Hogan Lovells

Summary of Covid-19 emergency regulatory measures impacting the pharmaceutical and healthcare industries

Updated 6 May 2020

Government announcements

Extension of the state of health emergency

- The **bill** extending the state of health emergency tabled by the Government aims to extend the state of health emergency until **24 July** and to adapt measures to prepare for the release of the population from confinement.

- The **senators** adopted the bill extending the state of health emergency on 5 May. Several amendments were made, such as **limiting the extension** of the state of health emergency to Friday, **10 July** included.

- **Reservations of the Conseil d'Etat**: in a notice published on 1 May on the draft law extending the state of health emergency, the Conseil d'Etat drew the Government's attention in particular to the consequences of the extension linked to the extension of the duration of the numerous measures decided by the ordinances issued pursuant to Article 38 of the Constitution, particularly with regard to deadlines.

  The Conseil d'Etat considers in this regard that the "necessity" and "proportionality" of these derogations should be subject to a systematic periodic review by the Government and assessed on a case-by-case basis, in view of the resumption of activity and the gradual deconfinement.

- **Reservations of the National Consultative Human Rights Commission (CNCDH):** in an opinion published on 3 May, the questioned the relevance of the creation of a state of health emergency in the light of pre-existing texts and its impact on the functioning of institutions, democratic life and respect for individual and collective freedoms.

Deconfinement

- On 28 April, the **deputies approved** the progressive and flexible deconfinement plan presented by Prime Minister Edouard Philippe to the Assembly as part of the fight against the Covid-19 pandemic.

- On 4 May, the **senators** rejected the deconfinement plan presented by the Prime Minister, by 89 votes against and 81 votes in favor, after a 4-hour debate conducted under Article 50-1 of the Constitution.

- On the basis of the plan presented by the Prime Minister, the Minister of Solidarity and Health, Olivier Véran, unveiled three daily **maps representing**, department by department, the circulation of Covid-19 on the national territory and its impact on hospital structures.

- The President of the Scientific Council attached to the Government, Jean-François Delfraissy, pointed out that the brigades and digital tracking tools, a large testing capacity and real-time monitoring, are the "**fundamentals**" for maintaining **control of the pandemic**.

Social contributions

- As part of the plan to support the economy in the face of the Covid-19 crisis, Gérald Darmanin, the Minister for Action and Public Accounts, decided to **extend** in May the measures to **defer social contributions** decided in March and April for all companies facing difficulties.

Masks

- **Production**: the Secretary of State to the Minister of the Economy and Finance, Agnès Pannier-Runacher, announced that new production lines for surgical masks and FFP2 will be created in order to reach 20 million masks produced per week in France by the end of May to cope with the Covid-19 pandemic.

- **Supply**: during the presentation of the deconfinement strategy to the National Assembly, Edouard Philippe assured that there will be enough masks in the country to meet the needs from 11 May, subject to general mobilization.

- **Access**: the Director General of Health (DGS) Jérôme Salomon declared that health professionals remain a priority for access to health masks, which will also be available in mass distribution.

Information Technology

- Edouard Philippe confirmed his commitment to organise a specific vote and debate in Parliament on the StopCovid application when it is up and running and before its implementation.

- The French Secretary of State for Digital Affairs, Cédric O, defended his choices for the development of the StopCovid tracking application and announced its deployment as of 2 June.

- In this context, the bill extending the state of health emergency authorizes the creation of an information system for the sole purpose of combating the Covid-19 pandemic and provides for the creation of two information systems (IS), Sidep and "Covid contact", to carry out the tracing of contact cases.

Shuffle/deportation

- **Deportation**: the attributions of **Christelle Dubos**, Secretary of State to the Minister of Solidarity and Health, have been modified so that she can deport herself on questions relating to the acquisition and storage of protective masks and surgical masks, a field in which her husband works.

- **Shuffle**: **Cécile Collin** has been appointed advisor to the Minister of Action and Public Accounts, Gérald Darmanin, effective 14 April, after serving as his chief of staff.

European measures

- **Clinical trials**: the Commission published on 28 April guidance to ensure that clinical trials can continue to take place in the EU during the Covid-19 pandemic (point 1.1).

- **Donations**: the EU has joined with international partners to organize from 4 May an "online pledging conference" with the aim of raising €7.5 billion to fund the development of and access to Covid-19 screening tests, treatments and vaccines (point 1.1).

National measures

The early stages of the financial consequences of Covid-19

- **New Finance Bill**: **the second Amending Finance Bill (LFR) for 2020**, which forecasts a deficit of EUR 185.5 billion at 9.1% of GDP, was published on 26 April in the Official Journal. Among the measures adopted is the reduction to 5.5% of the VAT rate applicable to protective clothing (gloves, gowns, overalls), protective masks and products for personal hygiene and adapted to the fight against the spread of Covid-19 (point 2.1).

- **Social security expenditures**: the National Health Insurance Fund (CNAM) announced in a press release that expenditure under the general scheme had risen by 2.8% at the end of March (point 2.1).

- **Financing of health care institutions**: the first circular of the 2020 budget and tariff campaign for health care institutions was put online on 27 April (point 2.1).

- **Financing of public hospitals**: on 28 April, Société de financement local (Sfil) launched a 1 billion euro social bond issue to finance public hospitals in France affected by the Covid-19 pandemic (point 2.1).

Acceleration of research

International cooperation

- **Vaccines**: during a World Health Organization (WHO) videoconference, the President of the Republic, Emmanuel Macron, expressed his wish to accelerate the research and production phases through multiple cooperative ventures and to give all countries access to the vaccine (point 2.2.1).

- **R&D**: the pharmaceutical industry defended the idea that the diversity of its R&D in the fight against Covid-19 was an asset, on Thursday 30 April at a press conference organised by the International Federation of Pharmaceutical Industries and Associations (IFPMA) (point 2.2.1).

- **Remdesivir**: the Director General of Gilead Sciences announced on 29 April in an "open letter" that the laboratory was working to set up a "global consortium of manufacturers" to increase the production capacity of remdesivir, following the positive results obtained by the molecule in Covid-19 (point 2.2.1).

Controversial use of some treatments

- **Excess mortality and chloroquine**: in a Brazilian trial and according to interim results published in JAMA Network Open, excess mortality was observed in patients treated with a high dose of the antimalarial drug chloroquine (point 2.2.2).

- **Derogatory access**: the Conseil d'Etat rejected four requests to extend access to hydroxychloroquine, alone or in combination with azithromycin, for patients with Covid-19 (point 2.2.2).

- **Vitamin C**: the Conseil d'Etat rejects a request to promote the administration of large doses of Vitamin C by infusion for the treatment of Covid-19 (point 2.2.2).

- **Remdesivir** (U.S.): the Food and Drug Administration (FDA) announced on May 1 that it had granted "emergency approval" (EUA) to remdesivir (Gilead Sciences) for the treatment of certain patients with Covid-19 (point 2.2.2).

- **Remdesivir** (France): positive results were observed with the antiviral drug remdesivir (Gilead Sciences) against the coronavirus Sars-CoV-2; however, the DGS, Jérôme Salomon, stated that these were "preliminary results" that require publication (point 2.2.2).

- **Online purchase**: ANSM warns anyone wishing to purchase products sold on the Internet that are presented as being able to cure or prevent infection with COVID-19, including Artemisia annua (point 2.2.2).

Derogatory use

- **Plasma**: in an opinion published on 4 May, the **High Council of Public Health (HCSP)** recommends that the indications of the clinical trials concerning the compassionate use of plasma from convalescent Covid-19 patients (point 2.2.3) should be respected. The **ANSM** provides a framework for the possible use of convalescent plasma for patients who cannot be included in clinical trials (point 2.2.3).

Update on ongoing research

- **Adverse effects**: the ANSM reported 321 cases of adverse reactions reported in connection with Covid-19 infection on April 24, 215 of which were attributed to drugs currently used in the treatment of the disease (section 2.2.5).

- **Discovery**: Florence Ader of the Hospices civils de Lyon (HCL) said that the French and European Discovery study evaluating several treatments against the Sars CoV-2 coronavirus is not yet ready to give reliable results and should continue (point 2.2.5).

  This is due in particular to the difficulties encountered in involving other European countries. This trial was initiated by France and has so far included almost only French patients (point 2.2.5).

  However, French President Emmanuel Macron announced on May 4 that the results of the Discovery study should be available on Thursday, 14 May, while remaining prude.

- **Remdesivir**: Positive results for remdesivir in a large randomized trial were announced by the US National Institutes of Health (NIH) on April 29 (point 2.2.5).

- **Tocilizumab**: the French Directorate General for Health (DGS) considered the initial results encouraging concerning the use of tocilizumab in hospitalized patients with moderate to severe forms of Covid-19 in the French CORIMUNO trial conducted by AP-HP (point 2.2.5).

- **Sarilumab**: Sanofi and Regeneron state in a press release that the evaluation of the anti-IL-6 sarilumab will be refocused on "critical" forms of the disease (point 2.2.5).

New studies

- **EpiCOV**: Inserm and the Directorate of Research, Studies, Evaluation and Statistics (DREES) are launching a national study to find out the immune status of the population with regard to the Sars-CoV-2 (point 2.2.6).

- **ANACONDA-COVID-19**: launch of a new trial to evaluate the IL-1 receptor antagonist anakinra (Kineret*, Sobi) in patients with Covid-19 (point 2.2.6).

- **Ivermectin**: The potential of the antiparasitic ivermectin appeared promising for the treatment of Covid-19 in an international observational study, the results of which were published on the SSRN preprint platform (point 2.2.6).

Vaccines

- Control of foreign investment: State control over foreign investment in French companies in the biotechnology sector has been strengthened in order to better protect companies involved in vaccine research against Covid-19 (point 2.2.7).

Screening

- **Reliability of tests**: in a press release published on 24 April, the independent medical journal Prescrire warned of the lack of evaluation of biological diagnostic tests for Covid-19 (point 2.3).

- **Pre-operative screening**: with a view to the resumption of non-emergency medical and surgical procedures, the Société de pathologie infectieuse de langue française (Spilf) has issued an opinion on the place of pre-operative screening for the Sars-CoV-2 virus, recalling the limitations of the tests (point 2.3).

- **Use of the tests**: the Haute autorité de santé (HAS) has put on line the framework note of the second part of its recommendations on the use of serological tests for Sars-CoV-2 (point 2.3).

- **Authorised places and persons**: the taking of samples for Sars-CoV-2 tests by RT PCR outside places authorised under ordinary law, and the intervention during the biological examination of persons who do not have a medical laboratory technician diploma are now authorised by way of derogation (point 2.3).

- **U.S.**: the U.S. Food and Drug Administration (FDA) announced on 4 May in a press release the introduction of new market access conditions for manufacturers of serological tests for Sars-CoV-2 because the great flexibility of the directives applied to date has led to an influx of uncontrolled tests on the U.S. market (point 2.3).

Supply

Risks of shortages

- **Resuscitation and chronic diseases**: the ANSM publishes an information point on its mobilization to ensure the availability of medicines and health products, in particular resuscitation medicines and those useful in the management of chronic diseases (point 2.4.1).

- **IgHN**: ANSM asks healthcare professionals to respect the prioritization of indications for normal human immunoglobulins (IgHN), blood-derived medicinal products (point 2.4.1).

- **Reduction of tensions**: a report from the Epi-Phare scientific interest group (SIG), published online on 4 May, reports a "return to normal consumption" of medicines for chronic diseases after five weeks of confinement, following a significant increase in the delivery of these products, probably linked to storage phenomena, observed at the beginning of confinement (point 2.4.1).

Centralized management

- **Transparency of allocations**: the National Union of Hospital Pharmacists and University Hospital Practitioners (SNPHPU) is calling for greater transparency on regional allocations of resuscitation drugs, based on a survey carried out in establishments which points to difficulties in the new purchasing and supply circuit put in place for these drugs under stress (point 2.4.2).

Masks

- **Sale in dispensary**: dispensary pharmacists may market non-sanitary masks manufactured according to an industrial process and meeting the applicable technical specifications (point 2.4.7). The National Council for the Order of Pharmacists (CNOP) and the unions representing dispensing pharmacists have invited pharmacies to start selling surgical masks "from their own stock with discernment", dispensing them "as a priority to fragile or at-risk persons" (point 2.4.7).

- **Importation**: the Ministry of Action and Public Accounts has issued an opinion on the importation of "general public" masks for non-health uses, which are intended to complement barrier measures in the context of the Covid-19 pandemic (point 2.4.7).

- **Widening distribution**: in a "DGS-urgent" note signed by Jérôme Salomon and distributed on 5 May, the Ministry of Solidarity and Health details its new distribution strategy for surgical and FFP2 masks, extending it for the first time to contact persons and persons at very high medical risk (point 2.4.7).

Price

- **Hydro-alcoholic gels and solutions**: reduction of 12% of the maximum selling price of hydro-alcoholic gels and solutions in the context of the state of health emergency (point 2.4.8).

- **Surgical masks**: the selling price of single-use surgical masks that meet the definition of medical devices is now capped at 95 eurocents (including tax) per unit. The wholesale selling price for resale of the products may not exceed 80 eurocents per unit (point 2.4.8).

Derogating measures

- **Opioid overdoses**: the Ministry of Solidarity and Health increased access to the antidote naloxone in the context of the Covid-19 pandemic due to an increased risk of opioid overdoses (point 2.4.9).

Information technology

- **StopCovid**: the National Council of Numerics (CNNum), the National Council of the Order of Doctors (CNOM) and the French Data Protection Authority (CNIL) have issued favourable opinions on the use of the StopCovid contact tracing application, albeit with certain reservations and conditions (point 2.6).

- **Covid contact**: the CNAM's Director General, Nicolas Revel, indicated that a "Covid contact" teleservice will be developed by Monday 11 May to enable private doctors to report contact cases of a person infected with Sars Cov-2 (point 2.6).

- **Connected objects**: the Secretary of State in charge of digital technology, Cédric O, indicated that part of the team developing the StopCovid application "is dedicated to trying to find another solution, for example, a box or bracelet that would make it possible to do without telephones" (point 2.6).

- **Ambulis Covid-19**: the Vivalto group of private clinics is equipped with the "Ambulis Covid-19" solution, published by Domicalis, a company specialising in e-health software, to organise the secure monitoring of Covid-19 patients at home (point 2.6).

Data processing

- **Datacovid**: the first waves of results of the barometer developed by the Datacovid association with the Ipsos institute, which measures French people's concern about Covid-19 and how they adapt their actions, have been published by the newspaper Le Monde (point 2.7).

  As part of the Datacovid observatory, a survey carried out by Amgen France, in partnership with Ipsos, makes it possible to assess the impact of confinement on access to care and treatment for chronic diseases during periods of confinement (point 2.7).

- **Risks to fundamental rights**: CNCDH) has taken action to alert the public authorities to the dangers to fundamental rights of any application for monitoring individuals and contacts, in particular the right to privacy (point 2.7).

Deadlines

- **Infringement of rights**: CNCDH calls for an end as soon as possible to the provisional legal regime established by the orders of 25 March 2020 on justice, adopted pursuant to the emergency law of 23 March 2020 to deal with the Covid-19 pandemic (point 2.8).

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1. European measures

1.1. European Commission

1. **Optimising supply optimisation**: the **European Commission has published guidelines** for Member States on how to maximise the supply of medicines during the Covid-19 epidemic (link).
   - These guidelines focus on **the rational supply, distribution and use of life-saving medicines for the treatment of patients with Covid-19**, and the risks of medicine shortages due to the pandemic.

2. **Fighting Covid-19 with new technologies:** the **European Commission issued a Recommendation** (EU) 2020/518 on 8 April 2020 establishing a common toolkit at EU level on the use of technologies and data to tackle and recover from the Covid-19 crisis, including **mobile applications and the use of anonymised mobility data** (link).
   - The recommendation provides a process for developing a common approach, known as a "toolbox", to use digital means to deal with the crisis. This "toolbox" will consist of concrete measures for the effective use of technology and data, with a particular focus on two areas.
   - The toolbox will be complemented by **Commission guidance**, in particular on the data protection and privacy implications of the use of mobile alert and prevention applications.

3. **Anti-competitive practices:** the Commission has issued a **notice effective from 8 April** on how to authorise limited cooperation between companies, in particular for critical hospital medicines during the coronavirus pandemic. Companies are responsible for assessing the legality of their agreements and practices themselves. However, given the context, the Commission is prepared to assist companies in assessing the legality of their cooperation projects and to implement sufficient safeguards against anti-competitive impacts in the longer term (link).

4. **Sharing of research data**: the European Commission announced the launch of a European platform for sharing research data on Covid-19, in order to accelerate research and provide an effective response to the Covid-19 crisis.
   - This platform should enable researchers to store and share datasets, such as DNA sequences, protein structures, data from pre-clinical research and clinical trials, as well as epidemiological data.
   - Other actions in the ERAvsCorona plan focus on coordinating funding, expanding large EU-wide clinical trials, increasing support for innovative companies and supporting a pan-European hackathon at the end of April to mobilise European innovators and civil society.

5. **Medical devices**: The European Commission has suggested postponing the enforcement of the European regulation on medical devices to 26 May 2020 (link). The implementation date of the regulation on in vitro diagnostic medical devices (IVDD), set for 26 May 2022, remains unchanged.
   - The European Parliament and the European Council have approved the Commission's proposal to postpone its implementation by 26 May 2021 in order to give priority to the fight against Covid-19.

6. **Clinical trials**: The Commission has published guidance to ensure that clinical trials can continue to take place in the EU during the Covid-19 pandemic (link).
   - The aim is to mitigate the disruption of clinical research in Europe and thus combat the negative effects of the pandemic without compromising quality and safety.
   - The main recommendations concern the distribution of medicines to patients, remote verification of source data and communication to authorities.
   - These measures will be used exclusively during the Covid-19 pandemic and will be repealed once the current health crisis in the European Union/European Economic Area is resolved.

7. **Donations**: The European Union has joined with international partners to organize from 4 May onwards an 'online pledging conference' with the aim of raising €7.5 billion to fund the development of and access to Covid-19 screening tests, treatments and vaccines (link).
   - The €7.5 billion target "only covers initial needs," they stressed, noting that "the global manufacture and delivery of medicines will require resources far in excess of this target".
   - The call for donations follows the G20 commitment at the end of March to establish an international initiative on "pandemic preparedness and response" and the global collaboration announced by the WHO on 24 April.

1.2. European Council

1. **Emergency financial support:** the European Council agreed to allocate EUR 2.7 billion to the health sector. The European Parliament is expected to take a decision to ensure that the funds are made available (link).
   - The initiative will be used in conjunction with other EU resources, in particular the medical reserve for RescUE (whose budget has been increased by EUR 300 million) to complement the EUR 80 million initially planned.
   - Urgent needs for medical equipment (masks, respirators), cross-border transport of medical equipment and patients, the recruitment of health personnel deployable throughout the EU and the construction of mobile hospitals will be firstly financed.

1.3. European Medicines Agency (EMA)

1. The EMA has published guidelines for clinical trial sponsors detailing the conditions under which a clinical study may be conducted during the pandemic (link).

2. The deadline for the transmission of information on the nitrosamine risk is postponed to 1 October 2020 (link).

3. **The EMA has published its recommendations for the compassionate use of remdesivir (link).**

- **Note:** the product is currently being tested on Covid-19 patients in two phase III trials conducted by Gilead Sciences and in a European clinical trial.

4. **Reporting shortages:** the EMA announced that the "European Union Executive Group on Shortages of Medicines Caused by Major Events" has set up a new system for sharing information with industry to speed up exchanges on medicines shortages during the Covid-19 health crisis (link).

5. **Task Force:** the EMA has published the composition and missions of the **"intervention and coordination force"** (Covid-ETF) created to ensure a rapid and coordinated response to the Covid-19 pandemic (link).

1.4. Council of Europe

1. **Corruption**: the Council of Europe's Group of States against Corruption (GRECO) has published guidelines for its 50 member states to prevent corruption in the context of the health emergency caused by the Covid-19 pandemic.

2. National measures

The emergency law n° 2020-290 dated 23 March 2020 to face the spread of the Covid-19, published in the French Official Gazette on 24 March 2020 provides that:

- A state **of health emergency is established until 24 May** 2020 (article 2).

- The Government may adopt, by Prime Ministerial decree, a number of temporary **measures for the sole purpose of ensuring public health** (article 2).

- The Government is empowered to issue **ordinances** in a wide range of areas to adapt to the health crisis and its consequences, particularly in the area of health (article 3).

2.1. Financial consequences

1. **Investment plan**: The French President of the Republic also spoke on Monday evening in favour of a "massive plan" for health, research and the elderly, following the crisis caused by the Covid-19 epidemic. The content and scope of this plan remains to be specified.

2. **First Amending Finance Bill (*Projet de Loi de Finances Rectificative* or PLFR):** a first PLFR, adopted on 20 March 2020, forecast a budget deficit increased by 15.4 billion euros (€Bn) to 3.9% of GDP, a public debt exceeding 100% of Gross Domestic Product (GDP) and an economic recession of 1%.

3. **Second amending finance bill:** a second PLFR was definitively adopted by Parliament on 23 April 2020 after final agreement by the National Assembly and the Senate in a joint committee (lien). This text amplifies and completes the measures introduced by the 1st amending finance act dated 23 March 2020.

- **Scope:**
  - The **public deficit** is projected at 9.1% and public debt at 115% of GDP, for a revised growth estimate of -8.0% in 2020 (instead of +1.3% foreseen in the initial finance bill for 2020 and -1% in the 1st amending finance act).
  - The **€45 billion economic emergency plan** voted in March to support the economy and employment is extended by €110 billion**.**

- **Key measures:**
  - **Enhanced support to businesses:**
    - Funding for short-time working is increased to €25.8 billion.
    - The solidarity fund for very small enterprises (VSEs) and the self-employed is increased to EUR 7 billion. The conditions of access to the fund are eased. Aid paid to entrepreneurs is exempt from corporate tax, income tax and all social contributions and charges.
    - A €20 billion fund is created to strengthen the State's financial holdings in strategic companies in difficulty. 20 companies would be concerned, in particular in the aeronautics and automotive industries.
    - The intervention capacity of the Economic and Social Development Fund (FDES) is increased to one billion euros.
    - State guarantee on loans granted by banks: Banks will have to give written reasons if they refuse to grant loans of less than €50,000 to companies complying with the specifications of this scheme. VSEs and SMEs, which have been refused a State-guaranteed loan, will be able to obtain equity loans backed by the FDES.
    - The ceiling for short-term export credit insurance is raised from 2 to 5 billion euros.

  - **Health financing**
    - A **provision of EUR 8 billion** is provided for exceptional health expenditure to deal with the epidemic.
    - The **VAT rate is lowered to 5.5%** on **masks and protective clothing** (overalls, hats, gloves, etc.) as well as on hydroalcoholic gels and all body disinfectants.

  - **Exceptional support measures for individuals**
    - Revaluation and exemption from taxes and contributions of the exceptional premium to be received by the mobilized caregivers.
    - Exceptional tax-exempt premium for government employees who are particularly mobilized during a state of health emergency.
    - Overtime worked by employees, from 16 March until the end of the state of health emergency, will be exempt from income tax and social security contributions, up to a limit of 7,500 euros per year.
    - Emergency aid for 4.1 million low-income households for 900 million euros.

- **Follow-up of such measures :**

- Extension of the missions of the committee for monitoring and evaluation of the implementation of financial support measures for enterprises.
- The Government shall submit a report on the solidarity fund for VSEs and the self-employed to the Parliament until 1 July 2020.
- Fund to recapitalize strategic companies: the Minister of the Economy shall inform in advance the chairmen and general rapporteurs of the Parliament's finance committees of the main equity investments made by the State (over €1 billion). Within 12 months, the Government shall present a report to Parliament "detailing the proper use of public resources and the state of implementation of the objectives of social, societal and environmental responsibility in the strategy" of recapitalized companies. The High Climate Council will then issue an opinion on this report.

4. **Amending Social Security Financing Bill (PLFSS)**

- **Social security deficit**: Gérald Darmanin, Minister for Action and Public Accounts, announces an "optimistic" forecast of 41 billion euros.
  - Note: the Social Security Financing Act (LFSS) for 2020 forecast a deficit of €5.9 billion for all compulsory schemes (€4.5 billion without the Old Age Solidarity Fund, FSV)) and €5.4 billion for the general scheme (€4.1 billion without the FSV).

- The Social Affairs Committee emphasizes that the amounts reflect the extraordinary nature of the situation created by the Covid-19 pandemic and the cushioning role that the social security administrations are playing in this context, both vis-à-vis social security contributors and employers.
  - A number of senators have raised the hypothesis of a rectifying PLFSS for 2020, particularly in view of the probable overrun of the Ondam, initially set at 205.6 billion euros (+2.5%).

- Nicolas Revel, Managing Director of the CNAM, considers it cautious to wait until stabilized numbers on the impact of the Covid-19 epidemic are obtained, and only then consider a rectifying PLFSS for 2020.

5. Alert Committee on the Evolution of Health Insurance Expenditure

- Due to the current context, and the announcement of new expenses for social security in the rectificative bill, the committee has not yet expressed an opinion on compliance with the Ondam 2020.

- The committee points out that Ondam 2019 has been respected (at 200.3 billion euros) with an under-execution of 60 million compared to the revised objective in LFSS for 2020.

- A new notice will be published by 1 June 2020 at the latest in which the Committee will examine health insurance expenses for the first months of 2020 and will assess the extent and nature of the risk of exceeding the Ondam set by the LFSS for 2020 (or the revised target in the event that an amending LFSS is voted by then).

6. **Donations**: a rescript has been published **exempting from VAT regularization** all donations of goods to social and medico-social establishments which receive elderly people, disabled people or people expecting chronic pathologies, health professionals, State and local authorities services, throughout the state of health emergency **(link)**.

   - The Leem requests the same exemption for medicines.

   - French Pharmaceutical Companies Association is donating 1 million surgical masks to the French Red Cross, which has expressed its needs to properly carry out its care missions for patients and disadvantaged people.

   - **Budgetary circular:** 377 million euros have been allocated to health establishments to deal with the exceptional expenses related to the Covid-19 pandemic.

7. **Budget circular**: the first circular of the 2020 budget and pricing campaign for healthcare institutions, signed by the Minister of Solidarity and Health, Olivier Véran, is set in the context of the Covid-19 epidemic and takes into account the adaptation efforts of healthcare institutions (link).

   - The circular leads to the delegation, as part of this first stage of allocation, of €22.76 billion for the Migac, DAF (annual funding allocations) and USLD (long-term care units) allocation envelopes, i.e. 96.4% of the overall objectives, excluding €89 million in prudential reserves for the DAF SSR (follow-up care and rehabilitation) and the DAF psychiatry.

   - As part of this delegation, the Ministry has earmarked an "exceptional emergency" envelope of €377 million (M€) to cover certain expenses related to the epidemic.

   - In addition to this envelope, another €246 million of appropriations has been delegated to institutions in serious financial difficulty. Compared to the credits paid out each year to institutions in cash flow difficulties, the increase is €100 million.

   - The circular also leads to the payment of all Ifaq (financial incentive for quality) credits for 2020, i.e. a total of €400 million, from the start of the budget campaign.

8. **General scheme expenses**: The French National Health Insurance Fund (CNAM) announced in a press release that expenditure under the general scheme had risen by 2.8% at the end of March, in 12-month moving data adjusted for working days.

   - Spending on drugs, which grew by 1.4% at the end of January, rose by 2.3% at the end of March in a sliding year (3.7% in the first quarter, 9.6% in March alone).

   - Expenditure on prescription medicines rose by 3.9% at the end of March (+6% in the first quarter, +12.5% in March alone), while expenditure on on-trade medicines continued to decline (-9.9%).

   - Expenditure on medical devices remains dynamic, with growth of 3.7% over a sliding year to the end of March.

- The circular also leads to the payment of the full Ifaq (financial incentive for quality) credits for 2020, i.e. a total of €400m, from the start of the budget campaign.

9. **Financing**: On 28 April, the Société de financement local (Sfil), a public development bank serving local areas and exports, launched a €1 billion social bond issue reserved for the financing of public hospitals in France affected by the Covid-19 epidemic.

   - This is the first Covid-19 covered bond aimed at directly or indirectly providing new financing to sectors affected by the pandemic.

   - As a reminder: the operation, in the form of covered bonds issued by its subsidiary Caisse française de financement local (Caffil), is Sfil's second operation "in social format" aimed at supporting hospital investment, following the inaugural transaction in February 2019.

2.2. Research and clinical trials

2.2.1. International cooperation

1. **Research**: France is launching an international initiative to accelerate research on treatments and vaccines. French President Emmanuel Macron has convened the Director General of WHO and several international actors involved in the fight against the Covid-19 pandemic to discuss the outlines of a joint initiative to accelerate the development of vaccines and treatments and guarantee access to them for all.

   - At a WHO videoconference on 24 April, French President Emmanuel Macron expressed his wish to "crush time and space" by speeding up the research and production phases through multiple cooperative ventures and by giving all countries access to the vaccine.

2. **Industrial**: the drug industry defended the idea that the diversity of their R&D in the fight against Covid-19 was an asset, Thursday April 30, at a press conference organized by the International Federation of Pharmaceutical Industries and Associations (IFPMA), bringing together executives from AstraZeneca, CSL Behring, Merck KGaA, Merck & Co, Pfizer, Sandoz (Novartis Group) and Takeda.

   - The conference, held just over a month after a first initiative on the pharmaceutical industry's unity in the fight against Covid-19, was aimed at highlighting the different approaches of industry players in research against Covid-19.

   - The IFPMA recalled that access to treatment will be a real challenge.

   - Questioned on the possibility of pharmaceutical companies giving up their patents on treatments showing efficacy, the Director General of the IFPMA considered that innovation should not be hindered, which allowed laboratories to "not start from scratch" in R&D against Covid-19.

2.2.2. Controversial use of several treatments

1. **Hydroxychloroquine**

- **Ongoing clinical trials:** the molecule is currently undergoing a European clinical trial (**Discovery**), an international trial, an "open" study at the Institut Hospitalo-Universitaire Méditerranée (IHU) in Marseille and a study promoted by the University Hospital (CHU) of Angers (**Hycovid**).
    - Sanofi is studying other therapeutic options in Covid-19, such as its anti-IL-6 Kevzera (sarilumab) which is currently being tested in a trial, CORIMUNO-19, conducted by AP-HP.

- **Controversial efficiency**
    - The ANSM, which did not authorise the second study on hydroxychloroquine conducted at the *Institut Hospitalo-Universitaire* (IHU) in Marseille by Pr Didier Raoult, is waiting for the investigators to provide objective elements to demonstrate its observational nature.
    - An American study, published on the medRxiv platform, shows that the number of deaths among patients on hydroxychloroquine has more than doubled.
    - Hydroxychloroquin/azithromicin combination:
        - The CHU of Angers has launched a multicentric clinical study evaluating hydroxychloroquine against placebo in the treatment of Covid-19 infection. In this trial, azithromycin was not associated with hydroxychloroquine due to concerns about the risk of toxicity, particularly cardiac toxicity.
        - The study conducted by Professor Molina at St. Louis Hospital (AP-HP) did not find evidence of strong antiviral activity or clinical benefit from the combination of hydroxychloroquine and azithromycin when treating hospitalised patients with a severe form of Covid-19.
        - According to a Brazilian clinical trial and interim results published in JAMA Network Open, excess mortality was observed in patients treated with a high dose of the antimalarial drug chloroquine, versus a low dose, while also receiving the antibiotic azithromycin and the antiviral oseltamivir (Tamiflu®, Roche).

- The use of **hydroxychloroquine and the anti-HIV pharmaceutical product lopinavir + itonavir in Covid-19** in health care institutions as an initial prescription, then at the patient's home if possible, is supervised (Decree n° 2020-314 dated 25 March 2020, JORF dated 26 March 2020, article 1).
    - **Prescriptions must be dispensed, after a collegial decision**, in compliance with the recommendations of the High Council of Public Health and, in particular, the indication for patients suffering from oxygen-requiring pneumonia or organ failure.

- The ANSM outlined the relevant rules applicable to the **Plaquenil® and Kaletra® specialties** (and their generics) tested to treat Covid-19 patients (link).

- **End of the compassionate use of the Plaquenil® specialty** (but not of the hydroxychloroquine molecule) for dispensing in pharmacies: Plaquenil® must be used in compliance with the indications of its MA (Decree n° 2020-314 dated 25 March 2020, JORF dated 26 March 2020, article 1). This restriction does not apply to hydroxychloroquine-based preparations or specialities containing the lopinavir/ritonavir combination.

- **Production of Plaquénil®**
    - **Available doses:** Sanofi® has reported to the press that the supply of "millions" of doses of hydroxychloroquine would be possible if its efficiency in Covid-19 is proven.
    - **Donations**: Sanofi has announced a donation of 100 million doses of hydroxychloroquine to 50 countries, but at the same time called for caution, emphasizing that the current clinical evidence is insufficient to reach any conclusion on the clinical efficacy or safety of Covid-19.
    - **Production capacity**: to meet demand, Sanofi has doubled its "additional" production capacity, i.e. beyond production for current indications, by mobilising its 8 hydroxychloroquine plants around the world.
    - **Coordination**: Sanofi is calling for coordination of all the players in the chain to ensure continuity of supply of this medicine, should it be well tolerated and effective in the treatment of Covid-19, and is ready to play its role in global coordination.

- **Plaquenil® Use**: the French State Council has rejected a request to require from the government to refer the matter to the ANSM in order to develop an RTU for Plaquenil® in patients with Covid-19 without waiting for the development of respiratory distress (Conseil d'Etat, Juge des référés, 28 March 2020, M. A. et al., n°. 439765).

- **Use of hydroxychloroquine**: the Conseil d'Etat rejected four requests to broaden access to hydroxychloroquine (Plaquenil®, Sanofi), alone or in combination with azithromycin, for patients suffering from Covid-19, citing in particular "methodological inadequacies" in the studies available to date on the efficacy of the compound in the treatment of the disease (Conseil d'Etat, 22 April, 2020, decisions n^{os}. 440009, 440026, 439951 and 440058).

  As a reminder: Article 12-2 of Decree n°. 2020-293 of 23 March 2020 (created by Decree no. 2020-314 of 25 March 2020 (OJ of 26 March 2020) and amended by Decree no. 2020-337 of 26 March 2020 (OJ of 27 March 2020) regulates the off-label use of hydroxychloroquine in healthcare institutions for the initial prescription, and then at the patient's home if the patient's condition allows it. In the context of dispensing in pharmacies, only hydroxychloroquine preparations may be used in this way, with Plaquenil® being used in compliance with the indications of its MA.

- **Bayer** will resume production of chloroquine in Europe. The German pharmaceutical group is taking over the manufacture of one of its old medicines indicated for the prevention of malaria, **Resochin®.**

3. Remdesivir

- **Encouraging results for Gilead Sciences' compassionate delivery of the antiviral pharmaceutical product Gilead Sciences remdesivir:** a study published in the New England Journal of Medicine finds encouraging results in the compassionate delivery of Gilead Sciences' antiviral pharmaceutical product Gilead Sciences remdesivir.

- **Positive results** for remdesivir have been announced by the U.S. National Institutes of Health (NIH) in a large randomized trial.

  - The new anti-viral remdesivir accelerated the recovery of patients infected with the Sars-CoV-2 coronavirus and may have an effect on mortality.

  - While positive results have been observed with the antiviral remdesivir (Gilead Sciences) against the Sars-CoV-2 coronavirus, Director General of Health (DGS) Jerome Salomon said these are "preliminary results" that require publication.

- The Food and Drug Administration (FDA) announced on May 1 that it has granted "**emergency approval**" (EUA) to remdesivir (Gilead Sciences) for the treatment of certain Covid-19 patients.

  - In a meeting at the White House the same day with U.S. President Donald Trump, Gilead Sciences' CEO announced that the pharmaceutical group was donating 1.5 million vials, which should make it possible to treat at least 140,000 patients. This donation represents the totality of the remanufacturing reserves made public by Gilead Sciences.

  - Gilead Sciences did not specify the price at which it intends to market the drug once the 1.5 million donated doses have been used.

- **Irrelevant information to be excluded:** results of an ongoing randomized clinical trial were accidentally posted online. According to Gilead Sciences, they are irrelevant and premature at this stage as they reflect difficulties in recruiting patients, particularly in China, to demonstrate the positive trends noted by the New England Journal of Medicine.
- As a reminder: remdesivir is available, through clinical trials or compassionate use, in at least 181 hospitals worldwide, including 27 in the United States.

- **Production time**: Gilead Sciences has announced that it has halved its remdesivir production time.

  - All available doses will be made available for individual compassionate use, which has recently been reduced to pregnant women and children under 18 years of age, through Complementary Access Programs, which have replaced Compassionate Access Programs, and through clinical trials. They will be given for wider distribution after obtaining possible regulatory approvals in the future.

  - The laboratory plans to make the treatment available to patients free of charge.

4. **Nicotinics**

- **Supervision**: following the information published on the possible effectiveness of nicotine in the treatment of patients with Covid-19, an Order limits the dispensing by retail pharmacies of nicotine based specialities used in the treatment of tobacco addiction to the

number of boxes necessary for a one-month treatment (Order of 23 April 2020, JORF of 24 April 2020).
    - The number of boxes dispensed is recorded in the pharmaceutical record, whether or not the patient has presented a medical prescription.
    - Online sale of these specialties is suspended.

- **Risks**: the ANSM has warned about the risks associated with the use of nicotine substitutes, particularly for non-smokers.
    - With the publication of the decree of 23 April 2020 limiting the dispensing of nicotine substitutes in pharmacies, the ANSM reiterates the rules of proper use and the risks associated with these medicines.
    - Nicotine substitutes must not be taken to prevent or treat coronavirus infection and access to them must be restricted to people who need them as part of smoking cessation.
    - At this stage, the evidence does not support the conclusion that nicotine has a protective effect against COVID-19. To test this hypothesis, clinical trials must be conducted.

5. **Vitamin C**: the Conseil d'Etat rejected a request to enjoin the Ministry of Solidarity and Health to "take measures" to "allow all hospitals in France to become familiar with the care protocol recommended by Dr Paul Marik, based in particular on the administration of large doses of vitamin C by infusion and to use it for the treatment of Covid-19" (Conseil d'Etat, 22 April 2020, n°. 440117).

6. **Online purchases**: ANSM warns against products presented on the Internet as solutions to VIDOC-19, including the Artemisia annua. Beyond a risk of ineffectiveness, the Agency points out that the use of this type of product in self-medication may present a health hazard (link).

    - The ANSM points out that products based on Artemisia annua have so far not demonstrated any therapeutic virtues.

    - The ANSM recalls that this plant has previously been the subject of the same type of message on alleged therapeutic virtues against malaria, even though its effectiveness had not been demonstrated. The Agency had been forced, in this context, to prohibit several operators from marketing products containing Artemisia annua in 2015 and 2017.

2.2.3. Derogatory use

1. **Veterinary medicines**:

    - **Supply shortages:** demand for cisatracurium, propofol and midazolam has increased to such an extent that veterinary medicines are increasingly needed to compensate for shortages of sedatives (midazolam), anaesthetics (propofol) and muscle relaxants (curares).
        - The Minister of Solidarity and Health has reported that global consumption of medicines such as curares and midazolam has increased by 2,000%.

- **If the supply of pharmaceutical specialities for human use is impossible**, veterinary medicines for the same therapeutic purpose, benefiting from a marketing authorisation mentioned in Article L. 5141-5 of the CSP for the same active substance, the same dosage and the same administration mean, may be prescribed, prepared, delivered and used in hospitals only (link).

- The **list of veterinary specialties** that may be used in humans as part of the health emergency to respond to the Covid-19 pandemic has been published on the ANSM website. The Agency has also published an evaluation report on the use of Proposur and Propovet in human medicine.

- **Requisitioning from manufacturers:** the National Agency for Veterinary Medicines (ANMV), a body of the National Agency for Health, Food, Environment and Work Safety (ANSES), specified that if the use of veterinary medicines to combat the Covid-19 epidemic turns out to be necessary, requisitions will only concern stocks of medicines available from veterinary pharmaceutical manufacturers. Stocks available from veterinary practitioners and veterinary wholesale distributors remain reserved for veterinary medicine (ANMV press release dated 31 March 2020).

2. **Paracetamol in injectable form:** possibility for internal pharmacies to dispense Paracetamol in injectable form as part of their MA until 11 May 2020, on presentation of a prescription from any doctor bearing the mention "Prescription as part of Covid-19" (Décret n° 2020-360 du 28 mars 2020, JORF du 29 mars 2020, article 1).

3. **Rivotril® :** possibility for retail pharmacies to dispense the speciality Rivotril® in injectable form outside of the MA until 11 May 2020, on presentation of a medical prescription bearing the wording "Prescription Outside of MA in the context of Covid-19" (Décret n° 2020-360 du 28 mars 2020, JORF du 29 mars 2020, article 1).
   - The Council of State has rejected a request for suspension of the Rivotril prescription waiver. The Council of State considers in particular that, despite the absence of a MA or an ATU for the molecule in dyspnea and the palliative treatment of respiratory distress, the Government was competent to broaden its access to these indications by way of derogation from the Public Health Code, in accordance with the provisions of the Emergency Law (Conseil d'Etat, Juge des référés, 15 avril 2020, Syndicat Jeunes médecins, n° 439948).

4. **Derogatory use and screening:** the Council of State overruled a decision of the Administrative Court of Guadeloupe ordering the Regional Health Agency (ARS) and the CHU to purchase 200,000 screening tests and treatments with hydroxychloroquine (Plaquenil®, Sanofi) and azithromycin for 20,000 patients (Conseil d'Etat, Juge des référés, *CHU de la Guadeloupe et Ministre des Solidarités et de la Santé*, n° 439904 et 439905).

5. **Use of plasma**: in view of the potential seriousness of Covid-19 disease and in order to increase the chances of survival of patients with a severe form, the ANSM publishes a decision governing the exceptional and temporary use of plasma from convalescent persons to the margin of ongoing clinical trials, when the inclusion of a patient in a trial is not (or no longer) possible (link).

- This use is possible:
  - in the same indications as those defined by the clinical trials conducted in France ;
  - in a limited number of specific situations, which must be the subject of a collegial medical decision at the level of the care unit where the patient is treated.

- The publication of this decision is accompanied by the provision of a Therapeutic Use Protocol (TUP) for healthcare teams, drawn up in connection with the HCSP's opinion of 27 April 2020 (to be published shortly) (link).

- The collection of plasma from volunteer convalescent patients is organized by the EFS, in compliance with the protection of donors.

In an opinion published a few days later, the High Council of Public Health (HCSP) recommends that the indications of the clinical trials concerning the compassionate use of plasma from convalescent patients of Covid-19 be respected.

2.2.4.Conduct of ongoing clinical trials (hors Covid-19)

1. **Modification of ongoing trials:** the National Agency for the Safety of Medicines (ANSM), in conjunction with the DGS and the DGOS, has proposed a guide to possible modifications in the conduct of ongoing clinical trials, to respond to the **unprecedented constraints** induced by the pandemic (link).

2. **Guidelines** : the European Medicines Agency (EMA) and French Medicines Agency (ANSM) have published separate guidelines for clinical trial sponsors detailing the conditions under which a study may be conducted during the Covid-19 period (link for EMA and link for ANSM).

   - The ANSM recommendations include:
     - Suspension measures;
     - Sites where research is conducted;
     - Patient follow-up and visits;
     - Dispensing of experimental treatments;
     - Monitoring of clinical tests;
     - Infections happening while testing;
     - Vigilance of clinical tests.

   - Both agencies state that priority is given to testing in Covid-19. ANSM, DGS and the Protection of Persons Committees (PPCs) have implemented fast-track procedures for the initial assessment of requests for authorisation.

2.2.5.Conduct on Covid-19 clinical trials

1. **Fast-track procedure**: ANSM, the Health Directorate (HB) and the Protection of Persons Committees (PPCs) have put in place fast-track procedures for the initial assessment of applications for authorisations:

- Exception to the random selection process, with direct solicitation of the PPC by the Health Branch for the review of projects on Covid-19.
- Sponsors are invited, as early as possible in the development of research involving the human person (RIPH), to inform ccs-pole-recherche@sante.gouv.fr of their initiative so that a scientific watch can be kept on the projects.

2. **Side effects**: the ANSM has published on its website an information note mentioning reinforced monitoring of undesirable effects for medicines used in patients suffering from Covid-19 (link).

   - In collaboration with the National Network of Pharmacovigilance Centres (NNPCs), the ANSM has established a **continuous monitoring of side effects to medicines** related to the use of such medicines in patients with Covid-19, particularly when used outside of clinical trials. Several molecules are being closely watched, including hydroxychloroquine and lopinavir/ritonavir.

   - The ANSM states in the protocol for therapeutic use (PUT) for hydroxychloroquine that "the combination of hydroxychloroquine with azithromycin to treat COVID19 has not been proven effective and also poses a cardiac risk. The use of this combination should only be considered in clinical trials. »

   - On April 10, the ASNM reported approximately 100 adverse reactions, half of which were reported for the HIV combination of lopinavir + ritonavir and hydroxychloroquine, alone or in combination. However, the Agency's director general, Dominique Martin, points out that the interpretation of these alerts should be treated with caution.

   - On 24 April, the ANSM reported 321 cases of adverse reactions reported in connection with Covid-19 infection, 215 of which were attributed to drugs currently used to treat the disease (link).

3. **Status update:** the ANSM has issued a status update on projects authorised since the beginning of the pandemic and up to April 10, 2020:

   - **52 applications** for clinical trial authorisations have been submitted to the ANSM. There are currently 860 studies underway worldwide, including more than 30 in France (1,600 patients) evaluating candidates for Covid-19 treatment.

   - **The main trials are conducted on**:
     - hydroxychloroquine and chloroquine,
     - Antivirals (remdesivir, ritonavir/lopinavir),
     - antibiotics (azithromycin), corticosteroids,
     - conversion enzyme/sartans inhibitors,
     - or on monoclonal antibodies (immunomodulators).

   - **Conduct:** in most cases, these trials are conducted on hospitalised patients and the large majority (78%) is conducted by academic sponsors. Sponsors are also very active in research against Covid-19.

- **International cooperation:** France is involved in 7 of the 10 main international trials currently underway.

4. The European Medicines Agency (EMA) encourages researchers to favour **large randomised controlled** studies.

2.2.6.Major Covid-19 clinical trials in progress

1. **Discovery trial:** this is a **randomised clinical study** to evaluate both the efficiency of these treatments against Covid-19 and the safety of these treatments, including the following five branches:
   - **Standard treatment**
   - **Standard treatment + remdesivir (Gilead Sciences)**
     - In addition to this European study, the pharmaceutical product is also being evaluated on adult patients diagnosed with Covid-19 in two phase III clinical tests conducted by Gilead Sciences in the United States and China.
     - **Standard treatment + lopinavir and ritonavir (Kaletra* – Abbvie and generics)**
       - This test is maintained despite a clinical trial conducted in China suggesting the ineffectiveness of the combination in improving the clinical condition of Covid-19 hospitalised patients.
     - **Standard treatment + lopinavir, ritonavir and interféron beta**
     - **Standard treatment + hydroxy-chloroquine (Plaquenil® - Sanofi)**

Florence Ader, from the Hospices civils de Lyon (HCL), said that the French and European Discovery study evaluating several treatments against Sars CoV-2 coronavirus is not yet ready to give reliable results and should continue.

This is due in particular to the difficulties encountered in involving other European countries. Launched by France, this trial has practically only included French patients for the time being (link).

However, French President Emmanuel Macron announced on 4 May that the results of the Discovery study should be known on Thursday 14 May, while remaining cautious about their potential impact.

2. **Trials on hydroxychloroquine** in combination with azithromycin: non-randomised study conducted at the *Institut Hospitalo-Universitaire* (IHU) of Marseille.

3. **Hycovid Trial**: this trial is designed to evaluate the efficacy of hydroxychloroquine on patients with a non-severe form of Covid-19 infection but at high risk of developing a more severe form of the disease.

4. **Coviplasm trial to evaluate the therapeutic value of plasma from cured patients:** the French Blood Agency (*Etablissement Français du Sang* or EFS) and AP-HP have launched a randomised study to evaluate the efficacy of injecting plasma from cured Covid-19 patients to stop the worsening of the disease in patients at risk of developing a severe form.

5. **Stroma-Cov2 trial to evaluate the therapeutic value of umbilical cord cells:** a randomised, double-blind trial conducted by AP-HP to evaluate the therapeutic value of umbilical cord cell injection in patients with severe forms of Covid-19 who are intubated-ventilated.

6. **CORIMUNO-19 trials to evaluate monoclonal antibodies targeting cytokine IL-6 in the treatment of severe forms of Covid-19: trials conducted on Sarilumab (Sanofi and Regeneron), and Tocilizumab (Roche).**
   - **Encouraging results:** a team from the Foch Hospital has made public the encouraging results of its preliminary compassionate experiment conducted on 30 patients with Covid-19, under oxygen therapy and unstable, treated with the anti-IL-6 tocilizumab (RoActemra®, Roche) (point 2.2.6).
     - The results, posted on Tuesday on the Medrxiv pre-publication platform, have not yet been peer-reviewed.

   - Negative results: Sanofi and Regeneron indicate in a press release that the evaluation of anti-IL-6 sarilumab (Kevzara®) will be refocused on "critical" forms of the disease, with preliminary results on "severe" but non-critical forms being negative.

7. **CORIMUNO-TOCI trial: the first randomized controlled trial to evaluate the efficacy of tocilizumab (Roche) in patients with moderate to severe Covid-19**.
   - The Directorate General of Health (DGS) considered the initial results encouraging, based on information published by PA-HP, the sponsor of the study.
   - The authors pointed out that their results are the first randomized results worldwide on this product in the treatment of Covid-19.

8. **ImmunONCOVID-20** to evaluate the efficacy of different treatments against Covid-19 in cancer patients. Evaluation of 3 treatments:
   - A chloroquine derivative already tested in phase I in cancer, without any safety problems having emerged (experimental molecule GNS561, Genoscience Pharma) ;
   - Anti-PD-1 nivolumab immunotherapy (Opdivo, Bristol-Myers Squibb), to stimulate the immune system;
   - The anti-IL-6 tocilizumab (RoActemra, Roche) already tested in the Covid-19 in the CORIMUNO-19 trial.

9. **Anti-CCR5 antibody**: an anti-CCR5 antibody initially developed against HIV and in oncology, a molecule marketed by the American biotechnology company CytoDyn, is now being evaluated in patients suffering from Covid-19.

10. **ICAR trial**: launch of a multicentre clinical trial, ICAR, to evaluate the administration of intravenous immunoglobulin (Igiv) for the treatment of the most severe forms of Covd-19 by the Paris Psychiatry & Neurosciences University Hospital Group.

11. **COVIDOC trial:** first **randomised trial** to compare the efficacy of the hydroxychloroquine-azithromycin combination against hydroxychloroquine alone and coordinated by the **Montpellier University Hospital.**

12. **PREP COVID trial**: trial conducted to evaluate the effectiveness of hydroxychloroquine or azithromycin in preventing Covid-19 infection in healthcare workers.

13. **Recombinant monoclonal antibodies**: a team of researchers from Inserm and *Institut Pasteur* is currently developing and producing recombinant monoclonal antibodies against the Sars-CoV-2 coronavirus, based on samples from patients in remission from Covid-19.

14. **EasyCov trial:** launch of a clinical trial to evaluate a salivary diagnostic test for Covid-19 by teams from Sys2Diag and Montpellier University Hospital.

15. **COVIDAXIS trial**: a randomised clinical trial to evaluate the placebo-controlled effect of hydroxychloroquine and lopinavir/ritonavir in hospital-based health professionals.

16. **COVERAGE trial**: the objective of this trial is to evaluate the efficacy of four treatments administered directly to Covid-19 patients aged 65 years and older in the home: hydroxychloroquine (Plaquenil®, Sanofi), the anti-influenza medicine favipiravir (Hisun Pharmaceutical), the tyrosine kinase inhibitor imatinib (Glivec®, Novartis) and the antihypertensive medicine telmisartan. The control group will receive dietary supplements.

17. **OUTCOV trial**: randomised controlled trial to evaluate the efficacy of three treatments in ambulatory patients over 50 years of age with Covid-19.

18. **Ivermectin trial**: The potential of the antiparasitic ivermectin appeared promising for treating Covid-19 in an international observational study, the results of which were published on the SSRN preprint platform.
    - This paper was not submitted for peer review.
    - The authors recall that these results need to be confirmed in a randomized trial.

19. **EpiCOV**: Inserm and the Department of Research, Studies, Evaluation and Statistics (DREES) of the Ministry of Solidarity and Health are launching the EpiCOV project, a national study to find out the immune status of the population with regard to the Sars CoV-2 coronavirus.

20. ANACONDA-COVID-19: a clinical trial to evaluate the IL-1 receptor antagonist anakinra (Kineret®, Sobi) in patients with Covid-19 will soon begin in France.

    - As a reminder: several clinical trials evaluating different immunomodulators in Covid-19 have been launched, notably on anti-IL-6 agents such as tocilizumab (RoActemra®, Roche) and sarilumab (Kevzara®, Sanofi/Regeneron).

21. **Children**: the Inserm's national paediatric clinical research network Pedstart has initiated a working group to improve the understanding of the specificities of Covid-19 for children, with some fifteen studies identified in France.

2.2.7. Vaccines

1. **Foreign investments**: the State now has greater power of control over foreign investment in French companies in the biotechnology sector, in order to better protect companies involved in vaccine research against Covid-19 (Order of 27 April 2020 on foreign investment in France, JORF of 30 April 2020, Article 1).

- This decree amends Article 6 of the decree of 31 December 2019 relating to foreign investment in France (OJ of 1 January 2020), in order to include biotechnology in the list of critical technologies falling within the scope of the protected activities listed in Article R.151-3 of the Monetary and Financial Code.

- Foreign investments relating to biotechnologies exceeding 25% of the capital or when they are intended to acquire control or all or part of a branch of activity of an entity governed by French law are therefore subject to prior authorization.

- The term "biotechnology", due to its imprecision, could give rise to controversy.
- At the same time, the Minister of the Economy and Finance, Bruno Le Maire, has indicated that he wants to lower the threshold for foreign investors to acquire control from 25% to 10% of the capital by the end of the year. This measure will concern all non-European investments in "very large companies".

2. Potential messenger RNA vaccines:

- **mRNA 1273 vaccine** (developed by the National Institute of Allergy and Infectious Diseases (NIAID) in collaboration with the biotechnology company Moderna): this vaccine is composed of messenger RNA encoding a Sars-CoV-2 protein that makes up the spicules on the surface of the viral particles responsible for attachment to the host cell. The objective of the phase I test is to assess the safety of the vaccine and its ability to induce an immunological response.

- **BTN162 vaccine** (developed by Pfizer in partnership with the biotechnology company BioNTech's).

- **CureVac** is working in partnership **with the Coalition for Epidemic Preparedness Innovations (CEPI)** on a messenger RNA vaccine.

2. Other vaccine research hypotheses:

- **Sanofi** has partnered with the U.S. Department of Health and Human Services (**BARDA**) to develop a vaccine using "**recombinant DNA technology**".
    - **As part of this agreement, Sanofi has partnered with GSK to develop a vaccine:** Sanofi will contribute its Sars-Cov-2 S protein antigen, obtained using recombinant DNA technology, and GSK will be responsible for the production of adjuvanted pandemic vaccines.
    - Sanofi projects to find a vaccine within 12 to 18 months, but its CEO, Paul Hudson, believes the challenge will be the production at a very large scale.

- **Johnson & Johnson** is collaborating with the **BARDA** to make its **Advac and Per.C6** technologies available for rapid scale-up of candidate vaccine production.

- **GlaxoSmithKline** has partnered with **CEPI** to make its technology platform for pandemic vaccine adjuvant development available to its partners.

- **Inovio Pharmaceuticals** launched a Phase I study in the US for a vaccine candidate and partnered with **Beijing Advaccine biotechnology** to conduct parallel trials in China.

- **Vaxart** has announced a research program on a vaccine against Covid-19, which would be administered orally rather than by injection.

- **Codagenix** has partnered with the Indian vaccine manufacturer **Serum Institute of India** to conduct a joint development project.

- **Novavax** and **Geovax** are also exploring opportunities for vaccine development.

2.3. Testing

1. **Procurement of equipment :** when the **medical biology laboratories** are unable to carry out the "detection of the SARS-CoV-2 genome by RT PCR" examination or to carry out a sufficient number of such examinations to deal with the health crisis, the State representative in the department is empowered to order general or individual measures, either the requisition of the **other laboratories** authorised to carry out this examination and the equipment and staff necessary for their operation, or the requisition of the equipment and personnel of these same laboratories necessary for the operation of the medical biology laboratories carrying out this examination (Decree No. 2020-400 of 5 April 2020, JORF of 6 April 2020, Article 1).

2. **Laboratories that can be mobilised:** when the medical biology laboratories are unable to carry out the "detection of the SARS-CoV-2 genome by RT PCR" examination or to carry out a sufficient number of such examinations to deal with the health crisis, the State representative in the department is authorised to authorise, by way of derogation from the provisions of Article L. 6211-18 and I of Article L. 6211-19 of the Public Health Code, laboratories using molecular biology equipment and techniques (in particular laboratories specialising in veterinary biology) to carry out the analytical phase of this examination (Order of 5 April 2020, JORF of 6 April 2020, Article 1).

3. **Laboratories and authorised personnel**: the taking of samples for tests for the detection of Sars-Cov-2 by RT PCR outside places authorised under ordinary law, as well as the intervention during the biological examination of persons who do not have a medical laboratory technician's diploma are now authorised by way of derogation (Order of 3 May 2020, JORF of 4 May 2020, article 1).

4. **Usable material:** laboratories are authorised to use in vitro **diagnostic medical devices** not having the CE marking for Sars-CoV-2 screening tests (Order of 14 April 2020, JORF of 15 April 2020, Article 1).

5. **The HAS has issued recommendations for assessing the reliability of serological tests for Covid-19** (link).

6. The HAS has posted the scoping note for the second part of its recommendations on the use of serological tests for Sars-CoV-2 (link).

7. The **Academy of Medicine** advocates the use of serological testing as a priority for people at high risk of severe disease or in exposed professions and the systematic screening of all hospital caregivers for Covid-19.

8. **Self-testing:** Sanofi and Luminostics plan to market a self-test on smartphones by the end of 2020. This project aims to develop a consumer test with high sensitivity and specificity from respiratory samples, using an adapter combined with an intelligent chemiluminescent signal detection device.

9. **Covisan:** AP-HP launches Covisan, a "multi-partner" project to control the Covid-19 epidemic. The aim is to offer screening to the entourage of the diagnosed patient and, if necessary, accommodation to enable him/her to isolate him/herself and provide protective equipment.

10. **Test capacity:** a first high-throughput sequencing device for Covid-19 out of the 20 ordered by the State is operational at the Hospices Civils in Lyon.
    - Like 19 other devices, which are not yet in service, it was purchased from the Chinese company MGI. These devices, as well as consumables and reagents, were purchased by the State with the aim of significantly increasing France's capacity to test the population for coronavirus during decontainment.

11. **Nurses:** the National Order of Nurses (ONI) recommends that "as of May 11, nurses may prescribe Covid-19 screening tests if they see clinical symptoms in their patients during home visits. The order is considered "priority action recommendations" for decontainment (link).

12. **Effectiveness of the tests:** in a press release issued on Friday 24 April, the independent medical journal Prescrire warns of the lack of evaluation of biological diagnostic tests for Covid-19.

    - Prescrire points out in its specifications for serological tests, that HAS requires a minimum performance of 98% for specificity and 90% to 95% for sensitivity.
    - A list available on the Ministry of Health website showed on 3 April that a small minority of the reagents used to detect viral infection by RT-PCR were clinically validated by the national reference centre.

13. **Pre-operative screening**: with a view to the resumption of non-emergency medical and surgical interventions, the Société de pathologie infectieuse de langue française (Spilf) on Wednesday issued an opinion on the place of pre-operative screening for the Sars-CoV-2 virus, recalling the limitations of the tests (link).
    - Spilf also stresses that the "best test currently available for detecting Sars-CoV-2, PCR on nasopharyngeal swabs, has an imperfect sensitivity, estimated at 70%".

14. **US restrictions**: the US Food and Drug Administration (FDA) announced in a press release on 4 May that it had introduced new market access requirements for manufacturers of serological tests for Sars-CoV-2 because the great flexibility of the guidelines applied to date has led to an influx of uncontrolled tests on the US market.

    - The FDA reminded that the only tests that can claim to be "FDA-approved" are those with emergency use authorization (EUA).

- The FDA now requires all manufacturers to submit an application for emergency use authorization within 10 days of the date of application of this new directive, or within 10 days of notifying the FDA of their test. Screening devices must also have sensitivity, i.e. a minimum 90% negative case detection rate and a minimum 95% specificity (positive case detection rate).

- Research laboratories wishing to develop their own tests can still do so provided they are certified under CLIA (Clinical laboratory improvement amendments) and notify the FDA, but are encouraged to apply for emergency use approval as well.

- Information on manufacturers who do not submit such a request "will be publicly disclosed".

2.4. Supplies

2.4.1. Reported Risks of Shortage

1. **Kaletra®:** ANSM reported on April 2 supply tensions on the anti-HIV pharmaceutical product **Kaletra®**, evaluated in Covid-19 (link).

2. **Resuscitation medicines:** Christelle Ratignier-Carbonneil, deputy director of ANSM, said that a large national production of resuscitation medicines would not have been sufficient to meet the demand. The deputy director of the ANSM, Christelle Ratignier-Carbonneil, recalled the provisions of Article 48 of the LFSS for 2020 which provides that manufacturers have stocks of up to four months' coverage of medicines needs.

3. The ASNM Director General, Dominique Martin, considers that the drop in activity in Asia has no impact at this stage.

4. The ANSM publishes an information point on its mobilization to ensure the availability of medicines and health products, particularly resuscitation drugs and those useful in the management of chronic diseases (link).

   - The Agency recalls that particular attention is paid on a daily basis to resuscitation medicinal products (midazolam, propofol atracurium, cisatracurium, rocuronium), medicinal products used in the management of COVID-19 patients and the various medicinal products tested in ongoing clinical trials.

   - With regard to the drugs useful in the management of chronic diseases that are currently being used against COVID-19, ANSM points out that they are also subject to ongoing monitoring both in terms of their availability and the adverse effects associated with this new use.

5. **IgHN**: ANSM is publishing an information point in which it asks health care professionals to respect the prioritization of indications for normal human immunoglobulin (IgHN).

- In the context of the Covid-19 pandemic, the ANSM has observed an increase in the consumption of normal human immunoglobulins (IgHN) and in particular subcutaneous forms, as the supply of IgHN is already tight (link).

- In order to ensure the availability of these essential medicines, the ANSM therefore reminds healthcare professionals of the importance of respecting the prioritisation of IgHN indications.

- The Agency also monitors weekly the supply of plasma-derived medicinal products (PDM), such as these immunoglobulins, to ensure that patients' needs are covered.

6. **Standardization**: A report from the Epi-Phare Scientific Interest Group (SIG) posted online on Monday notes a "return to normalized consumption" of chronic disease medicines after five weeks of containment, following a significant increase in the dispensing of these products, probably linked to storage phenomena, observed at the beginning of containment.

    - Epi-Phare notes a "collapse" in the dispensing of medicines whose administration or monitoring requires the physical presence of a healthcare professional.

    - After a "peak" in the dispensing of chloroquine on prescription on February 27 and another for hydroxychloroquine (Plaquenil*, Sanofi) on March 18, Epi-Phare reported a reduction in the initiation of these treatments and their reimbursement since the end of March.

    - Finally, the ISU report highlights a spike in paracetamol consumption on March 16. This peak was followed at the end of the month by a "normalized and even low" delivery with the lowest level recorded since the beginning of 2020.

2.4.1.Centralised Procurement Management

1. **Equipment and raw materials purchasing fund:** on 31 March 2020, the French President announced an allocation of 4 billion to a fund managed by the ANSP dedicated to the purchase of equipment and raw materials to deal with the Covid-19 epidemic.

2. **Coordination of the pharmaceutical sector:** an *ad hoc* working group of 20 companies has been set up to deal with the risks of shortages and supply tensions in close cooperation with the highest levels of government.

3. **National Centralised Supply Plan:** in order to secure the **supply of health facilities**, a National Centralised Supply Plan should be put in place in coordination with pharmaceutical companies in the coming days:
    - Constitution of a national stock through government purchases;
    - Priority is given to State orders than orders from health facilities;
    - Flows to health establishments decided by the State at the central level with the support of the ARS;
    - Sourcing from all suppliers to purchase the volumes available on the national territory or internationally.

4. **Supply of health care facilities :**

- **New purchasing and supply system for health establishments: the Directorate General for Health (DGS)** has set out the new purchasing and supply system for health establishments in response to the persistence of "extremely high supply tensions" over five molecules in injectable forms: **three curares (atracurium, cisatracurium, rocuronium) and two hypnotics (midazolam, propofol)** (Decree No. 2020-466 of 23 April 2020, JORF of 24 April 2020, Article 1).

    - This new system for purchasing and supplying health facilities with these medicines will be implemented as of April 27, 2020.
    - **The State will purchase, alone, medicines whose active ingredient corresponds to one of the above-mentioned molecules.** Health institutions will no longer purchase these medicines;
    - A supply system for health establishments will be set up via the depositories and in conjunction with the ARS. It will aim to supply the institutions according to the number of patients hospitalized in an intensive care unit (COVID and non-COVID) and the stock of medicines available within the institution. RHAs are also invited to take into account the needs of hospitalization at home and their activity in terms of palliative care.
    - The **first deliveries will be made by the evening of April 30 at the latest**. A decree and an instruction will very soon specify the **operational and contractual scheme** that will be implemented.

- **Transparency**: in this context, the National Union of Hospital Pharmacists and University Hospital Practitioners (SNPHPU) has called for greater transparency on regional allocations of resuscitation drugs, based on a survey conducted in institutions that points to difficulties in the new purchasing and supply circuit put in place for these drugs under stress. The SNPHPU has made several requests in this regard:
    - Access to regional allocations by LRAs to PUI managers and communication of quantities to be delivered by stock delivery persons in medicine boxes (CIP and UCD codes) from Tuesday evening.
    - The establishment in all health establishments of a steering committee, formed under the aegis of the establishment medical commission (CME), which must include the managing pharmacist.
    - The taking into account for future allocations not only of activities related to Covid-19 but also the restarting of other activities.

- **Situational analysis by the Minister of Solidarity and Health:**
    - Destocking of 5 million surgical masks for paramedics, pharmacy assistants, midwives, laboratory technicians, home care workers and radio manipulators.
    - The supply situation for overalls, hats, aprons and sometimes gloves is also very tight worldwide.
    - By the end of June, France should have 15,000 resuscitation respirators and 15,000 lighter transport respirators.
    - Resuscitation medicines are another point of great vigilance. World consumption of medicines such as curare and midazolam has increased by 2,000%.

5. **Government order for respirators:** the government placed an order for 10,000 units.

   - The government clarified the situation following the publication of an investigation by Radio France's investigation unit: the thousands of artificial respirators currently being produced by Air Liquide and its partners, ordered by the State, would not be suitable for use in patients suffering from Covid-19.
     - He specifies that out of the 10,000 respirators ordered from Air Liquide, "1,500 are of the Monal T60 model, which is now widely used in French and international hospitals to treat patients suffering from Covid-19".
     - The other 8,500 are of the Osiris model. "These are emergency and transport respirators, with all the necessary certifications from health agencies, including the CE mark".

   - The government says that by the end of June, 15,000 resuscitation ventilators will be available, as well as 15,000 other emergency and transport ventilators, more than the expressed and anticipated needs.

2.4.3.Production

1. **Industrial consortium for the production of respirators:** the French President announced the creation of a consortium of French manufacturers, composed of Air Liquide, Schneider Electric, Valeo and PSA, which should "enable the production of 10,000 respirators by mid-May" (Communication from the President of the Republic of March 31, 2020).

2. **Consortium of manufacturers of blood-derived medicinal products:**

   - The consortium includes the French Laboratory of Fractionation and Biotechnology (LFB), the British Bio Products Laboratory (BPL), the German company Biotest, the American-Australian CSL-Behring, the Swiss company Octapharma and the Japanese company Takeda.

   - The partners plan to collaborate on various aspects such as plasma collection, clinical trial set-up and production.

   - Their goal is to develop and produce a hyper-immune anti-Sars-CoV-2 polyclonal immunoglobulin for the treatment of patients with severe forms of Covid-19.

   - The **Academy of Medicine** has called for the production of hyperimmune anti-coronavirus immunoglobulin as soon as possible. The Academy of Medicine recommends that **pools of plasma** collected from patients who are immune to the Sars-CoV-2 coronavirus (convalescent or cured) should be assembled "as of now" to prepare **hyperimmune immunoglobulins for therapeutic purposes.**

3. **Resuscitation medicines:** faced with the **exponential demand** linked to the health crisis, manufacturers of drugs used in intensive care are studying "all possible options to ensure the supply of medicines", are closely monitoring their **stocks**, but are not considering **reorienting certain production lines.**

- Among the measures studied are order **quotas** to regulate flows and ensure a good distribution of medicines throughout the country, the mobilization of **international stocks** and the **reinforcement of teams** at production sites, in particular to replace sick employees.

4. **Generic medicines**: the Gemme published a communication informing that generic producers are also putting in place "preventive and corrective measures to secure market supply, such as readjusting production schedules (increase by setting up additional teams, advancement) or mobilising stocks for export".

2.4.4.Import

1. **The National Public Health Agency (ANSP) is now authorised to import medicines subject to an import authorisation issued by the ANSM, in the event of difficulties in the supply of medicines with a marketing authorisation** (Decree No. 2020-447 of 18 April 2020, JORF of 19 April 2020, Article 1).

- Imported medicines must appear on a list drawn up by the ANSM and published on its website (list not yet online).

- The ANSP's purchases are intended to supply: health establishments, army hospitals, the National Institution for Handicapped, the departmental fire and rescue services, the Marseilles marine fire brigade, the Paris fire brigade and the army health service (SSA) medical supply establishment when supplying means of transport and operational medical structures under the authority of the Minister of Defence deployed in the context of a state of health emergency.

- Concerning the listed medicines, ANSM may:
    - prepare an information document on their use for health professionals and patients;
    - designate a Regional Pharmacovigilance Centre (CRPV) for the collection of safety data; and
    - implement reinforced pharmacovigilance monitoring.

- The collection of information concerning the adverse effects of these medicines and their transmission to the CRPV is carried out by the health professional taking care of the patient. The CRPV transmits this information to the ANSM.

2. The Ministry of Action and Public Accounts has issued an opinion concerning imports of masks for the "general public" reserved for non-sanitary uses and whose wearing is intended to complement the barrier measures in the context of the Covid-19 epidemic (Notice to importers of masks for the "general public" reserved for non-sanitary uses, JORF of 5 May 2020).

- Two new categories of masks exclusively reserved for non-sanitary uses are created to prevent droplet projections and their consequences:
    - individual mask for professional use with contact with the public (intended for personnel assigned to posts or missions involving regular contact with the public)

- mask for collective use to protect an entire group wearing these masks (intended for persons in the professional environment having occasional contact with other persons).

- The placing on the market of masks for the general public and the related technical specification process are distinct from the regulatory procedure applicable to personal protective equipment (FFP1, 2, 3 masks) and medical devices (surgical masks).

- Importers of these products must first have tests carried out, under their responsibility, by a competent third party, demonstrating the performance of these masks with regard to filtration and breathability criteria specific to each of these two categories. These criteria are described in the revised information note of 29 March 2020 (link).

2.4.5.Export

1. **The export of specialities containing the combination lopinavir + ritonavir or hydroxychloroquine by wholesaler-distributors is prohibited** in order to guarantee the appropriate and continuous supply of patients on the national territory in city pharmacies as well as in the internal pharmacies (Decree No. 2020-314 of 25 March 2020, JORF of 26 March 2020, Article 1).

2. **Extension of restrictions: in spite of the EU's instructions,** on 21 April the ANSM provided pharmaceutical distributors with a list of new medicines whose export is restricted in the context of a health crisis. These temporary restrictions apply to distributors but manufacturers, such as Sanofi, are exempted.

   - The updated list includes antibiotics, analgesics, sedatives and muscle relaxants, as well as several medicines tested as possible treatments for Covid-19, including remdesivir (Gilead Sciences).
     - The European Commission sent a letter to the government urging it to lift restrictions on the export of some ten essential medicines for the treatment of patients with Covid-19.
     - The only **export bans** that have been published in the Official Journal concern hydroxychloroquine (Plaquenil®, Sanofi) and Kaletra® (lopinavir + ritonavir, AbbVie).

   - According to the European Commission, discussions are under way to convince Paris to lift these restrictions, which are considered disproportionate. If no compromise is found, the Commission could take legal action against France.

2.4.6.Requisitions and nationalisations

1. **Respiratory masks and masks of specified protection will be requisitioned** (Decree No. 2020-293 of March 23, 2020, JORF of March 24, 2020, Article 12) in exchange of a compensatory indemnity, pursuant to the Defense Code, subject to 6 month imprisonment and a 10,000 euro penalty (Law No. 2020-290 of March 23, 2020, Article 2).

2. **Managing the influx of patients:**

- Health or medico-social establishments and any goods, services or persons necessary for the operation of these establishments may be **requisitioned** if the influx of patients or victims or the health situation justifies it (Decree No. 2020-337 of 26 March 2020, JORF of 27 March 2020, Article 1) under penalty of 6 months' imprisonment and a fine of 10,000 euros (Law No. 2020-290 of 23 March 2020, Article 2).

- The State representative in the department is authorised, if the influx of patients or victims or the health situation justifies, to order, through general or individual measures, the requisition of any goods, services or persons necessary for the operation of the *ARS*s as well as the agencies responsible, at the national level, for the protection of public health, in particular the **ANSM** and the **ANSP** (Decree n° 2020-384 of 1 April 2020, JORF of 2 April 2020, Article 1).

3. The Council of State rejected a request from the party "Debout la France" to increase the production of protective **masks** and **screening tests, to nationalise** the pharmaceutical manufacturer Famar and the industrialist Luxfer, for their respective capacities to produce **chloroquine** and **medical oxygen** on French territory, and to ensure uniform compliance with the applicable **containment** measures and **sanctions** throughout the country (State Council, Judge in summary proceedings, 29 March 2020, Party "Debout la France" and Mr Nicolas Dupont-Aignan, n° 439798).

2.4.7.Masks and protections

1. The **masks** will be made available free of charge by dispensing pharmacies to health professionals until 11 May 2020 (Order of 23 March 2020, JORF of 24 March 2020, article 3).

2. Sale of masks in pharmacies:

- The president of the National Council of the Order of Pharmacists (CNOP) considers that the sale of surgical masks in pharmacies, beyond the protection distributed to caretakers from State stocks, is not reasonable as long as city pharmacies do not have sufficient reserves, particularly for professionals.
    - As a reminder, the president on CNOP has obtained from the Union of Associations of Pharmacists (*Union des groupements de pharmaciens d'officine (UDGPO)*) and the Trade Union Chamber of Pharmacy Groups and Signs (*Chambre syndicale des groupements et enseignes de pharmacies)* that they postpone their decision to start selling surgical masks to the general population.

- Pharmacists may now market "non-health masks manufactured according to an industrial process and meeting the applicable technical specifications" (Order of 25 April 2020, OJ of 26 April 2020, Article 1).
    - The authorisation, which had been requested by the pharmacists' unions for almost three weeks, was granted on the basis of a proposal from the National Council of the Order of Pharmacists (CNOP) dated 15 April 2020.
    - In a message published for its members, the Federation of Pharmaceutical Unions of France (FSPF) also reminds that "the sale of surgical masks and FFP2 remains

impossible. As long as their quantity remains insufficient, they must be reserved for caretakers in accordance with the instructions of the health authorities "(link).

- Following the publication of the above-mentioned order, the CNOP and the unions representing dispensing pharmacists invited city pharmacies to start selling surgical masks "from their own stock with discernment", dispensing them "as a priority to fragile or at-risk persons ».

3. **Gowns**: UniHA and Resah undertake to provide the health and medico-social sectors with gowns.

   - This initiative, supported by the Ministry of Health, aims to have more than one million fabric gowns manufactured in a few weeks to meet the most urgent needs of all structures in the health and medico-social sectors, whether in the public or private sector (hospitals, clinics, Ehpad, etc.).

   - The two centres have decided to call on a group of economic operators made up of three firms (ALM-Halbout, Granjard and Mulliez) specializing in clothing in the health sector and already holders of contracts from the Resah and UniHA purchasing centres. The group has launched the manufacture of 580,000 fabric gowns, to be delivered in stages by the end of June.

   - An additional programme for the purchase of plastic aprons to supplement the use of cloth gowns in the event of a risk of splashes has also been launched.

4. **Price**: the selling price of single-use surgical type masks meeting the definition of medical devices, made from 3 May 2020, is now capped (Decree No. 2020-506 of 2 May 2020, JORF of 3 May 2020, Article 1):

   - This cap applies to retail and wholesale sales:
     - Retail sale: the sale price may not exceed 95 eurocents (including tax) per unit, regardless of the distribution method, including in the case of online sales. This price does not include possible delivery costs.
     - Wholesale: the sale price may not exceed 80 eurocents (VAT excluded) per unit.

   - The provision concerns anti-projection masks complying with standard EN 14683 that have not been subject to requisition of stocks by the State, and masks manufactured in France or imported that have benefited from a derogation granted by the Director General of ANSM.

5. **Deconfinement**: the Ministry of Solidarity and Health details, in a "DGS-urgent" note signed by Jérôme Salomon and distributed on 5 May, its new distribution strategy for surgical and FFP2 masks, extending it for the first time to contact persons and persons at very high medical risk (link).

   - The Director General of Health (DGS) has set the objective of distributing 100 million health masks weekly, "modulo an adaptation each week according to the reality of supplies".

2.4.8.Hydro-alcoholic gels

1. **Hydro-alcoholic solutions** intended for human hygiene can be prepared by dispensing pharmacies and internal pharmacies until 11 May 2020 (Order of 23 March 2020, JORF of 24 March 2020, Article 2).

2. The **price of all hydro-alcoholic gels intended for personal hygiene is frozen** until 31 May 2020 (Decree No. 2020-293 of 23 March 2020, JORF of 24 March 2020, Article 11). Violation of these rules is punishable by a lump-sum fine of 135 euros for the first offence, between 1,500 and 3,000 euros if repeated within 15 days, and up to 3,750 euros and six months' imprisonment if repeated more than three times within 30 days (Law n° 2020-290 of 23 March 2020, article 2).

   - The provisions of Book IV of the Commercial Code apply to the rules on the **retail and wholesale selling price** of gels (Decree No. 2020-396 of 4 April 2020, JORF of 5 April 2020, Article 1).

   - **Sales by pharmacies and internal pharmacies:** application of a "correction coefficient" leading to an increase in the maximum selling price of hydro-alcoholic products prepared by pharmacies and dispensaries for internal use (Decree of 4 April 2020, JORF of 5 April 2020).

   - **Revalorisation:** the maximum price of hydro-alcoholic gels intended for personal hygiene packaged in special containers for legal entities is revalorised (Order of 10 April 2020, JORF of 11 April 2020).

   - **Lowering**: the maximum price of hydroalcoholic gels for personal hygiene packaged in special containers for legal entities is lowered by 12% (Decree No. 2020-477 of 25 April 2020, OJ of 26 April 2020, Article 1).

     - The text also includes the price increase coefficients established in an order of 4 April for products prepared by dispensing pharmacies and PUIs and sold in retail or bulk.
     - As a reminder: the Minister responsible for the economy may amend the maximum selling prices and mark-up coefficients by order to take account of changes in the market situation in all or part of the territory, up to a weighting not less than 0.5 or more than 1.5.

4. **Grouped purchasing:** the cooperative network of hospital purchasing, UniHa, has set up a new platform for the supply of hydro-alcoholic solutions and gel for public and private non-profit healthcare institutions.

2.4.9.Derogations to facilitate the availability of treatment

1. **Serialisation:** the ANSM provides for the possibility for laboratories located on the national territory to suspend **serialisation** until 31 May 2020, on a voluntary and temporary basis, in order to speed up the manufacture, release and availability of batches of medicinal products (link).

2. **Labelling and risk of medication errors:** in order to respond to the **emergency**, the ANSM has specified that there are **no plans to label** medicines imported from abroad in French language, as is usually done. The ANSM asks hospital pharmacists to share with health care teams, and particularly with resuscitation teams, the conditions and special precautions for using these medicines (link).

3. **Innovative medical devices:** in the context of the Covid-19 pandemic and due to the increase in hospitalizations, the ANSM has developed a temporary framework adapted to the context of Covid-19, proposing guidelines whose objective is to facilitate the use of alternative medical devices, while preserving patient safety.

4. **Single-use medical devices:** ANSM has issued an opinion on the reprocessing and **reuse** of single-use medical devices to mitigate the risks of supply disruption.
   - Supply tensions on single-use laryngoscope blades have been identified.
   - The ANSM, consulted on 14 April 2020 a group of experts to decide on the possibility of reprocessing these devices and to define a secure procedure to allow their reuse (link).
   - As a reminder, a previous opinion has been published on the reuse of single-use ventilation consumables (link).

5. **Alternative transport measures:** in view of the difficulties in transporting health products to overseas territories, the General Directorate of Civil Aviation (DGAC - Ministry of Ecological and Solidarity Transition) recommends directly soliciting freight forwarders and specialized air brokers to place orders and identify available offers, as Air France represents only a small part of the capacity.

6. A **patient unable to move around** on the premises of an internal pharmacy will be able to obtain his or her medication via a pharmacy (Order of 23 March 2020, JORF of 24 March 2020, article 4).

7. Pharmacies will be able to distribute medicinal treatments on the basis of **non-renewed prescriptions** until 11 May 2020 (Order of 23 March 2020, JORF of 24 March 2020, article 5).

8. When the period of validity of **an order prescribing nursing care has expired** and in order to avoid any interruption of treatment prejudicial to the patient's health, the nurse may continue, under the conditions provided for by the initial prescription, care listed exhaustively by order until 11 May 2020 (Order of 31 March 2020, JORF of 1 April 2020, Article 1).

9. Restrictions apply to the **sale of paracetamol** until 11 May 2020 (Order of 23 March 2020, JORF of 24 March 2020, Article 6).

10. **Dispensation:** the pharmaceutical speciality based on belatacept may be dispensed, until 31 May 2020, by authorised internal pharmacies, to guarantee maintenance treatments for graft rejection in adult patients who have received a kidney transplant (Order of 2 April 2020, JORF of 3 April 2020, Article 1).

11. **Substitution of medical devices:** a service provider, an equipment distributor or a dispensing chemist can now substitute a medical device that is out of stock with another (Order of 1 April 2020, JORF of 2 April 2020, Article 1).

12. **Postponement** from 15 April to 31 May 2020 of the **deadline** for the preparation of hydro-alcoholic solutions, the derogatory renewal of chronic treatments, anxiolytics or hypnotics and opiate substitution treatments by internal pharmacies (Order of 1 April 2020, JORF of 2 April 2020, Article 1).

13. **Tracheal cannulas** and **respiratory prostheses for tracheotomy** are included in the list of medical devices whose prescription can be renewed by the pharmacist despite an expired prescription (Order of 1 April 2020, JORF of 2 April 2020, article 1).

14. **Opioid overdoses**: The Ministry of Solidarity and Health increased access to the antidote naloxone in the context of the Covid-19 epidemic due to an increased risk of opioid overdoses.

    - Last weekend, the ministry released three fact sheets, one giving the general doctrine (link) and two memos, one for professionals (link) and the other for the general public (link).

    - The ministry points out that in addition to the appropriations delegated in 2019 for the purchase of naloxone kits, the structures are encouraged to renew their stock to make them available to users and that, if necessary, expenditure linked to the supply of naloxone will be regulated by the LRAs as part of the forthcoming 2020 budget campaign.

15. **Overseas :**
    - Overseas Ministry recommendations: the Minister for Overseas France, Annick Girardin, announced new measures for overseas departments, regions and territories concerning the fight against the spread of Covid-19. The measures are based on the advice of the scientific council, which includes ten recommendations (link).
    - The recommendations include the following:
        - Ensuring that masks, personal protective equipment and hydro-alcoholic solutions are readily available, without stock shortages for caregivers.
        - To allow compassionate use, or even within the framework of research protocols for certain territories, access to antiviral treatments that have demonstrated their effectiveness against Covid-19 in an intermediate analysis of the effectiveness of ongoing clinical studies.

    - The Government has taken measures to adapt the state of health emergency system (Ordinance No. 2020-463 of 22 April 2020, JORF of 23 April 2020):
        - Article 1 concerns the adaptation of the state of health emergency in the islands of Wallis and Futuna.
        - Article 2 concerns the adaptation of the state of health emergency in New Caledonia and French Polynesia.
        - These new provisions do not apply to Saint Martin, Saint Barthélemy and Saint Pierre and Miquelon, which are governed by the principle of legislative identity.

2.5. Assessment, management and pricing of health products

2.5.1. Economic Committee for Health Products (CEPS)

1. The CEPS has adapted its operating procedures:
   - The CEPS has postponed several **price cuts for pharmaceutical specialties** by several months (publication of several notices of cancellation of price cuts accompanied by postponements);
   - Committee meetings have been cancelled and CEPS members are not in attendance. The Committee meetings are cancelled and the CEPS members are not present. However, they still follow up on the files;
   - The pre-calculations of the discount amounts for 2019 were sent last week to the laboratories;

2. **Continuity of activity:** CEPS has released an information note informing companies and CEPS institutional partners about the measures implemented by CEPS during the period of restriction related to Covid-19 (link).
   - These measures shall apply until a normal situation of activity is recovered.
   - They are designed to ensure that the pricing and regulation of health products is maintained within the framework of priorities defined by a business continuity plan validated at the inter-ministerial level.
   - This plan aims to focus the CEPS on priority missions, in particular market access for products deemed indispensable.

3. The declaration of the Safeguard Clause is postponed to 15 May (guide link), an extension to 11 June is requested by the Leem.

2.5.2. National Authority for Health (HAS)

1. HAS shall continue to pursue the continuity of its essential missions and maintain the meetings of its college and its committees, while adapting the agenda to the **priorities:**
   - Prioritisation of the programming of files for passage to the Transparency Commission (link).
   - Prioritisation of the programming of files for passage to the CNEDiMTS Committee (link).

2. **Economic Evaluation and Public Health Commission (CEESP): CEESP** has adopted a plan to conduct its activities and maintain its activities in the period of health emergency, using the dematerialised format (link).

3. **Early meetings:** the Transparency Commission has updated the procedure.
   - From now on, the schedule of early meetings (for both procedures) will be online, and all key dates for the procedure will be known as soon as they are submitted.
   - This will be done via SESAME, and a notice for the submission of the briefing document will be put online by the HAS (clarification of expectations, in particular on the PROs and real-life data: these 2 subjects will be addressed systematically during the early meetings).
   - The exchange of information can also be done in English (to avoid mixing French and English). If the meeting, documents, emails are in English, then the HAS will answer in English.

- The choice of procedure is the responsibility of the HAS services on the basis of the briefing document provided by the laboratory, but the laboratory may indicate the procedure it would like to follow.
- The criteria for access to early meetings are not modified.

2.5.3. Technical Agency for Hospitalisation Information (ATIH)

1. The ATIH has detailed **the indications for taking over Covid-19** and given coding instructions for the PMSI MCO (link).

2.6. Information Technology

1. **Tracking data and StopCovid:** the government is negotiating with Apple and Google to allow applications such as StopCovid to exchange information.
   - Inria has published a first version of the protocol for tracing the Covid-19 epidemic, which is based on Bluetooth technology and will be the basis of what will be submitted to the CNIL and used in the parliamentary debate (link).

   - Cédric O, Secretary of State for Digital Technology, says Apple must change a number of its operating conditions for the application to be effective.

   - Researchers have pointed out that the applicable law (RGPD and e-Privacy Regulation Proposal), prohibits the obligation to use and bases its existence only on consent, i.e. voluntariness.

2. **Task force in charge of the development of StopCovid:**
   - The *Institut national de recherche en sciences et technologies du numérique (INRIA)* is leading the French task force for the development of the StopCovid application, initiated by the public authorities to enable contact tracing and is participating in the PEPP-PT (Pan-European Privacy-Preserving Proximity Tracing) initiative, which aims to provide governments with a basic contact tracing solution that respects personal data and European law.

   - The protocol, called ROBERT (ROBust and privacy-presERving proximity Tracing) will be the basis of what will be submitted to the CNIL and will be used in the parliamentary debate scheduled for 28 and 29 April on the StopCovid application.

   - The Secretary of State for Digital Affairs, Cédric O, declared he was not sure whether Stop Covid would be ready by 11 May 2020.

3. **Opinions on StopCovid**: the Conseil national du numérique (CNNum), the Conseil national de l'ordre des médecins (CNOM) and the Commission nationale de l'informatique et des libertés (CNIL) have issued opinions in favour of the use of the StopCovid contact tracing application, albeit with certain reservations and conditions.

   - The National Digital Council's opinion on StopCovid is accompanied by 15 recommendations (link).

- The opinion of the National Council of the Order of Physicians on the challenges of digital tracing stresses that the application cannot be the central element, as several prerequisites are indispensable (link).

- The CNIL considers that the application can be deployed, in accordance with the RGPD, if its usefulness for crisis management is sufficiently proven and if certain guarantees are provided (link):

    - its use must be temporary;

    - the data must be kept for a limited period of time;

    - it therefore recommends that the impact of the system on the health situation be studied and documented on a regular basis, to help the public authorities decide whether or not to maintain it.

4. **Covidom:** the telemonitoring application will be deployed throughout the metropolitan territory in preparation for deconfinement.
    - Launched on March 9 by AP-HP and co-developed with the start-up Nouvéal, the Covidom application allows patients carrying or suspected of carrying Covid-19 without signs of severity to benefit from remote monitoring at home.
    - The Nouvéal company announced that the application is available free of charge to all private doctors and nurses in mainland France to prepare and support the deconfinement.
    - To enable rapid deployment throughout metropolitan France, Nouveal has joined forces with the laboratories Novo Nordisk and Johnson & Johnson France, as well as the mutualist group Malakoff Humanis and the La Poste group.

5. **Contact Covid**: the director general of the Cnam, Nicolas Revel, indicated that a teleservice "contact Covid", accessible via the platform ameli pro, will be developed by Monday, May 11 to allow private doctors to report contact cases of a person infected with Sarsov-2.

    - This platform as well as the "contact Covid" tool will benefit from an ad hoc legal framework resulting from the Emergency Health Law 2 project, currently under review.

    - The Regional Health Agencies (ARS) and Public Health France will be responsible for "managing complex contamination chains and the beginnings of clusters", using the "Covid contact" tool.

    - Concerning the "pricing conditions" under which the doctors will intervene, "two measures will be taken from 11 May".

6. **Connected object**: The Secretary of State for Digital, Cédric O, indicated that part of the team developing the Covid-19 contact tracking application, StopCovid, "is dedicated to trying to find another solution, for example, a case or a bracelet that would make it possible to do without telephones". The Secretary of State added that the feasibility of the StopCovid device remains "uncertain and will require at least additional weeks of development" (link).

7. Ambulis Covid-19: the group of private clinics Vivalto is equipped with the "Ambulis Covid-19" solution, published by Domicalis, a company specialising in e-health software, to organise the secure monitoring of patients suffering from Covid-19 in their homes.

   - The group of private clinics Vivalto Santé is the first beneficiary of a support supported by Lilly and Roche within the framework of the Coalition innovation santé.

2.7. Data processing

1. **Data collection:** the HealthDataHub and the CNAM, which are now authorised to receive categories of personal data listed exhaustively, may only collect the data necessary for the pursuit of a purpose in the public interest in connection with the current Covid-19 epidemic and for the duration of the state of health emergency (Order of 21 April 2020, JORF of 22 April 2020, Article 1).

2. **Examination of applications for authorisation of research projects concerning Covid-19:** the CNIL **will examine as a priority applications for authorisation of research projects concerning Covid-19** in the event that the data processing envisaged does not comply with the reference methodologies.
   - Applicants must include the words "COVID-19" in the "purpose" or "name" section of the form to enable the CNIL to **identify the file as a priority.**
   - If only certain documents are missing, a **pre-instruction** may already be required at recherchecovid19[@]cnil.fr.

3. **Digital tracing:** the President of the **CNIL** was heard by the National Assembly's Law Commission on the use of **digital tracing** as part of the fight against the Covid-19 epidemic (link):
   - CNIL discusses issues surrounding technologies based on the analysis of individual location data and health research
   - At the European level, data protection authorities are networked within the European Data Protection Committee (EDPS).

4. **AP-HP Task Force:** the *Assistance Publique-Hôpitaux de Paris (AP-HP)* has set up a "**Covid-19 task force**" within its health data warehouse to analyse and monitor the coronavirus epidemic but also to help research thanks to the "mass of data" produced.

5. **Datacovid:** the first results of the barometer developed by the Datacovid association with the Ipsos institute to measure French people's concern about Covid-19 and how they adapt their actions have been published.
   - This study is a citizen science project, whose primary aim is to provide open data to researchers and public authorities.

   - The study is funded by private partners: Gilead Sciences, Amgen, Johnson & Johnson, Roche, CNP, Vinci Autoroutes and RATP.

   - The first wave of data (link) was followed by a second wave showing a slight decrease in French compliance with barrier gestures in front of Covid-19 (link), then by a third wave identifying a stabilisation of the observed laxity.

- As art of the Datacovid observatory, Amgen France asked Ipsos to conduct a survey of 5001 people representative of the French population aged 18 and over, among whom 1300 people suffering from certain chronic pathologies (diabetes, cancer, respiratory disease, kidney failure, high blood pressure, etc.) were questioned (link).
  The detailed figures are particularly eloquent and demonstrate a phenomenon of global renunciation of care and delays in treatment.
  This major disruption in the management of chronic diseases thus highlights the need for rapid intervention by the authorities on the subject.

6. **CNCDH**: the National Consultative Commission on Human Rights (CNCDH) has taken action to alert the public authorities to the dangers to fundamental rights of any application for monitoring individuals and contacts, particularly the right to privacy (Opinion on the digital monitoring of individuals, JORF of 3 May 2020).

- The CNCDH emphasizes several points:
  - A disproportionate infringement of fundamental rights and freedoms: free and informed consent subject to doubt, relative anonymity, effects on social cohesion, indeterminate temporality, uncertain effects and the need for democratic debate.
  - Broader concerns about contact tracing: ratchet effect, risks of cross-cutting infringements of fundamental rights and freedoms, and digital sovereignty.

2.8. Deadlines

2.8.1.Principle of extension by law

1. **Any appeal, legal action, formality, notification prescribed on pain of nullity, penalty, inadmissibility or otherwise** that had to be completed between 12 March 2020 and 24 June 2020 shall be deemed to have been completed on time if it is completed within the time limit set for acting under ordinary law conditions counted from 24 June, within the limit of two months, i.e. until 24 August 2020 (Ordinance No. 2020-306 of 25 March 2020 on the extension of time limits during the period of health emergency and the adaptation of procedures during the same period, published in the JORF of 26 March 2020, Article 2).

2. **Administrative or jurisdictional measures** whose term expires between 12 March and the end of the state of public health emergency are automatically extended until the end of a period of two months following the end of this period (Ordinance No. 2020-306 of 25 March 2020 on the extension of time limits during the public health emergency and the adaptation of procedures during the same period, published in the JORF of 26 March 2020, Article 3). The following measures are concerned :
   - Precautionary, investigative, investigative, conciliatory or mediatory measures,
   - Prohibition or suspension measures that have not been imposed as a sanction,
   - Authorisations, permits and approvals,
   - Measures to assist, accompany or support people in social difficulty,
   - Measures to help the management of the family budget,
   - The judge or competent authority may modify or terminate such measures where they were ordered before 12 March 2020.

3. The **list of measures concerned** was supplemented by an order which also specified the **measures and procedures excluded** from the scope of application of Order No. 2020-306 of 25 March 2020 (Order No. 2020-427 of 15 April 2020 laying down various provisions on deadlines for dealing with the Covid-19 epidemic published in the JORF of 16 April 2020). It specifies that :

   - **Such extension shall not be construed as a relinquishment of jurisdiction.** The extension shall not prevent the judge or competent authority from modifying or terminating such measures or, if the interests on which they are based so justify, from ordering their application or from ordering new ones for a period of time to be determined by the judge or competent authority.
   - A **further extension** may be granted in the absence of a decision by the competent authority within the legally protected period.
   - **Difficulties resulting from the health crisis shall be considered** while ordering such extensions.
   - **Deadlines for public and private persons to carry out works and controls or comply with requirements of any kind:** the Order specifies that the administrative authority may, during the period from 12 March 2020 to the end of the state of public health emergency plus one month, exercise its powers to modify or terminate these obligations or, where justified by the interests for which it is responsible, to prescribe their application or order new ones, within the time limit it determines. **In all cases, the administrative authority shall, while determining the obligations or deadlines to be respected, consider the constraints of the state of health emergency.**

2.8.2.Contracts

1. **Constraints, termination clauses, penalty clauses, clauses providing for forfeiture** "shall be deemed not to have come into force or effect" when they are intended to sanction the non-performance of an obligation within a given period if this period has expired between 12 March and 24 June 2020.
   - The constraint payments are effective and the clauses will be enforceable as of July 24, 2020.
   - The application of constraint payments and penalty clauses enforceable before 12 March 2020 is suspended until 24 June 2020.

2. Where an **agreement** may be **terminated or renewed** only during a specified period, that period shall be extended to 24 August if it expires between 12 March and 24 June 2020.

2.8.3.Administrative Procedures

1. **Extended concept of administrative authority:** extension of rights applies to :
   - All State administrations: central administration (Ministries) and decentralized services (Prefecture and ARS), public administrative establishments (e.g. CNAMTS, ANSM, hospitals, etc.), independent administrative authorities (e.g. HAS);
   - Local authorities and their public establishments;
   - Legal entities under private law with a public service mission (e.g. Urssaf).

2. **Derogations :**

- For various reasons of public interest, including public health and safety, an order in council may derogate from the rules of continuance;
- The provisions of points 8 to 14 are subject to compliance with European Union law.

3. **Decisions and opinions:** the time limits within which **an administrative decision or an opinion of an administrative body** had to be issued and which had not expired by 12 March 2020 shall be suspended until 24 June 2020.
   - **Urssaf:** The deadline for the **URSSAF's amicable appeal commission** to rule on a complaint expired between 12 March and the end of the state of health emergency. It is suspended until 24 June.

4. **Administrative police:** where they have not expired by 12 March 2020, the time limits imposed by the administration on any person to carry out checks or work or to comply with prescriptions of any kind shall be extended until 24 June, unless the measure has otherwise been ordered by a court decision. The time limits for compliance shall be extended under the same conditions if the starting point is between 12 March and 24 June 2020.
   - **Example**: The six-month period allowed by the ANSM to **bring a manufacturing line into compliance** ended between 12 March and the end of the state of health emergency. It is suspended until June 24.
   - **Example:** The decision of the Director General of the ANSM prescribing the bringing into conformity of the manufacturing line within six months of its notification was notified between 12 March and the end of the state of health emergency. The starting point of the six-month period is postponed to 24 June.

5. **Tax audit:**
   - The **limitation periods for the right of recovery** which expire on 31 December 2020 are suspended for a period equal to the period between 12 March 2020 and the expiry of a period of one month from the end of the health emergency period;
   - Both for the taxpayer and for the tax administration services, **all the time limits provided for the conduct of an audit and investigation procedures in tax matters shall be suspended for the same period, without the need for a decision to that effect by the administrative authority**;
   - The time limits **applicable to rescripts** shall be suspended under the same conditions;
   - Identical provisions are made for the time limits for resumption of control and rescript provided for in the Customs Code;
   - **The deadlines provided for in Article 32 of Law No. 2018-727 of 10 August 2018** for a State in the service of a trust company, relating to the experimentation of the limitation of the duration of administrative controls on certain companies in the regions of Hauts-de-France and Auvergne-Rhône-Alpes are suspended.
     - Example: For VAT refunds, the starting point of the deadline is postponed to 24 June when it is between 12 March and 24 June 2020.

6. **Recovery and contestation of public debts:** the collection periods for public accountants are suspended until 24 August 2020 when they were in progress on 12 March 2020 or when they started after that date.

7. **Consultative procedures:**

- Draft regulations directly intended to prevent the consequences of the extension of Covid-19 or to respond to situations resulting from a state of health emergency are exempt from mandatory prior consultation, subject to obligations under international and European Union law.
- Consultations of the Council of State and the authorities seized for assent are maintained.

2.8.4.Jurisdiction

1. **The extension of rights applies to measures pronounced by all the judicial authorities, including professional regulatory or ordinal authorities** (which may be assimilated to judicial or administrative authorities).
   - Where the period for appeal provided for by law ends between 12 March 2020 and the expiry of a period of one month after the end of the state of emergency, it shall begin to run again from the latter date - i.e. 24 June if the duration of the state of public health emergency is not modified - for its initial duration, calculated as a straightforward period, up to a limit of two months.
   - In the case of an appeal subject to the two-month time limit under ordinary law, if the time limit for appeal expired on 30 March, the application will be admissible up to and including 24 August 2020.

2. The **specific provisions applicable to the civil, criminal and administrative courts** have been specified by special orders (Orders Nos. 2020-303, 2020-304 and 2020-305 published in the JORF of 26 March 2020).

3. **As a matter of principle, hearings** are maintained by recourse to derogatory means (e.g. hearings before the administrative court may be held using an audio-visual means of telecommunication which makes it possible to ensure the identity of the parties and guarantees the quality of the transmission and the confidentiality of exchanges between the parties and their lawyers). In the opposite case, the parties are informed. For special provisions :
   - **Criminal courts:** Order No. 2020-303 of 25 March 2020
   - **Civil courts:** Articles 3 to 9 of Ordinance No. 2020-304 of 25 March 2020
   - **Administrative courts:** Articles 6 to 10 of Order No. 2020-305 of 25 March

   - **In practice**, since 16 March, only hearings concerning the handling of essential litigation have been maintained.

   - It is nevertheless necessary to check with each court to ensure that hearings are maintained and under what conditions, particularly for written procedures (e.g. social security litigation).

4. **Administrative courts:** an order clarified and supplemented the order No. 2020-305 of 25 March 2020 adapting the rules applicable before the administrative courts (**Order No. 2020-405 of 8 April 2020 on various adaptations of the rules applicable before the administrative courts, JORF of 9 April 2020**):
   - It allows the judge to reduce the **deadline extension for measures and closures of investigation** in the context of a state of health emergency, when the case is ready for trial or the urgency justifies it.

- It includes further relaxation of the rules governing the functioning of the courts with regard to the posting of court dockets and the notification of court decisions.
- It stipulates that where the **time limits set for a judge** to rule on a case run or have run in whole or in part during the period between 12 March and the end of the state of public health emergency, their starting point is postponed to the first day of the second month following the date of cessation of the state of public health emergency.

5. **QPC procedure:** an organic law suspended the deadlines for transmission and examination of priority constitutionality issues by the Constitutional Council until **30 June 2020** (Organic Law No. 2020-365 of 30 March 2020 on emergency measures to deal with the Covid-19 epidemic published in the JORF of 31 March 2020, declared compliant by the Constitutional Council in its decision No. 2020-799 DC of 26 March 2020).

6. **Violations of human rights:** the National Consultative Commission on Human Rights (CNCDH) calls for an end as soon as possible to the provisional legal regime established by the orders of 25 March 2020 relating to justice, adopted pursuant to the emergency law of 23 March 2020 to deal with the Covid-19 epidemic.

- The CNCDH regrets this treatment of the public service of justice, which disregards its role as a pillar of the rule of law. In this regard, the Commission notes in particular
  - The attack on the continuity of the public service of justice;
  - The risk of perpetuating infringements of fundamental rights and freedoms.

- As a reminder: the CNCDH was created in 1947. As an independent administrative authority (AAI), it is a State structure whose 64-member assembly is composed of representatives of State bodies and qualified individuals from civil society. It advises the Government and Parliament on human rights, law and humanitarian action and ensures respect for the fundamental guarantees granted to citizens for the exercise of public freedoms. It acts on a referral from a member of the Government or on its own initiative. It issues opinions including recommendations.

2.8.5.Specific deadlines

1. **Extension of tax deadlines**

- The Minister for Action and Public Accounts, Gérald Darmanin, presented a new calendar of the main fiscal deadlines for professionals for May taking into account the health crisis (press release)

- The Director General of Public Finance, Jérôme Fournel, provided some details on the deferral conditions of these tax deadlines (link) :
  - Measures to defer payment and filing dates to support businesses in difficulty
  - Declarations that are not subject to deferral
  - VAT declarations
  - Accelerated refunds of tax credits
  - The payment schedule for the IS and the contribution on the CVAE

- Companies that have no balance of corporate income tax to pay on 15 May and therefore do not benefit from any deferral, may file their bundles before the 30 June, without, in the case of large groups, the distribution of dividends being subject to any penalty whatsoever.

- Ongoing discussions on the DAC 6 declaration for cross-border arrangements are likely to extend the deadline initially fixed on 31 August by a few months.

2. **Waste from healthcare activities involving infectious risks:** the storage of waste from healthcare activities involving infectious risks is subject to new provisions relating to its duration, by derogation from the provisions of the order dated 7 September 1999 relating to the methods of storage of waste from healthcare activities involving infectious risks and similar and anatomical parts (Order dated 18 April 2020, JORF dated 22 April 2020, article 1).

3. **An instruction from the Directorate General for Social Cohesion (DGCS),** dated 27 March 2020, was sent to the directors general of regional health agencies (ARS) and regional state-representatives (*Préfets*). It specifies the information provided for in the Order dated 25 March 2020 adapting the rules for authorising, operating and financing medico-social establishments.

4. The deadlines for registration renewals are suspended pursuant to Article 8 of Ordinance No. 2020-306 of 25 March 2020 on the postponement of expired deadlines (press release of the Social Security Directorate – DSS).

5. **French Agency of Medicine Security (*Angence Française de Sécurité du Médicament* or ANSM)**

   - Deadline for the transmission of information on nitrosamine risk extended to 1 October 2020 (link).

   - Deadline for submitting the annual statement of pharmaceutical establishments provided for in Article R.5124-46 of the French Health Code has been extended to 31 May 2020 (link).

   - **Advertising visas:** The Agency informed Leem of its final position on the terms and conditions of deposits and valuation during the Covid-19 period. Among the measures taken by the Agency:
     - The extension of visas expiring during the periods set out in the Ordinance, to 31 December 2020;
     - The possibility of explicit agreement by the ANSM without waiting for the end of the period for visas filed in January, February (and for which the Ordinance has extended the deadlines to 12 August 2020 for the PM and 15 July 2020 for the PM), and for future filing periods on 25 June;
     - The possibility for a specialty with several indications to file 3 advertising media per therapeutic area.

   - **Marketing authorisation (MA):** the Agency has communicated information on the procedures to be followed concerning MA applications, applications for changes to MA, renewals of MA and the obsolescence of this period of health crisis.

6. **French Data Protection Agency (*Commission nationale de l'informatique et des libertés* or CNIL)**
   - The CNIL has released a communication stating that priority is given to files relating to Covid-19 and other referrals, as far as possible, within the usual time limits.
   - The CNIL also provides further details on the amended Order No. 2020-306 dated 25 March 2020 on the extension of the deadlines during the health emergency period and the adaptation of procedures: it reconsiders the extension of the deadlines applicable to certain procedures implemented by the CNIL and specifies that a tighter deadline may be required when justified by the interests at stake.

7. The **Competition Authority** has specified how its deadlines and procedures are adapted following the publication of the Ordinances issued on 25 March 2020 (press release dated 27 March 2020).

8. **Authority for Transparency in Public Life (*Haute autorité pour la transparence de la vie publique* or *HATVP)*:** Deadlines for filing a declaration on assets and interests, and deadlines to report on activities carried out by lobbyists are extended by 3 months as from the end of the state of health emergency (link).

2.9. Appointments

1. **Ministry of Solidarity and Health**
   - Ségolène Redon as communication advisor (JORF dated 11 March 2020);
   - Antoine Tesnière as advisor (JORF dated 21 March 2020);
   - Deborah de Lieme replaces Murielle Fayolle as head of the Cabinet (JORF dated 31 March 2020);
   - Aude Muscatelli, Jean-Luc Izard and Marie Daude as deputy directors of the Cabinet (JORF dated 4 April 2020);
   - Baltis Mejanes, Claire Bonnetier and Christelle Dernon as deputy chiefs of the Cabinet (JORF dated 4 April 2020).

2. **ANSM**
   - **Nomination du Directeur Général**: **Appointment of the Head of the Agency**: Under organic law No. 2020-364 and law No. 2020-366 dated 30 March 2020, the appointments made by the French President for the Head of the ANSM are subject to parliamentary control (JORF dated 31 March 2020, n° 1 and n° 2).

3. **ANSES**
   - **Appointment of the Head of the Agency**: Organic Law No. 2020-364 and Ordinary Law No. 2020-366 dated 30 March 2020 require parliamentary approval of the appointments made by the President of the Republic (JORF dated 31 March 2020, n° 1 and n° 2).

CONTACT

Charlotte Damiano
Partner
Paris
T +33 1 53 67 47 47

www.hoganlovells.com