

# TACKLING CORONAVIRUS (COVID-19) CONTRIBUTING TO A GLOBAL EFFORT



# Regulatory Quality and COVID-19: Managing the Risks and Supporting the Recovery

Note by the Secretariat in consultation with the Chairs and the Bureaus of the Regulatory Policy Committee and the Network of Economic Regulators

- Regulatory issues are vital at nearly every stage of resolving the health crisis and its social
  and economic effects. Lifting non-critical administrative barriers can help expedite the delivery
  of critical products. "Emergency" regulations can be adopted through "fast-track" procedures. This
  does not mean, however, an absence of scrutiny, and can be combined with careful review after
  implementation and, potentially, sunset clauses.
- Ensuring that enforcement of such measures is proportionate to the level of risk can help limit unnecessary administrative burdens on citizens, businesses and the public sector.
- In a context where consulting with all potentially affected parties on urgent measures is challenging, policy makers may rely on advisory groups consisting of experts from all relevant areas. On crucial decisions, at least social partners and local governments might still be consulted, if time allows.
- A wide array of international regulatory co-operation approaches can be used to align
  government responses. This may involve international evidence gathering and sharing to aid in
  the design of emergency rules, aligning regulations or using mutual recognition to expedite
  administrative processes and facilitate the trade of essential products, such as protective
  equipment, for example.
- Innovative approaches can make policies more effective. Digital technologies, including
  artificial intelligence and big data, can help provide relevant information, faster, to those designing
  regulations. Recognising the behavioural drivers of human actions and factoring them into policy
  responses can increase effectiveness.
- Ensuring optimal outcomes for investors, workers and consumers is more important than
  ever in network sectors such as e-communications, energy, transport and water. By
  adhering to good governance practices and robust decision-making processes, economic sector
  regulators can help ensure the quality, reliability and affordability of critical services and the
  soundness and predictability of their own decision-making.

## Regulation – at the heart of the response to COVID-19

Resolving the health crisis and the ensuing economic and social predicament involves regulatory decisions at nearly every stage and in nearly every area. Regulation affects the availability of tools and products to identify and fight the disease (tests, products and devices). Regulation frames the ability of public utilities to maintain critical services, of food to be produced and delivered, of essential services to continue functioning – even in a lockdown situation, where much of both the private and the public sector no longer function normally. The current situation makes the need for trusted, evidence-based, internationally co-ordinated and well-enforced regulation particularly acute. Without it, potential consequences include the collapse of healthcare facilities and major avoidable loss of life. Beyond the immediate crisis response, regulatory issues are also at the heart of economic and social recovery, as well as better preparedness for future crises.

### Applying good regulatory practice, even in a crisis

During a crisis, when time is of the essence, it becomes hard to anticipate, analyse and thoroughly discuss the impacts of regulations designed to deal with urgent issues. This, however, need not mean that these "emergency" regulations adopted in haste receive "carte blanche" treatment. Well-designed regulatory systems can comply with tried and tested recommendations on regulatory policy and governance, even in a crisis. This is also true for the rule of law: citizens might agree with limiting their rights (e.g. movement, privacy) at one point during these challenging times -- though caution and discernment remain critical (e.g. confinement measures adopted across a wide range of countries or the tracking of Covid-positive patients using GPS). Nevertheless, this need not imply that they be stripped of their essential rights over the longer term. Once the crisis is over or its impacts dip below a critical threshold, all regulations adopted through a fast-track procedure should be subject to careful post-implementation reviews. A number of regulators already include sunset clauses and obligatory review clauses in the emergency regulations they are adopting. For example, the Canadian Transportation Agency has adjusted certain regulatory requirements related to compensation up to 30 June.

Similarly, during this crisis, consultation with all potentially affected parties on urgent measures becomes challenging. A rapid response, to be effective, still needs to be based on and informed by evidence and scientific expertise. Policy makers can therefore rely on advisory groups consisting of experts from all relevant areas, such as the *comité analyse recherche et expertise* (CARE) in France). Also, if time allows, crucial decisions may be subject to consultation through snap meetings with representatives of the tripartite, local governments or major NGOs. The political responsibility and accountability for these decisions still lies with those making the decisions – politicians and policy makers. It is, however, very important to provide sufficient information in a transparent manner to all stakeholders so that they clearly understand the purpose and necessity of these, sometimes drastic, measures.

#### Stronger together

As the world has become more closely interconnected, the risks posed by infectious diseases epidemics have grown. Pandemics such as the COVID-19 know no borders, and are hard to address through individual and isolated country responses. **Co-ordinating government policies can make crisis response more effective,** because solutions often require inputs from a number of countries, including flows of goods and expertise, and because control (of borders, spread etc.) is – at best – extremely difficult, if not impossible. However, immediate reactions to COVID-19 have often been unilateral, relying on national approaches to protect from a threat perceived as largely coming from outside. Overwhelmingly, in

the extremely short time it took the virus to spread, countries have struggled in their responses and rarely managed to effectively learn from other each other's' experience.

The work of the OECD Regulatory Policy Committee shows that collective action is critical when it comes to guaranteeing the effectiveness and relevance of regulatory efforts worldwide. This can involve a wide array of approaches: from international evidence gathering and sharing (on the profile of the virus and the affected population, the means and routes of contagion and remedies - medical or other) to inform the emergency rules that need to be adopted; to regulatory alignment and mutual recognition processes aimed at expediting administrative approvals (by accepting product certification and approval from other jurisdictions for example)3 and limiting the regulatory barriers to trade in essential products,4 including personal protective equipment, medical devices and new diagnostic tests and treatments. International organisations (IOs) provide essential platforms to promote cooperation, exchange scientific expertise, design evidence-based policies and co-ordinate approaches across countries. 5 There is a wide range of IOs supporting governments in their fight against the pandemic and in dealing with its aftermath. To cite just two examples, the WHO collects scientific evidence on diseases, informs the public with constant updates on the situation throughout the world,8 and develops a range of technical guidance to reinforce readiness and responses to COVID-19.9 The OECD compiles real-time data and analysis on the multifaceted consequences of the global health crisis, from health to education, employment and taxes and providing tailored guidance to help countries during and after the crisis in a consolidated website. 10

#### **Ensuring compliance**

The effectiveness of the adopted measures hinge on the quality of regulatory enforcement. 11 Enforcement of health and safety regulations on urgently needed medical or protective supplies can be organised and conducted in a way that minimizes delays and obstacles, and is commensurate to risk. While safeguarding patients and medical workers as well as the general public from unsafe products is indispensable, time is of the essence, and undue burden or delays can create considerable harm. This was all too evident in the barriers to production and distribution of masks and ventilators in several countries. Administrations can avoid unnecessary burdens for citizens, businesses and other stakeholders by enabling the use of digital instruments such as mobile applications (as was done e.g. in Greece from the start, and more recently adopted in France) rather than paper forms, and avoiding procedures altogether if these do not demonstrably help address contagion risks. 12 The enforcement of quarantine and lockdown measures can be geared toward promoting and sustaining voluntary compliance. Controls can focus on behaviours that effectively create risks (e.g. groups of people or disrespect of safety distances etc.) rather than on "formal" non-compliances (e.g. paper documentation). Finally, for economic activities that continue to operate (e.g. food production), controls can be kept only for situations identified as presenting extreme risks, and focus exclusively on critical safety issues, so as to minimise possible virus exposure for both inspectors and workers.

#### **Cutting red tape**

Administrative barriers that might have their rationale in "normal" times could be lifted, at least temporarily, to expedite the delivery of critical products. <sup>13</sup> Relevant examples include the procedures for obtaining all necessary permits for putting masks, testing kits, protective equipment, disinfection supplies and also life-supporting devices etc. on the market. There are many recent examples of such temporary lifting or of "relaxed application" of requirements, e.g. in the US for PPE and ventilators, and the Australian Government Therapeutic Goods Administration (TGA) cutting red tape to allow distilleries to produce hand sanitiser). <sup>14</sup> Of course, strict procedures for using eventual vaccines or treatments might remain in place, but the testing procedures could be accelerated as much as possible. Avoiding formal

approvals on products or suppliers that do not substantially reduce risk, or are not risk-proportionate can help save time, and lives. Restrictions on the involvement of adequately qualified and accredited testing providers can be reconsidered and lifted if there is no overwhelming public health reason for them, as one of the main challenges faced by governments in implementing effective responses is the lack of detailed and reliable data on the spread of the virus among their populations. Testing e.g. in France and Italy was slowed down by such limitations, which have been gradually but not always entirely lifted.

#### Using new technologies for better, faster regulation

Digital technologies, powered by artificial intelligence and big data, provide great opportunities to cut through this major information problem and increase regulatory capacity, but this need not be done without safeguarding essential individual rights. They provide avenues for monitoring the outbreak (e.g. BlueDot software in Canada), track symptoms (e.g. NCOVI mobile app in Vitenam, Self Diagnosis Mobile App in South-Korea or C-19 COVID Symptom Tracker mobile app in UK), trace contacts (e.g. TraceTogether in Singapore, StopCovid In France or Private Kit developed by the MIT) and support containment measures (e.g. drones in France or Home Quarantine app in Poland). These, in turn, can help policy makers adapt regulatory responses accordingly and monitor compliance with the measures taken by governments. There may be issues of balancing or reconciling privacy, individual rights and effectiveness, all of which can benefit from the insights developed in regulatory policy and regulatory management.

Recognising the behavioural drivers of human actions, and factoring them into policy responses is particularly important.<sup>17</sup> The effects of social context and behavioural biases on "rational" decision making<sup>18</sup> may be amplified in ways that make effective policy responses more difficult to manage. Some examples have already emerged – people may not take heed of government policies to socially distance or quarantine despite clear evidence of the need to do so, or "hoarding behaviour" may spread by the mere image of some others doing exactly the same. Policy responses require quick and widespread behavioural change, including significant changes to daily routines that become difficult to manage amidst fear and panic. Mixed, confusing, or excessively "confident" messaging by public authorities (which are later reversed or overtaken by events) may worsen the risk of growing distrust.<sup>19</sup> Excessively rigid or disproportionate enforcement and burdensome procedures tend to harm the legitimacy of public authorities, voluntary compliance, and longer-term support.

## Keeping the economic engine running

Guaranteeing security of supply and quality of service, protecting customers and bolstering the efficient use of resources and competition are objectives shared by economic regulators worldwide. At a time of unprecedented change in the use of infrastructure services such as e-communications, energy, water and transport, as lives and ways of working are disrupted globally, regulators need to significantly and rapidly adapt. Across jurisdictions, immediate measures have included suspending specific charges for consumers (e.g. emergency measures to defer or stagger the payment of utility bills), relaxing some compliance or reporting requirements for regulated entities (e.g. prolongation of deadlines to meet regulatory requirements), or providing guidance to consumers on usage of network services (e.g. on the use of mobile data and internet during confinement).

More than ever, economic regulators require robust governance to deliver on their mandates. The crisis highlights the importance of co-ordinated action and information sharing, as a variety of public bodies are required to act jointly to uphold the functioning of markets. Economic regulators may be required to provide data on, for example, vulnerable consumers, network capacity, the changing patterns of individual markets and the financial prospects of market actors to governments designing support and relief

packages. For example, the Italian Regulatory Authority for Energy, Networks and Environment (ARERA) reports more frequent contacts between the regulator and operators, public institutions and local regulators, through formal co-ordination roundtables. Regulators also need to ensure that their special measures and those of governments are appropriately aligned - while at the same time maintaining a reasonable level of institutional autonomy and independent and evidence-based decision making. International co-operation is key and is already taking place, mainly through existing sectoral or regional networks of regulators (e.g. the Joint Statement from the European Commission and the Body of European Regulators for Electronic Communications (BEREC) on coping with the increased demand for network connectivity due to the Covid-19 pandemic<sup>20</sup>). In addition, the internal governance and processes of regulators - the robustness of rapid decision making, the adaptability of staff, the capacity for non-digital essential inspections, and so on - are key contributors to effective performance in the face of these unprecedented conditions. Finally, while attention today is on urgent priority measures, medium and long term considerations are important elements to inform immediate responses. These considerations can include setting time limits for exceptional measures, and projecting how industries and market structures will evolve in light of the crisis and what impact this may have on the mandate and resourcing of regulators themselves.

This exceptional situation underlines the importance of regulation as one of the most relevant levers of government action, along with taxing, spending and communicating and the relevance of the tools and procedures recommended in the 2012 *OECD Recommendation on Regulatory Policy and Governance* to uphold its quality even in times of crisis.

#### **Notes**

<sup>1</sup> This is reflected in the recent G20 statement on trade and investment: "...emergency measures designed to tackle COVID-19, if deemed necessary, must be targeted, proportionate, transparent, and temporary, and that they do not create unnecessary barriers to trade or disruption to global supply chains, and are consistent with WTO rules...". G20 Trade and Investment Ministerial Statement, 30 March 2020, <a href="https://q20.org/en/media/documents/q20">https://q20.org/en/media/documents/q20</a> trade%20&%20investment ministerial statement en.pdf.

<sup>&</sup>lt;sup>2</sup> OECD (2013), International Regulatory Co-operation: Addressing Global Challenges, OECD Publishing, Paris, <a href="https://doi.org/10.1787/9789264200463-en">https://doi.org/10.1787/9789264200463-en</a>.

<sup>&</sup>lt;sup>3</sup> "Beyond Containment: Health systems responses to COVID-19".

<sup>&</sup>lt;sup>4</sup> On IRC approaches to mitigate regulatory barriers to trade, see OECD (2017), International Regulatory Cooperation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies, OECD Publishing, Paris, <a href="https://doi.org/10.1787/9789264275942-en">https://doi.org/10.1787/9789264275942-en</a>.

<sup>&</sup>lt;sup>5</sup> OECD (2016), International Regulatory Co-operation: The Role of International Organisations in Fostering Better Rules of Globalisation, OECD Publishing, Paris, <a href="https://doi.org/10.1787/9789264244047-en">https://doi.org/10.1787/9789264244047-en</a>.

<sup>&</sup>lt;sup>6</sup> This is documented in a forthcoming work of the OECD Regulatory Policy Division, dedicated to international regulatory co-operation.

<sup>&</sup>lt;sup>7</sup> www.who.int/gho/publications/world\_health\_statistics/en/.

<sup>8</sup> www.who.int/emergencies/diseases/novel-coronavirus-2019.

- <sup>9</sup> The dedicated WHO technical guidance website now includes specific Guidance for laboratories shipping specimens to WHO reference laboratories that provide confirmatory testing for COVID-19 virus: www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance.
- 10 www.oecd.org/coronavirus/en/.
- <sup>11</sup> OECD (2014), *Regulatory Enforcement and Inspections*, OECD Best Practice Principles for Regulatory Policy, OECD Publishing, Paris, <a href="https://doi.org/10.1787/9789264208117-en">https://doi.org/10.1787/9789264208117-en</a> and OECD (2018), *OECD Regulatory Enforcement and Inspections Toolkit*, OECD Publishing, Paris, <a href="https://doi.org/10.1787/9789264303959-en">https://doi.org/10.1787/9789264303959-en</a>.
- <sup>12</sup> The suspension of deadlines and of the submission of paper documents has been adopted in a number of countries. See e.g. in Brazil: <a href="http://tozzinifreire.com.br/en/boletins/covid-19life-scienceshealthcare-anvisa">http://tozzinifreire.com.br/en/boletins/covid-19life-scienceshealthcare-anvisa</a>.
- <sup>13</sup> On this section, see also this 2015 study: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355722/#bib22">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355722/#bib22</a>.
- <sup>14</sup> See e.g. the UK relaxing administrative requirements and barriers to imports of PPE and hand sanitiser, details available at <a href="https://www.gov.uk/government/news/regulations-temporarily-suspended-to-fast-track-supplies-of-ppe-to-nhs-staff-and-protect-companies-hit-by-covid-19">https://www.gov.uk/government/news/regulations-temporarily-suspended-to-fast-track-supplies-of-ppe-to-nhs-staff-and-protect-companies-hit-by-covid-19</a> In Brazil, the National Health Surveillance Agency (ANVISA) published ANVISA RDC No. 348/2020, available at <a href="https://tozzinifreire.com.br/en/boletins/covid-19life-scienceshealthcare-anvisa">https://tozzinifreire.com.br/en/boletins/covid-19life-scienceshealthcare-anvisa</a>. The US FDA issued guidance relaxing enforcement of requirements on PPE:
  <a href="https://www.fda.gov/media/136449/download">www.fda.gov/media/136449/download</a> and most recently has done so also on ventilators' approval:
  <a href="https://www.theregreview.org/2020/04/03/runkle-fda-relaxes-rules-ventilators-covid-19">https://www.theregreview.org/2020/04/03/runkle-fda-relaxes-rules-ventilators-covid-19</a>.
- <sup>15</sup> This is the result of research by a joint team of OECD and World Bank Group experts who reviewed a number of initiatives developed across the world in this context (both in OECD and non OECD countries). The work is under finalisation.
- <sup>16</sup> See recent proposals on technical solutions to reconciling privacy and "track-and-trace" e.g. here: <a href="https://www.pepp-pt.org">https://www.pepp-pt.org</a> and <a href="https://www.pepp-p
- <sup>17</sup> During this emergency situation, the OECD has been supporting the development of the COVID-19 Behavioural Insights Working Group as a forum for policy makers and practitioners to collaborate and exchange ideas, resources, findings and approaches in addressing COVId-19. The first event, taking place in early April 2020, will provide lightning talks from France, Japan, South Africa and the United Kingdom on their use of behavioural insights to address the pandemic and facilitate an action-oriented discussion between policy makers.
- <sup>18</sup> For more information about how context and biases impact decision making, as well as solutions for address them, see OECD (2019), *Tools and Ethics for Applied Behavioural Insights: The BASIC Toolkit*, OECD Publishing, Paris, <a href="http://www.oecd.org/gov/regulatory-policy/tools-and-ethics-for-applied-behavioural-insights-the-basic-toolkit-9ea76a8f-en.htm">http://www.oecd.org/gov/regulatory-policy/tools-and-ethics-for-applied-behavioural-insights-the-basic-toolkit-9ea76a8f-en.htm</a>.
- <sup>19</sup> See <a href="https://aisel.aisnet.org/cgi/viewcontent.cgi?article=1166&context=ecis2016\_rp">https://aisel.aisnet.org/cgi/viewcontent.cgi?article=1166&context=ecis2016\_rp</a> on communication in a crisis context and the importance of trust.
- <sup>20</sup> See <a href="https://berec.europa.eu/eng/document\_register/subject\_matter/berec/others/9236-joint-statement-from-the-commission-and-the-body-of-european-regulators-for-electronic-communications-berec-on-coping-with-the-increased-demand-for-network-connectivity-due-to-the-covid-19-pandemic\_for the joint declaration.