developed by the European Standards Bodies above, (3) address essential health and safety requirements; and (4) notification of their development has been published in the Official Journal of the European Union.

Technically, the use of a Harmonized Standard is voluntary. That is, a manufacturer can elect to use a Harmonized Standard, or decide to use a non-Harmonized Standard (an American Standard, for example) to meet essential requirements. However, when using a Harmonized Standard, the manufacturer is presumed in conformity with the law (Presumption of Conformity). Specific EU harmonized standards which confer presumption of conformity are listed in the directive or regulation usually in Annex Z or ZZ. On the contrary, using a standard that is not a Harmonized Standard will impose additional responsibilities. The use of anything but an EU Harmonized Standard places a burden of proof upon the manufacturer that the product meets essential requirements. This proof may be provided by the manufacturer's Technical File, by the employment of a third party (consultant, testing house, etc.), or by a combination of the two.

### **Standards**

In addition to the three EU standards developing organizations, the European Commission funds the participation in the standardization process of EU small- and medium-sized companies and EU non-governmental organizations, such as environmental, labor and consumer groups. The Commission also provides money to the European standards bodies when it mandates standards development for harmonized standards that will be linked to EU legislation. The Commission requests CEN/CENELEC or ESTI to develop standards - see [Mandates](#).

There are also a large number of European Standards (ENs) also developed by CEN, CENELEC, and ETSI that are not mandated by the Commission and which do not necessarily define essential requirements. In theory, their use is voluntary. They may define other characteristics, such as durability, appearance, quality levels, or even cultural preferences. They may be test methods, or measurement guides. These ENs often have the advantage of recognition in the European marketplace. A standard that does not emanate from one of the European Standards Bodies is not always recognized by insurers, lending institutions, retailers, developers, market surveillance organizations, conformity assessment bodies, and consumers, and may hinder acceptance of the product in the marketplace, particularly when a well-known European Standard already exists for the same product.

Finally, given the EU's vigorous promotion of its regulatory and standards system as well as its generous funding for its development, the EU's standards regime is wide and deep - extending well beyond the EU's political borders to include affiliate members (countries which are hopeful of becoming full members in the future). Another category, called "companion standardization body" includes the standards organization of Morocco, Israel, Kazakhstan and Australia, among others which are not likely to become a CEN member or affiliate for political and geographical reasons.

View [CEN and CENELEC's work plan](#) for future standardization activities .. Other than their respective annual work plans, CEN's "what we do" page provides an overview of standards activities by subject. Both CEN and CENELEC offer the possibility to search their respective database. [ETSI's portal](#) links to ongoing activities.

**Key Link:** [Standardization Policy](#)

The establishment of harmonized EU rules and standards in the food sector has been ongoing for several decades, and in January 2002 the EU publicized a general food law establishing the general principles of EU food law. This Regulation introduced mandatory traceability throughout the feed and food chain as of Jan 1, 2005. For specific information on agricultural standards, please refer to the [Foreign Agricultural Service's website/](#)

There are also export guides to import regulations and standards available on the Foreign Agricultural Service's website: [FAIRS Export Certificate Report](#)

## Testing, Inspection and Certification

### Conformity Assessment

Conformity Assessment is the demonstration that specified requirements relating to a product, process, system, or group are fulfilled. Conformity assessment can include: the supplier's declaration of conformity, different types of sampling and testing, inspection, certification, management system assessment and registration, the accreditation of the competence of those activities, and the recognition of an accreditation program's capability. Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific EU harmonized legislation. As mentioned above under CE Marking, EU harmonized product legislation gives manufacturers some choice regarding conformity assessment, depending on the level of risk involved in the use of their product. Certification for defined lesser risk products can be done by the manufacturer themselves by building a technical file in many cases. Higher risk products will need third party testing through accredited testing labs. Types of compliance certification ranges from self-certification, type examination and production quality control system certification, to full quality assurance system certification. In the case of CE Mark directives or regulations, each directive or regulation stipulates the processes which can be used for which products. This is usually found in an annex and called a "Module".

Modules vary in complexity. For example, Module A permits the manufacturer to assume total responsibility for conformity assessment. If the product is manufactured to Harmonized Standards, and if the risk is not unusually high (as in most machinery, for example), the manufacturer may rely on internal manufacturing checks. He or she compiles a Technical File, issues a Declaration of Conformity to the appropriate directives, and if appropriate, standards, applies the CE marking, and places the product on the market. Modules for higher risk products, for example, a medical device, on the other hand, could call for a type examination of the product plus a production quality assurance system that conforms to the standard. Another choice for a medical device manufacturer would be a complete quality assurance program that would conform to ISO 9001 (or EN 29001) for example. These later modules may call for the involvement of third party testing and assessment for a Declaration of Conformity. In Europe, these third parties are designated by member states' authorities, accepted by the European Commission, and are called Notified Bodies. Each directive provides the module choices available, but there are no choices beyond the modules specified.

When third party testing is required, that testing must be done by accredited member state organizations called Notified Bodies which must be domiciled in an EU-27 member state. The official list of approved Notified Bodies for each EU harmonized directive/regulation is found in the EU Commission's website under NANDO.

**Key Link:** [NANDO](#) (the left navigation on this page allow a search by member state, by legislation, or by the name of the notified body)

The only exceptions to this EU-domiciled rule are U.S.-based organizations and test labs for products covered under [U.S.-EU mutual recognition agreements](#) (MRAs) for certain types of marine equipment, products under the Electromagnetic Compatibility MRA, and the Radio Equipment MRA.

Finally, to promote market acceptance in the EU market of a product, there are a number of voluntary conformity assessment programs. CEN and Cenelec's certification system is known as the [Keymark](#). ETSI does not offer conformity assessment services.

### Publication of Technical Regulations

[Official Journal of the EU](#) is the official publication of the European Union. It is published daily on the internet and consists of two series covering adopted legislation as well as case law, and studies by committees, among others. It also lists the standards reference numbers linked to legislation ([Harmonized Standards](#)).

## **National Institute of Standards and Technology's (NIST) Notify U.S. Service**

Members of the World Trade Organization (WTO) such as the EU are required under the Agreement on Technical Barriers to Trade (TBT Agreement) to notify to the WTO proposed technical regulations and conformity assessment procedures that could affect trade. [Notify U.S. \(www.nist.gov/notifyus\)](http://www.nist.gov/notifyus) is a free, web-based e-mail registration service that captures and makes available for review and comment key information on draft regulations and conformity assessment procedures. Users receive customized e-mail alerts when new notifications are added by selected country or countries and industry sector(s) of interest and can also request full texts of regulations. This service and its associated web site are managed and operated by the USA WTO TBT Inquiry Point housed within the National Institute of Standards and Technology, part of the U.S. Department of Commerce.

Proposed EU member state technical regulations are published on the [Commission's website](#) to allow other countries and interested parties to comment.

### Contact Information

#### **[U.S. Mission to the EU](#)**

Rebecca Balogh, Standards Attaché

[Rebecca.Balogh@trade.gov](mailto:Rebecca.Balogh@trade.gov)

Tel: +32 2 811 42 44

#### **[National Institute of Standard & Technology](#)**

Gordon Gillerman Standards Coordination Office 100 Bureau Dr.

Mail Stop 2100

Gaithersburg, Maryland 20899

Tel: (301) 975-4000

#### **[CEN- European Committee for Standardization](#)**

Rue de la Science 23

B – 1040 Brussels, Belgium

Tel: 32.2.550.08.11

Fax: 32.2.550.08.19

#### **[CENELEC- European Committee for Electrotechnical Standardization](#)**

Rue de la Science 23

B – 1040 Brussels, Belgium

Tel: 32.2.519.68.71

Fax: 32.2.519.69.15

#### **[ETSI- European Telecommunications Standards Institute](#)**

Route des Lucioles 650

Sophia Antipolis

F-06560 Valbonne France

Tel: 33.4.92.94.42.00

Fax: 33.4.93.65.47.16

## **Trade Agreements**

For a list of trade agreements of the EU to other countries in the world, as well as concise explanations, please see [EU Trade Agreements](#)

U.S. – EU Trade Negotiations

In July 2018, President Trump and European Commission President Juncker issued a joint statement in Washington announcing the formation of an Executive Working Group to reduce transatlantic barriers to trade, including the elimination non-auto industrial tariffs and non-tariff barriers. In October 2018, U.S. Trade Representative officially notified Congress that the Administration intended to start negotiations following the completion of necessary domestic procedures. This began a congressionally-mandated 90-day consultation period under [Trade Promotion Authority](#) prior to the launch of negotiations and resulted in the publication of the report “[United States-European Union Negotiations Summary of Specific Negotiating Objectives, January 2019](#)” which lay out the goals and objectives of U.S. negotiations with the EU.

[USTR U.S. – EU Trade Negotiations](#)

## **Licensing Requirements for Professional Services**

The recognition of skills and qualifications acquired by EU citizens in EU Member States, including the corresponding recognition procedures and charges are, in correspondence with article 165 of the TFEU, the responsibility of Member States. Similarly, recognition of skills and qualification earned in third countries is also a national responsibility.

However, the European Commission takes initiative to facilitate recognition procedures. For example:

- Recognition of [professional qualifications](#) obtained in one Member State for the purposes of access and pursuit of [regulated professions](#) in another Member State is subject to Directive 2005/36.
- Recognition of qualifications for academic purposes in the [higher education sector](#), including school-leaving certificates is subject to the *Lisbon Recognition Convention*. The ENIC-NARIC network provides advice on (cross-border) recognition of these qualifications.

Recognition in other cases is assessed and granted (or denied) by the receiving educational provider or employer. For them to be able to recognise skills and qualifications an **understanding of the level, content and quality** is needed. The Commission currently explores the possibilities on how to better support these recognition decisions.

The “Your Europe” website maintains a webpage dedicated to help citizens identify what the regulated professions are and what document are needed for their recognition in each Member State. Please see: [Recognition of Professional Qualification](#).



## **Selling U.S. Products and Services**

### **Distribution & Sales Channels**

#### **Overview**

U.S. business representatives find that selling in Italy offers new challenges, but it presents no overwhelming problems. U.S. executives may find that some commercial practices differ from those in the United States, but most will be very familiar. The system of retail and wholesale distribution, for instance, centers on small, family-operated stores. Despite this phenomenon, the supermarket-type operation has gained importance, and there are a number of substantial department stores.

#### **Using an Agent or Distributor to Sell U.S. Products and Services**

Companies wishing to use distribution, franchising and agency arrangements need to ensure that the agreements they put into place are in accordance with EU laws and member state national laws. Council Directive 86/653/EEC establishes certain minimum standards of protection for self-employed commercial agents who sell or purchase goods on behalf of their principals. The Directive establishes the rights and obligations of the principal and its agents, the agent's remuneration, and the conclusion and termination of an agency contract. It also establishes the notice to be given and indemnity or compensation to be paid to the agent. U.S. companies should be particularly aware that according to the Directive, parties may not derogate from certain requirements. Accordingly, the inclusion of a clause specifying an alternate body of law to be applied in the event of a dispute will likely be ruled invalid by European courts.

**Key Link:** [Self Employed Commercial Agents](#)

The European Commission's Directorate General for Competition enforces legislation concerned with the effects on competition in the internal market of "vertical agreements." U.S. small- and medium-sized companies (SMEs) are often exempt from these regulations because their agreements likely would qualify as "agreements of minor importance," meaning they are considered incapable of impacting competition at the EU level but useful for cooperation between SMEs. Generally speaking, companies with fewer than 250 employees and an annual turnover of less than €50 million are considered small- and medium-sized. The EU has additionally indicated that agreements that affect less than 10 percent of a particular market are generally exempted (Commission Notice 2014/C 291/01).

**Key Link:** [European Law](#)

The EU also looks to combat payment delays. Directive 2011/7/EU covers all commercial transactions within the EU, whether in the public or private sector, primarily dealing with the consequences of late payment. Transactions with consumers, however, do not fall within the scope of this Directive. Directive 2011/7/EU entitles a seller who does not receive payment for goods and/or services within 30 days of the payment deadline to collect interest (at a rate of eight percent above the European Central Bank rate) as well as 40 Euro as compensation for recovery of costs. For business-to-business transactions a 60-day period may be negotiated subject to conditions. The seller may also retain the title to goods until payment is completed and may claim full compensation for all recovery costs.

**Key Link:** [Late Payments](#)

Companies' agents and distributors can take advantage of the European Ombudsman when victim of inefficient management by an EU institution or body. Complaints can be made to the European Ombudsman only by businesses and other bodies with registered offices in the EU. The Ombudsman can act upon these complaints by investigating cases in which EU institutions fail to act in accordance with the law, fail to respect the principles of good administration, or violate fundamental rights. In addition, SOLVIT, a network of national centers, offers online assistance to citizens and businesses who encounter problems with transactions within the borders of the single market.

## **Key Links:**

[European Ombudsman](#)

[EU Solvit](#)

## **Establishing a Local Office**

Establishing an office in Europe, whether a subsidiary or a new business, requires knowledge of the relevant national legislations in the country of interest. While there are several EU level policies in effect, many key areas such as taxation are still largely a member state prerogative. The European Commission manages the [Your Europe](#) website where investors can find useful information on various topics ranging from taxation and customs to employment contracts.

To learn more about incorporating and registering a business in Italy, please visit the World Bank's Doing Business website:

<http://www.doingbusiness.org/data/exploreeconomies/italy/starting-a-business/>

## **Franchising**

### **Overview**

Franchising is widespread throughout Italy and is dramatically growing. With a turnover of approximately \$28.5 billion in 2018 (+2% compared to 2017), Italy is the fourth largest market for franchises in Europe, after France, Germany, and Spain.

In 2018, the number of Italian franchises reached more than 53,800. In 2018, the Italian market experienced a growth rate of 3.4% in terms of active franchising networks. Of the 961 network and 3 retail stores, 861 were Italian. Also, the number of foreign master franchisors in Italy went from 61 in 2016 to 72 in 2018 (+7.5%). In fact, employment in this sector now totals 206,791 (+3.8% since 2016).

The highest concentration of franchise networks can be found in Northern Italy (Lombardy and Veneto), primarily in city centers, commercial districts and shopping malls. With Lombardy leading, making up 16.5% of the total franchising turnover outcomes, Lazio and Veneto follow closely behind. Traditionally, new franchise concepts have launched in large cities, such as Rome and Milan. Nevertheless, the creation of franchising business opportunities has also been successful in smaller cities. This trend is mainly due to the presence of a relatively large middle class with strong demand for new and sophisticated goods and services. During the past four years, in fact, more and more franchises have opened in airports and train stations in addition to their traditional presence in malls, department stores and main streets.

U.S. firms interested in entering the Italian market should be aware of the challenges for new entrants. With its unique cultural and entrepreneurial spirit, the Italian market presents opportunities for franchising ventures as well as some challenges. Despite Italy's structure of family locally-owned businesses and small-scale operations, there is an opportunity for franchising, in a way that preserves quality. Success depends on finding the right partner. Potential franchisors must have the ability to adapt their franchise concept to that of the Italian market and have a strong organizational structure.

We recommend that American companies do the following: conduct extensive market research; commit to building a sound, long-term business plan and allow enough flexibility to adjust their business model to accommodate differences in the Italian market; have a legally bound franchise agreement, detailed operations manual, good training program, and relevant support system in place; have a well-defined master licensee candidate profile to aid the search process; and work out a development schedule realistic to the master licensee. Furthermore, the most recent approach of Italian banks is to evaluate first the franchisor and later the potential franchisee.

## The Legal Frameworks and Regulations

U.S. businesses looking to franchise within the European Union will likely find that the market is quite robust and friendly to franchise systems in general. There are a number of laws that govern the operation of franchises within the EU, but these laws are fairly broad and generally do not constrain the competitive position of U.S. businesses. The potential franchiser should take care to look not only at the EU regulations, but also at the local laws concerning franchising. More information on specific legislation can be found on the website of the [European Franchise Federation](#).

In 2004 Italy enacted a general law on franchising and an implementing regulation in 2005. The relevant laws are: Act No. 129 of 6 May 2004 (the Franchising Act), Ministerial Decree No. 204 of 2 September 2005 (the Franchising Regulation), Act no. 287 of 10 October 1990 (the Italian Antitrust Law), Commission Regulation No. 330/2010 (EU Block Exemption Regulation on vertical restraints), and Act. No. 192 of 18 June 1998 (the Anti-Economic Abuse Law). As a Code of Ethics and/or a standards-based accrediting system the EFF Code of Ethics is followed.

### Resources

#### Trade Events

[Bologna Licensing Trade Fair](#) (April 12-13, 2021): trade fair dedicated to the business of subsidiary rights for companies and professionals, with the participation of the main Italian and international licensors and licensing agencies.

[Salone Franchising Milano](#) (October, 2021, digital only October 22-24, 2020): a professional distribution trade fair to support the encounter among franchisors, franchisee and potential franchisees and to develop supply chain innovation, focusing on retail, franchising and e-commerce.

#### Business Associations

[Assofranchising](#): the Italian Franchising Association, member of EFF and WFC.

[Confimprese](#): the Italian Association of Retailers and Franchise Networks.

[Federfranchising](#) - Confesercenti: the Italian Franchising Federation.

#### Publications

[AZFranchising](#): Magazine and communication agency that promotes growth of enterprises through development of franchising networks, providing industrial and operative know-how.

[Beesness](#): Quarterly magazine focused on franchising, retail and entrepreneurship for young entrepreneurs, professionals and businessmen.

[BeTheBoss.it](#): Franchising search engine to help find the best franchising opportunities in Italy by industry, investment, territory or company name.

[Millionaire](#): Magazine and web platform dedicated to new business trends and franchising. They also manage [www.franchisingicity.it](http://www.franchisingicity.it)

### U.S. Commercial Service Contact:

Elisa Martucci, Commercial Specialist

U.S. Commercial Service, U.S. Embassy Rome

Tel: +39 064674 2252

E-mail: [elisa.martucci@trade.gov](mailto:elisa.martucci@trade.gov)

## **Direct Marketing**

The EU has yet to adopt legislation harmonizing the direct-selling of consumer products. However, there is a wide range of EU legislation that impacts the direct marketing sector. Compliance requirements are stiffest for marketing and sales to private consumers. Companies need to focus on the clarity and completeness of the information they provide to consumers prior to purchase and on their approaches to collecting and using customer data. The following gives a brief overview of the most important provisions flowing from EU-wide rules on distance-selling and on-line commerce. In addition, it is important for exporters relying on a direct-selling business model to ensure they comply with member state requirements.

The Italian data protection authority (DPA) “Il Garante della Privacy” oversees direct marketing in Italy, which has stricter rules than many other countries. Promotional offers often require the prior consent of the recipient in writing, with a clear way to opt out. Likewise, prior consent is required for profiling purposes or to transfer personal data to third parties. The DPA grants an exception for companies sending promotional emails to customers who have purchased similar goods or services. According to the DPA’s guidelines, even if personal data is available on the Internet, companies may not send automated promotional messages. Companies and firms may send promotional messages to their followers on social media as long as their followers have given consent to receiving promotional messages.

## **Processing Customer Data**

The EU has strict laws governing the protection of personal data, including the use of such data in the context of direct marketing activities. For more information on these rules, please see the Data Privacy section above.

## **Distance Selling Rules**

In 2011, the EU overhauled its consumer protection legislation and merged several existing rules into a single rulebook - “the Consumer Rights Directive”. The provisions of this Directive have been in force since June 13, 2014. The Directive contains provisions on core information to be provided by traders prior to the conclusion of consumer contracts. It also regulates the right of withdrawal, includes rules on the costs for the use of means of payment and bans pre-ticked boxes.

## **Alternative Dispute Resolution**

In 2013, the EU adopted rules on Alternative Dispute Resolution which provide consumers the right to turn to quality alternative dispute resolution entities for all types of contractual disputes including purchases made online or offline, domestically or across borders. A specific Online Dispute Resolution Regulation, operational in January 2016, sets up an EU-wide online platform to handle consumer disputes that arise from online transactions.

Italy is taking steps to encourage the broader use of alternative dispute resolution (ADR) as a means to resolve civil disputes, with 2016 seeing the highest recorded number of settlements reached through court-supported ADR. The average time to settle a case through mediation in Italy was 115 days, compared to an average of 882 days to receive a judgment from the court of first instance. The most commonly mediated matters involve bank contracts and property disputes. While pre-filing ADR is “mandatory” in cases involving certain types of cases (including property, inheritance disputes, lease, insurance cases, banking and financial contracts), there are no penalties enforced for non-participation or an unwillingness to participate in good faith to settle the claim.

The Chambers of Commerce in Milan and Florence also strongly support the use of ADR and have established mediation centers and rules of procedure. Italy is a signatory to the 1958 New York Convention on the Recognition and Enforcement of Foreign Arbitration Awards. It is worth noting that mediation in Italy tends to take place before the suit is filed, rather than afterwards, as is more common in the United States.

## **New Legislation**

In December 2015 the European Commission released a package of two draft Directives, respectively on “contracts for the supply of digital content” and another on “contracts for the online and other distance sales of goods.” This package addresses the legal fragmentation and lack of clear contractual rights for faulty digital content and distance selling across the EU. The package would only address B2C contracts, although its draft scope uses a very broad definition of both digital content (including music, movies, apps, games, films, social media, cloud storage services, broadcasts of sport events, visual modelling files for 3D printing) and distance selling goods so as to cover Internet of Things (such as connected households’ appliances and toys). It could also apply to transactions whether in the context of a monetary transaction or in exchange of (personal) consumer data. Healthcare, gambling and financial services are excluded from the proposal.

The package is currently under scrutiny at both the European Parliament and Council. Its adoption is expected in the course of 2018.

### **Key Links:**

[Consumer Affairs Homepage](#)

[Consumer Rights](#)

## **Distance Selling of Financial Services**

Financial services are the subject of a separate directive that came into force in June 2002 (2002/65/EC). This piece of legislation amended three prior existing Directives and is designed to ensure that consumers are appropriately protected with respect to financial transactions taking place where the consumer and the provider are not face-to-face. In addition to prohibiting certain abusive marketing practices, the Directive establishes criteria for the presentation of contract information. Given the special nature of financial markets, specifics are also laid out for contractual withdrawal.

**Key Link:** [Distance Marketing](#)

## **Direct Marketing over the Internet**

The e-commerce Directive (2000/31/EC) imposes certain specific requirements connected to the direct marketing business. Promotional offers must not mislead customers and the terms that must be met to qualify for them have to be clear and easily accessible. The Directive stipulates that marketing e-mails must be identified as such to the recipient and requires that companies targeting customers on-line must regularly consult national opt-out registers where they exist. When an order is placed, the service provider must acknowledge receipt quickly and by electronic means, although the Directive does not attribute any legal effect to the placing of an order or its acknowledgment: this is a matter for national law. Vendors of electronically supplied services (such as software, which the EU considers a service and not a good) must also collect value added tax (see Electronic Commerce section below). The European Commission has performed a stakeholder’s consultation and is currently assessing the opportunity to propose a revision of the e-commerce Directive. See Data Privacy Section above.

**Key Link:** [Direct Marketing over the Internet](#)

## **Joint Ventures/Licensing**

In recent years, joint venture arrangements have become more popular in Italy. All joint ventures must be registered with the National Revenue Agency in Italy. Corporate joint ventures fall under the scope of the “[Company Act](#),” Antitrust laws and other legislation.

## **Express Delivery**

Italian consumers have grown accustomed to a fairly slow and at times unreliable domestic postal service. However, the rise of e-commerce is raising demands and expectations on speed and quality of service. While the range of delivery

options available to online shoppers is expanding (including lockers and collection/return points across major cities), these are still in their infancy. As the e-commerce market develops, the options for alternative delivery points or timed slots will increase.

A number of express delivery options exist for U.S. SMEs wishing to ship goods to Italy. These include services offered by global logistics companies such as FedEx, UPS, DHL, TNT and others which usually guarantee a second business day delivery to Europe from the U.S. To date the B2C delivery has been dominated by national postal service Poste Italiane and local couriers SDA and Bartolini.

Most logistics companies will offer a range of options for international delivery at different price points to meet customer needs. These usually feature different levels of tracking and insurance. Logistics companies can also help with bulk deliveries to help cut costs and provide advice on packaging, address formats and labelling.

Italian consumers will search for the lowest possible price. Therefore, when domestic retailers offer speedy delivery, it may be worth exploring domestic fulfilment options in order to compete. Logistics companies either run their own fulfilment centers or can recommend reliable local fulfilment partners.

### **Due Diligence**

The U.S. Commercial Service helps companies do due diligence through our International Company Profile (ICP) report. An ICP helps companies evaluate potential business partner reliability and capabilities. The reports include available information on the company and insights gleaned from our due diligence.

Product safety testing and certification is mandatory for the EU market. U.S. manufacturers and sellers of goods have to perform due diligence in accordance with mandatory EU legislation prior to exporting.

### **eCommerce**

[The eCommerce Innovation Lab \(EIL\)](#) is a national office within the U.S. Field that positions the U.S. Commercial Service as a pacesetter resource for U.S. businesses through empowering client-facing staff with a baseline understanding of digital trade, enabling quicker response to client needs by providing value add digital client counseling. This helps ITA to adapt alongside industry to remain ahead of the curve on client service, trade promotion, and trade policy development through more knowledgeable and effective collaboration.

Our office has created a U.S. Field-based client digital strategy counseling process that focuses on these key concepts:

- [eCommerce is a sales channel](#) that crosses all industries that sell or promote brand awareness online. eCommerce as a sales channel is part of a businesses' B2B and/or B2C digital strategy;
- [A digital strategy](#) addresses the basic needs of a business required to succeed in cross-border eCommerce sales channels. Our counseling process focuses on identifying these needs;
- [eCommerce Key Performance Indicators](#) allows businesses to understand where their digital efforts are paying off;
- [eCommerce Business Service Provider Directory \(BSP\)](#) provides the much-needed follow-up to our digital strategy recommendations that will help the client to succeed in overseas markets;

### **Overview**

Italian consumers are increasingly embracing digital services and the market is becoming more sophisticated. The digital evolution and growing internet penetration rates are fueled by investment in infrastructure from the Italian Government and key operators. Nevertheless, Italy still lags behind in fixed broadband and many SMEs lack funds to upgrade infrastructure. In Italy only 19% of SMEs have connection speeds of 100 Mbit/s or higher. E-commerce in Italy is developing rapidly and has registered annual double-digit growth since 2014. Although the Italian digital economy trails other major European countries, e-commerce is poised to continue its upward trend with Business-to-Consumer (B2C), Business-to-Business (B2B), and Consumer-to-Consumer (C2C) transactions all posting solid

growth. Turnover from e-commerce in Italy was estimated at 48.5 billion EUR in 2019, totaling a 17% growth over 2018. The sales of goods and products online increased by 15% in 2019 for a total market value of \$36 billion, while services sold online will grow by a factor of 7%.

### ***Current Market Trends***

The number of Italian web shoppers is constantly increasing. In 2019, 7% of all Italian retail sales were completed online, up from 6% in 2018. Sales are increasingly being conducted from mobile devices, which now account for roughly 40% of all digital sales. The main factors fueling growth of e-commerce in Italy are:

- improved Internet access infrastructure and wider broadband connection availability;
- one of the world's highest rates mobile and smartphone diffusion, which will enable business and consumer segments to take advantage of new technologies for e-commerce transactions;
- increasing recognition of e-commerce as a tool to serve and support customers more cheaply and efficiently;
- improved transaction security; and
- Italian legislation recognizing the legal validity of digital signatures and digital contracts.

### ***Domestic e-commerce (B2C)***

The B2C e-commerce market in Italy generated \$36 billion in 2019, an increase of 14% over 2018. The number of Italian web shoppers is constantly increasing and 93% of the Italian population is now online. Despite the positive trends, in absolute terms the Italian B2C e-commerce market was still only worth one third of the market in the United Kingdom, half of the German market and two third of French market in 2019. About 80% of online shoppers make at least one purchase per month with an average annual expenditure of \$755 per user per year.

### ***Cross-Border e-Commerce***

The 2019 Milan Polytechnic University E-commerce Report estimates that the total sales from Italian websites to foreign consumers totaled \$29.5 billion. Of the sales originating from .it domains, 85% were sold domestically while 15% were sold abroad. On the other hand, Italian imports of foreign goods and services online reached \$8.1 billion. According to Postnord's 2018 E-commerce in Europe Report, the most popular foreign e-shops used by Italian customers are located in the United Kingdom (19%), China (18%), and Germany (16%) In terms of foreign e-commerce sales, Italian companies sell to the European Union with 21% selling online in France, 18% in Germany, and 14% in the United Kingdom. Outside the EU, 14% of Italian companies sell to the United States, 6% to Asia (5% to China, 2% to Japan, and 4 % to other Asian markets), and 3% to South America.

### ***B2B eCommerce***

ECommerce B2B transactions accounted for \$463 billion in 2019 with a 14% increase in value from 2018. Transactions between businesses and central/local government only accounts for 15% of all B2B transactions in Italy.

Despite its rising trend, digitalization rates among Italian firms is quite low, and the majority of small- and medium-sized companies are far from embracing a digital transformation process which would improve and cut the costs of B2B relations. In 2019, about 50% of e-commerce B2B transactions were between producers and resellers. About 120,000 companies used B2B tools in 2019 (EDI – Electronic Data Interchange, Extranet, and B2B Portals) in their relationships with clients and suppliers. 250 eProcurement platforms are used in Italy by large enterprises to manage the electronic orders of clients and suppliers.

In addition, the obligation of delivering electronic invoices to the Italian Public Administration (PA) has resulted in a push towards digitalization for both private and State-owned companies.

The most common B2B e-commerce model is e-business, which entails the digitalization of corporate processes in conjunction with clients and suppliers (supplier selection, management of customer orders, after-sale services, etc.). In addition, over the last few years web portals for B2B e-commerce (like e-commerce B2C models) have become increasingly popular, as well as B2B Marketplaces.

B2B e-commerce applications and e-procurement are registering continued growth. The most active players implementing B2B solutions are in the automotive, pharmaceutical, consumer goods, electronics and consumer electronics sectors. Specialized B2B applications in key "Made in Italy" sectors are also gaining momentum; there is an estimated 350 B2B platforms across different industries. Virtually all major Italian industrial groups utilize e-procurement and forecasts indicate that in the next few years up to 80% of all company purchases will be online.

For information on public sector e-procurement, see the “Selling to the Public Sector” section below.

### ***eCommerce of Services***

International B2C retailing platforms have a strong influence on the Italian eCommerce market. Popular eCommerce websites in Italy include: Subito.it, Aliexpress.com, Zalando.it, Autoscout24.it, Groupon.it, Yoox, and Pixmania. Furthermore, Banzai Srl, Italy’s leading e-commerce operator controls ePrice.it and Saldiprivati.it.

Many companies in Italy offer successful omnichannel digital solutions and international eCommerce sites which are multilingual, multi-currency, multi-collection and multi-brand. These types of businesses support brands in managing all aspects of their own e-stores, including retail strategy, activity planning, communication, web marketing, store management, customer care, invoicing, and payment collection. These channels offer opportunities for U.S. small- and medium-sized companies interested in selling to the Italian market.

### ***eCommerce Business Service Provider Ecosystem***

Popular marketplaces, offering products in a wide variety of categories, including: [www.amazon.it](http://www.amazon.it), [www.ebay.it](http://www.ebay.it), [www.mediashopping.it](http://www.mediashopping.it), [www.aliexpress.it](http://www.aliexpress.it), [www.subito.it](http://www.subito.it), [www.dmail.it](http://www.dmail.it). In addition, there are a range of online marketplaces specialized by sector. The following list is a selection and is not meant to be comprehensive.

- Travel and tourism: [www.edreams.it](http://www.edreams.it), [www.expedia.it](http://www.expedia.it), [www.it.lastminute.com](http://www.it.lastminute.com), [www.trenitalia.com](http://www.trenitalia.com), [www.italotreno.it](http://www.italotreno.it), [www.volagratis.it](http://www.volagratis.it), [www.tripadvisor.it](http://www.tripadvisor.it), [www.opodo.it](http://www.opodo.it), [www.kayak.it](http://www.kayak.it), [www.skyscanner.com](http://www.skyscanner.com), [www.trivago.it](http://www.trivago.it), [www.booking.com](http://www.booking.com)
- Information technology and consumer electronics: [www.eprice.it](http://www.eprice.it), [www.euronics.it](http://www.euronics.it), [www.monclick.it](http://www.monclick.it), [www.mrprice.it](http://www.mrprice.it), [www.mediaworld.it](http://www.mediaworld.it), [www.unieuro.com](http://www.unieuro.com), and [www.trony.it](http://www.trony.it)
- Fashion: [www.yoox.com](http://www.yoox.com), [www.zalando.it](http://www.zalando.it), [www.saldiprivati.com](http://www.saldiprivati.com), [www.privalia.com](http://www.privalia.com), [www.vente-privee.com](http://www.vente-privee.com),
- Books, music and video: [www.amazon.it](http://www.amazon.it), [www.ibs.it](http://www.ibs.it), [www.unilibro.it](http://www.unilibro.it) and [www.lafeltrinelli.it](http://www.lafeltrinelli.it)
- Couponing: [www.groupon.it](http://www.groupon.it), [www.groupalia.it](http://www.groupalia.it) are among the most important sites.
- In addition to these marketplaces -- mostly B2C -- there are many B2B marketplaces and virtual malls specialized by industrial sector.
- Web Resources
- Acquisti in Rete – AiR (“Public Procurement Online”) -- The AiR portal provides access to a fully functional e-procurement platform  
[https://www.acquistinretepa.it/opencms/opencms/menuLivello\\_1/header/Inglese/PROGRAM](https://www.acquistinretepa.it/opencms/opencms/menuLivello_1/header/Inglese/PROGRAM)
- Netcomm -- Italian E-Commerce Consortium <http://www.conorzionetcomm.it/>

Google is the most popular search engine, primarily the Italian version ([www.google.it](http://www.google.it)), but also in its .com version in English. The other most popular search engines are [www.yahoo.it](http://www.yahoo.it), [www.virgilio.it](http://www.virgilio.it), [www.libero.it](http://www.libero.it), <http://it.msn.com>, [www.bing.com](http://www.bing.com), and [www.tiscali.it](http://www.tiscali.it).

U.S. companies can contact each search engine to submit their sites for listing free of charge but can also subscribe to special advertising services for a fee. U.S. companies may also hire local firms specialized in "web positioning" and search engine marketing services for website optimization. Although not required, it is advisable for any U.S. company that wishes to rank high on a local search engine to translate at least keywords and some text into Italian.

## **Selling Factors & Techniques**

### **Overview**

Many U.S. firms maintain their own sales organizations in Italy. Others sell through specialized importers or appoint sales agents who often are manufacturers' brokers. A large, well-established Italian firm with an efficient nationwide sales organization is likely to insist on an exclusive arrangement. About 1,800 U.S. firms are represented in the Italian market through agents, branches, subsidiaries, or licenses. Of these, about half have a substantial direct capital investment in the form of stock as a sole owner or partner in an enterprise. Generally, the sales territory includes all of Italy. In other cases, the territory also covers all or part of the European Union, depending on the type of product and degree of technical support needed. Italian distributors tend to have excellent contacts within Eastern Europe and the Mediterranean Basin



## Trade Promotion & Advertising

### *General Legislation*

Laws against misleading advertisements differ widely from member state to member state within the EU. To respond to this issue in the internal market, the Commission adopted a directive, in force since October 1986, to establish minimum and objective criteria regarding truth in advertising. The Directive was amended in October 1997 to include comparative advertising. Under the Directive, misleading advertising is defined as any "advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behavior or which for those reasons, injures or is likely to injure a competitor." Member States can authorize even more extensive protection under their national laws.

Comparative advertising, subject to certain conditions, is defined as "advertising which explicitly or by implication identifies a competitor or goods or services of a competitor." Member States can, and in some cases have, restricted misleading or comparative advertising.

The EU's Audiovisual Media Services Directive (AMSD) lays down legislation on broadcasting activities allowed within the EU. Since 2009, the rules allowing for U.S.-style product placement on television and the three-hour/day maximum of advertising has been lifted. However, a 12-minute/hour maximum remains. The AMSD is currently under revision. The European Commission is aiming to extend the scope of the Directive to video-sharing platforms which tag and organize the content. The Commission is also aiming to provide more flexibility about the 12-minute/hour maximum restriction. Children's programming is subject to a code of conduct that includes a limit on junk food advertising to children. Following the adoption of the 1999 Council Directive on the Sale of Consumer Goods and Associated Guarantees, product specifications, as laid down in advertising, are considered as legally binding on the seller.

The EU adopted Directive 2005/29/EC concerning fair business practices in a further attempt to tighten consumer protection rules. These rules outlaw several aggressive or deceptive marketing practices such as pyramid schemes, "liquidation sales" when a shop is not closing for business, and artificially high prices as the basis for discounts in addition to other potentially misleading advertising practices. Certain rules on advertising to children are also set out.

### **Key Links:**

[Misleading Advertising](#)

[Unfair Commercial Practices Directive](#)

[Audio video Media Services](#)

### Trade promotion in Italy

The primary trade show organizers in Italy are:

Fiera Milano <http://www.fieramilano.it/>

Bologna Fiere <http://www.bolognafiere.it/>

Verona Fiere <http://www.veronafiere.it/>

Rimini Fiera <http://www.riminifiera.it/>

Fiere di Parma <http://www.fiereparma.it/>

Primary national media outlets include:

TV

RAI	<a href="http://www.rai.it">http://www.rai.it</a>
Mediaset	<a href="http://www.mediaset.it/">http://www.mediaset.it/</a>
Sky Italia	<a href="http://www.sky.it/">http://www.sky.it/</a> (pay TV)
Mediaset Premium	<a href="http://www.mediasetpremium.it/">http://www.mediasetpremium.it/</a> (pay TV)

Press:

Corriere della Sera	<a href="http://www.corriere.it/">http://www.corriere.it/</a>
Sole 24 Ore	<a href="http://www.ilsole24ore.com/">http://www.ilsole24ore.com/</a>
La Stampa	<a href="http://www.lastampa.it/">http://www.lastampa.it/</a>
La Repubblica	<a href="http://www.repubblica.it/">http://www.repubblica.it/</a>

Radio

Rtl 102.5	<a href="http://www.rtl.it">www.rtl.it</a>
Rds	<a href="http://www.rds.it">www.rds.it</a>
Radio 105	<a href="http://www.105.net">www.105.net</a>
Radio Italia	<a href="http://www.radioitalia.it">www.radioitalia.it</a>
Radio Rai 1	<a href="http://www.radio1.rai.it">www.radio1.rai.it</a>
Radio 2	<a href="http://www.radio2.rai.it">www.radio2.rai.it</a>

Below is a list of key industry publications:

Apparel

Fashion	<a href="http://fashionmagazine.it/English.aspx">http://fashionmagazine.it/English.aspx</a>
Linea Intima	<a href="http://www.lineaintima.net/index_eng.html">http://www.lineaintima.net/index_eng.html</a>
Intimo Piu' Mare	<a href="http://www.intimopiumare.com/">http://www.intimopiumare.com/</a>

Architecture Engineering Building Products

Edilizia e territorio	<a href="http://www.ediliziaeterritorio.ilsole24ore.com/">http://www.ediliziaeterritorio.ilsole24ore.com/</a>
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Automotive

Pneurama	<a href="http://www.pneurama.com/en/index.php">http://www.pneurama.com/en/index.php</a>
Quattroruote	<a href="http://www.quattroruote.it/">http://www.quattroruote.it/</a>

Construction Machinery

Quarry and Construction [http://www.edizionipei.it/uscite\\_riviste-quarry\\_and\\_construction.html](http://www.edizionipei.it/uscite_riviste-quarry_and_construction.html)

Consumer Electronics

Trade – Consumer Electronics <http://www.e-duesse.it/Riviste/Trade-Consumer-Electronics>

E-commerce/Digitale

Corcom <http://www.corrierecomunicazioni.it/>

Energy

Nuova Energia <http://www.nuova-energia.com/>

Furniture

Interni <http://www.internimagazine.com/>

DDN Design Diffusion News <http://www.designdiffusion.com/en/>

Jewelry

VO + Jewels & Luxury Magazine <http://www.vicenzaoro.com/en/main/publications/vo-magazine>

Industrial Machinery

L'industria Meccanica <http://www.industriameccanica.it/>

Pet Products

Vimax <http://www.vimaxmagazine.it/sito/en/>

PetTrend <http://www.pettrend.it/>

Retail in Italy

Largo Consumo <http://www.largoconsumo.info/>

Sporting goods

Sport Industry <http://www.sportindustry.com>

TopSport <http://www.topsport.it/>

### Tourism

Guida Viaggi

[www.Guidaviaggi.it](http://www.Guidaviaggi.it)

L'Agenzia di Viaggi

[www.lagenziadiviaggi.it](http://www.lagenziadiviaggi.it)

TTG Italia

<http://www.ttgitalia.com/>

### **Pricing**

Italian importers generally prefer price quotes on a [CIF](#) or [CIP](#) basis, since they are usually familiar with the Italian customs charges and value-added taxes levied on the product at the time of importation, but may not be familiar with U.S. costs for trucking, ocean, or air freight. Large Italian firms and department stores, however, may prefer to buy on other terms when they arrange for the shipping and insuring the goods. Quotes and invoicing are usually in terms of the currency of the selling country.

Sales made on cash terms call for payment before delivery, on delivery, or shortly thereafter, typically within 10 days from the date of delivery. A two to five percent discount is given for payment of the full amount of the transaction at the end of the specified period from one to four months from the date of the invoice. The length of the period depends on the commodity involved, the credit standing of the buyer, and the marketing and sales objective of the seller. A period of up to two years is often allowed for payment of capital goods, store equipment, trucks, and similar heavy equipment.

Italian firms indicate that some U.S. suppliers are too rigid in their payment terms and have thus lost business to other suppliers. Financing is as much a competitive factor as the product itself, the delivery date, or after-sales service. While some U.S. manufacturers request payment upon receipt of the goods, more successful sellers offer terms allowing settlement of the account from 60 to 120 days following the invoice date, which is the most common practice in Italy. U.S. firms should note that Italians can be slow to pay.

The use of irrevocable letters of credit for the Italian market has declined appreciably in recent years. Although U.S. exporters sometimes require such instruments, especially when the Italian customer's credit reputation is not well known, the growing reluctance of Italian firms to provide letters of credit has required U.S. exporters to turn to other methods to assure payment or lose the sale to other suppliers in the competitive Italian market. The Italian businessperson is reluctant to pay a high fee for a letter of credit when other suppliers or means of payment are available. U.S. firms are increasingly using the export credit insurance and guarantee programs available through the Export-Import Bank of the United States ([Ex-Im Bank](#)), the Foreign Credit Insurance Association ([FCIA](#)), Fidelity & Deposit, the Overseas Private Investment Corporation ([OPIC](#)), American International Group – AIG Global & Political Risk Insurance Co. ([AIG](#)), Multilateral Investment Guarantee Agency ([MIGA](#)) and other export credit insurers.

### *Quotes and Payment Terms*

The Italian buyer may request a quote or shipment of goods under other INCOTERMS ([International Commercial Terms](#)). This is a set of international rules defining the important commercial terms and practices. By referencing INCOTERMS in contracts or invoices, both buyer and seller will have a uniform understanding of their responsibilities in an agreement. You can find copies of the 90-page publication, Guide to INCOTERMS from ICC Publishing, 156 Fifth Avenue, New York, NY 10010, (212) 206-1150. Exporters can also obtain information from the International Chamber of Commerce website: <http://www.iccwbo.org/> or from Dun & Bradstreet [Exporters' Encyclopaedia](#).

The Italian importer may examine the merchandise for inventory purposes before customs clearance. Goods cannot clear customs without shipping documents and payment of any required customs duty, applicable value-added taxes and excise taxes. The importer must undertake these formalities at the time of clearing customs. The importer should present import licenses, if required, within the period for which they were issued.

## **Sales Service/Customer Support**

Conscious of the discrepancies among member states in product labeling, language use, legal guarantee and liability, the redress of which inevitably frustrates consumers in cross-border shopping, the EU institutions have launched a number of initiatives aimed at harmonizing national legislation. Suppliers within and outside the EU should be aware of existing and upcoming legislation affecting sales, service and customer support.

### *Product Liability*

Under the 1985 Directive on Liability of Defective Products, amended in 1999, the producer is liable for damage caused by a defect in his product. The victim must prove the existence of the defect and a causal link between defect and injury (bodily as well as material). A reduction of liability of the manufacturer is granted in cases of negligence on the part of the victim. The first step in the review process of this law was launched at the end of 2016.

**Key link:** [Liability of Defective Products](#)

### *Product Safety*

The 1992 General Product Safety Directive introduced a general safety requirement at the EU level to ensure that manufacturers only place safe products on the market. It was revised in 2001 to include an obligation on the producer and distributor to notify the Commission in case of a problem with a given product, provisions for its recall, the creation of a European Product Safety Network, and a ban on exports of products to third countries that are not deemed safe in the EU. The legislation is still undergoing review.

**Key link:** [Product Safety Legislation](#)

### *Legal Warranties and After-sales Service*

Under the 1999 Directive on the Sale of Consumer Goods and Associated Guarantees, professional sellers are required to provide a minimum two-year warranty on all consumer goods sold to consumers (natural persons acting for purposes outside their trade, businesses or professions), as defined by the Directive. The remedies available to consumers in case of non-compliance are:

- Repair of the good(s);
- Replacement of the good(s);
- A price reduction; or
- Rescission of the sales contract.

Other issues pertaining to consumers' rights and protection, such as the New Approach Directives, CE marking, quality control and data protection are dealt with in the Trade Regulations section of this report.

**Key link:** [Sales and Guarantees](#)

### *Local Professional Services*

The following is a sample of service providers in Italy and the European Union. Please note that their inclusion in this guide is not an endorsement of their services.

Local service providers focusing on EU law, consulting, and business development can be viewed on the website maintained by the Commercial Service at the U.S. Mission to the European Union at: <http://export.gov/europeanunion/businessserviceproviders/index.asp>.

For information on professional services located within each of the EU Member States, please see EU member state Country Commercial Guides which can be found at the following website EU Member States' Country Commercial Guides <https://export.gov/ccg>

Italian market research firms:

ACNielsen Italia: [www.acnielsen.it](http://www.acnielsen.it)

Databank S.p.A.: [www.databank.it](http://www.databank.it)

Inter@ctive Market Research: [www.imrgroup.com](http://www.imrgroup.com)

M&T Marketing & Trade S.r.l.: [www.marketingtrade.it](http://www.marketingtrade.it)

Italian commercial banks:

Intesa Sanpaolo S.p.A.: [www.intesasanpaolo.com](http://www.intesasanpaolo.com)

Unicredit Group S.p.A.: <https://www.unicreditgroup.eu/en.html>

Banca Nazionale del Lavoro BNL S.p.A.: [www.bnl.it](http://www.bnl.it)

Banca Monte dei Paschi di Siena S.p.A.: [www.mps.it](http://www.mps.it)

### Principal Business Associations

[American Chamber of Commerce in Italy](#), which is based in Milan

[Confindustria](#) - Confederazione Generale dell'Industria Italiana. The Confederation of Italian Industry is a principal trade association acting as an umbrella organization covering numerous industry trade associations

[AIAD](#) – Associazione Industrie per l’Aerospazio, i Sistemi e la Difesa: Italian Association of Aerospace and Defense Industries

[ABI](#) - Associazione Bancaria Italiana: Italian Banking Association

[ANFIA](#) - Associazione Nazionale fra Industrie Automobilistiche: Italian Automotive Industry Association:

[ANIA](#) - Associazione Nazionale fra le Imprese Assicuratrici: Italian Association of Insurance Companies

[ASSOFRANCHISING](#) – Associazione Italiana del Franchising: Italian Franchising Association

[CONFAPI](#) - Confederazione Italiana della Piccola e Media Industria” Italian Confederation of Small and Medium Industries:

[FARMINDUSTRIA](#) – Associazione Nazionale dell’Industria Farmaceutica: Italian National Association of Pharmaceutical Industries

[FEDERCHIMICA](#) – Federazione Nazionale dell’Industria Chimica: Italian Federation of Chemical Industries

[UNIONCAMERE](#) - Unione Italiana delle Camere di Commercio Industria Agricoltura e Artigianato: Italian Union of the Chambers of Commerce, Industry, Handicraft and Agriculture. Umbrella organization responsible for all chambers of commerce in Italy.

For industry-specific business associations, please visit our best prospect section, which lists key contacts and resources by sector.

Organizations in Brussels focused on representing U.S. business interests and engaging with EU institutions including the European Commission, European Parliament and the Council include: [AmChamEU](#)

Limitations on Selling U.S. Products and Services

We are not aware of any limitations on manufacturing or service sectors that prohibit non-Italians from owning or selling these businesses in Italy. For more information please visit the [trade barriers](#) section in this document.

## **Trade Financing**

### **Methods of Payment**

U.S. firms most frequently provide the Italian buyer with a price quote that includes packing costs, insurance, and freight (CIF or CIP price). The average Italian business representative can then usually determine the charges for customs, taxes, and local transportation to arrive at the importer's final landed cost. The customary terms of sale in Italy are either cash or net. Sales made on cash terms call for payment before delivery, on delivery, or shortly after delivery -- usually within 10 days. A two- to five-percent discount is made for payment of the full amount of the transaction at the end of the specified period from one to four months from the date of the invoice. The length of the period depends on the commodity involved, the credit standing of the buyer, and the motivation of the seller. A period of up to two years is often allowed for payment of capital goods, store equipment, trucks, and similar heavy equipment.

Some U.S. suppliers have lost business because Italian firms believe their payment terms are too rigid. Exporters should regard financing as another competitive factor, on par with the product itself, the delivery date, or after-sales service. U.S. manufacturers will be more competitive by allowing accounts to be settled from 60 to 120 days following receipt of the order.

Although originally an Italian creation, the use of irrevocable letters of credit has declined appreciably in Italy in recent years. Because of the growing reluctance of Italian firms to pay high fees associated with letters of credit, U.S. exporters should explore other mechanisms to ensure payment from Italian customers of uncertain credit worthiness, or risk losing the sale. Alternatives include export credit insurance and guarantee programs available through the Foreign Credit Insurance Association (FCIA).

Just as sales offer terms should be clear and detailed, shipment terms should conform to contract specifications and should be consistent with any samples that were sent to the Italian importer. Agreed delivery schedules should be met, as prompt delivery may be a decisive consideration of the importer in placing additional orders. When shipping on letters of credit, all terms specified in the letter of credit must be strictly observed. If all the terms are not followed, the bank may not honor the letter of credit.

For more information about the methods of payment or other trade finance options, please read the Trade Finance Guide available at <https://www.trade.gov/trade-finance-guide-quick-reference-us-exporters>.

### **Banking Systems**

Italy has a well-developed banking and credit system with numerous correspondent U.S. banks. Italian banks are subject to close government supervision, and the Bank of Italy (BOI, Italy's central bank) must authorize the establishment of any new bank. In November 2014, the European Central Bank (ECB) assumed primary supervisory responsibility for "significant banks" and may exercise supervision over less significant national banks. As of 2018, there are 12 banking groups in Italy deemed "significant" and therefore subject to ECB supervision.

U.S. firms seeking to finance major portions of their capital investment outside the United States may find capital available in Italy. As of the December 2018, there were 505 banks in Italy, 138 fewer than in December 2015. Of these, 85 banks are branches of foreign banks. Currently, the country's largest private banks, by assets are: Intesa Sanpaolo and UniCredit Group. These two banks combined accounted for over half of total bank assets in Italy and are a principal source of credit information. U.S. bank branches in Italy can also assist in financing capital investment.

Italy's banking sector has undergone significant consolidation since the mid-nineties, decreasing from approximately 1,000 banks through mergers, takeovers or asset transfers, liquidations or, the conversion of a bank into a financial company, which involved 60 percent of total Italian banking assets. The government is taking steps to encourage the consolidation process to continue over the next several years to boost the international competitiveness of the Italian banking sector.

Banks in Italy that have the authority to participate in foreign exchange usually have a U.S. correspondent. Foreign currency transfers and foreign exchange transactions must be channeled via authorized intermediaries (the Bank of Italy). Larger Italian banks usually have branches in one or more U.S. cities.

The Bank of Italy follows euro notes issues, performs credit, financial and market supervision, and regulates bank mergers. The Bank of Italy Governor's term is for six years in line with European Central Bank (ECB) standards, and the Governor is limited to two terms in office. Banking competition oversight responsibilities are divided between the Bank of Italy and Italy's anti-trust authority. CONSOB, Italy's security markets and company accounting regulator, holds authority to raid firms suspected of securities violations and to impound evidence.

A prohibition on non-bank companies (either Italian or foreign) acquiring more than 15 percent of a bank's capital was abolished by the legislature in late 2008, with the aim of implementing a new European directive. Firms have used complex cross-shareholding arrangements to fight off takeover attempts in the financial sector. Still, the presence of foreign intermediaries in the Italian market increased in the last several years.

### **Foreign Exchange Controls**

In accordance with EU directives, Italy has no foreign exchange controls. There are no restrictions on currency transfers; there are only reporting requirements. Banks are required to report any transaction over EUR 1,000 due to money laundering and terrorism financing concerns. Profits, payments, and currency transfers may be freely repatriated. Residents and non-residents may hold foreign exchange accounts. In 2016, the GOI raised the limit on cash payments for goods or services to €3,000 (from €1,000). Payments above this amount must be made electronically. Enforcement remains uneven. The rule exempts e-money services, banks and other financial institutions, but not payment services companies.

Italy is a member of the European Monetary Union (EMU), with the euro as its official currency. Exchange rates are floating.

### **U.S. Banks & Local Correspondent Banks**

Several U.S. banks perform services in Italy through branches, subsidiaries, or representatives. Many U.S. banks provide their commercial customers with services such as bank reports on overseas buyers, assistance for letters of credit, and foreign exchange. Citi (Citigroup), JP Morgan Chase, and Bank of America, as well as numerous smaller, regional banks maintain offices in Italy.

## **Protecting Intellectual Property**

### *Protecting Your Intellectual Property in the EU:*

Several general principles are important for effective management of intellectual property ("IP") rights in the EU. First, it is important to have an overall strategy to protect your IP. Second, IP may be protected differently in the EU than in the United States. Third, rights must be registered and enforced in the EU under local laws. For example, your U.S. trademark and patent registrations will not protect you in the EU. There is no such thing as an "international copyright" that will automatically protect an author's writings throughout the entire world. Protection against unauthorized use in a country depends, basically, on the national laws of that country. However, most countries do offer copyright protection to foreign works in accordance with international agreements.

Granting patents registrations generally is based on a first-to-file (or first-to-invent, depending on the country) basis. Similarly, registering trademarks is based on a first-to-file (or first-to-use, depending on the country), so you should consider how to obtain patent and trademark protection before introducing your products or services to the EU market. It is vital that companies understand that intellectual property is primarily a private right and that the U.S. government cannot enforce rights for private individuals in the EU. It is the responsibility of the rights holders to register, protect, and enforce their rights where relevant, retaining their own counsel and advisors. Companies may wish to seek advice from local attorneys or IP consultants who are experts in EU law. The U.S. Commercial Service can provide a list of local lawyers upon request.



While the U.S. government stands ready to assist, there is little we can do if the rights holders have not taken these fundamental steps necessary to securing and enforcing their IP in a timely fashion. Moreover, in many countries, rights holders who delay enforcing their rights on a mistaken belief that the U.S. government can provide a political resolution to a legal problem may find that their rights have been eroded or abrogated due to legal doctrines such as statutes of limitations, laches, estoppel, or unreasonable delay in prosecuting a law suit. In no instance should U.S. government advice be seen as a substitute for the responsibility of a rights holder to promptly pursue its case.

It is always advisable to conduct due diligence on potential partners. A good partner is an important ally in protecting IP rights. Consider carefully, however, whether to permit your partner to register your IP rights on your behalf. Doing so may create a risk that your partner will list itself as the IP owner and fail to transfer the rights should the partnership end. Keep an eye on your cost structure and reduce the margins (and the incentive) of would-be bad actors. Projects and sales in the EU require constant attention. Work with legal counsel familiar with the EU laws to create a solid contract that includes non-compete clauses, and confidentiality/non-disclosure provisions.

It is also recommended that small- and medium-size companies understand the importance of working together with trade associations and organizations to support efforts to protect IP and stop counterfeiting. There are a number of these organizations, both EU or U.S.-based. These include:

- The U.S. Chamber and local American Chambers of Commerce
- National Association of Manufacturers (NAM)
- International Intellectual Property Alliance (IIPA)
- International Trademark Association (INTA)
- The Coalition Against Counterfeiting and Piracy
- International Anti-Counterfeiting Coalition (IACC)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Biotechnology Industry Organization (BIO)

#### IP Resources

A wealth of information on protecting IP is freely available to U.S. rights holders. Some excellent resources for companies regarding intellectual property include the following:

- For information about patent, trademark, or copyright issues -- including enforcement issues in the United States and other countries -- call the STOP! Hotline: **1-866-999-HALT** or visit [STOP Fakes](#)
- For more information about registering trademarks and patents (both in the United States as well as in foreign countries), contact the [U.S. Patent and Trademark Office](#) (USPTO) at: **1-800-786-9199**
- For more information about registering for copyright protection in the United States, contact the [U.S. Copyright Office](#) at: **1-202-707-5959**.
- For more information about how to evaluate, protect, and enforce intellectual property rights and how these rights may be important for businesses, please visit the “Resources” section of the [STOPfakes website](#).
- For information on obtaining and enforcing intellectual property rights and market-specific IP Toolkits visit: [STOPfakes Business tools](#). The toolkits contain detailed information on protecting and enforcing IP in specific markets as well as contact information for local IPR offices abroad and U.S. government officials available to assist SMEs.

In any foreign market companies should consider several general principles for effective protection of their intellectual property. For background, link to our article on [Protecting Intellectual Property](#) and [Stopfakes.gov](#) for more resources.

The U.S. Department of Commerce has positioned IP attachés in key markets around the world. Contact information for European based IP attachés in below:

#### **Geneva, Switzerland**

Deborah Lashley-Johnson

[deborah\\_e\\_lashley-johnson@ustr.eop.gov](mailto:deborah_e_lashley-johnson@ustr.eop.gov)

Kristine Schlegelmilch

[SchlegK@state.gov](mailto:SchlegK@state.gov)

#### **Brussels, Belgium**

**Susan Wilson**

[Susan.Wilson@trade.gov](mailto:Susan.Wilson@trade.gov)

**Kyiv, Ukraine**

Dorian Mazurkevich

<mailto:dorian.mazurkevich@trade.gov>

For more information, contact ITA's Office of Intellectual Property Rights Director, Stevan Mitchell at [Stevan.Mitchell@trade.gov](mailto:Stevan.Mitchell@trade.gov).

**Selling to the Public Sector**

Government procurement in Europe is governed by both international obligations under the WTO Government Procurement Agreement (GPA) and EU-wide legislation under the EU Public Procurement Directives. U.S.-based companies are allowed to bid on public tenders covered by the GPA, while European subsidiaries of U.S. companies may bid on all public procurement contracts covered by the EU Directives in the European Union.

The EU directives on public procurement have recently been revised and new legislation on concession has also been adopted. Member States were required to transpose the provisions of the new directives by April 16, 2016. The four relevant directives are:

- [Directive 2014/24/EU](#) (replacing Directive 2004/18/EC) on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts applies to the general sector;
- [Directive 2014/25/EU](#) (replacing Directive 2004/17/EC) coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors;
- [Directive 2009/81/EC on defense and sensitive security procurement](#). This Directive sets Community rules for the procurement of arms, munitions and war material (plus related works and services) for defense purposes, but also for the procurement of sensitive supplies, works and services for non-military security purposes;
- [Directive 2014/23/EU](#) on the award of concession contracts. A concession contract (either for the delivery of works or services) is conducted between a public authority and a private enterprise that gives the right to the company to build infrastructure and operate businesses that would normally fall within the jurisdiction of the public authority (e.g. highways).

The EU has three remedy directives imposing common standards for all member states to abide by in case bidders identify discriminatory public procurement practices.

Electronic versions of the procurement documentation must be available through an internet URL immediately on publication of the Official Journal of the European Union (OJEU) contract notice. Full electronic communication (with some exceptions) will become mandatory for all public contracts from October 2018. Central purchasing bodies are required to publish their contracts and requests for tenders since April 2017.

Electronic invoicing (e-invoicing) will be introduced beginning the 3<sup>rd</sup> quarter of 2018, based on the requirement set forth in [Directive 2014/55/EU](#). The Directive makes the receipt and processing of electronic invoices in public procurement obligatory. Standards for e-invoicing are being developed by the European Committee for Standardization (CEN).

There are restrictions for U.S. suppliers in the EU utilities sector, both in the EU Utilities Directive and in EU coverage of the GPA. Article 85 of Directive 2014/25 allows EU contracting authorities to either reject non-EU bids where the proportion of goods originating in non-EU countries exceeds 50 percent or give preference to the EU bid if prices are equivalent (meaning within a three percent margin). Moreover, the Directive allows EU contracting authorities to retain the right to suspend or restrict the award of service contract to undertaking in third countries where no reciprocal access is granted.

There are also restrictions in the EU coverage of the GPA that apply specifically to U.S.-based companies. U.S. companies are not allowed to bid on works and services contracts procured by sub-central public contracting authorities in the following sectors:

- Water sector
- Airport services
- Urban transport sector as described above, and railways in general
- Dredging services and procurement related to shipbuilding

## Public Procurement in Italy

Italy's public procurement system is bound by international obligations under both the WTO Government Procurement Agreement (GPA) and EU Public Procurement Directives. Through a series of legislative decrees enacted since the GPA became part of EU domestic law in January 1996, Italy has generally brought its domestic procurement laws into compliance with the above international obligations. Italy has over 22,000 contracting agencies at the central and local level that are subject to EU Directives on public procurement. GOI Ministries are the main central contracting agencies. At the local level, principal contracting agencies include regions, provinces, municipalities and entities controlled by the municipalities, including local healthcare authorities responsible, among

other things, for hospital administration. There is an ongoing effort to reduce the number of contracting agencies and streamline procurement protocols and processes.

#### E-procurement

The need for the Italian public sector to improve efficiency is driving the growth of e-procurement. To rationalize expenditures for goods and services, both the central and local Italian government offices utilize the Italian Public Administration eMarketplace (MEPA), an e-procurement platform managed by Consip SpA, the Italian Central Purchasing body, 100% owned by the Italian Ministry of Economy and Finance (MEF) through its division “Acquisti in Rete PA” (Public Procurement Online). MEPA connects Italian public bodies to thousands of suppliers throughout Italy.

The public sector utilizes e-sourcing to purchase most information technology equipment and office supplies, furniture, uniforms. The online procurement of services is also growing, particularly in the areas of energy (fuel, electric power), printing services, vehicle rental, cleaning services and financial services.

Announcements of tenders on public procurements are monitored by the U.S. Mission to the European Union and can be accessed through the webpage: <http://export.gov/europeanunion/grantstendersandfinancing/index.asp>

The official European Gazette and the official Italian Gazette publish invitations to bid. The U.S. Commercial Service at the U.S. Mission to the European Union has developed a database of all European public procurement tenders that are open to U.S.-based firms by virtue of the [Government Procurement Agreement](#)

For more information visit: [http://www.wto.org/english/tratop\\_e/gproc\\_e/memobs\\_e.htm](http://www.wto.org/english/tratop_e/gproc_e/memobs_e.htm).

Visit [EU public procurement announcements free of charge](#).

We recommend that the U.S. firm have agent/distributor representation rather than try to deal directly with Italian government agencies. This is in part because many contracting agencies often target the local procurement market first, which does include subsidiaries, branches and agents of U.S. companies.

U.S. companies bidding on Government tenders may also qualify for U.S. Government advocacy. A unit of the U.S. Commerce Department’s International Trade Administration, the Advocacy Center coordinates U.S. Government interagency advocacy efforts on behalf of U.S. exporters bidding on public sector contracts with international governments and government agencies. The Advocacy Center works closely with our network of the U.S. Commercial Service worldwide and inter-agency partners to ensure that exporters of U.S. products and services have the best possible chance of winning government contracts. Advocacy assistance can take many forms but often involves the U.S. Embassy or other U.S. Government agencies expressing support for the U.S. bidders directly to the foreign government. Consult Advocacy for Foreign Government Contracts for additional information.

#### Financing of Projects

Multilateral Development Banks and Financing Government Sales. Price, payment terms, and financing can be a significant factor in winning a government contract. Many governments finance public works projects through borrowing from the Multilateral Development Banks (MDB). A helpful guide for working with the MDBs is the Guide to Doing Business with the Multilateral Development Banks. The U.S. Department of Commerce’s (USDOC) International Trade Administration (ITA) has a Foreign Commercial Service Officer stationed at each of the five different Multilateral Development Banks (MDBs): the African Development Bank; the Asian Development Bank; the European Bank for Reconstruction and Development; the Inter-American Development Bank; and the World Bank

Learn more by contacting the Commercial Liaison Office to the [European Bank for Reconstruction and Development](#).

EU financial assistance programs provide a wide array of grants, loans, loan guarantees and co-financing for feasibility studies and projects in several key sectors (e.g., environmental, transportation, energy, telecommunications, tourism, public health). A number of centralized financing programs are also generating procurement and other opportunities directly with EU institutions.

The EU supports economic development projects within its member states, as well as EU-wide "economic integration" projects that cross both internal and external EU borders. In addition, the EU provides assistance to candidate and neighbor countries. The EU provides project financing through grants from the EU budget and loans from the European Investment Bank. Grants from the EU Structural and Investment Funds program are distributed through the

member states' national and regional authorities. Projects in non-EU countries are managed through the Directorate-Generals Enlargement, Development and Cooperation (EuropeAid), Humanitarian Aid and Civil Protection (ECHO).

## **Business Travel**

### **Business Customs**

In general, similar business practices in the United States apply when doing business in Italy. The "golden keys" of customary business courtesy, especially replying promptly to requests for price quotations and orders, are a prerequisite for success. Business people in Italy appreciate prompt replies to their inquiries and expect all correspondence to be acknowledged. We recommend conservative business attire at all times. Business appointments are required, and visitors are expected to be punctual.

European business executives are usually more formal than their U.S. counterparts; therefore, it is best to refrain from using first names until a solid relationship is formed. Italian business executives tend to use titles indicating their position in the firm. During the first stages of conducting business, it is best to let the prospective buyer take the lead since the U.S. approach of "getting down to business" is considered abrupt. Avoid commenting on political events or making negative comments about the country. Some positive and sincere observations about the Italian culture, style, art, history, cuisine, or music are always appropriate.

Italian buyers appreciate style, quality, and service, but are also interested in delivered price. Take care to assure that stated delivery dates are maintained and that after-sales service is promptly honored. Italians, and Europeans in general, expect that, after placing an order with a supplier, the delivery date be honored. While numerous factors may interfere with prompt shipment, the U.S. exporter must allow for additional shipping time and keep in close contact with the buyer. Meeting delivery schedules is of prime importance. It is much better to quote a later delivery date that can be guaranteed than promise an earlier delivery that is not completely certain.

### **Travel Advisory**

Italy has a moderate rate of crime, especially for theft and economic crimes; violent crimes are rare. Petty crime (pick-pocketing, theft from parked cars, purse snatching) can be a problem problem, especially in large cities. Most reported thefts occur at crowded tourist sites, at airports, car rental agencies, on public buses, metros and trains, and at the major railway stations. More detailed information on travel to Italy is available from the following [Department of State website](#) and the [advisories](#) on the U.S. Embassy's website

### **Visa Requirements**

Every U.S. traveler must have a valid passport which must be valid for at least six months beyond the planned date of departure from the Schengen area. No visa is required of U.S. citizens travelling to Italy for tourism or general business for less than 90 days. A visa is required for longer stays. Under Italian law, all non-residents are required to complete a dichiarazione di presenza (declaration of presence). Tourists arriving from a non-Schengen-country (e.g. the United States) should obtain a stamp in their passport at the airport on the day of arrival. This stamp is considered the equivalent of the declaration of presence. The registration form submitted to the hotel management upon check-in, signed by the tourist on arrival, constitutes the declaration of presence.. For more information please refer to the [Ministry of Foreign Affairs](#) and the Polizia di Stato.

U.S. citizens planning to work in the country must obtain a work visa in the United States from the Italian Embassy or an Italian Consulate before entering Italy. The prospective Italian employer must first obtain approval for a work permit. This permit is usually granted only for specialized work or skills. The prospective Italian employer files an application at an Ufficio Provinciale del Lavoro e della Massima Occupazione (Provincial Labor Office). If clearance is granted, the prospective employer is further required to obtain a work permit with the approval of the regional and central authorities. The permit is then sent to the worker so that he or she may apply for the entry visa in the United States. There are Italian consular offices in all of the largest U.S. cities. It is necessary to initiate the application process

at least three to four months before the visa is needed. In some of the larger cities such as Rome and Milan, there is a long backlog in the processing of work permits, so it is advisable to apply well in advance if at all possible.

A person seeking to work in Italy in an independent or self-employed capacity files an application directly with the Italian Embassy or Consulate along with needed credentials demonstrating experience in the field of work. If approved, the Italian Embassy or Consulate will issue the appropriate visa and the person must then apply for a *permesso di soggiorno* (permit of stay) within eight business days of arrival in Italy.

For further information concerning entry requirements for Italy, travelers can consult the Italian Embassy website:

[http://www.ambwashingtondc.esteri.it/ambasciata\\_washington/en](http://www.ambwashingtondc.esteri.it/ambasciata_washington/en).

They can also contact the Consular Section of the Embassy of Italy at 3000 Whitehaven Street, NW, Washington, DC 20008, telephone: +1(202) 612-4400, or fax +1 (202) 518-2154, or the nearest Italian Consulate General in Boston, Chicago, Detroit, Houston, Los Angeles, Miami, New York, Philadelphia, or San Francisco.

U.S. Companies that require travel of foreign businesspersons to the United States are advised that security evaluations are handled via an interagency process. Visa applicants should go to the following link(s): State Department Visa Website.

### **Currency**

The official currency in Italy is the euro. Dollars not widely accepted. All commercial banks are authorized to conduct foreign exchange transactions. Dollar currency, travelers checks, and, in some cases, personal checks, may be exchanged at banks, exchange offices, authorized tourist offices, and hotels. Major credit cards are accepted with proper identification, and ATMs are ubiquitous.

### **Telecommunications/Electric**

Italy's telephone dialing procedures require that the city code be a part of each telephone number. An example of a local call within Rome would be: 06-46741 (06 is the city code). Incoming long distance calls to Italy also require that the "0" in the city code be included when dialing. An example of an incoming long distance call from the U.S. to Rome is as follows: +39-06-46741 (39 being the country code, 06 the city code for Rome). Milan's city code is 02. Italians are avid users of cellular phones and will generally provide their cellular telephone number. When dialing to cellular phones, please note that no city code is used. Also, the "0" has been dropped from the prefix of all cellular phone numbers. An example of an incoming call from the U.S. to a cellular phone is as follows: +39-328-6187041 (39 being the country code, 328 a sample cellular prefix).

For Internet access, there is an abundance of Internet stations and cafes. Many of these stations cater to tourists and also provide easy access to international calling.

### **Transportation**

Rental automobiles are available at numerous locations. A valid state driver's license is acceptable, accompanied by an international license (which serves as a translation only). High speed trains run between major cities and there are slower regional trains. Highways are well maintained and have well serviced rest stops including restaurants, gas stations etc.

### **Language**

Italian is the official language and is spoken in all parts of Italy, although some minority groups in the Alto Adige and Aosta regions speak German and French, respectively. Correspondence with Italian firms, especially for an initial contact, should be in Italian. If a reply comes in English then the subsequent correspondence with the Italian firm can be in English. The use of Italian is not only regarded as a courtesy, but assures prompt attention, and prevents inaccuracies that might arise in translation. Most large commercial firms are able to correspond in various languages

in addition to English and Italian, but a business overture or proposal is given more serious attention if written in Italian.

The importance of having trade literature, catalogs, and instructions printed in Italian cannot be overemphasized. The agent representative in Italy who has such material is in a far better competitive position than the one who can only show literature in English to prospective customers and consumers.

## Health

Medical services are good and medical standards compare with those in the United States. Common medical needs are easily accessible, and special supplies are normally available on short notice, including most pharmaceuticals. An international certificate of vaccination is not required for travelers from the United States. Drinking water is generally acceptable, although in the Naples area the use of bottled water is recommended.

## Local Time, Business Hours and Holidays

The time zone for Italy is 6 hours ahead of U.S. Eastern Standard Time, except during periods at the beginning and end of daylight savings time (Italy begins daylight savings time later in the year and ends earlier than in the U.S.).

The usual Italian business hours are from 8 or 9 A.M. to Noon or 1 P.M. and from 3 to 6 or 7 P.M., Monday through Friday. Working hours for the various ministries of the government are normally from 8 A.M. to 2 P.M. without intermission. Bank hours are from 8:30 A.M. to 1:30 P.M. and 3:00-4:00 P.M.; they are closed on Saturdays and Sundays. Retail establishments are closed on Sundays although exceptions exist, primarily in tourist areas. In recent years, Italy has enacted legislation providing flexibility in retail store operating.

Italian holidays must be taken into account when planning a business itinerary. July and August are not good months for conducting business in Italy since most business firms are closed for vacation during this period. The same is true during the Christmas and New Year period. Italian commercial holidays are listed below and are when most commercial offices and banks are closed. Certain other days are celebrated as holidays within local jurisdictions. Italian holidays are also observed by the U.S. Embassy and Consulates and should be considered when telephoning or visiting the U.S. and Foreign Commercial Service offices. When an Italian holiday falls on a Saturday, offices and stores are closed.

**Listed below are Italian holidays (I) for 2020:** [U.S. holidays (A) observed by the U.S. Embassy are also indicated]:

January 1, Wednesday	New Year's Day (I)
January 6, Monday	Epiphany (I)
January 20, Monday	Martin Luther King's Birthday (A)
February 17, Monday	President's Day (A)
April 13, Monday	Easter Monday (I)
April 25, Saturday***	Anniversary of the Liberation (I)
May 1, Friday	Labor Day (I)
May 25, Monday	Memorial Day (A)
June 2, Tuesday	Foundation of the Italian Republic (I)

June 24, Wednesday	St. John's Day (I) (Florence only)
June 29, Monday	St. Peter and St. Paul's Day (I) (Rome only)
July 3, Friday*	Independence Day (A)
August 15, Saturday***	Assumption Day (I)
September 7, Monday	Labor Day (A)
September 19, Saturday***	St. Gennaro's Day (I) (Naples only)
October 12, Monday	Columbus Day (A)
November 1, Sunday**	All Saints' Day (I)
November 11, Wednesday	Veterans' Day (A)
November 26, Thursday	Thanksgiving Day (A)
December 7, Monday	St. Ambrogio's Day (I) (Milan only)
December 8, Tuesday	Feast of the Immaculate Conception (I)
December 25, Friday	Christmas Day (I)
December 26, Saturday***	St. Stephen's Day (I)
December 26, Thursday	St. Stephen's Day (A&I)

### **Temporary Entry of Materials or Personal Belongings**

Italy participates in the International Convention to Facilitate the Importation of Commercial Samples and Advertising Materials. Samples of negligible value imported to promote sales enjoy duty-free and tax-free treatment. Prior authorization is not required. To determine whether the samples are of negligible value, their value is compared with a commercial shipment of the same product. Granting of duty-free status may require that the samples be rendered useless for future sale by marking, perforating, cutting, or other means.

Imported samples of commercial value may be granted a temporary entry with exemption from custom charges. However, a bond or cash deposit may be required as security that the goods will be removed from the country. This security is the duty and tax normally levied plus ten percent. Samples may remain in the country for up to one year. They may not be sold, put to their normal use (except for demonstration purposes), or utilized in any manner for remuneration. Goods imported as samples may be imported only in quantities constituting a sample according to normal commercial usage.

### **Carnets**

As a result of various customs agreements, simplified procedures are available to U.S. business and professional people for the temporary importation of commercial samples and professional equipment. A carnet is a customs document that facilitates clearance for temporary imports of samples or equipment. With a carnet, goods may be imported without the payment of duty, tax, or additional security. The carnet also usually saves time since formalities



are all arranged before leaving the United States. A carnet is usually valid for one year from the date of issuance. A bond or cash deposit of 40 percent of the value of the goods covered by the carnet is required, in addition to the price of the carnet. This will be forfeited in the event the products are not re-exported and duties and taxes are not paid.

Carnets are sold in the United States by the U.S. Council for International Business at the following locations: 1212 Avenue of the Americas, New York, NY 10036, (212) 354-4480; or 1400 K Street NW, Suite 905, Washington, DC 20005, (202) 371-1316, email at [info@uscib.org](mailto:info@uscib.org)

Business travelers to Italy seeking appointments with U.S. Embassy Rome officials should contact the Commercial Section in advance. The Commercial Section can be **reached by** telephone at +39-06-4674-2382; fax at +39-06-4674-2113; or e-mail at [Rome.Office.Box@trade.gov](mailto:Rome.Office.Box@trade.gov)

Travel Related Web Resources

[Bureau of Consular Affairs' homepage](#)

[State Department information site](#)

[United States Visas](#)

[U.S. Embassy website](#)

[Italian Embassy website](#)

[Italian Culture, Customs and Etiquette](#)

## **Investment Climate Statement (ICS)**

The U.S. Department of State's Investment Climate Statements provide information on the business climates of more than 170 economies and are prepared by economic officers stationed in embassies and posts around the world. They analyze a variety of economies that are or could be markets for U.S. businesses.

Topics include Openness to Investment, Legal and Regulatory systems, Dispute Resolution, Intellectual Property Rights, Transparency, Performance Requirements, State-Owned Enterprises, Responsible Business Conduct, and Corruption.

These statements highlight persistent barriers to further U.S. investment. Addressing these barriers would expand high-quality, private sector-led investment in infrastructure, further women's economic empowerment, and facilitate a healthy business environment for the digital economy. To access the ICS, visit the U.S. Department of State's [Investment Climate Statement](#) website.

Direct link:

[ICS Italy](#)

## **Political Environment**

For background information on the political and economic environment of the country, please click on the link to the U.S. Department of State [Countries & Areas](#) website.