



AGENDA COVID-19

NUMBER 3

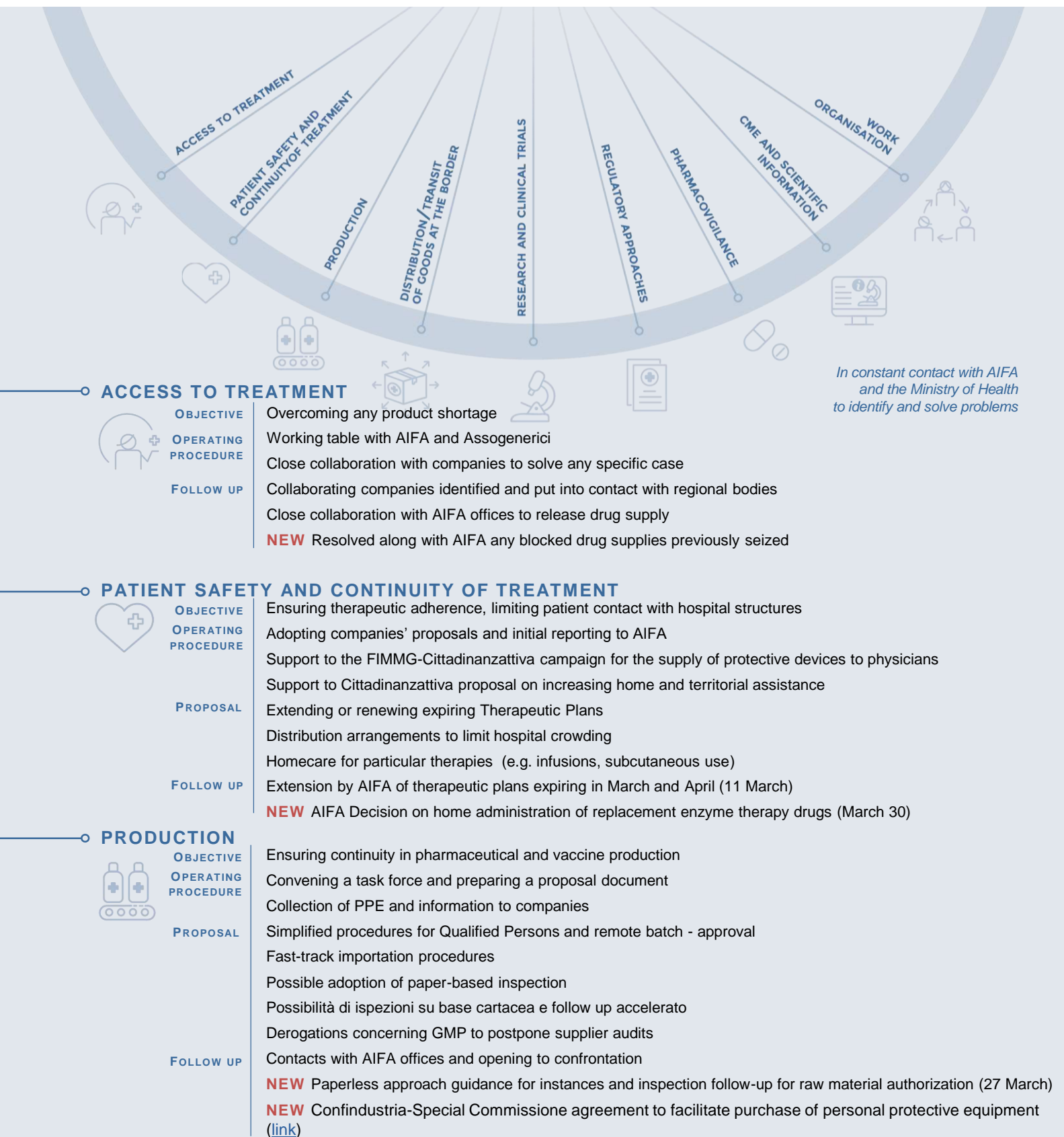
3rd APRIL 2020



FARMINDUSTRIA

1.

SUMMARY OF ACTIONS AND PROPOSALS TO ENSURE CONTINUITY OF TREATMENT AND COMPANY OPERATIONS



○ DISTRIBUTION/TRANSIT OF GOODS AT THE BORDER



OBJECTIVE

Ensuring continuity in pharmaceutical and vaccine production

OPERATING PROCEDURE

Convening a task force and contacts with Supply chain associations

Coordination with Confindustria on border transits

PROPOSAL

Full coordination/ updating among all supply-chain operators

Possibility of fast transport for importing raw materials in case of need

Proposed automatic release at border of PPEs intended for pharmaceutical companies (as an essential activity)

FOLLOW UP

Joint press release with the supply-chain (10 March)

Resolving critical border-transit cases

NEW Release of seized masks intended for companies producing medicinal products

○ RESEARCH AND CLINICAL TRIALS



OBJECTIVE

Ensuring safety of patients and continuity of clinical research

OPERATING PROCEDURE

Convening a task force and preparing a proposal document

PROPOSAL

Simplified arrangements for clinical trials applications and substantial amendments

Ethical committees operating from remote

Management of studies outside the trial centre (consignment of medicinal products directly to patients, possibility of home therapy, possible adoption of remote clinical monitoring)

FOLLOW UP

AIFA communication with affirmative replies to proposals (12 March)

A working group to finetune amendments to the first AIFA communication and additional proposals already submitted to AIFA

AIFA explanatory note clarifying definitions of compassionate use and related implementation of the legislative decree 18/2020 (March 26)

NEW Ministry of Health - Call for research on Covid-19, published on 1 April 2020 (expiring on 24 April 2020)

○ REGULATORY APPROACHES



OBJECTIVE

Ensuring continuity in marketing authorisation maintenance and AIFA negotiations

OPERATING PROCEDURE

Acting on company reports and dialogue with AIFA

PROPOSAL

Simplified arrangements for approving variations and significant reductions in regulatory timescales for minor changes

Acceptance of digital documentation (paperless approach)

Using a company's PEC (certified email address) to receive instructions that cannot be collected physically

On-line payment of revenue stamps on official deeds

Where possible adoption of online negotiation and arranging video conferencing

FOLLOW UP

AIFA has endorsed several company's request by providing:

- first indications on simplifying some applications (MAH, variations, renewals, free sale certificates) to be submitted via its portal only (March 12)

- further information on "paperless" MAH transfer and ASMF procedures (26 March);

- clarification on payment of stamp duty for electronically submitted applications (26 March)

- **NEW** Additional guidance on "paperless" procedure for changes to labeling and patient information leaflet (1 April)



PHARMACOVIGILANCE



OBJECTIVE OPERATING PROCEDURE

Ensuring ongoing pharmacovigilance activity

Collecting reports from companies and monitoring ongoing dissemination of safety information to HCPs

PROPOSAL

Derogations from the timescales laid down and sending information in paperless modes

FOLLOW UP

AIFA's agreement to derogations from the timetable for sending paper-based educational material

CME AND SCIENTIFIC INFORMATION



OBJECTIVE OPERATING PROCEDURE

Ensuring continuity in training activities/scientific information and for meetings and congresses

Convening a task force and preparing a proposal document

Arranging a table for discussion with FIMMG/FNOMCeO

PROPOSAL

New methods to manage scientific information material

Alternative modes for requesting and collecting samples

Foreseen shorter timescales for CME and non-CME remot-learning events

Flexibility in transforming a residential to a remote-learning event, while retaining the contents of the scientific programme

Participation in non-ECM events by general practitioners, paediatricians and pharmacists

FOLLOW UP

Making changes to and immediately distributing already-authorized material

Contacts with the competent offices of AIFA on matters of scientific information, conventions and congresses

Farmindustria Ethics Committee extraordinary meeting (March 19):

- confirmed prohibition to hold congresses in tourist locations in summer
- assessed possible flexibility for the current rules to allow a rapid resumption of activities, (as soon as allowed by Authorities), in compliance with the regulations and principles of ethics

Planned meeting with Federcongressi and other associations to share proposals on how to resume activities

NEW Extraordinary changes for conventions and conferences: postponed date and conversion

of events from residential to distance training ones (2 April)



WORK ORGANISATION



OBJECTIVE

Ensuring operational continuity and guaranteeing the highest standards of safety for workers
 Guaranteeing the salaries of workers who are unable to work
 Ensuring production to guarantee operational continuity
 Managing workers for access/avoiding social shock absorbers
 Ensuring rapid regional access to the Special Earning top-up fund
NEW On-site business recovery with gradual approach

OPERATING PROCEDURE

Convening a task force
 Meetings with trade unions and a joint letter to the Ministry of Labour and Social Welfare
 Joint notices with Federchimica and the trade unions on safety standards and flexibility in the organization of work
 Sinergy with Confindustria and territorial Associations (especially Assolombarda)
 Skype calls with labour consultants on work management and social shock absorbers
 Confrontation on Circulars by INPS and Ministry of Labour, post Legislative Decree no. 18/2020
NEW Legal assistance on term-time hirings to intensify production
 Confrontation on Circulars by INPS and Ministry of Labour, post Legislative Decree no. 18/2020
NEW Opinion exchange on how to organize the resumption of on-site activities safely

PROPOSAL

Shared business initiatives on personnel management
 Request for social shock absorbers
 Trade union work management support
 Sharing approaches to access social shock absorbers and thereto related trade union procedures

FOLLOW UP

Implementation of the protocol for infection containment and safety in the workplace
 Access to social shock absorbers for the entire external network
 Trade union agreements on greater flexibility in working hours and production shifts, advance deployment of holidays, furloughs, leave and social shock absorbers request forms
 General strike in Lombardia avoided
 Close dialogue with the trade unions to stem protests and massive absenteeism phenomena (also in light of the new permits and leave introduced by Legislative Decree no. 18/2020)
NEW First trade union procedures/union agreements to access the Special Earning top-up funds
 Clarification from INPS and Labour Ministry on salary supplements, leave, permits and bonuses provided for by Legislative Decree no. 18/2020
NEW Admission of ENASARCO agents to bonus as per Legislative Decree no. 18/2020
NEW Convention with Ministry of Labour, Italian Bank Association and social parties for the advance on the Special Earning top-up fund

2.

RESEARCH, SOLIDARITY, ACCESS TO TREATMENT. THE CONTRIBUTION OF PHARMACEUTICAL COMPANIES TOWARDS CRISIS MANAGEMENT IN ITALY

[Click here for a press review of the donations and the efforts of our companies](#)



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COMPANIES HAVE SO FAR ANNOUNCED INITIATIVES

These range from international groups, large Italian-owned companies, to various SMEs. The number is growing day by day, increasing the entire industry's commitment. In addition to research projects, companies have undertaken many initiatives to assist patients, doctors, the personnel of the entire supply chain and health organisations, and in collaboration with the institutions and frequently with patient associations.



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RESEARCH AND CLINICAL TRIALS IN ITALY ON COVID-19

Biopharmaceutical companies have commenced clinical trials in Italy to treat pneumonia caused by COVID-19 or have specific research projects on this pathology, also thanks to funds awarded under the European Horizon 2020 programme.

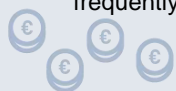


11 mln €

IN THE DIRECT DONATION OF MEDICINES (excluding clinical studies)

This is the value of medicines that 15 associated companies announced to have donated to Italian hospitals involved in the fight against COVID-19.

This value **does not include** medicines provided gratuitously for compassionate use and clinical trials



24,6 mln €

IN FINANCIAL AND MATERIAL DONATIONS

This is the value of donations in money and materials such as respiratory, personal protective equipment, and disinfectant gels, given to hospitals, especially in Lombardy, and of technology for telemedicine and Patients' remote assistance. Donations, hitherto communicated by 42 companies, are often carried out together with other bodies such as the Italian Red Cross, the Civil Protection, FIMMG or patient associations.



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CHANGE IN THE USE OF PRODUCTION LINES TO MEET SPECIAL HEALTH NEEDS

Five companies have modified their production lines in order to meet health needs, especially to satisfy the growing demand for disinfectant products which are transferred gratuitously to the Civil Protection. All companies are producing at maximum capacity to ensure the provision of medicines to whoever needs them, while making organisational changes to ensure the highest conditions of safety for employees.



72 %

HOME DELIVERED MEDICINES, WELFARE, VOLUNTARY WORK, AND OTHER FORMS OF ASSISTANCE

This is percentage of companies engaged in other Social Responsibility actions, namely home delivered medicines, welfare for the employees, in particular to facilitate them to manage this emergency through supplementary insurance covers, consultancy and training courses that also extend to psychological and pedagogical support also extended to family members, or voluntary work initiatives carried out with collaborators. And, where possible, all have adopted smart working procedures.

*This note has been closed with data communicated by companies as of April 3rd.
They will be updated on the basis of the activities announced in the coming days.*

3.

INSTITUTIONAL NEWS: NATIONAL, REGIONAL AND EUROPEAN

NATIONAL



President Conte signed the [DPCM](#) extending until 13 April the effectiveness of the provisions for the containment of the contagion provided for in the following measures, if still effective as of 3 April: DPCM [8](#), [9](#), [11](#) and [22](#) March 2020, [ordinance](#) by the Minister of Health of 20 March and [ordinance](#) of 28 March 2020 adopted by the Minister of Health in consultation with the Minister of Infrastructure and Transport. The provisions of the decree will be effective as from 4 April 2020.

Presentation of [amendments](#) to DL n. 18/2020 "Cura Italia" ([S. 1766](#)), in the Senate Budget Committee.

Health Minister Speranza's statement on the epidemiological emergency from COVID-19 to the Senate and the Chamber of Deputies in the afternoon. He recalled the full cooperation relationship with pharmaceutical companies and cited the **Working table with Farmindustria and Assogenerici on shortages** ([Intervention and debate in the Senate](#))

Farmindustria circular [TS20008A](#) was published on "AIFA - Update on how to apply for changes to labelling and package leaflet"



The Social Affairs Committee started examining the DL n. 19/2020 "Urgent measures to cope with the epidemiological emergency from COVID-19" [C. 2447](#) (published on OJ no. 79 of 25/03/2020 and approved by the Council of Ministers on 24 March). For the measures of interest see circular [DG20031](#)

Unioncamere adopted a declaration model, following the MISE Circular on the possibility of the **Chambers of Commerce to issue statements to companies on the state of emergency** following the COVID-19 outbreak and restrictions (see [circular RI20007](#) and [note Confindustria](#)).



Farmindustria circular [AG20013L](#) was published on the Antitrust measures of 27 March 2020 on blocking **websites offering unauthorised medicines for sale**.

The **Minister of Labour in consultation with the Minister of Economy** signed the [Interministerial Decree](#) on how to award the allowance, provided for by the Decree-Law "Cura Italia", **in favour of the self-employed and professionals** enrolled in the institutions of private law of compulsory pension damaged by the epidemiological situation by Covid-19.

The **Minister of Health** in consultation with the Minister of Infrastructure and Transport signed the [ordinance](#) "Additional urgent measures to contain and manage the epidemiological emergency from COVID-19" on the entry into the **national territory** (published in OJ 84 of 29/03/2020).

The President of the Council signed the [DPCM Training and distribution Criteria of the Municipal Solidarity Fund 2020](#) (published in OJ 83 of 29/03/2020).

The **INPS** (the Italian Social Security Service) issued, in agreement with the Ministry of Labour and Social Policy, **Circular 47**, which provides **the first application guidelines of the COVID-19 social shock absorbers**, introduced by DL 18/2020 "Cura Italia", to which a special regime applies and in derogation from the ordinary tools of protecting the income of workers in constancy of employment relationship (see circular [AR20009](#)).

Farmindustria circular [AG20012L](#) was published on "Drug shortages - Covid-19 Emergency".

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Farmindustria circular [TS20007P](#) was published on **How to present documentation** relating to applications and inspection **follow-up to AIFA's GMP Raw Materials Inspection and Authorization Office**

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The [new self-certification](#) form on movement of people has been published

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The Minister of Economic Development, after confrontation with the Minister of Economy, and the Trade Unions, signed the [decree](#) that replaces annex 1 of DPCM 22 March 2020 with the **ATECO code list that identifies the activities, among which the pharmaceutical industry, that may maintain the production** (published in the OJ no. 80, 26 March 2020). For the measures of interest see Circular [DG20031](#).

Provisions and documents of major interest on Coronavirus at the link [Covid-19](#) page – Farmindustria website

Note closed with information available on 2 April, h. 12.00 a.m.

REGIONAL

NEW
1
APR
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CALABRIA region – [Order no. 24](#)
MARCHE region – [Order no. 17](#)
SICILIA region – [Order no. 13](#)
TOSCANA region – [Order no. 22](#)

NEW
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2020

ABRUZZO region – [Order no. 20](#)
BASILICATA region – [Order no. 13](#)
CALABRIA region – [Order no. 23](#)
CAMPANIA region – [Order no. 26](#)
FRIULI VENEZIA GIULIA region – [Order Environment no. 1](#)
LAZIO region – [DGR n. 126](#)
LIGURIA region – [Order no. 14](#)

NEW
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ABRUZZO region – [Order no. 19](#)
CALABRIA region – [Order no. 22](#)
LAZIO region – [Order no. 21](#)
LIGURIA region – [Order no. 13](#)
UMBRIA region – Order [no. 12](#) and [no. 13](#)

NEW
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ABRUZZO region – [Order no. 18](#)
PIEMONTE region – [Decree no. 35](#)
SICILIA region – [Order no. 12](#)
TOSCANA region – Order [no. 20](#) with [annex 1](#) and [no. 21](#)

NEW
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CALABRIA region – [Order no. 21](#)
CAMPANIA region – [Order no. 25](#)
PROV. BOLZANO – [Order no. 15](#)

NEW
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2020

ABRUZZO region – [Order no. 17](#)
BASILICATA region – [Order no. 12](#)
CALABRIA region – Order [no. 19](#) and [n. 20](#)
LAZIO region – [Order no. 20](#)
LIGURIA region – [Order no. 12](#)
PROV. TRENTO – Order [no. 185699](#) and [no. 185834](#)
UMBRIA region – [Order no. 11](#)
VAL D'AOSTA region – [Order no. 124](#)

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ABRUZZO region – [Order no. 16](#)
LAZIO region – [Order no. 19](#)
MARCHE region – [Order no. 16](#)
MOLISE region – [Order no. 12](#)
PROV. BOLZANO – [Order no. 14](#)
VAL D'AOSTA region – [Order no. 123](#)

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ABRUZZO region – [Order no. 15](#)
BASILICATA region – [Order no. 11](#)
CAMPANIA region – Order [no. 23](#) and [no. 24](#)
EMILIA ROMAGNA region – [Decree 49/2020](#)
FRIULI VENEZIA GIULIA region – [Order no. 5](#)
LAZIO region – Order [no. 14](#), [no. 15](#) and [no. 16](#)
LIGURIA region – [Order no. 11](#)
MARCHE region – Order [no. 14](#) and [no. 15](#)
SARDEGNA region – Order [no. 12](#) e [no. 13](#)
SICILIA region – [Order no. 11](#)
TOSCANA region – [Order no. 18](#)
UMBRIA region – [Order no. 10](#)

All Regional orders on Covid-19 are available at the following [link](#) and the major content in the [summary of the main contents](#)

Note closed with information available on 2 April, h. 12.00 a.m.

EUROPEAN (EU COUNCIL AND PARLIAMENT)



The Internal Market and Consumer Protection Commission of the **European Parliament** has heard ([video](#)) the **Commissioner for the Internal Market, Mr Breton**.

He reiterated, among other things, the strong commitment of the EU Commission to ensure the **free movement of goods in the European Union**, in particular medical equipment and **medicines**.

- [the extension of the EU Solidarity Fund](#) to cover **serious health emergencies**, up to a total of around EUR 800 million in 2020;
- [derogation until 24 October 2020](#), from the requirement that airlines should use at least 80% of **airport slots** in order not to lose them next year.

For further information see circular [RI20008](#)



The Presidents of the European Council, the Commission, the ECB and the Eurogroup reviewed the socio-economic impact of the COVID-19 crisis.

The final [press release](#) states the need to **relaunch the European economy** using all the levers available, adapting the EU budget, "thinking outside the box" and considering any option compatible with the EU Treaty.

Published in the Official Journal of the EU L 99 the three **Regulations** quickly approved by Parliament and the EU Council to give a first response to the Coronavirus emergency through:

- [the establishment of the Initiative](#) to give Member States access to **EUR 37 billion of Structural and Investment Funds** to provide liquidity to SMEs, strengthen health systems and support the labour market;



The European Council adopted the following [statement](#) on Coronavirus emergency. **No agreement was reached on new measures to meet the economic crisis**. The matter was referred to the Eurogroup for consideration, which must submit proposals within two weeks. This period will be devoted to the negotiations between the member countries, with Italy leading the 9 countries [calling](#) for a European instrument of common debt (so-called "Coronabond"). In the statement, the European Council reiterates its commitment to addressing the problems of the supply of goods and essential services, whether by land, sea or air. Reaffirmed support for research, particularly on the vaccine.

Document of interest adopted on COVID-19 are available at the following [link](#)

Note closed with information available on 2 April, h. 12.00 a.m.

EUROPEAN (EUROPEAN COMMISSION)

[A COVID-19 response team set up](#) to help Member States assess their needs and provide recommendations for joint actions across the EU.



[Q&A on EU Emergency](#) support instrument for the healthcare sector

[Proposal for Regulation](#) on the establishment of a European instrument for temporary support to mitigate unemployment risks in an emergency (SURE) following the COVID-19 outbreak to set up a €100 billion solidarity instrument to help workers and enterprises and to redirect all available structural funds to the response to the coronavirus.

[Proposal for Regulation](#) activating the emergency support under Council Regulation (EU) 2016/369 of 15 March 2016 and amending its provisions in respect of the COVID-19 outbreak

[Proposal for Decision](#) on the mobilisation of the Contingency Margin in 2020 to provide emergency assistance to Member States and further reinforce the Union Civil Protection Mechanism/rescEU in response to the COVID-19 outbreak

[Proposal for Decision](#) as regards adjustments to the amounts mobilised from the Flexibility Instrument for 2020 to be used for migration, refugee inflows and security threats, for immediate measures in the framework of the COVID-19 outbreak and for reinforcement of the European Public Prosecutor's Office

[Draft amending Budget to General Budget 2020](#) providing emergency support to Member States and further reinforcement of the Union Civil Protection Mechanism/rescEU to respond to the COVID-19 outbreak

[Proposal for Regulation](#) as regards specific measures to provide exceptional flexibility for the use of the European Structural and Investments Funds in response to the COVID-19 outbreak



[Guidance on using the public procurement framework](#) in the emergency situation related to the COVID-19 crisis. It outlines options and flexibilities provided by the EU legislation and provides an overview of the choice of tendering procedures available to public buyers and applicable deadlines.

EUROPEAN (EUROPEAN COMMISSION)



[Communication on Guidelines](#) concerning the **exercise of the free movement of critical workers** during COVID-19 outbreak. It concerns, but is not limited, to those working in the healthcare and food sectors, and other essential services like childcare, elderly care, and critical staff for utilities.

[Communication COVID-19 Guidance](#) on the **implementation of the temporary restriction on non-essential travel** to the EU, on the facilitation of transit arrangements for the repatriation of EU citizens, and on the effects on visa policy”

Q&A documents to assist manufacturers in ramping up production of essential medical equipment and material in three areas: the production of [masks and other PPEs](#), [leave-on hand cleaner](#) and [hand disinfectant](#), [3D printing](#)



Revised short-term export credit [Communication](#) amending the Annex to the Communication **on the application of Articles 107 and 108 of the TFEU** to short-term export-credit insurance, therefore further expanding the flexibility introduced by the State Aid Temporary Framework (19 March 2020)



[Proposal to increase](#) the resources available for repatriation flights coordinated by the EU civil protection, based on a principle of solidarity, and the total budget of the **rescEU stockpile of medical equipments** (ventilators, protective masks and essential medical gear).



[European Commission Guidelines](#): Facilitating **Air Cargo Operations** during COVID-19 outbreak.



[Communication Guidance to the Member States concerning foreign direct investment and free movement of capital from third countries](#), and the protection of Europe's strategic assets", notably in areas such as health, medical research, biotechnology and essential infrastructures for security and public order.

[The Italian State guarantee](#) supporting a **debt moratorium from banks to SMEs** has been approved under the State Temporary Framework adopted on 19 March 2020.

Note closed with information available on 2 April, h. 12.00 a.m.

4.

AIFA NEW ON COVID-19 EMERGENCY

The Italian Medicines Agency collects in a dedicated [section of its website](#) all the most relevant and up-to-date information on the ongoing health emergency

- [Continuous information on drugs](#)
- [Update on drugs that can be used to treat the COVID-19 disease](#)
- [Recommendations on the use of drugs in the population exposed to the virus](#)
- [Clinical Trials - COVID-19](#)
- [Compassionate Use programs – COVID-19](#)

Hereafter the news, starting from the latest



- [COVID-19 – EMA recommendations for compassionate use of remdesivir in UE](#)
- [COVID-19 - AIFA authorizes a new clinical trial with tocilizumab](#)



- [Fact sheets on medicines used for COVID-19 emergency and how to prescribe them](#)
- [EMA Communication on the use of chloroquine and hydroxychloroquine in the treatment of COVID-19](#)
- [Update: Guidance on submission of MA/extension, MA variation and renewal application, transfer, ASMF up to the end of the restrictions provided by the emergency COVID-19](#)



- [AIFA Communication on the use of chloroquine and hydroxychloroquine in the treatment of COVID-19-safety information](#)
- [COVID-19: EMA update on treatments and vaccines under development](#)



- [COVID-19 - Update on authorized clinical studies](#)
- [EMA advises continued use of medicines for hypertension, heart or kidney disease during COVID-19 pandemic](#)



- [COVID-19: clarifications on definitions of compassionate use and related applications of the Legislative Decree 18/2020](#)
- [Update: Guidance on submission of MA/extension, MA variation and renewal application, MAH transfer, ASMF up to the end of the restrictions related to COVID-19 emergency](#)
- [Electronically submitted applications to AIFA: how stamp duty will be paid](#)

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- [Global Regulatory Agency requirements for Vaccine against COVID-19 phase 1 clinical studies](#)
- [Beware of falsified medicines from non registered web sites](#)
- [COVID-19 - Update on TOCIVID-19 studies](#)
- [Update on medicines made available against Covid-19 outside therapeutic indications](#)

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- [Favipiravir: update on Scientific and Technical Committee](#)

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- [AIFA specifies that the use of favipiravir for the COVID-19 has not been authorised in either Europe or the USA, and that the scientific evidence on its effectiveness is scarce](#)

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- [COVID-19 - Update on TOCIVID-19 studies](#)

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- [Clinical trials on the treatment of COVID-19](#)
- [COVID-19: EMA urges EU researchers to prioritise large randomised controlled studies](#)

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- [AIFA specifies that the use of umifenovir for the COVID-19 has not been authorised in either Europe or the USA: and that the scientific evidence on its effectiveness is scarce](#)
- [Shortage of medicinal products and the COVID-19 emergency](#)
- [EMA's communication on the use of NSAIDs for COVID-19](#)

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- [AIFA and the National Institute for the study and treatment of cancer in Naples have initiated a study for the use of Tocilizumab in COVID 19](#)
- [Actions to promote research and access new medicines for the treatment of COVID-19](#)
- [Fast-track methods to submit applications relating to CPPs and parallel imports](#)
- [AIFA's clarifications on the coronavirus disease Covid-19 and use of ACE-inhibitors and ARBs](#)