



AGENDA COVID-19

NUMBER 1

25th MARCH 2020



FARMINDUSTRIA

1.

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



*In constant contact with AIFA
and the Ministry of Health
to identify and solve problems*

ACCESS TO TREATMENT



OBJECTIVE	Overcoming any product shortage
OPERATING PROCEDURE	Regular consultation with AIFA to ensure supplies Info on Active Ingredients in short supply shared among companies
FOLLOW UP	Collaborating companies identified and put into contact with regional bodies

PATIENT SAFETY AND CONTINUITY OF TREATMENT



OBJECTIVE	Ensuring therapeutic adherence, limiting patient contact with hospital structures
OPERATING PROCEDURE	Adopting companies' proposals and, where appropriate, reporting to AIFA
PROPOSAL	Extending or renewing expiring Therapeutic Plans Ad hoc distribution arrangements to limit hospital crowding Homecare for particular therapies (e.g. infusions)
FOLLOW UP	AIFA Communication on the extension of therapeutic plans (11 March)

PRODUCTION



OBJECTIVE	Ensuring continuity in pharmaceutical and vaccine production
OPERATING PROCEDURE	Convening a task force and preparing a proposal document Collection of PPE and information to companies
PROPOSAL	Simplified procedures for Qualified Persons and remote batch - approval Fast-track importation procedures Possible adoption of paper-based inspection Derogations concerning GMP to postpone supplier audits
FOLLOW UP	Initial contacts with AIFA offices and opening to confrontation

○ 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
FOLLOW UP	Joint press release with the supply-chain (10 March) Resolving critical border-transit cases

○ 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

○ REGULATORY APPROACHES



OBJECTIVE	Ensuring continuity in marketing authorisation maintenance and AIFA negotiations
OPERATING PROCEDURE	Acting on company reports and first evaluations
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 already provided indications on simplifying some operations, such as, for example, submitting requests through its portal, e-mail requests for FSCs (12 March)

PHARMACOVIGILANCE



OBJECTIVE	Ensuring ongoing pharmacovigilance activity
OPERATING PROCEDURE	Collecting reports from companies and ongoing despatch of safety information to healthcare workers
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	Ensuring continuity in training activities/scientific information and for meetings and congresses
OPERATING PROCEDURE	<p>Convening a task force and preparing a proposal document</p> <p>Arranging a table for discussion with FIMMG/FNOMCeO</p>
PROPOSAL	<p>New methods to manage scientific information material</p> <p>Alternative modes for requesting and collecting samples</p> <p>Foreseen shorter timescales for CME and non-CME remot-learning events</p> <p>Flexibility in transforming a residential to a remote-learning event, while retaining the contents of the scientific programme</p>
FOLLOW UP	<p>Participation in non-ECM events by general practitioners, paediatricians and pharmacists</p> <p>Making changes to and immediately distributing already-authorised material</p> <p>First contacts with the competent offices of AIFA on matters of scientific information, conventions and congresses</p> <p>Farindustria's Ethical Committee to meet and evaluate procedures for the resumption of congresses that are in line with ethical considerations</p>

○ WORK ORGANISATION



OBJECTIVE	<p>Ensuring operational continuity and guaranteeing the highest standards of safety for workers</p> <p>Guaranteeing the salaries of workers who are unable to work</p>
OPERATING PROCEDURE	<p>Convening a task force</p> <p>Meetings with trade unions and a joint letter to the Ministry of Labour and Social Welfare</p> <p>Joint notices with Federchimica and the trade unions on safety standards and flexibility in the organization of work</p> <p>Synergy with Confindustria and territorial Associations (especially Assolombarda)</p> <p>Skype calls with labour consultants on work management and social shock absorbers</p>
PROPOSAL	<p>Shared business initiatives on personnel management</p> <p>Request for social shock absorbers</p> <p>Trade union work management support</p>
FOLLOW UP	<p>Implementation of the protocol for infection containment and safety in the workplace</p> <p>Access to social shock absorbers for the entire external network</p> <p>Trade union agreements on greater flexibility in working hours and production shifts, advance deployment of holidays, furloughs, leave, etc.</p> <p>No strikes, protests or absenteeism thanks to the measures in the legislative decree Cura Italia</p>



2.

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



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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.



3

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.

over

6.3 mln €

IN THE DIRECT DONATION OF MEDICINES



This is the value of medicines that 11 member companies announced to have donated to Italian hospitals involved in the fight against COVID-19, to which should be added the medicines provided gratuitously for compassionate use and during clinical trials. Farmindustria supports the fund-raising activities of FIMMG and Cittadinanzattiva for the purchase of collective protection devices and cooperates with physicians in their communication campaigns to patients.



12.9 mln €

IN FINANCIAL AND MATERIAL DONATIONS

This is the value of donations in money and materials such as respiratory protective equipment, PPEs, masks, gloves, infection-proof garments, protective screens, and disinfectant gels, given to health structures, especially those in Lombardy. Donations, hitherto communicated by 24 companies, are often carried out together with other bodies such as the Italian Red Cross, the Civil Protection, FIMMG or patient associations such as, for example, Cittadinanzattiva.



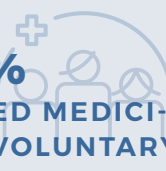
3

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

Three 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.

70%

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 was closed with data provided by companies as at 24 March. It will be updated on the basis of activities made known in the coming days



3.

INSTITUTIONAL NEWS: NATIONAL, REGIONAL AND EUROPEAN

NAZIONALI

24
MAR
2020

The Council of Minister meeting is underway to discuss the **Law decree "Urgent measures to deal with the epidemiological emergency from COVID-19"** to give constitutional value to the provisions adopted so far and mandate for subsequent ones. Among the subjects that should be in the provision: urgent measures to avoid the spread of COVID-19 and their implementation; regulation of measures at regional or intra-regional level; sanctions and controls.

23
MAR
2020

The **Circular of the Interior Ministry** issued on March 23 2020. It concerns "Urgent measures for the containment and management of the epidemiological emergency from COVID-19 applicable on the whole national territory". It provides **clarifications regarding the provisions of the Prime Minister's Decree, 22 March 2020, on production activities** that can continue to operate and not and on travel. At the [link](#) the new self-certification form for the movement of people.

22
MAR
2020

The President of the Council of Ministers signed the **DPCM [Decree of the President of the Council of Ministers]** introducing **additional measures to contain and manage the COVID -19 epidemiological emergency**, for the entire national territory, in which the pharmaceutical industry is listed among the activities for which production, transport, marketing and delivery continue to be allowed.

22
MAR
2020

The Minister of Health signed the **Order of the Minister of Health** 22 March 2020 (published in the Official Gazette No. 75, 22 March) concerning "Additional urgent measures regarding the containment and management of the epidemiological emergency from COVID-19, applicable throughout the country", it concerns people movement.

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MAR
2020

The **Regulatory Protocol** for the containment of the spread of COVID-19 in the **transport and logistics sector** has been published, shared between the Ministry of Transport and the main Confederations and reference Trade Unions. At the following [link](#) the folder containing the summary prepared by Confindustria.

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MAR
2020

The order **"More urgent measures to contain the contagion throughout the national territory"** was signed by the Minister of Health and ([published](#) in the Official Gazette no. 73 of 20 March 2020). The provisions are related to the entrance to access to parks, recreational activities, food and drink administration exercises and transfers to second houses.

17
MAR
2020

A decree issued by the Minister of Infrastructure and Transport, together with the Minister of Health ([no. 120 of 17 March 2020](#)) on measures to be observed by persons returning to Italy for justified reasons of work.



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MAR
2020

Circular [DG20026](#) with additional documents to facilitate the implementation of or supplement anti-infection protocols regarding measures in force in companies and which refer to the agreement reached between the government and the trade unions on **"The shared Protocol on measures to fight and contain the spread of the Covid-19 virus in the workplace"**, in implementation of the DPCM (decree of the President of the Council of Ministers) dated 11 March 2020 ([published in the OJ no. 64 of 11-03-2020](#)).

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MAR
2020

A special edition - n. 70 - of the Official Gazette published [Law Decree n. 18](#) of 17 March 2020 **"Measures to strengthen the NHS and provide economic support to families, workers and businesses in relation to the COVID-19 epidemiological emergency"**, approved by the Council of Ministers on 16 March 2020, and currently under scrutiny by the Budgetary Committee of the Senate ([S.1766](#)). The principal measures of interest are set out in [Circular DG20030](#) of 18 March 2020.

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

REGIONAL

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MAR
2020

CALABRIA region – [Order no. 17](#)

CAMPANIA region – [Order no. 21](#)

EMILIA ROMAGNA region – [Decree 47/2020](#)

LOMBARDIA region – [Order no. 517](#)

PROVINCE OF BOLZANO – Order no. [12](#) and no. [13](#)

SARDEGNA region – [Order no. 10](#)

SICILIA region – Order no. [8](#), no. [9](#) and no. [10](#)

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2020

ABRUZZO region – Order no. [12](#) and no. [13](#)

BASILICATA region – [Order no. 10](#)

CALABRIA region – Order no. [15](#) and no. [16](#)

CAMPANIA region – [Order no. 20](#)

LOMBARDIA region – [Order no. 515](#)

VAL D'AOSTA region – [Order no. 117](#)

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BASILICATA region – Order no. [8](#) and no. [9](#)

CALABRIA region – Order no. [13](#) and no. [14](#)

EMILIA ROMAGNA region – [Decree 45/2020](#)

FRIULI VENEZIA GIULIA region – [Order no. 4](#)

LOMBARDIA region – [Order no. 514](#)

MARCHE region – [Order no. 13](#)

MOLISE region – [Order no. 10](#)

PIEMONTE region – [Order no. 34](#)

PROVINCE OF BOLZANO – [Order no. 11](#)

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2020

ABRUZZO region – [Order no. 11](#)

CALABRIA region – [Order no. 12](#)

CAMPANIA region – [Order no. 19](#)

EMILIA ROMAGNA region – [Decree 44/2020](#)

LAZIO region – [Order no. 13](#)

LIGURIA region – [Order no. 9](#)

MARCHE region – Order no. [11](#) and no. [12](#)

PROVINCE OF TRENTO – [Order no. 176798](#)

SICILIA region – [Order no. 7](#)

VENETO region – [Order no. 33](#)

All Regional orders on Coronavirus-19 are available at the following [link](#), and the major content in the [summary note](#).

EUROPEAN (EU COUNCIL AND PARLIAMENT)

23
MAR
2020

The **EU Ministers of Economy and Finance** [discussed](#) the economic impact of the COVID-19 crisis, [approving](#) the activation of the safeguard clause of the Stability and Growth Pact which allows Member States to derogate from European budgetary obligations.

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MAR
2020

The **EU Ministers responsible for the internal market and industry** discussed the impact of Covid-19 on the single European market ([link](#) to the final statement). The Ministers dwelt on the importance of ensuring that the production of protective and medical materials was sufficient and returned to the question of the free movement of goods.

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MAR
2020

The **EU Council** defined its position on **two Proposals for Regulation** designed to release funds to counter the outbreak of COVID-19, through:

- the institution of the **Coronavirus Response Investment Initiative** ([testo](#) to the text of the Commission confirmed by the Council) - € 37 billion from the EU cohesion funds to finance SMEs' working capital and reinforce investments in products and services necessary to deal with the crisis of the healthcare services;

- the extension of the scope of the **EU Solidarity Fund** to public health emergencies ([link](#) to the text of the Commission confirmed by the Council).

Now the **European Parliament** in an extraordinary plenary session on 26 March will be called upon to define its position on these proposals.

18
MAR
2020

The Transport Ministers of member states met to discuss the impact of the COVID-19 emergency on their sector, stressing the need to ensure the smooth flow of essential goods, including medicines. See their final statement at the following [link](#).

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MAR
2020

The European Council ([Conclusions](#)) stated its priorities in the fight against the COVID-19 epidemic. It, inter alia, approved the [Eurogroup's declaration](#) on 16 March that full use should be made of the flexibility allowed by the Stability and Growth Pact and State aid regulations, as well as the 30-day restriction of non-essential travel to the EU. The European Council also emphasised the need to ensure the movement of medicinal products, as proposed by the Commission.

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

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.

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2020

Call for collaboration with European pharmaceutical industries

[A supercomputing platform for Europe:](#)

[Empowering smart in-silico design for addressing the COVID-19 virus](#)

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MAR
2020

New practical advice on how to implement the Commission Guidelines for border management, in order to keep freight moving across the EU during the current pandemic, and related annexes.

[Communication from the Commission on the implementation of the Green Lanes of the Guidelines for border management measures to protect health and ensure the availability of goods and essential services](#)

22
MAR
2020

[Approval of Italy's € 50 mln plan](#) to sustain the production and supply of medical devices and PPE equipment, in line with regulations on temporary state-aid (19 March).

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MAR
2020

[European standards for medical supplies](#) given away to promote the production of PPE and other medical supplies and maximize their availability.

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MAR
2020

[The publication of the Commission's Communication to the Council](#) on

activating the general escape clause of the Stability and Growth Pact. The Commission proposed to trigger the pact's escape clause. Once approved by the Council, this decision will allow Member States to adopt measures to meet the crisis, releasing them from normal budgetary obligations.

19
MAR
2020

Publication [of the guidelines](#) and associated [annex](#) regarding the authorisation requirements for exports of personal protective equipment (PPE) outside of the European Union, in force from 15 March.

19
MAR
2020

[Communication on regulations governing temporary state-aid measures](#) to support the economy. This provision allows Member States to take full advantage of the flexibility offered by the rules on state aid in response to the COVID-19 economic emergency.

EUROPEAN (EUROPEAN COMMISSION)

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MAR
2020

[The setting up of the first strategic stock rescEU](#) (EU civil protection mechanism) of medical equipment for intensive therapy, personal protective equipment, vaccines, therapeutic substances, and laboratory supplies.

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2020

Recommendations for good practices on community [public health](#) measures and on [screening methods](#) issued by a team of experts set up at the request of Member States.

16
MAR
2020

[Guidelines](#) on the management of borders to protect health and ensure the availability of essential goods and services and to coordinate measures for the transit of people and goods within the internal market.

16
MAR
2020

[Communication to the European Parliament and to the Council](#) on temporary travel restrictions.

15
MAR
2020

[Enforcement Regulations of the European Commission](#), which make the export of certain products conditional upon the presentation of an export authorisation, with immediate measures to protect the availability of supplies of personal protective equipment (PPE).

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2020

Measures to address to the COVID-19 emergency and mitigate the economic impact that concern: -health system supplies while safeguarding the integrity of the single market; support to citizens and companies; the liquidity needed for the financial sector; full flexibility for Member States.

The texts included in the package:

- [Communication on the economic aspects of the COVID-19 crisis](#) and related [annexes](#);
- [Proposal for Regulations on the Coronavirus Response Investment Initiative](#);
- [Regulatory proposal amending the regulation on the Solidarity Fund](#);
- [Proposal for a Council regulations concerning airport slots](#).

4.

AIFA NEW ON COVID-19 EMERGENCY

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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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2020

- [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](#)

18
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2020

- [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](#)

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- [AIFA, COVID-19 emergency: "Coronavirus Crisis Unit" set up](#)
- [Management of current COVID emergency -19 \(coronavirus disease 19\) clinical trials in Italy](#)
- [Interim measures concerning the extension of AIFA's therapeutic plans for the containment and management of the Covid -19 epidemiological emergency](#)
- [AIFA and Gilead announce that Italy is one of the countries where the remdesivir antiviral for the treatment of COVID-19 will be trialled](#)
- [Supplementary documents on new or extended marketing authorisations, and on variations to and renewals of marketing authorisations until the end of the restrictions required by the COVID-19 emergency](#)
- [Extension for compiling AIFA monitoring registers](#)