# Managing the new political risks in life sciences

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# Managing the new political risks in life sciences

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# Section 1: Foreword

**By John Connolly**

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There are disadvantages to the limelight. As the world hangs on every COVID-related announcement from Pharmaceutical, Research and Medical Device organizations, companies have found that any decision they make is likely be subjected to intense political scrutiny then endlessly analyzed and debated by commentators taking full advantage of hindsight. Some ESG specialists advise companies to act as if all corporate decision-making occurs in the public eye (because even the most private correspondence can become public in an era of state-sponsored hacking and instant social media posts). Many Life Science Companies have had experience of living in such a hyper-transparent future, as the world's hopes and fears rest on the latest laboratory tests or vaccine trials and companies have the undivided attention of the world's political leaders as a result.

This report is based on interviews with a panel of nine executives representing leading life science companies and industry analysts, including pharmaceutical and biotech companies, medical devices companies, and an industry association. We asked our interviewees to speak candidly, and off the record, about the new political risks their industry is facing, and they did so. We have used their views to compile the political risk radar that opens the report.

We then commissioned scholars from Oxford Analytica's global network to produce essays on two of the top concerns the sector faces: first, whether public health budgets will face deep cuts in the wake of the pandemic, and second, how health data privacy will be regulated (particularly for foreign companies doing business in emerging markets).

I want to take this opportunity to thank our clients in the sector for the extraordinary effort they have put forward in these very difficult times. I hope you find this report useful in rising to the new political risk challenges life sciences leaders must manage, and I welcome your feedback.

# Section 2: Introduction

**By Stuart Ashworth**

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## New heroes

The pandemic gave us many new heroes. In the early days, public attention focused on health care workers who worked long hours and struggled against healthcare system capacity limits, along with essential workers who kept services going despite infection risks that were at that time largely unknown. As the world settled in for a series of lockdowns, delivery people became heroes, whether they worked for high-tech retailers or corner grocery stores in the emerging world. Much public gratitude was also directed at technology firms whose new videoconferencing and social media technologies kept us productive and entertained.

Today, a new set of heroes have come to the fore: life sciences companies. In the pandemic's early days, we were informed that the fastest a vaccine had ever been developed was four years; in those first months of lockdown, a four-year wait seemed unimaginably long. But, miraculously, the first COVID-19 vaccines were produced in less than twelve months. Effectiveness of vaccines could be low, we were told (in summer 2020, US coronavirus advisor Dr. Anthony Fauci warned that 75 percent was a more realistic target). Early vaccine tests, however, showed extraordinary efficacy rates, in some cases exceeding 90 percent.

Inevitably, much of the spotlight has shone on the innovators whose science produced these vaccines. But of course, it was a joint effort, requiring heroic performances from companies delivering not only vaccine breakthroughs but also trials, tests, medical devices, and a cold chain of unprecedented complexity. Moreover, the rapid vaccine rollout could not have happened without long hours and unsung heroes in areas ranging from regulatory approval to supply chains, where executives found ways to source pharmaceutical inputs to demanding specifications on an unbelievably short timeline.

As we write, in early 2022, economic output in both the US and Eurozone have exceeded pre-pandemic levels. In many European countries, an equivalent recovery took a decade following the global financial crisis. This relatively rapid rebound from the pandemic recession is little short of a miracle, and it is only possible because of what the life sciences industry has achieved – particularly, but not only, with vaccines, that have given people the freedom to resume working, playing, socializing, and spending.

The pandemic is still with us, of course, with new variants regularly identified. Particularly in the emerging world, many people remain unvaccinated. That said, we move into 2022 with more hope than might have seemed possible in those first days of the pandemic.

## New risks

Of course, life in the political spotlight is not without its downsides. On the one hand, the COVID-19 emergency has boosted public investment in life sciences to levels that may well be unprecedented, and some life sciences companies have reaped share price rewards from being at the front lines of the struggle against the pandemic. On the other hand, political attention can create political risks. Political decisions taken in an emergency – such as weakening patent rights – may prove to have long-term detrimental consequences, some of them unanticipated.

The pandemic has also shaken up geopolitics, adding another source of political risk. The relationship between China and the West has become increasingly tense. Countries have stepped back from their initial beggar-thy-neighbor responses to the pandemic but health nationalism remains an issue. In addition, unprecedented levels of public spending have racked up pandemic debt, including in emerging economies that struggle to repay that debt.

Can life sciences companies manage these new political risks? What risks will companies face if politicians seek to unwind global healthcare supply chains? What risks might arise from pandemic-related economic turmoil? What political risk perils might be lurking "under the radar?"

We asked Oxford Analytica to join us in researching these questions. Willis Towers Watson and Oxford Analytica convened a panel of nine external affairs and risk management professionals, representing pharmaceutical and biotech companies, medical devices companies, industry analysts and an industry association.

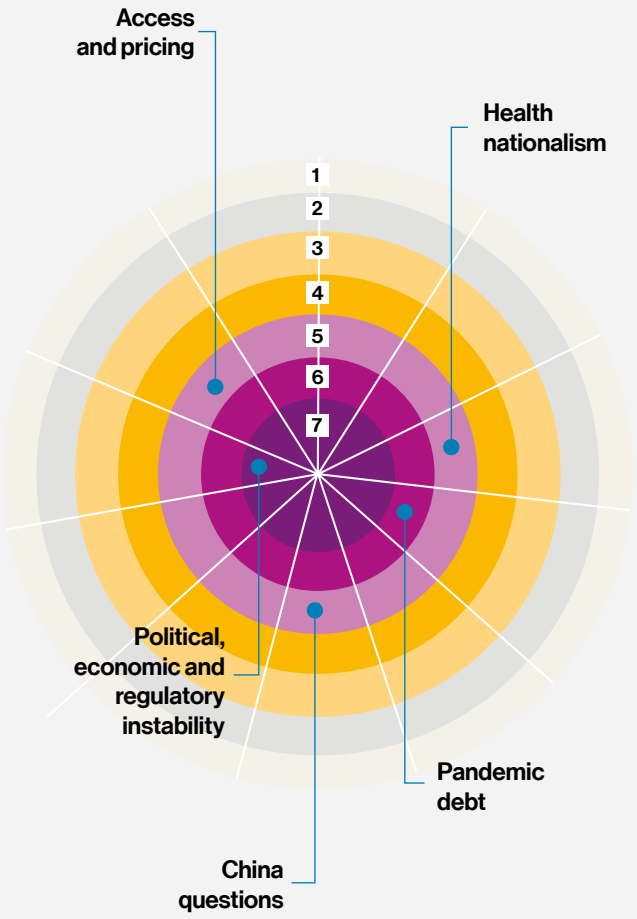
Oxford Analytica and Willis Towers Watson then conducted in-depth interviews with these professionals, to produce the risk radar that appears in the next section. For two of the top risks the executives identified, Oxford Analytica commissioned scholars in its global expert network to produce peer-reviewed essays. These essays cover "Will Europe cut health budgets in the wake of the pandemic?" and "How will regulation of health data privacy evolve in emerging markets?"

We hope you will find Oxford Analytica's findings in these articles to be useful. We sincerely thank the Oxford Analytica contributors who authored the following essays, but most of all we thank the expert panel of life sciences executives who guided the research for their time and insights.

# Section 3: The political risk radar 2022

## Political risk radar for the life sciences sector (ranked by number of mentions)

**Fig 1 –** Risk Radar 2022




*Source: Willis Towers Watson and Oxford Analytica interviews with the executive panel. "Mentions" count the number of panelists who mentioned each risk topic.*

**Under the radar:**
Regulation of health data privacy
IP nationalization

**To identify the top political risks facing the life sciences sector in 2022, Oxford Analytica and Willis Towers Watson convened a panel of nine external affairs and risk management professionals, representing pharmaceutical companies, medical devices companies, industry analysts and industry associations. Oxford Analytica and Willis Towers Watson then conducted in-depth interviews with this panel of executives, to produce the risk radar that appears at left. Below, for each risk on the radar, Oxford Analytica summarizes some of the interview highlights. The views expressed do not necessarily reflect those of Willis Towers Watson.**

## Political, economic and regulatory instability

The top risk on the radar came as a surprise. One thinks of political instability as a problem mainly for companies operating in frontier markets in Africa, Asia or the Middle East. But in nearly every conversation we had with life sciences executives, political, economic or regulatory instability was mentioned as a key concern.

Perhaps one reason for this focus is the elongated timescale on which life sciences companies conduct their business. "When I was working in oil and gas, we had to plan for 30-year life cycles," a risk management executive at a US biotechnology company commented. "For life sciences, it's indefinite." The scale of financial commitment in research, production and relationship development, means life sciences companies are usually in it for the long haul if their investments are to pay off.

Perhaps no sector is more intensely embedded in the political economy of the countries it serves. Life sciences is not only a regulated industry, but also, in many cases, sells to public sector buyers. Hence life sciences companies are profoundly exposed to the quality of a country's politics and governance. "We need a strong national health care system [in our markets]," as one interviewee from an Australian biotech company commented. "It's a long-term strategic risk for us." Another executive came at the same issue from a different angle. "Our market has to be a country with a large middle class," he noted. "Political changes can cause the size of the middle class to grow and recede so this is another reason stability is important."

Middle class citizens, with valuable technical and managerial skills, are often the first to leave if a country becomes unstable. Without long-term stability, of course, it is also questionable whether a large middle class will grow in the first place.

To some degree, globalized business models provide a "hedge" against instability in any single market. But life sciences companies have a harder time utilizing that hedge than many other sectors. "We have multiple locations, but each location needs to be cleared [by regulators] for us to source from that location," one executive pointed out. Hence even if a company has the technical capacity to change production locations, the process of obtaining regulatory clearances may make it impossible to switch in a timely manner. In addition, globalized business models are increasingly coming under threat from trade tensions (an issue discussed further in "health nationalism," below).

Of course, some life sciences companies also face the classic political risks associated with severe turmoil. "We feel a large obligation to patients, and so we will go where they are, even if that country is unstable," said an executive at a European pharmaceuticals company. An industry analyst pointed out that "sanctions are becoming part of the political toolkit," and sanctions are increasingly being used by major trading nations against each other. An executive at an Asian medical device manufacturer noted specific concerns, such as "tensions between military and civilian power, particularly in Thailand and Myanmar;" a US pharmaceuticals executive worried about the "possibility of a China-Taiwan maritime dispute, because such a dispute would interrupt our supplies to Japan, which are all sent by sea."

These varied exposures to political and geopolitical instability put a premium on accurate analysis, as well as risk mitigation. "When we enter a country, we do a deep dive on stability," said an executive at a biotechnology company. "We look at fiscal stability, we look at whether a legislature can bind future instances of that legislature." Several interviewees mentioned a strategy of gradually building up investment to understand a market deeply before committing to it – even if those initial investments are uneconomic. Those early investments may, in some cases, enable a company to influence the long-term stability of the business environment. "Any newly formed regulator will be working out how to regulate," as one executive put it. "We will try to work with them hand in hand as they go." (This point is discussed further in the essay section, below, on regulation of health data privacy in emerging markets, below.)

## Pandemic debt

Given the vital importance of public funding to the health care sector, the second risk on our radar, "pandemic debt," is less of a surprise. Many entities have taken on unusually high debt burdens during the pandemic, from out-of-work households to sectors that have faced declining demand. The primary "pandemic debt" of concern to our panel, however, was the debt taken on by governments – usually public debt relating to healthcare spending, bailout packages, or countercyclical programs such as unemployment insurance.

Since the onset of lockdowns, government debt has skyrocketed. Countries in the Eurozone increased their government debt by an average of a fifth between 2019 and 2021 (and public debt levels now exceed one hundred percent of annual economic output in Italy, Greece, Portugal, Spain, Belgium, France and Cyprus). In the US, government debt rose by roughly a quarter over the same period. In the emerging world, average debt-to-GDP ratios have soared. IMF Fiscal Monitor estimates indicate emerging market debt has risen from 55 percent of output, on average, to 65 percent, over the past two years alone.

For most of our panel, "pandemic debt" concerns involved policy changes impacting national health systems – particularly changes that might be made in the heat of a fiscal crisis, with less consideration for the long-term impacts on public health, innovation or resilience. While the onset of COVID-19 has resulted in a surge in public health spending, pandemic debt could lead politicians to overshoot in the other direction in the years ahead. "Cost containment measures due to recession or austerity, for example, would have significant impact," as one pharmaceuticals executive put it. Healthcare makes up a significant portion of national expenditure in

many advanced economies, and, as a medical devices executive noted, some national healthcare systems are already "underfunded." Japan, despite its relatively strong performance in managing COVID-19 thus far, was singled out for mention.

In addition, a few panelists worried that advanced economies could suffer outright debt crises – perhaps a resurgence of the Eurozone debt crisis – in which countries would be "politically stable but financially unstable and can't afford to pay." In addition to the impact on public healthcare systems, there was concern about rising corporate taxation, as rich countries seek to bring their debt burdens under control. "Efforts by the G20 on big profitable companies" might lead to higher tax rates for pharmaceuticals companies in coming years, noted an executive at an industry association.

Regarding emerging economies, the panel's key concern was debt crises. "Argentina is a good example because of its repeated defaults on its debt," as one executive at a European pharmaceutical company put it. "This risk is hard to hedge." Life sciences companies that avoid the risk by refusing to sell in volatile emerging markets may leave people without access to lifesaving medicines, which can damage the industry's reputation, the executive further noted.

This issue is discussed further in the essay section, below, (see "Will Europe cut health budgets after the pandemic?")

## Access and pricing

As healthcare cost pressures rose in the years prior to the pandemic, many governments increased their use of public tenders. It is possible this trend will spread or intensify in the coming years (especially given the pressures of pandemic debt just discussed). Having the right tender strategy has become an increasingly important pillar of success in life sciences, and a new source of commercial risk.

The use of public tenders has also, arguably, increased political risks relating to access and pricing. "We have to go into tenders for access and the tenders involve exclusivity, so our products could be excluded from a market," as one pharmaceuticals executive noted. Particularly in countries where governance is weak, tenders may be subject to corruption or favoritism, or simply be poorly designed.

Perhaps the panel's greatest concerns, however, revolved around the US market – indeed, specific concerns about US pricing reform were mentioned by five of our panelists. "There is a feeling [among US politicians] that the US is expected to fund the healthcare requirements of the world," as an industry analyst we interviewed put it. The United States has for many years delivered "global public goods," such as international security, global agreements around trade and investment, and international protection of intellectual property rights. The life sciences industry has benefited from many of these policies. As the US "unipolar moment" ends, though, the US may reap less reward from its global efforts, and potentially become more unwilling to provide such global benefits, including in the healthcare field (or so some scholars of international relations argue).

In life sciences, the United States has arguably played a pivotal role in incentivizing global innovation, in part through relatively high prices paid for healthcare goods and services. Will the US continue to play that role? "It is not clear that [the US] Congress is able to resolve the issues of pricing and affordability," as an industry analyst noted. A European pharmaceuticals executive pointed to a "lack of predictability at the US federal level." Because of the outsized role played by the United States in the life sciences sector, US decisions will reverberate globally. As an executive at an industry association noted, "This [access and pricing] is a global challenge, but a significant shift in US domestic policy on this issue could prompt changes in many countries."

The issue of access can also apply to questions of whether individuals can access expensive but life-saving medicines and medical devices – an issue discussed further in "Under the radar," below.

## Health nationalism

For proponents of globalization, the early days of the COVID-19 pandemic were deeply troubling. The initial reaction was, in many cases, "every nation for itself" – countries imposed restrictions on exports of goods they believed to be vital and scarce. More than 75 countries restricted export of medicine or medical products, for instance. This alarming trend then threatened to spread into food. Russia imposed limits on exports of grain; a handful of countries began to follow suit, limiting exports of food commodities. Fortunately, before such controls could produce a global food crisis, most of the measures involving food and both medical products were reversed. (In part, China played a stabilizing role by controlling the initial COVID-19 variant's spread and continuing to export medical products.)

That experience, however, left a scar. "Countries are worried about serving themselves so they are putting up local requirements – especially off the back of COVID-19," as a panelist from a large pharmaceuticals company put it. The public tender process, discussed in relation to the previous risk, has given governments another tool to pursue health nationalism, by favoring local content or requiring local production. "To sell medicine in many countries, you must establish local production, so it becomes a market access play," an executive at a European pharmaceutical company noted. These local production requirements tend to undermine efficiency, because small facilities lack economies of scale. That said, as the executive noted: "we will sometimes make the decision to go in, in order to gain long-term market access."

An industry analyst we spoke to projected that while larger markets would impose localization requirements, "smaller countries seem likely, if political will and capacity allow it, to push for regional access." Supporting that view, the countries our panelists mentioned most commonly as "health nationalism" concerns were the world's largest economies: the United States and China. "The Buy American Act introduced by [US President Joe] Biden's executive order – we are following it closely with respect to where medicines need to be produced," as one panelist noted. That said, localization requirements have also been introduced in smaller markets where operating environments can be challenging; one example mentioned was Algeria.

Over the long term, such measures will tend to undermine the gains in innovation and efficiency that globalized life sciences business models have created. That risk extends beyond localization of production. "At the people level, collaboration and the movement of talent has provided spectacular results for invention," an industry analyst noted. "Parochial nationalism is blocking such movement."

## China questions

For the last risk on our radar, we chose a broad category of risk issues: "China questions." Our panelists mentioned China in regard to every risk discussed above, ranging from localization requirements, to pricing and access, to geopolitical stability. That prominence is in large part due to China's success. "China accounts for 70 percent of the global life sciences supply chain," one industry analyst we spoke to claimed, "and India is not a realistic competitor outside the manufacture of generic drugs for at least a decade." That estimate may be high; by another estimate, China is home to "only" about 13 percent of the plants registered to produce active pharmaceutical ingredients for the US market, for instance (although the share has doubled over the past ten years). But China's role in the life sciences industry, not only as a supplier but also as a market for medicines, is clearly vital.

As the pandemic unfolded, tensions rose between China and many countries with which China maintains active trading relationships. The UK and China sparred over Hong Kong; the EU imposed sanctions over alleged human rights violations; the Japanese government announced that it would pay its companies to relocate production from China; there was a high-altitude conflict between China and India; and the list goes on. In late 2020, trade relations between China and Australia worsened sharply following a dispute about the origins of the novel coronavirus. "We are also worried about China because we are an Australian company," as one executive noted. Some companies are taking action as a result. A US biotech executive said: "We offset every new supply agreement [involving China] with a specific alternate CMO [contract manufacturing organization]."

Of course, China is not simply a production location; as China has grown wealthier, it is becoming a key market for life sciences products. This process brings great opportunities but also a new set of worries. "Tensions between China and the US/EU relate [not only to supply chains but] to access, data, infrastructure, and distribution," a Europe-based interviewee noted. Other executives chimed in on concerns regarding data privacy and data storage regulation (discussed further in "Under the radar," below, and in the essays section – see "How will regulation of health data privacy evolve in Brazil and China?"). In the medical devices sector, panelists worried that China might become increasingly nationalist as it seeks to nurture its own corporate champions: "how to deal with a protectionist China that may not guarantee patents, intellectual property, or free trade" is a key worry, said one executive we spoke to.

## Under the radar

We conclude our risk radar for 2022 by looking at what might be flying below the radar – the risks that might become top concerns tomorrow. Our panel proposed several nominees, including trade tensions that might gradually undermine the globalized business models of life sciences companies, and state sponsored cyber-attacks – including the possibility that such attacks might be used for competitive purposes in an increasingly "health nationalist" world.

We decided to focus on two "under the radar" risks noted by the panel. The first we chose is "IP (intellectual property) nationalization." One much-discussed policy response to the pandemic has been to weaken patent rights, with the goal of producing life-saving drugs more widely. The life sciences industry has pushed back, contending that weakened patent rights will not lead to faster, more efficient, or more reliable production; and could undermine innovation. Still, "this is something that could happen in a future PHEIC [Public Health Emergency of International Concern]," as one panelist put it. Another panelist suggested that "experimentation with sub-licensing may help address the drug availability issue."

The second under-the-radar risk we chose is "regulation of health data privacy." As one industry analyst we spoke to put it, "life sciences is an industry of data, from clinical trials to efficient production, distribution and real-world results, and it depends on free movement of that data." There are growing concerns that data will not be allowed to move globally, for instance due to rising geopolitical tensions or concerns about privacy.

Even within countries (or regional customs unions), limits on data use by life sciences companies may escalate. "Europe is likely to go it alone given differences in preferences as relates to privacy as well as views on public healthcare," an analyst at an industry association forecast. Restrictions on data use may be more than a compliance headache; they may limit the rollout of new business models. "This is a huge issue because the future of our industry depends on more personalized healthcare," as one executive at a European pharmaceutical company put it.

This is issue is discussed further in the essay section, below (see "How will regulation of health data privacy evolve in Brazil and China?").

# Section 4: How will regulation of health data privacy evolve in Brazil and China?

**In the words of one of our panelists: "life sciences is an industry of data, from clinical trials to efficient production, distribution and real-world results, and it depends on free movement of that data." While European measures on data privacy have been widely-publicized, what is the outlook in emerging markets? We asked analysts from Oxford Analytica's global network to assess and contrast the situation in two key markets: Brazil and China, both of which have implemented major data protection legislation in recent years. The views expressed do not necessarily reflect those of Willis Towers Watson.**


## The Brazilian data protection framework

The COVID-19 pandemic created significant momentum for the pharmaceutical industry globally and particularly in Brazil – the largest pharma market in Latin America and one of the most important in the developing world.

Research partnerships expanded globally and Brazil has been at the center of several clinical trials and other research initiatives. At the heart of these collaborations is the circulation of relevant data, including health related personal information. Concerns over patient data confidentiality were already present in the local legislation, yet at the start of the pandemic, there was no general data protection regulation in place.

The Brazilian General Data Protection Legislation ("LGPD" in its Portuguese acronym) – an omnibus data protection law – entered into force in August 2020 concomitantly to the establishment of several R&D arrangements. The LGPD, which resembles the European General Data Protection Regulation ("GDPR"), imposes requirements processing personal information and establishes stricter criteria for health data – understood as "special category of data" ("sensitive data").

The LGPD thus creates a general data protection framework that should guide all processing of personal data, including for research and health related purposes. This means that the legislation should work in harmony with existing and future ethical and legal frameworks dealing with healthcare information, which include the Charter of Rights of Health Users', the Code of Medical Ethics, Good Pharmacy Practices, and the Clinical Trials Resolution (No. 9/2015) from the Brazilian Food and Drug Agency ("ANVISA" in the Portuguese acronym), among others.

Hence, such existing regulations, mostly covering healthcare information confidentiality, may need to be adjusted to follow the data protection guarantees and safeguards of the new data protection regulation. This may not have been a significant issue if it was not for the Brazilian institutional structure where several authorities may have overlapping mandates. The LGPD, for instance, establishes a data protection supervisory authority ("ANPD") with a mandate to coordinate both regulatory and enforcement data protection initiatives. This mandate does not, however, supplant the mandate of other regulatory agencies such as the ones that are part of the health regulation framework. There is, thus, a possibility of dissonant regulations and overregulation. In addition, the resulting potential for litigation should not be overlooked.

## Overlapping mandates

There are several institutions that oversee the provision of health services in the country. Among them, the following should be highlighted: i) National Supplementary Health Agency ("ANS"); ii) the National Health Regulatory Agency ("Anvisa") and iii) the Brazilian Federal Council of Medicine ("CFM").

Even if the core of their mandates differ, personal data is a common concern among them. It is no wonder, then, that all these bodies have specific regulatory provisions concerning personal data. See below a summary of the different competent authorities, their duties and examples of data protection related regulations from each:

| Name | Duties | Examples of data protection practices |
|---|---|---|
| **National Agency for Supplementary Health (ANS)** | Responsible for the private health care plans and insurance sector. Agency has several functions that relate to the implementation of the principles and purposes of data protection. | **Law No. 9,961/2000:** The agency is competent to proceed with the integration of information with the Unified Health System databases (art. 4, XIX). |
| **National Health Surveillance Agency (Anvisa)** | Responsible for promoting the protection of the population's health, through the sanitary control of the production and consumption of products and services subject to sanitary surveillance. The agency's role is to regulate, control and inspect products, substances and services of interest to health (art. 2, III, of Law No. 9,782/1999). | **Resolutions of the Collegiate Board No. 9/15 and No. 10/15:** deal, respectively, with the regulation for conducting clinical trials with medicines and medical devices in Brazil.<br><br>The agency elaborated **Guide No. 38/2020 "Principles and practices of cybersecurity in medical devices"**. Among the best practices mentioned are recommendations that medical device manufacturers adopt data protection measures. |
| **Federal Council of Medicine (CFM)** | Responsible for overseeing the professional ethics. It works alongside the Regional Councils to represent the interests of the medical profession, contributing to the constant development of good practices in the sector. Responsible for the Medical Code of Ethics. | **CFM Resolution 2.217/2018:** deal with professional secrecy (namely articles 73 to 79), and with medical research (namely article 101). |
| **National Research Ethics Commission (CONEP)** | Responsible for implementing the standards and regulatory guidelines for research involving human beings, approved by the Council. | |

The Brazilian data protection supervisory authority ("ANPD") adds further complexity to the health regulatory framework. In accordance with the data protection legislation, the ANPD has the mandate to coordinate data protection efforts. However, this does not mean that the authority necessarily has the initiative in this process. In fact, the likeliest scenario is that the other agencies will regulate under their mandates and may consult ANPD in the process.

Equally important is the fact that several general regulatory movements from ANPD may impact directly or indirectly the flow of health data. One example is international data transfers (discussed below). Although the rules do not refer to health matters in particular, they may impact health matters.

One solution put forward has been cooperation agreements amongst the regulatory bodies. In a technical note, for instance, the ANS highlights the need to coordinate with the Civil House of the Presidency of the Republic to identify the best ways to align its responsibilities and actions with the ANPD. In addition, ANS's Data Protection Officer has expressed interest in working alongside ANPD and following its guidance.

## International data transfers

International data transfers are also regulated by the general data protection regulation. The LGPD establishes a regime where all cross-border data flows can only occur under particular circumstances where the entity is in an importing country considered to have an adequate level of protection or through specific mechanisms that otherwise guarantee such protection including standard contractual clauses (published by the data protection supervisory authority). Derogations and particular exceptions are also provided, yet they tend to focus on specific one time, usually low risk data transfers.

The regulation of these international data flows by the ANPD is scheduled for 2022. It is very likely that the supervisory authority will regulate the matter directly. Consultations or coordination with health data agencies is unlikely as it does not refer to health data specifically. That said, this regulation may impact, for instance, all international medical research arrangements – including clinical trials – dependent on the cross-border data flows.

## Use of health data

Under the LGPD, health data is "special category data." All data subjects have the right to know i) what are the objectives of processing their data, ii) how it will be processed and iii) who will process it. They also have the right to know the duration and purpose of data processing, what is the responsibility of professionals, and what are the risks associated with handling the data. The LGPD also recognizes the possibility of revoking previously granted authorizations. Some medical institutions have worried that these new rights create points of tension with current medical practices, particularly in standard "terms of consent" for data use.

### *Storage of health data*

There is specific regulation regarding the digitization and use of "computerized systems" for the safekeeping, storage and handling of patient records. For instance, patients' medical records should be preserved for at least 20 years and the elimination process must protect patients' privacy and the confidentiality of information.

The recent data protection legislation, however, invites a review of such specific sectoral regulation in light of the principles of purpose, necessity and minimization. The regulation provides for the elimination of personal data whenever it has already served its informed purpose. A general rule of 20 years may simplify procedures, but may not be appropriate in all circumstances. A more nuanced approach is being discussed

### *Health research protocols*

The LGPD covers not only processing of patients' data for the health treatment purposes – which, in contrast to the EU's GDPR, has a specific legal basis (article 7(vii)) – but also for research purposes (including clinical trials).

In terms of processing for research purposes, the Brazilian data protection legislation has a specific legal base for accredited research institutions (article 7(iv)). Other institutions participating in the arrangement may have to find other legal bases to justify the processing of personal data.

Data protection issues may arise in several instances in the research process: in the collection of health data specifically to conduct the research , in the transfer and processing of data amongst the partners of the arrangement (sponsor, researchers, medical teams

and research facilities), and in the development, registration and final monitoring of the end result (be it a drug or treatment). One should note that it is a common research practice in Brazil to use pre-existing databases to enrich the data available for the study. This data collected for other purposes (even other studies) may be processed in conjunction. The new data protection legislation requires transparency in the processing of any personal data. This may lead to an obligation to inform data subjects (patients) of this secondary use (in another study or research).

Another challenge arises from the fact that current clinical trial regulations tend to require the consent of the patient, thus leading institutions to frequently have consent as the legal basis for processing the data. Under LGPD, consent may be an unstable legal basis as it can be withdrawn at any time. Hence, absent clear guidelines, lack of transparency, authorization or consent, may hinder further uses of existing databases.

### *Research ethics and data protection*

Brazil structured the Research Ethics Committee (CEP) and the National Research Ethics Commission (Conep) to establish strict ethical criteria for the approval of research involving human beings. There are 848 Research Ethics Committees (CEP), distributed across the 5 regions of the country, with more than 13,000 people working on them. These commissions and the committee are in charge of ensuring the quality of the research and should guarantee the ethics of the studies.

This complex institutional arrangement allows Brazil to participate in a growing number of research programs, especially for the development of new drugs. Yet these committees will also be involved in adapting the data protection rules to the specific context of each study and trial. Thus, there is a high risk of dissonant interpretations of how to protect health data and the necessary requisites to process it.

### *Use of post mortem data for research purposes*

Another relevant issue arises in terms of post mortem data. Strictly speaking the Brazilian data protection legislation – unlike the European GDPR framework that it is inspired by – does not expressly exclude data from deceased persons from its scope. This generates an important gap particularly for health data used for clinical trials where a significant number of persons may pass away during the trial period.

This does not mean that there are no regulations for the matter. According to professional secrecy rules (Resolution CFM 2.217/218) doctors are required to provide to family members the records of their deceased patients. Additionally, the Federal Council of Medicine recommends that patients may authorize the disclosure of their medical record postmortem.

During COVID-19 pandemic, specific resolutions allowing uses for scientific research were applied to justify the waiver of the consent form by the patient or the family member for the use of the relevant data. This is, however, only a temporary solution and does not solve the issue for the future.

There are Bills being proposed in The National Congress of Brazil to regulate what is called "digital inheritance," yet these proposals intend to regulate data in terms of digital assets and focus on access to data from accounts and profiles in social networks. This approach may not be consistent nor appropriate for health data particularly for purposes of clinical trials and medical research.

### *Innovation and artificial intelligence*

Health data is also of relevance to the development and implementation of a series of new technologies, chiefly among them is artificial intelligence (AI). Such innovations are being applied to support the research of new drugs, to develop better treatments and diagnostics.

Today, Anvisa only has rules on health software and on administrative procedures for the authorization of its use in the country. The Agency focuses on classifying medical products according to the risk they pose to health, requiring their registration. AI tools or products with embedded AI are currently under the same obligations as health software. There are no explicit rules in terms of health data processed for AI training, development or even testing.

The House of Representatives has recently, however, approved a draft Bill on development and use of AI. The proposal does not regulate health data protection per se, yet proposes a general liability regime for AI, which includes its development and application of AI. This aims at establishing more legal certainty and limiting liability, yet in view of the lack of social consensus on the proper extent of regulation and the allocation of responsibilities around the AI development chain, this may lead to more litigation, not less. In terms of the pharmaceutical industry that has long chains of development, the proposition on the bill may generate more friction and difficulty in allocating the costs of developing and using AI based tools.

## Conclusion

As public interest in COVID-19 vaccine and treatment research has grown, so has the awareness in Brazil of processing of health data for clinical trials and drug development. The fact that several of such R&D projects, including a large number of clinical trials, are being conducted in the country reinforced a latent concern about the (mis-)use of personal data, particularly in terms of international arrangements.

It is expected that public authorities will seek to regulate health data flows. This will likely provide more clarity as to the ethical and legal requirements to process health data both in terms of patient as well as research and clinical trial data. Yet, the fragmented regulatory environment in Brazil with several agencies with overlapping mandates – from medical ethics to data protection specifically – create a regulatory patchwork complex to navigate leading to dissonant obligations or overregulation. Coordination amongst the public authorities will be key to both protect individual's data privacy rights and to maintain and foster the sector's growth.

Risks include diminished access to data (granular and aggregated), barriers to internationalization of research, hurdles to data export, higher complexity (and costs) for sponsor-research arrangements, and administrative and judicial litigation. A vibrant health research ecosystem – as proposed by the 2018 Clinical Research Action Plan – will not come into fruition without clear regulations on data flows. Less economically affluent initiatives may be squeezed out of the market, limiting the growth of the sector.

There are also opportunities, however. As one of the largest and most diverse and complex health systems in the world, if the arrangements are well developed, Brazil can contribute significantly with health data for R&D purposes, surpassing even the UK's NHS health trove. Moreover, during this period of regulatory innovation – often following international models – opportunities exist in terms of proposing unified data protocols, interoperable health data transfers regime and even an "open health initiative." If the right environment and incentives for partnerships to share risks and costs can be created, more new drug R&D can be taken up by smaller specialized companies and startups, creating a more vibrant life sciences sector in Brazil.

# China

## The Chinese data protection framework

China lags Brazil, in many ways, in terms of institutionalizing data protection practices in the healthcare sector. That said, over the past year, the Chinese government has created the foundations of a new and comprehensive legislative framework for data protection, and ministries are expected to issue clarifying legislation rapidly. This new framework will have a major impact on all forms of data collection, processing, storage, use and export in the years ahead, and likely cause compliance costs in the digital and data-enabled industries to rise significantly.

The Chinese legislative framework rests on two pillars: The Personal Information Protection Law (PIPL) and the Data Security Law (DSL). These two laws passed through the legislative process in tandem and were promulgated within months from each other in the summer of 2021. Both have now taken effect and are binding.

Like Brazil's framework law, the PIPL is, in very many ways, similar to the personal data protection frameworks in Europe, most notably the GDPR – although PIPL appears to place more emphasis on consent as the primary legal basis for processing data. The main focus of the PIPL is protecting the individual from potential abuse of data that can be used to identify them or affect their personal rights and interests. As such, it lays down basic principles on elements such as consent for data collection, limitations to permissible business models and required notification to individuals about the use of their data.

Unsurprisingly, however, the PIPL also provides wide exemptions to state bodies to fulfill their statutory duties. In other words, the PIPL does not intend in any meaningful way to establish a fundamental right of privacy in China, or effective restrictions on data-enabled surveillance. Rather, it primarily serves to manage the relationship between individuals and data-holding companies, and to limit the purposes to which these companies can put personal information.

The DSL, in contrast, appears to be unique in the world. It intends to protect national security and the public interest from harms enabled using any kind of data: personal information, but also data emerging from companies, infrastructure, and so on. To do so, the DSL institutes a matrix-type form of protection, where data is classified according to category and tier, with concomitant security requirements. In principle, the DSL covers every byte of data generated or stored in China, although the tiering process indicates that the law intends to focus primarily on those data whose abuse, distortion, leakage or destruction may have a severe impact on Chinese political, economic or social stability.

## Overlapping mandates

As with the Brazilian case, these new laws create certain complexities, and the promulgation of these laws raises as many questions as it answers. As is often the case in Chinese legislation, they are formulated in vague and general terms, offering few details or practical handholds for companies to base their compliance strategies on. This is a feature, not a bug: the law mainly serves to create mandates for line ministries who will draft implementing regulation over the coming years that will add actionable detail to the principles of the law. Where the DSL is concerned, for instance, it will be up to each individual ministry to draft catalogues of data covered within their respective jurisdictions, and how they should be assigned to security protection tiers.

Another matter that remains unclear is the relationship between the PIPL and the DSL. It is already clear that there will be considerable overlap between the two regimes, but although the central government pays lip service to the notion that duplicate compliance burdens should be avoided, few actual moves in that direction are visible thus far.

While new regulations in Brazil have been put in place in a context where laws need to be interpreted by judges and courts, in China, any question of coordination will be in the hands of the Party. Already, ministries have issued specific sets of implementing regulations. One particular area of concern over the past few months has been the automobile industry. As cars are increasingly equipped with cameras, radars and other sensor systems, particularly in order to facilitate autonomous driving, the Chinese government has demonstrated increasing concern about the possible malicious purposes to which this data could be put, ranging from insurance scams to all-out espionage by the United States. Illustratively, certain US-made electric vehicles have been banned from military facilities and government compounds over concerns that the data about their environment they collect might end up in the hands of US intelligence services.

## International data transfers

Similarly, greater clarity is emerging around the requirements for data export. Again, reflecting Beijing's concerns about the transfer of large amounts of potentially useful information to its prime strategic adversary, regulations concerning foreign IPOs have been tightened in recent months. Most notably, a Chinese ride-hailing company was subjected to a thorough cybersecurity review process after its listing on the New York Stock Exchange. In the wake of this incident, new regulations emerged that require a cybersecurity review in case of a foreign IPO of a company holding personal data on more than 1 million Chinese residents. De facto, this makes the Cyberspace Administration of China a financial regulator.

At the end of October, draft measures emerged for the export of data. These measures provide criteria for when data export security reviews are required and the parameters to be taken into account during this process. They also indicate there will be standard contractual clauses offered for data export contracts and agreements.

## Use of health data

Perhaps surprisingly, given events of the past two years, healthcare data has not played a prominent role in data protection legislation thus far. While policy documents and leadership speeches have demonstrated far greater priority accorded to the digitization of healthcare and addressing concomitant data protection issues, few specific initiatives or regulations have been issued. In 2018, the CAC released trial regulations on big data in the healthcare sector, which contained little more than the most basic norms on personal information protection, as well as the usual data localization requirements. This document came out before the pandemic and has not seen any update since then.

There are multiple contributing factors to this. Perhaps what is forgotten most often is that China is, in many ways, still a developing country. Particularly outside of the major metropolitan centers, healthcare provision is often not technologically sophisticated, and much work remains to be done to ensure that basic IT systems are up to scratch.

China's burgeoning private sector plays an important role in this regard, so there may be some reticence to introduce stricter regulation that might result in less investment in the sector. Furthermore, the COVID-19 pandemic demonstrated painfully the shortcomings in China's healthcare emergency response systems, as well as its medical research structures. These considerations should limit the likelihood that excessively onerous requirements will be introduced.

That said, Beijing has also been reluctant to join in with international efforts to develop and distribute vaccines and assess their long-term effectiveness. In other words, where healthcare may have been a sensitive area before, the pandemic propelled it into a raw political nerve in the international context. It must thus be expected that foreign businesses will have a harder time engaging with data collection, processing and export in the Chinese context.

## Conclusion

China's new data protection architecture is not finished by far. The PIPL and DSL represent the beginning of a legislative and regulatory process, rather than an end. Much of the actionable detail will emerge in ministerial rules and technical standards, some of which are in the drafting process, but some of which are in no way public. However, the thrust of the efforts is clear: Beijing intends to be far more interventionist in the way that it regulates how data can be used and should be protected, particularly where it comes to international exchange. Companies should adapt their strategies to take this reality into consideration and expect that the trend will continue to strengthen.

While it is difficult to say with certainty, China appears likely to be a far more difficult environment than Brazil for international life sciences businesses. In Brazil the international data transfer regulation focuses particularly on personal data, while the Chinese DSL covers other categories of data, thus potentially restricting anonymized data. Additionally, the political context concerning what has been called "data sovereignty" seems to be moving in different directions. The Chinese government seems to be more inclined to mandate forced data localization than the Brazilian government. The Brazilian data protection authority, while still concerned with international data transfers, has already hinted that it intends to promote "secure and responsible" international data transfers under a somewhat flexible framework. The same cannot be said of the Chinese case.


COVID-19

# Section 5: Will Europe cut health budgets after the pandemic?

**In the wake of the Eurozone debt crisis, cuts in public health spending in some European countries were profound – exceeding 20 percent in Greece, Ireland and Portugal, for instance (see graph). As a result of the pandemic, public debt burdens in many European countries now exceed the levels prior to that crisis. Is another wave of severe cuts to health budgets on the way? We asked scholars in Oxford Analytica's global network to provide their analysis. The views expressed do not necessarily reflect those of Willis Towers Watson.**

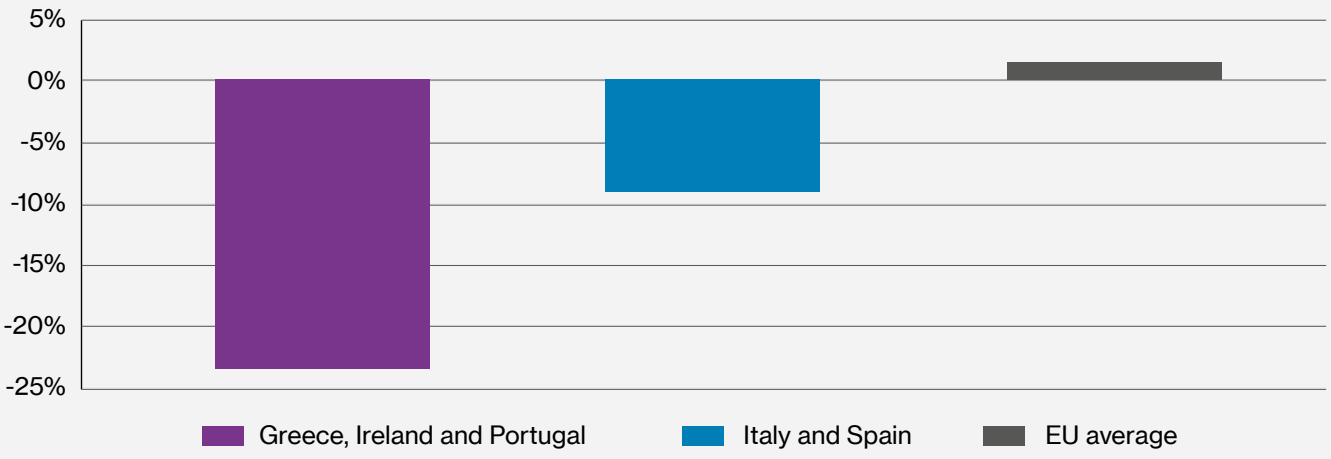
## Europe's "pandemic debt" problem is particularly severe

There is no question that, although Europe has survived formidable challenges since the 2008 financial crisis, the measures made necessary by the COVID-19 pandemic now create a serious dilemma for the region. In Europe, government debt burdens are among the world's highest and the Stability and Growth Pact (SGP) sets rules regarding public debt and deficits. In many European countries, a return to the SGP in the wake of the pandemic – currently scheduled for 2023 – would require fiscal adjustment on a significant tscale (see graph).

To be sure, the economic challenges associated with the pandemic have been, in some respects, less acute than earlier challenges. There has so far been no bond market crisis, and no existential threat to the European financial sector. Yet the size of the recession has forced the EU to suspend key elements of the SGP's rules-based system of fiscal discipline and to accompany this suspension with some first tentative steps towards a new regime of transnational fiscal transfers beyond those in the normal EU budget.

Suspending the SGP temporarily was unavoidable, but so too is reactivation at some point, in some form. The problem now is how to achieve agreement on reactivation of the Pact and in the longer term how to get past what is

Average changes in EU government health spending during the Eurozone debt crisis



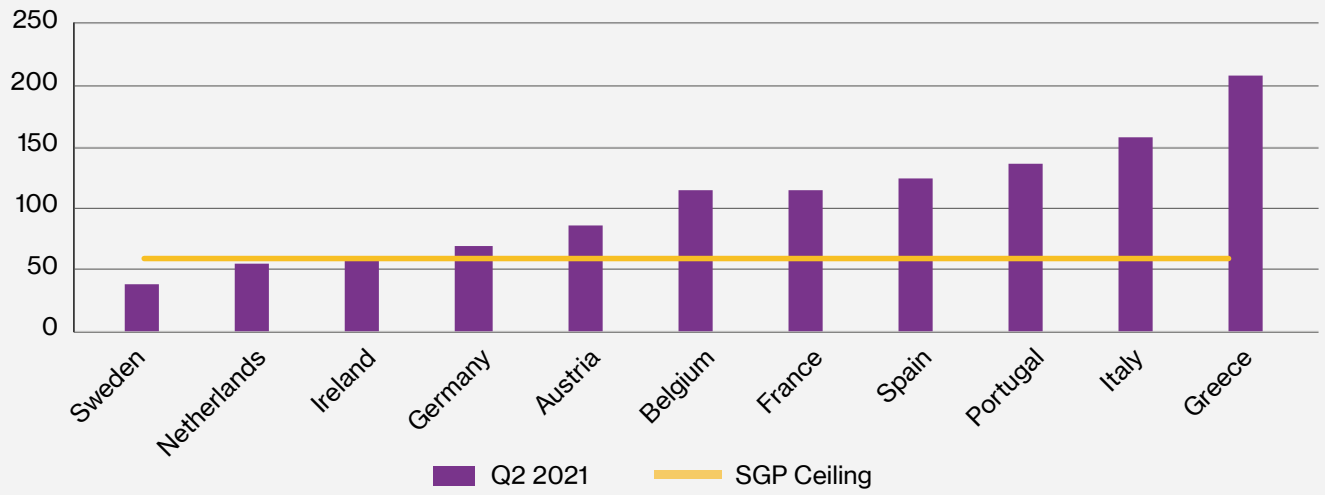

*Source: Bruegel*

arguably the Eurozone's greatest economic weakness: the absence of a centralized fiscal system, and of a central bank with unlimited powers to create money. Without these features, the need for a rules-based system of fiscal and monetary stability cannot simply be ignored or abandoned.

That said, re-imposing the SGP as it currently stands in 2023 would require all-but-unthinkable levels of austerity. These extreme adjustments would by produced by the rule that requires, roughly speaking, European governments to adjust towards a 60 percent debt-to-GDP target at a rate of 1/20th of the size of the difference (see table). In the Italian case, other things being equal, that would imply an annual repayment of debts equivalent to nearly five percent of the country's economic output; in the Greek case, the annual repayment would exceed seven percent of output.

| Measure | Target | Notes |
|---|---|---|
| **Debt-to-GDP ratio** | 60 | The gap should be closed at 1/20th the difference annually |
| **Ratio of budget deficit to GDP** | 3 | |
| **Structural budget balance** | MTO | A MTO (medium term objective) is set that would lead the country to the above target**s** |
| **Expenditure benchmark** | | For countries above their MTO, expenditure growth should not exceed economic growth |

Current and target public debt levels (percent of GDP)




*Source: Eurostat*

## How could Europe avoid excessive austerity?

If new policies at SGP level are to emerge, they will likely require a technical reworking of the SGP itself and its accompaniment by greater inter-state fiscal transfers.

SGP targets were not being met consistently even before the COVID-19 shock. It is even less likely they will be met in the future, if the recovery entails a new level of enduring weakness compared to the EU's previous growth trajectories. Indeed, even if growth resumes at something close to past levels it is unlikely the SGP targets will be met. For countries with already high debt levels the SGP would imply the continuation of the requirement for strong primary surpluses in the structural balance even in a benign interest rate environment. There is also a broadening political consensus that austerity measures since the financial crisis have done little to support European growth and prosperity (although, as discussed below, these measures were adopted for reasons that go beyond the SGP).

One approach to a reformed SGP would be to substitute the generalized-exception provision introduced in March 2020 with specific and flexible targets by country, which might particularly affect the rate of reduction of spending. A second solution is a recalibration of the general reference value for the debt-to-GDP target itself. No less a figure than Klaus Peter Regling, director general of the SGP, and traditionally a guardian of fiscal orthodoxy, has recently been reported as saying the 60 percent target was no longer reasonable.

Other proposals suggest taking more account of the long-term benefits of public investment. The concept of the stock of debt itself could be modified from gross to net, which would help those countries with higher stocks of public capital. And constraints on an already-existing exemption to deficit financing for new public investment could also be loosened. (In the wake of the Eurozone debt crisis, cuts to health spending were extreme – but cuts to public investment even more so, with Italy and Spain cutting investment budgets by nearly half.)

Taken together, these policies would imply what some have called a shift from a debt brake to a debt anchor, the latter to denote a more flexible and articulated set of constraints. At the very least there seems an emerging consensus that the old 60% ceiling for the debt-to-GDP ratio is both unattainable and out of date, that higher debt levels are sustainable, and that markets would find such levels sustainable. According to researchers at the European Stability Mechanism, the euro zone's stability and growth pact should incorporate a higher debt ceiling of 100 percent of GDP.

In sum, the SGP that is reinstated in 2023 will almost certainly take a modified and more growth-friendly form.

The second part of the formula – whether the EU can also find the internal cohesion to agree greater inter-state fiscal transfers – is more complex. For some countries, Italy most notably, the inter-state fiscal transfers in the Next Generation Recovery Program have provided a formidable lifeline which, along with the currently highly credible government of Mario Draghi, appears to be making a significant contribution to the revival of investment and consumer confidence.

There are certainly signs of some new thinking, then, but major difficulties persist. The fiscal redistribution of the Next Generation Recovery Program is (for now) a one-off, and there is no guarantee it will be a success in itself, or that member states will find the political will to repeat if the pandemic passes. Making it a permanent solidarity mechanism still faces great political resistance from the eurozone member states most committed to fiscal orthodoxy (the center-right parties in Germany and the Netherlands, and possibly even Finland and the Baltic states as well, remain relatively supportive of fiscal discipline and hostile to transfers).

## The main risk to public spending is market pressure

When the SGP is reimposed, it is likely to be reimposed in a modified form. Hence the SGP is unlikely to force major cuts in budgets. Does that mean that major cuts are unlikely?

Unfortunately, no. Without further centralization of EU fiscal policy, market pressure is likely to force countries to impose cuts – although the impact will be different across different member states.

The fact that the SGP has been more honored in the breach than the observance reminds us that financial markets have historically been more important in imposing fiscal restraint on governments than the formal fiscal framework. At present, the key factor in lightening this constraint is clearly a benign environment for inflation and interest rates. The less benign that environment, the more a given country's fiscal stance is likely to be questioned by markets. How exactly these elements interact with the

underlying matter of public demand for higher spending, and with public resistance to taxation, then becomes a further complication in the equation.

The austerity Europe has experienced over the last decade, as reflected in extremely cautious and restrictive fiscal stances, low consumer confidence, and weak investment, has numerous causes. The external discipline of financial markets has been at least as important as the formal SGP rules in forcing countries towards austerity and, subject to the interest rate environment, would bear down on countries with high accumulations of public debt whatever the SGP rules say.

Unless inter-state fiscal transfers are increased dramatically market pressure is likely to continue to apply. This market pressure will fall differently on different member states. Fiscally virtuous EU member states are likely to feel little market pressure and be constrained by the vectors of domestic politics much more than by the anxieties of financial markets. For the less virtuous the opposite applies, and this pattern will continue to hold for many years in the absence of significant further moves towards true fiscal federalism.

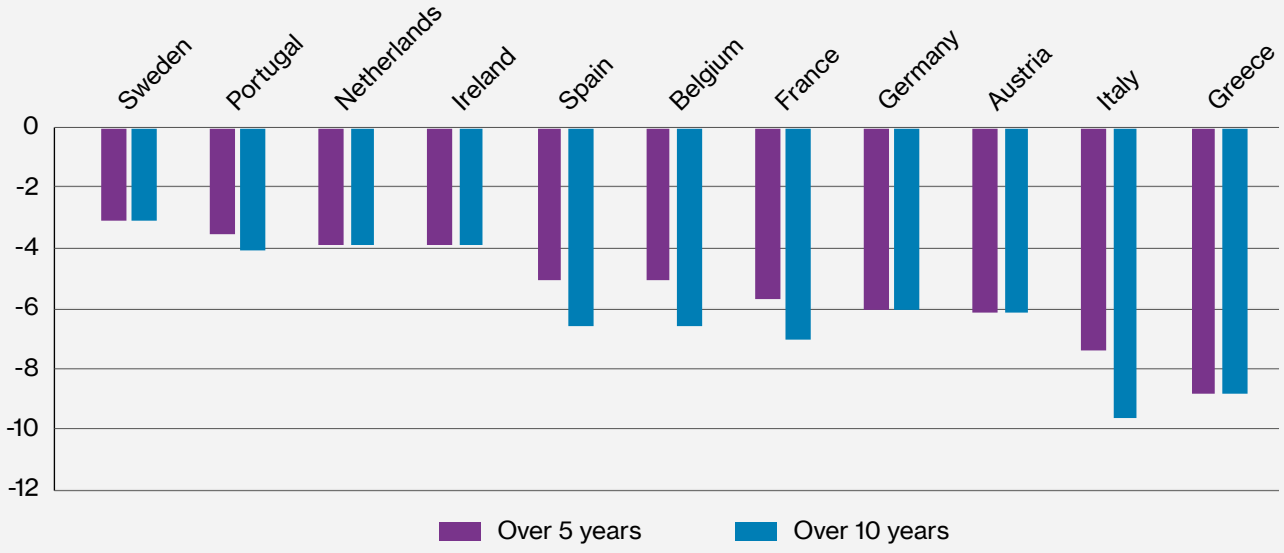
Even in countries that are able to spend, on a sectoral level, the competition for a share of any given increment to public expenditure after long years of austerity will be intense. In many of the SGP reform proposals currently under discussion, capital spending is favored over transfer spending (this transfer spending includes health care, adult social care and late-life support, family credit, and so on).

Addressing urgent problems of climate change will add to both the current and capital sides of spending, crowding out more traditional public spending. Demographic change will impinge on multiple aspects of economic life, including labor costs and labor supply for public services, pension costs, and the fiscal base of adult social care. In short, even the relaxation of the SGP and absence of market pressure would not automatically benefit the health budget, event thought that has traditionally been a top priority for welfare-oriented governments.

In sum, absent a dramatic increase in inter-state fiscal transfers, countries in weaker fiscal positions are eventually likely to face substantial pressure to cut health budgets, and this pressure is likely to increase if the inflation and interest rate environment worsens. We can have some idea of where the pressure is likely to be most acute by looking at the most indebted countries (see graph at the beginning of this section).

In addition, we can consider the level of cuts that would be required to restore fiscal discipline. The think tank Bruegel calculates that, if a relaxed version of the SGP were to be imposed, a combination of tax hikes and spending cuts in excess of five percent of economic output would be required for several countries. In contrast to the cuts following the Eurozone debt crisis, the countries forced to cut most would include not only Greece but also Austria, France and Italy (see graph). Of course, bear in mind that market pressures would be the main force imposing this discipline, rather than the SGP itself.

Spending cuts required if a modified SGP is imposed in 2023 (percent of GDP)




*Source: Oxford Analytica*

The downside risk factor that would do most harm to a revival of public consumption expenditure would be an implementation of the SGP that is not considered credible by markets (unlikely, given the hawkish stances of many EU member states), or a resumption of the path towards populist radicalism, political fragmentation, unstable policymaking and, therefore, low confidence in the capacity of the EU to remain a cohesive bloc. A fear in financial markets that, after Brexit and in the face of continuing unilateralism in central European states like Poland and Hungary, the EU stands on the verge of further centrifugal tendencies even at its very core, would force the fiscally more exposed member states back into more extreme austerity measures, with extremely harmful consequences for health budgets.

## Could inter-state fiscal transfers solve the austerity problem?

Is it possible that inter-state fiscal transfers could grow to a scale that would reduce market pressure on the budgets of weaker EU states? One positive sign is the emergence of a tentative consensus in favor of greater emphasis on collective EU solutions to major societal threats, be they in health, the environment, global supply chains, and social and inter-generational inequality. For such a consensus to strengthen, voters need to support the benefits of higher taxation at the European level, greater solidarity transfers, and increased social and infrastructure investment.

Arguably, this consensus would need to be supported by a shift in European politics. At present, dissatisfaction with the EU tends to be expressed through the at times incoherent and contradictory demands of populist parties. It is difficult to imagine a "populist coalition for EU reform" emerging that supports inter-state fiscal transfers.

Perhaps a reformist consensus would be more powerful if supported by established, more aggregative, and more moderate parties: namely Social Democrats and Christian Democrats. There are some tentative signs in very recent elections of an electoral shift in this direction. Social democracy is having its best results for many years, perhaps helped by the apparent lack of credibility of extreme competitors on its left.

But this is only the beginning. Moderate parties of the center and center-right also need to be convinced, and, as in Germany's (hitherto) ruling Christian Democrat Party, a line of cleavage still tends to run right through the middle of the party. Moreover, it is unclear that these parties will respond to such electoral shifts in an effective way by rethinking fiscal orthodoxy and its consequences for the Euro area collectively.

In a sense this a "swing of the political pendulum" theory of policy change. In high welfare societies voters eventually start to resist tax increases and higher public expenditure, putting pressure on costly welfare services and infrastructure. Eventually many are tempted towards populist solutions that resist austerity without accepting the fiscal burdens of doing so. But the populist approach is rarely if ever successful in producing policy that enhances long-term growth, and at least in a European context voters may eventually return to negotiated centrist politics, now willing to accept the real constraints on policy choice and the risks of unilateralism.

The Greek and especially Italian experience in the last decade shows signs of this pattern. The outcome for EU inter-state transfers is likely to be far messier than a simple political learning process, however, with political fragmentation a potential biproduct. Indeed, given the upcoming Italian presidential elections in 1Q22 and parliamentary elections to be held by March 2023 at the latest, the current moment of political stability may be about to end.

Thinking through potential scenarios ahead, the factor that would most benefit public health expenditure in the EU as a whole will almost certainly be a series of center-left victories that feed demand for immediate welfare benefits. The thesis that the shift away from austerity is affecting the whole political spectrum still leaves open the possibility that moderates and economic liberals broadly win the argument about the balance between long-term and short-term measures, so that the EU's "New Deal," whatever shape it takes, and whatever the balance between EU-level measures and national-level measures, is driven by longer-term considerations. Assuming everyone moves away from austerity, the nature of the policies it entails will in part depend on how strong and enduring the revival of social democracy turns out to be.

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