I. SUMMARY

EUROPEAN UNION

Number of cases: 1,203,381 (including the UK)
Number of deaths: 141,999

- The Medical Device Coordination Group (MDCG) published a guidance document on the regulatory requirements for ventilators and related accessories, setting out regulatory options for supporting production and/or placing ventilators and related accessories on the market during the COVID-19 pandemic.

- On 4 May, the European Commission published an article on the Exscalate4CoV project, which is a scientific consortium established to combat the spread of COVID-19. The project has two working streams: to obtain the virus structure and docking operations.

- On 4 May the European Commission has adopted a package of exceptional measures to further support agriculture and the food sector affected by the current crisis. This package has been proposed on 22 April, and has now been fully adopted and published.

- On 4 May the European Medicines Agency (EMA) published a press release detailing its ‘rapid’ procedures to fast-track development support and approval of medicines and vaccines against COVID-19.
- The EMA chaired the global regulators’ meeting on COVID-19 under the International Coalition of Medicines Regulatory Authorities (ICMRA) on 5 May. Discussions focused on the development of medicines and vaccines and alignment of regulatory requirements to help speed this process.
  - The EMA also published an updated guidance on 4 May on adaptations to the regulatory framework to address challenges arising from the COVID-19 pandemic. It aims to help marketing authorisation holders (MAH) on submitting COVID-19 Individual Case Safety Reports (ICSRs) associated with medicinal products used for treatment of prevention of COVID-19.

- On 5 May, the President of the European Parliament David Sassoli and parliamentary group leaders met with Commission president Ursula von der Leyen to discuss several key issues.
  - The S&D group issued a statement on 5 May after the meeting claiming that the Multiannual Financial Framework and an Recover Strategy must be ambitious and target the countries most affected by the crisis.
  - President Sassoli issues a statement on 6 May, stating that the recovery package must be “sizeable and add value”, and be embedded in a strong MFF.

- Members of the European Parliament (MEPs) have recently submitted parliamentary questions on potentially setting up a European COVID-19 Monitoring Council to coordinate the search of a vaccine and courses of treatment, and on how the Commission would assist Member States in buying vital medical equipment.

- On 7 May, an interview with the EU’s Minister for Foreign Affairs Josep Borrell was published on Euronews regarding the current situation at a European level. Mr. Borrel states that the pandemic emphasised that health is a security issue and not just a Member State’s issue. The European Union would need to be given more competencies, which is currently not part of the EU agenda. Nonetheless, this issue brings forward a debate that is expected to take central stage when planning future strategies for dealing with cross-border health emergencies.

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

**Number of cases:** 137,150  
**Number of deaths:** 25,809 *(including retirement homes)*

- The end of confinement measures will take place on 11 May as per the decision by the French President and confirmed by the Prime minister today.
- Prime Minister Edouard Philippe presented the official exit strategy today (7 May) at 4pm. He confirmed the end of confinement measures taking place on 11 May and presented the precise measures of the exit strategy as well as the colour category map.
- The number of daily admissions in intensive care has increased again since 2 May, according the Health Ministry, strengthening fears of second wave of the pandemic.
- The State Secretary for digital matters, Cédric O, announced on 5 May that the tracking application “Stop Covid” will be ready on 2 June.
- French President Emmanuel Macron presented his plan for culture on 6 May, acknowledging the fact that he will extend the payment rights to artists for one year.

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GERMANY

**Number of cases:** 168,276  
**Number of deaths:** 7,277

- Following a conference of the Federal Prime Ministers and Chancellor Angela Merkel on 6 May, the Chancellor and Bavarian Prime Minister Markus Söder announced the loosening of confinements as well as the decentralisation of the decision competence.
- Angela Merkel and the Prime Minister agreed upon following: (1) the resumption of attendance classes in schools before the summer holidays, (2) the extension of emergency childcare, (3) the permission for certain persons to visit hospitals as well as nursing and
retirement homes, (4) the opening of all shops independently from their size, (5) the permission of resumption of sports training in the open air.

- In addition to that, the Bundesliga, the German Football League, can resume football matches without spectators from Mid-May. The gradual opening of cinemas, theatres, restaurants, hotels as well as beauty salons behave the competence of the federal states.

- Contact restrictions remain until 5 June. Nevertheless, visits of people that belong to two households are allowed. Local authorities now possess the competence to implement confinements if an increase of infection rates becomes evident.

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

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ITALY

- Number of cases: 214,457
- Number of deaths: 29,684

- Italy is now the second country with the highest death toll in Europe, the United Kingdom has surpassed Italy.

- The government is closely monitoring the impact of the containment measures which started on 4 May. If there are encouraging signs, it may become possible for some regions to open up more than others.

- The government is also expected to present a new decree in May, featuring extraordinary investments to reinforce the regional care network and hospitals combatting COVID-19.

- The Italian Minister for Regional Affairs, Francesco Boccia, has said that some shops may be allowed to reopen already before the date first scheduled in the government’s strategy. Around 14 or 15 May, new guidelines will be presented in this regard.

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SPAIN

Number of cases: 256,855
Number of deaths: 26,070

- The Congress approved a fourth extension of the state of emergency, up until 24 May. All legislative measures put into place so far remain in force, although the opposition has shown strong rejection towards the extension, and a fifth initiative is unlikely to go through.

- Almost all regions have requested the Ministry of Health a transition within the exit plan launched by the government last week from phase 0 to phase 1 from May 11. The Ministry will assess the criteria established to approve the transition within the next few days.

- The Health Institute Carlos III has published a report on the impact of COVID-19 on health professionals in Spain. It is the first official evaluation launched by the Institute, attached to the Ministry of Health.

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

UNITED KINGDOM

Number of cases: 201,101
Number of deaths: 30,076

- Prime Minister Boris Johnson will announce the Government’s exit strategy to ease lockdown measures on Sunday (10 May), subject to a strategic review today by the Government’s Scientific Advisory Group for Emergencies (SAGE). Lifting is expected to come incrementally from Monday; outdoor activities beyond essential activities and one daily exercise are expected to be sanctioned. Businesses where social distancing can be managed, such as those working on construction sites, will be encouraged to return from Monday.

- Scottish First Minister Nicola Sturgeon has indicated limited social gatherings will be permitted within weeks, and Scottish primary school children will return to school in June.
• The Bank of England predicts the UK economy will shrink by 14 percent this year if social distancing measures are only phased out from June through September. The Government’s support measures are phased out over the same timeframe. The BoE warns this might be the worst economic crisis in 300 years.

• The UK Government has faced criticism for artificially inflating the number of daily tests to meet its self-imposed 100,000 target by the end of April, as capacity remains low. Johnson has set a new target capacity of 200,000 a day by the end of May; Opposition leader Keir Starmer has urged the target to be raised to 250,000, and for the Government to recruit an additional 32,000 contact tracers beyond the Government’s 18,000 tracers currently in training.

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

- The Medical Device Coordination Group (MDCG) published a guidance document on the regulatory requirements for ventilators and related accessories. This guidance document sets out several regulatory options for supporting production and/or placing ventilators and related accessories on the market during the COVID-19 pandemic. The Covid-19 context warrants the application of the derogation procedure, meaning that the competent authorities may authorise devices even if the applicable conformity assessment procedures are incomplete, if needed.

- On 4 May, the European Commission published an article on the Exscalate4CoV project, which is a scientific consortium established to combat the spread of COVID-19. This is part of EXCALATE (ExaSCale smArt pLatform Against paThogEns), one of most powerful supercomputing platforms in the world. It is supported by EUR 3 million of emergency EU funding and coordinated by Italian pharmaceutical company Dompé. The project has two working streams: to obtain the virus structure, and docking operations. Should no promising results be found, a search for a completely new drug will take place.

- On 4 May the European Commission has adopted a package of exceptional measures to further support agriculture and the food sector affected by the current crisis. This package has been proposed on 22 April, and has now been fully adopted and published. Measures include private storage aid, flexibility for market support programmes, and temporary derogation from EU competition rules. Member States with remaining rural development funds can also use this to support farmers and small agri-food businesses in 2020.

- On 4 May the European Medicines Agency (EMA) published a press release detailing its ‘rapid’ procedures to fast-track development support and approval of medicines and vaccines against COVID-19. In terms of support, some mechanisms include rapid scientific advice of a maximum of 20 days compared to the usual 40-70, and rapid agreement of paediatric investigation plans (PIPs) to 20 days compared to the usual 120 days, and compliance checks to a maximum of 4 days. Regarding evaluation in authorisation and post-authorisation procedures, a rolling review procedure approach is taken with each cycle requiring around 2 weeks, as well as an accelerated assessment of maximum 150 days compared to the usual 210.

- The EMA chaired the global regulators’ meeting on COVID-19 under the International Coalition of Medicines Regulatory Authorities (ICMRA). The EMA published the highlights of the meeting on 5 May. Discussions focused on the development of medicines and vaccines and alignment of regulatory requirements to help speed this process. Participants expressed concerns about multiple small, rather than large, clinical trials, the need for development of priority criteria for planned trials, and the need for inclusion of vulnerable or neglected populations in such trials.
The EMA also presented the guidance on adaptations to the regulatory framework to address challenges arising from the COVID-19 pandemic, which it jointly developed with the European Commission and the European medicines regulatory network. More specifically, an update guidance was published on 4 May for marketing authorisation holders (MAH) on submitting COVID-19 Individual Case Safety Reports (ICSRs) associated with medicinal products used for treatment of prevention of COVID-19.

- On 5 May, the President of the European Parliament David Sassoli and parliamentary group leaders met with Commission president Ursula von der Leyen to discuss several key issues. These included the Commission Work Programme for 2020, the revised Multiannual Financial Framework (MFF) proposal, and a Recovery Plan for COVID-19.
  - The S&D group issued a statement on 5 May after the meeting claiming that these plans must be ambitious and target the countries most affected by the crisis.
  - President Sassoli issues a statement on 6 May, stating that the recovery package must be “sizeable and add value”, and be embedded in a strong MFF. This should keep in mind the asymmetry caused by the pandemic within Europe and address this issue in a timely manner.

- Members of the European Parliament (MEPs) have also been actively addressing the European Commission regarding COVID-19. Most notably, MEP Victor Negrescu (EPP, Romania) on 4 May submitted a parliamentary question on potentially setting up a European COVID-19 Monitoring Council to coordinate the search of a vaccine and course of treatment. Also, MEP Miriam Dalli (S&D, Malta) submitted a PQ on 6 May asking the Commission how it would assist Member States in buying vital medical equipment, including in prices negotiations.

- On 7 May, an interview with the EU’s Minister for Foreign Affairs Josep Borrell was published on Euronews regarding the current pandemic situation at a European level. Mr. Borrell states that the pandemic emphasised that health is a security issue and not just a Member State’s issue. He also stated that better coordination of future health emergencies is needed, such as pooling resources. On this regard, the European Union would need to be given more competencies, which would need to be discussed among Member States. This would also require renegotiation of Treaties, which is currently not part of the EU agenda. Nonetheless, this issue brings forward a debate that is expected to take central stage when planning future strategies for dealing with cross-border health emergencies.

### III. FRANCE

- Confinement measures in France will officially end on 11 May, however, this could be postponed if the pandemic rises in the next days, or if violations of confinement measures increase.
• The Prime Minister Edouard Philippe presented the official exit strategy on 7 May at 4pm. He confirmed the end of confinement measures will effectively take place on 11 May and also presented the precise measures of the exit strategy.

• Moreover, the Prime Minister also presented today (7 May) the definitive French coloured map categorising the various French regions in terms of infection severity. Three colours were presented: red, orange and green, and special measures are attached for all of them. Red regions have a stricter end of confinement measures than orange and green.

• The number of daily admissions in intensive care has increased again since 2 May, according to the Health Ministry. This increasing is the result of a loosening in confinement measures observed two weeks ago across the country, mainly because of the good weather. However, these numbers show the real risks of a second wave of the pandemic.

• The State Secretary for Digital Matters, Cédric O, announced on 5 May that the tracking application “Stop Covid” will be ready on 2 June. This application will not be mandatory to use, and will help tracking infected people, and inform the individuals who have been in contact with the infected ones. It will be subject to a separated vote by the Parliament, according to the Prime Minister.

• The official airline Air France has published a press release on 7 May in which it announced a net loss at EUR 1,8 billion, entirely cause by Covid-19 pandemic. The company will start negotiations with the unions to a potential workforce cut. The French State announced a EUR 7 billion bank loan to help the company.

• French President Emmanuel Macron presented his plan for culture on 6 May, acknowledging the fact that he will extend the payment rights to artists for one year. He plans also to reopen libraries, museums, bookstores, art galleries from 11 May. Theatres will open afterwards.

• The national survey company (Ipsos) published the results of an inquiry on 6 May: 51% of French people cancelled at least one medical appointment since the beginning of the pandemic.

IV. ITALY

• Italy is now the second country with the highest death toll in Europe, the United Kingdom has now surpassed Italy.

• The Italian Minister for Health, Roberto Speranza has said that the government will closely monitor the impact of the lifting of containment measures which started on 4 May. He underlined that he wanted to accelerate as much as possible the lifting of the containment measures, if there are encouraging signs. It may become possible to open up more in some regions that in others, while remaining cautious where needed, he said. However, scientists remain cautious.
• The government is also expected to present a new decree in May, featuring “extraordinary investments” to reinforce the regional care network and hospitals combatting COVID-19.

• On 6 May, The Italian Minister for Regional Affairs, Francesco Boccia, said that some shops may be allowed to reopen already before the date first scheduled in the government’s strategy. Around 14 or 15 May, new guidelines will be presented regarding the reopening of beauty salons and hairdressers, some of which may be allowed to reopen already by 18 May in some regions. It was initially scheduled that these would have to wait until 1 June.

V. GERMANY

• Following a conference of the Federal Prime Ministers and Chancellor Angela Merkel on 6 May, the Chancellor and Bavarian Prime Minister Markus Söder announced the loosening of confinements as well as the decentralisation of the decision competence in terms of establishing and loosening further restrictive measures to the federal states.

• Angela Merkel and the Prime Minister agreed upon following: (1) the resumption of attendance classes in schools before the summer holidays, (2) the extension of emergency childcare, (3) the permission for certain persons to visit hospitals as well as nursing and retirement homes, (4) the opening of all shops independently from their size, (5) the permission of resumption of sports training in the open air.

• In addition to that, the Bundesliga, the German Football League, can resume football matches without spectators from Mid-May. The gradual opening of cinemas, theatres, restaurants, hotels as well as beauty salons behove the competence of the federal states.

• Several prime ministers, including Schleswig-Holstein’s prime minister Daniel Günther as well as prime minister of North-Rhine Westphalia, Armin Laschet, welcomed the decision to decentralise the competences and to grant the federal states to decide on confinements.

• Contact restrictions remain until 5 June. Nevertheless, visits of people that belong to two households are allowed. Local authorities now possess the competence to implement confinement measures if an increase of infection rate becomes evident.

• On 6 May, the Federal Government announced to lower the value-added tax for dishes in restaurants from 19% to 7% in order to flatten the negative economic impact on the gastronomy sector. This regulation applies from 1 July 2020 to 30 June 2021. A respective draft law will be initiated by the government parties and can be expected for the coming weeks.
VI. SPAIN

- A fourth extension of the state of emergency was approved in the Congress with 178 votes in favour, 75 against and 97 abstentions. While the Catalan Republican Left party and the Popular Party opposed, both the Basque National Party and the Citizen’s Party supported the President’s initiative. These moves show a different party dynamic within the crisis and increasing tensions amongst political forces. The state of emergency will in any case be prolonged until 24 May, a fifth extension being possible yet unlikely. All legislative measures such as decrees and legal orders put into place to tackle the crisis remain in force. During his intervention, President Pedro Sánchez informed that the government is planning on setting days of official mourning and a tribute for COVID-19 victims.

- Most of the regions in Spain have requested the Ministry of Health a transition from phase 0 to phase 1 of the exit strategy as of 11 May, except for Catalonia and Castilla y León. The Ministry is currently reviewing the proposals. Phase 1 would mean a partial start of some activities such as social contact in small groups, opening of markets, bars and restaurants, cultural centres, and places of worship under capacity restrictions.

- The non-permanent parliamentary Committee for social and economic reconstruction had its first session in the Congress today 7 May. During the inaugural meeting, the Committee has set up its workplan and elected its president, Patxi López (PSOE); first vice president, Enrique Santiago (UP); and second vice president, Guillermo Mariscal (PP).

- The Health Institute Carlos III has published a report on the impact of COVID-19 on health professionals in Spain, which analyses 30,660 cases. The results are as follows:
  - 76% of health professionals infected with COVID-19 are women aged 46 on average;
  - The most common symptoms for these workers are cough, fever, shivers, and sore throat.
  - 10.9% of infected workers have been hospitalized, 16.5% have developed pneumonia, 1.2% has been transferred to an intensive care unit, and 0.1% has died.
  - The study evaluates demographic, clinic and epidemiologic features as well as other conditions affecting the severity of the virus.
VII. UNITED KINGDOM

- Boris Johnson will announce the Government’s exit strategy to ease lockdown measures on Sunday (10 May), subject to a strategic review today (7 May) by the Government’s Scientific Advisory Group for Emergencies (SAGE). Lifting is expected to come incrementally from Monday, with each easing increment subject to subsequent government scrutiny to assess the impact of measures on the reproduction rate of the virus.

- The Government is set to ease restrictions on outdoor leisure activities from Monday. Sunbathing, rambling and general idling outside will now be permitted, social distancing permitting; outdoor activities have been restricted to essential activities and one daily exercise through April. The Government has changed its core message to urge people to ‘Stay Safe’ rather than ‘Stay Home’, while the Communities Secretary Robert Jenrick has said localised lockdowns could be introduced as national restrictions are lifted.

- Scottish First Minister Nicola Sturgeon has already announced plans to ease lockdown measures. A consultation on lockdown easing has been running for two weeks, and the Scottish Government will permit limited social gatherings within weeks and allow primary school children to return to school in June.

- Opposition leader Keir Starmer has called for national consensus on the next phase of the COVID-19 response as public approval of stringent lockdown measures remains high but the COVID-19 economic crisis deepens. Starmer has indicated his support for an extension of lockdown measures and a structured approach to easing restrictions done in conjunction with local authorities and devolved nations; he has further urged the Government to introduce bespoke support measures for industries and sectors.

- Reopening the UK economy is the key aim through May as the scale of the economic crisis elicited by COVID-19 deepens. The Bank of England has predicted the economy will shrink 14 percent this year if social distancing measures are only phased out from June through September and warned the UK might be facing the worst recession in 300 years. The Government’s support measures such as the job retention scheme will likely have to be phased out over the coming months and a greater onus put on people to return to or find work. Chancellor Rishi Sunak has already indicated that financial support to suspended workers will be reduced by at least 20 percent to 60 percent of their wage from July as concerns mount that firms have taken advantage of support schemes to unnecessarily suspend workers and ease their own wage burden. Businesses to be encouraged to return from next week will be those where social distancing can be observed, such as businesses operating on construction sites. Those commuting to work will likely be required to observe social distancing on public transport, while hauliers and taxi drivers may be required to leave every other
seat in their vehicles empty as they return to work; such alternate seating has already been observed in parliament buildings across the UK.

- The Scottish, Welsh and UK governments are continuing to develop their ‘test, track and trace’ approaches to combatting COVID-19. The Scottish Government will introduce its ‘test, trace, isolate, support’ programme to groups already being tested, such as NHS and social care workers, before quickly expanding coverage as testing capacity increases. The Scottish Government aims to process 8,000 tests a day by mid-May. The UK Government has been criticised after artificially inflating the number of daily testing figures to meet its self-imposed 100,000 target by the end of April; tests have since fallen to around 70,000. Capacity for testing has stubbornly plateaued at just over 100,000, and persistent logistical difficulties and lack of demand for testing have pushed the daily testing figure down this week. The Government faces further logistical challenges as hundreds of thousands of tests taken at new ‘drive-through’ diagnostic centres are yet to be issued to GPs and local authorities. In his return to Prime Minister’s Questions on Wednesday, Johnson nonetheless set a target of UK capacity for 200,000 tests a day by the end of May. Keir Starmer has pushed the Government to raise its targets to 250,000 daily tests, and to recruit an additional 32,000 contact tracers beyond the Government’s 18,000 tracers currently in training.