I. SUMMARY

Number of cases: 1,009,762 (including the UK)
Number of deaths: 108,223

- The EU Executive Steering Group on Shortages of Medicines Caused by Major Events held a meeting on 15 April to discuss the progress of the measures regarding availability of medicines for European patients during the COVID-19 pandemic. They also updated the Q&A document on regulatory expectations for medicinal products for human use during the COVID-19 pandemic on 20 April. On 21 April, they set up the fast-track system to support essential medicines for COVID-19 treatment, which includes i-SPOC (industry single point of contact).

- The 21 April publication of the Official Journal of the European Union included several relevant Decisions by the European Parliament and of the Council on COVID-19 measures, such as flexibility instruments to finance budgetary measures, mobilisation of these instruments, and on the mobilisation of the Contingency Margin in 2020 for emergency assistance.

- On 22 April the European Council has voted to adopt the proposal to postpone by one year the date of implementation of the Medical Devices Regulation.
• On 22 April the European Commission announced exceptional measures to support the agri-food sector.

• On 23 April the EMA published a reminder that use of chloroquine and hydroxychloroquine for treatment of COVID-19 patients should be done with caution.

For more information, please get in touch with Charline Quillérou, Associate Director EU at c.quillerou@rpp-group.com

FRANCE

Number of cases: 119,151
Number of deaths: 21,340 (including retirement homes)

• The number of incoming patients to hospitals due to Covid-19 has been steadily decreasing for 9 days. This reinforces the belief that the curve is now a flattening.

• The end of confinement measures will take place 11 May as per the decision by the French President announced, however, this date may be postponed.

• The French Senate adopted the special budget to face the Covid-19 crisis on 23 April. The National Assembly previously adopted the same budget on 17 April. A special committee will meet on 23 April to approve the EUR 110 billion project presented by the government. It will then enter into force after another vote by the National Assembly.

• The French Medical Academy published an opinion on 23 April arguing for an obligation of wearing masks in public space. Town halls will have to provide reusable masks to citizens according to the government, which has renewed the scandal over the mask shortage.

• Some tensions and incidents were recorded between the population and the police in Paris suburban areas, especially in Seine-Saint-Denis from 20 April. The Minister for Internal Affairs called for respect of confinement measures everywhere in France.

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**GERMANY**

**Number of cases:** 150,648  
**Number of deaths:** 5,315

- On 23 April, Chancellor Angela Merkel gave a government statement in the German Bundestag. She once again called for the current social restrictions to be observed in order to prevent a relapse into a negative course of the pandemic. She also declared her support for an EU economic stimulus package and stressed the importance of cooperation between EU countries in the fight against COVID-19.

- On 23 April, the German Government coalition agreed in a meeting on new measures to minimise the negative impact of COVID-19 on German economy and other sectors. Consequently, the short time working allowance for childless persons will be increased from 60% to 80%. The short time working allowance for persons with children will be increased from 67% to 87%. Furthermore, in the gastronomy sector, the VAT rate will be adjusted from 19% to 7% for meals. The reference period for unemployment allowance is extended. In addition to that, home schooling shall be supported with EUR 500 million. Thus, pupils in need will receive EUR 150 and schools will be provided with subsidies for digital equipment.

- On 22 April 2020 the Paul Ehrlich Institute, the Federal Institute for Vaccines and Biomedical Drugs, informed in a press release that the first clinical trial of a COVID-19 vaccine by the drug developer BioNTech is approved in Germany.

For more information, please get in touch with Franziska Schoeps, Associate Director Germany at f.schoeps@rpp-group.com

**ITALY**

**Number of cases:** 187,327  
**Number of deaths:** 25,085

- On 21 April, during a speech in the Senate, Prime Minister Conte said that the government’s strategy for the so-called phase 2 should focus on the following five points:
  1) maintaining social distancing and spreading the use of protective equipment,  
  2) strengthening local health networks,
The Prime Minister also pledged additional measures to support the economy worth at least EUR 50 billion. This is to be added to a EUR 25 billion package approved last month.

More detailed guidelines for the phase 2 are expected to be available by the weekend.

For more information, please get in touch with Daniela Lemme, Associate Director Italy at d.lemme@rpp-group.com

SPAIN

Number of cases: 213,024
Number of deaths: 22,157

The Congress approved a third extension of the state of emergency until 10 May. Although the Ministry of Health stated that Spain is still under a containment phase, the gradual lifting of the lockdown is likely to begin mid-May.

A national seroprevalence study for SARS-CoV2 will begin on 27 April across the territory to provide with accurate information on antibodies developed by 60,000 individuals, and therefore help the government making future decisions on phasing out containment measures.

Several pieces of legislation have been approved concerning a tax reduction to 0% of VAT for medical material, and the setting of maximum retail prices for essential health products such as face masks and hydroalcoholic solutions.

For more information, please get in touch with Kit Greenop, Director RPP Spain at k.greenop@rpp-group.com
UNITED KINGDOM

Number of cases: 133,495
Number of deaths: 18,100

- The Government has shifted its focus from an ‘exit strategy’ from the lockdown measures as Chief Medical Adviser Chris Whitty indicated he expects some degree of lockdown measures to continue until a vaccine or highly effective drug treatments are widely available. The new strategy focuses on increased testing, contact tracing and isolating and designates an Army of 15,000 contact tracers as well as a contact-tracing NHS app.

- Britain’s largest network of diagnostic labs has now been completed; three laboratories each with capacity for testing thousands of samples every day will test samples gathered at ‘drive-through’ testing sites. There are now 27 such sites and work is ongoing to set up a further 50.

- The Government has committed to reaching 100,000 tests a day by the end of April; testing currently sits at around 20,000 a day, just half of the total testing capacity of 40,000.

- Human trials of potential COVID-19 vaccines start in Oxford today (23 April), supported by the Government’s new Vaccine Taskforce. Professor Sarah Gilbert, head of the Oxford team, has suggested a vaccine will be ready by the end of the year if research proceeds without fault, however Chris Whitty predicted the chances of attaining a vaccine this year are ‘incredibly small’.

For more information, please get in touch with Martyna Giedrojc, Associate Director UK at m.giedrojc@rpp-group.com

II. EUROPEAN UNION

- The EU Executive Steering Group on Shortages of Medicines Caused by Major Events held a meeting on 15 April to discuss the progress and implementation of the measures adopted to ensure the continued availability of medicines for European patients during the COVID-19 pandemic.

- On 20 April the European Commission, EMA and the national competent authorities have updated the Q&A document they have developed jointly on regulatory expectations for medicinal products for human use during the COVID-19 pandemic.
On 21 April the EMA, the pharmaceutical industry, and EU Member States launched a fast-track system to support essential medicines for COVID-19 treatment. This includes industry single point of contact, or i-SPOC. The system was set up by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events.

The 21 April publication of the Official Journal of the European Union included several relevant Decisions by the European Parliament and of the Council:
- **Decision** on the mobilisation of the Flexibility Instrument to finance immediate budgetary measures in the context of the COVID-19 outbreak and a reinforcement of the European Public Prosecutor’s Office was officially published in the Official Journal of the European Union.
- **Decision** on the mobilisation of the Flexibility Instrument to finance immediate budgetary measures in the context of the COVID-19 outbreak was also published in the same day.
- **Decision** on the mobilisation of the Contingency Margin in 2020 to provide emergency assistance to Member States and further reinforce the Union Civil Protection Mechanism/rescEU in response to the COVID-19 outbreak.

On 22 April the European Council has voted to adopt the proposal to postpone by one year the date of application of the Medical Devices Regulation to 26 May 2021 instead of 2020. This was tabled by the European Commission and has already been approved by the European Parliament. It will enter into force upon publication in the Official Journal of the European Union, and exceptional derogation from EU competition rules.

On 22 April the European Commission announced exceptional measures to support the agri-food sector. This includes measures for private storage aid (PSA), market support programmes. These measures should be adopted by the end of April, after consulting Member States and potentially adapting the measures.

On 23 April the EMA published a reminder that chloroquine and hydroxychloroquine medicines are known to potentially cause serious side effects, and its use for treatment of COVID-19 patients should be done with caution, particularly for vulnerable patients such as ones with heart conditions or on other medication with similar side effects.

### III. FRANCE

The number of hospitalised patients due to Covid-19 has been steadily decreasing for 9 days. This suggests a flattening of the pandemic curve. On 22 April, 29,741 people were hospitalised, compared to 30,610 on 19 April.

French President Emmanuel Macron announced that confinement measures are extended until 11 May. Further details about the exit strategy were given by the Prime Minister Edouard Philippe and the Health Minister Olivier Véran, on 19 April:
Masks would potentially be mandatory on public transport for the next months. Town halls will have to provide reusable masks to citizens.

Elderly people and vulnerable people will stay at home after the date of 11 May, on a voluntary basis. This concerns 18 million people in France.

Schools, nurseries will reopen from 11 May, but universities will remain closed until September. They will reopen specific measures, depending on the needs of the various regions in France.

The precise exit strategy will be officially launched by the end of the month.

- The French Senate adopted the special budget on 23 April. The National Assembly previously adopted the same budget on 17 April to finance the pandemic crisis. The EUR 110 billion project presented by the government will then enter into force after the meeting of the joint committee on 23 April and a new vote of the National Assembly. This budget will be allocated to health workers bonus, to finance partial unemployment plan, and to help companies facing bankruptcies.

- The Minister for Economy announced on 23 April that companies with headquarters in tax havens will not benefit from bonuses coming from the government.

- The French Medical Academy published on 23 an opinion arguing for an obligation of wearing masks in public space. This opinion restarted the scandal over the mask’s shortage in France. The government is accused by many citizens of failing its duty to protect them by not providing protective masks to the population.

- Riots and other incidents were recorded between the population and the police in Paris suburban areas, especially in Seine-Saint-Denis since 20 April. The police is accused of unnecessary violence. The Minister of Home Affairs declared on 23 April that almost 200,000 controls were realised in Seine-Saint-Denis, which is more than twice the average number of other areas. He acknowledged that confinement measures must be respected everywhere across the territory.

IV. ITALY

- On 21 April, Prime Minister Giuseppe Conte informed the Senate about the government’s plan to move into phase 2, and start gradually lifting the lockdown measures. The Italian government is set to slowly ease the measures from 4 May. The plan should be homogenous and at national level, including the use of protective masks and disinfectant in the workplace and in public spaces.

- The Prime Minister said that the government’s strategy should focus on 5 points – including:
  1) maintaining social distancing and spreading the use of protective equipment,
  2) strengthening local health networks,
  3) support especially ‘Covid hospitals’ specialized in dealing with the virus,
4) boosting the use of tests, both molecular and serological ones,
5) promoting the mapping and tracking of suspicious cases with the use of new technologies
   (e.g. apps and digital solutions).

• The Prime Minister, however, did not give any specific details about which businesses would be
  allowed to reopen first or what limits on movement will be maintained. He said that a more detailed
  plan would be unveiled by the weekend (25-26 April).

• Speaking to the Italian Parliament, the Prime Minister also pledged additional measures to support
  the economy worth at least EUR 50 billion. This is to be added to a EUR 25 billion package approved
  last month. The Italian government has in recent weeks been under pressure by businesses
  organizations to start re-opening the economy.

• Ahead of the meeting of EU leaders on April 23, Conte underlined the need for a powerful European
  response, including the mutualisation of debt. Italy is also backing Spain’s proposals for a EUR 1.5
  trillion EU rescue fund.

V. GERMANY

• On 23 April, Chancellor Angela Merkel gave a government statement in the German Bundestag.
  She once again called for the current social restrictions to be observed in order to prevent a relapse
  into a negative course of the pandemic. She also declared her support for an EU economic stimulus
  package and stressed the importance of cooperation between EU countries in the fight against
  COVID-19.

• On 23 April, the German Government coalition agreed in a meeting on new measures to minimise
  the negative impact of COVID-19 on German economy and other sectors. Consequently, the short-
  time working allowance for childless persons will be increased from 60% to 80%. The short-time
  working allowance for persons with children will be increased from 67% to 87%. Furthermore, in the
  gastronomy sector, the VAT rate will be adjusted from 19% to 7% for meals. The reference period
  for unemployment allowance is extended. In addition to that, home schooling shall be supported
  with 500€ Mio. Thus, pupils in need will receive 150€ and schools will be provided with subsidies
  for digital equipment.

• On 22 April 2020 the Paul Ehrlich Institute, the Federal Institute for Vaccines and Biomedical Drugs,
  informed in a press release that the first clinical trial of a COVID-19 vaccine by the drug developer
  BioNTech is approved in Germany. The approval is the result of a careful evaluation of the potential
  benefit-risk profile of the vaccine candidate. The vaccine candidate is a RNA vaccine, which
  contains the genetic information for the construction of the so-called spike protein of CoV-2 or parts
  thereof in the form of ribonucleic acid (RNA). In the approved first part of the clinical trial, 200 healthy
  volunteers aged 18 to 55 years will be vaccinated with one of several slightly modified vaccine
variants. After an observation period of the vaccinated volunteers, further volunteers of the same age range will be vaccinated in the second part of the clinical trial. The additional inclusion of volunteers with an increased risk of infection or with an increased risk of a severe course of COVID-19 disease is planned in the second part of the clinical trial as well. Different RNA types and different lengths and modifications of the spike protein are tested and the influence of a second vaccination is also examined. The Paul Ehrlich Institute currently assumes that further clinical trials of COVID-19 vaccine candidates in Germany will begin within the next few months.

- A draft of a Second Law for the protection of the population in the event of an epidemic situation of national importance was published on 20 April. The Act introduces a catalogue of regulatory measures that aim to mitigate the impact of COVID-19 on various target groups and sectors.
  - COVID-19 Testing: the Infection Protection Act (IfSG) is amended with an obligation to report any COVID-19 and SARS-CoV-2 cases. This includes notification requirements for patients that are recovered as well as those that received negative laboratory tests.
  - The testing of COVID-19 infections will be increased and extended to individuals that do not show any symptoms which will be covered by the statutory health insurance (GKV).
  - A regulation of the allocation of costs for the reimbursement of pandemic-related additional expenses and shrinking income of hospices is included.
  - A legal framework will be established to ensure the smooth implementation of pilot projects enabling the use of e-prescriptions as well as digital health applications.
  - Privately insured individuals that are in the basic tariff of private health insurance due to a temporary need for assistance, can return to the previous insurance tariff without a new health check.
  - The German Federal Government will cover the costs of European patients with severe COVID-19 that are treated in German hospitals.
  - Immunity can be proven in an immunisation status documentation that is similar to the documentary of vaccination.
  - There will be policy measures developed that aim to ensure the supply of Influenza vaccines in the Influenza season 2020/2021.
  - The German Public Health Institute, the Robert-Koch Institute, will establish an additional contact office for public health services staffed with 40 persons.
  - Veterinarians are allowed to carry out laboratory diagnostic tests to detect pathogens for threatening communicable diseases.
  - With respect to respective decisions by the European Court of Justice, requirements for provisions on blood donations for certain groups such as homosexual, transsexual as well as bisexual individuals will be regularly updated and examined for their necessity.
VI. SPAIN

- The Congress approved on 22 April a third extension of the state of emergency tabled by the government. As of 27 April and until 10 May containment measures will remain the same, except for children up to 14 years old who will be allowed to spend some time outdoors. The Ministry of Health informed that Spain is not yet in a de-escalation phase, but still containing the virus. The gradual lifting of the current lockdown will not happen at least until 10 May.

- A 60,000 population-based seroprevalence study for SARS-CoV2 led by the Ministry of Health and the Carlos III Health Institute will start on 27 April in 36,000 households across the national territory. The survey aims at finding out the percentage of population having developed antibodies against the COVID-19 virus. The results will be taken as a reference for future key political decisions on public health, currently under discussion by a multidisciplinary task force advising the government on how to proceed. The composition of the 16 experts forming the group has been published.

- As part as a decree establishing additional urgent economic measures to face the coronavirus crisis, the government has set a 0% VAT to medical equipment. The full list of 41 products subject to the tax reduction can be found in the Annex of the decree.
  - As a follow up to the order published by the Ministry of Health to set maximum retail prices for health products both for professional and individual use such as masks, medical gloves and hydroalcoholic solutions, the Inter-ministerial Commission for Medicine Prices (CIPM) has established prices for masks and hydroalcoholic solutions in a separate resolution.

VII. UNITED KINGDOM

- Parliament returned on Tuesday (21 April) in a hybrid form of physical and virtual participation. First Secretary Dominic Raab led the Government in Parliament and chairs his first virtual Cabinet meeting today (23 April), though the Government is expected to wait before amending lockdown legislation.

- The Government has shifted its focus from an ‘exit strategy’ from lockdown measures as Chief Medical Adviser Chris Whitty indicated he expects some degree of lockdown measures to continue until a vaccine or highly effective drug treatments are widely available. The Government now pursues a model of testing, contact tracing, and isolating individuals in the hopes of reducing all local infection rates across the country to below the virus perpetuation rate of 1. The NHS’s contact-tracing app using Bluetooth technology tells individuals they are either ‘OK now’ or need to ‘isolate [themselves] and stay at home’, is being trialled at an airbase. The app will use data deliberately anonymised by Apple and Google to ensure authorities and external parties cannot identify specific
users. The app will run in conjunction with an army of 15,000 contact tracers, comprising public officials whose normal duties have been suspended; an elite tier of tracers will be reserved for outbreaks in hospitals and care homes.

- Tracing will build on a projected increase in the number of tests carried out daily, as the first secretary has now indicated that there is capacity for 40,000 tests to be carried out per day. Britain’s largest network of diagnostic labs has now been completed; three laboratories each with capacity for testing thousands of samples every day will test samples from ‘drive-through’ testing sites. There are now 27 such sites and work is ongoing to set up a further 50. Labour leader Keir Starmer has criticised the persistent disconnect between the capacity for testing and the number of tests carried out; daily testing remains around 20,000, half of the total daily testing capacity. The Government is expected to expand the Army’s logistical role to upscale mobile testing units and distribute personal protective equipment (PPE) to meet testing and PPE supply with demand.

- A lack of PPE remains an issue, as the Royal College of Anaesthetists warns three quarters of anaesthetists fear for their own health. The Government’s expert Scientific Advisory Group for Emergencies (SAGE) is now recommending that Britons wear face coverings in crowded environments such as public transport. Masks will protect others from aerosols released by the wearer and are considered necessary to any resumption of normal public services after 26 London transport workers have died from COVID-19. Simple face coverings, rather than real masks, are recommended to ensure hospitals have unabridged supply to appropriate PPE.

- Hopes of comprehensively lifting lockdown measures are firmly pinned on the development and distribution of a vaccine or efficacious drug treatments. Facilitated by the Government’s Vaccine Taskforce, the UK’s first human trials of potential COVID-19 vaccines begin at the Jenner Institute in Oxford today. The trials have had 5,000 volunteers and spearhead the UK’s vaccination development effort along with a leading team at Imperial College London. Professor Sarah Gilbert, head of the Oxford team, suggested that a vaccine will be ready by the end of the year if research proceeds without fault, however Chris Whitty predicted chances of attaining a vaccine this year are ‘incredibly small’.