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REGULATOR APPROACHES TO FACILITATE, SUPPORT AND ENABLE INNOVATION

Final Report

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Executive summary

As set out in its White Paper on Regulation for the Fourth Industrial Revolution, the government plans to transform the UK's regulatory system to support innovation while protecting citizens and the environment. This research has been commissioned by the Department for Business, Energy and Industrial Strategy to explore the practical methods that regulators can adopt to stimulate and support innovation.

New types of products, services and business models can present a significant problem for mechanisms of governance and regulation. Innovation is an important source of economic growth and societal and public benefit, but innovations can also have unintended consequences, sometimes leading to public or environmental harm. In delivering their primary objectives, such as consumer protection, regulators may not always adopt an approach that is conducive to enabling innovation.

Technological developments have only intensified this issue as new capabilities, products and services emerging in areas like big data and AI where new products or services erode sectoral boundaries, scale extremely quickly and allow vast numbers of actors the ability to do things they have not been able to do in the past. To manage the competing needs for innovation and public protection, against a backdrop of continuing technological disruption, regulators are developing and testing new approaches.

The aim of this study is to explore the range of methods that regulators around the world are using to facilitate, support or enable innovation while fulfilling their regulatory objectives. There has been a proliferation of innovation-friendly regulatory approaches in recent years, but little has been done to understand these practices better; in particular, what works in different contexts and the kinds of positive outcomes they can create.

This study used an extensive literature search and 35 interviews with regulators, government actors and companies to map and analyse different innovation-friendly approaches adopted by regulators. The primary focus of the analysis was to build on the limited data available on how these approaches have been employed and the kinds of outcomes they can achieve. In particular, this study tried to identify where and how the following positive outcomes may have occurred:

- Greater number of new ideas and innovations
- New types of products, services or business models made possible that might otherwise not have happened
- Innovations brought to market (or licensed) quicker
- Increase in the amount of investment and trust given to innovations
- New businesses entering different markets increasing competition
- Greater consumer confidence and engagement
- Increase in business trust and satisfaction with respect to regulation/regulators

Key findings

We have identified five broad types of innovation-friendly approaches to regulation:

Approach	**Aim**
Providing regulatory advice to innovators	These programmes use dedicated innovation teams or contact points to: • Help innovators or businesses navigate the regulatory system • Ensure new products, services or business models align with existing regulations or regulatory expectations • Gather intelligence on new products, services and business models to support future regulatory reform
Supporting experimentation and testing of innovations	Live-testing environments, such as sandboxes or testbeds, can: • Help innovators or businesses trial novel products, services or business models, in a safe space, to test the viability of an innovation before fully accessing the market • Ensure novel products, services or business models align with existing regulations or regulatory expectations and do not cause adverse effects (in the areas measured during the trial) • Facilitate regulatory learning and adaptation in response to innovation
Streamlining regulatory approvals for innovators	Streamlining approval processes can: • Help innovators or businesses with new products or services achieve full market access faster by providing alternative routes to authorisation • Lessen the initial regulatory burden for innovations where there is an unmet need or a strong potential for consumer benefit in a critical area like health

Approach	Aim
Setting regulatory challenges to drive innovation	Challenges can help regulators to: • Direct or stimulate innovation towards a specific challenge or outcome • Use business-led innovation as an alternative way to meet regulatory objectives and respond to key risks or market failures • Facilitate regulatory learning and adaptation in response to innovation
Collaborating internationally on innovation	International agreements or regulatory harmonisation can: • Help innovative firms navigate different jurisdictions and interact with regulators to test and bring novel products, services or business models to market quickly in several countries at the same time • Reduce international regulatory barriers or burdens to innovation • Support cross-border information sharing, regulatory learning and adaptation in response to innovation

Evidence on impact

Despite an extensive literature search and in-depth interviews, we were not able to find or build a strong evidence base on the impacts, positive or negative, of these approaches. As pointed out elsewhere (ESMA 2018), little openly available information was available on impacts, and there seemed to be only limited attempts by regulators to record relevant data related to possible impacts. The lack of data is also in part due to the short timeframes for which many of these examples have been in operation. The evidence available primarily relies on proxy information (for example, numbers of companies participating in an initiative) or anecdotal evidence from case studies or interviews with regulators and businesses.

While most of the activities we have described could be used in virtually any context, we found that their usefulness and impact will depend on several important considerations:

- The scope of the regulator(s) involved, including their objectives and level of willingness (or culture)
- The role innovation can play in meeting those objectives (it is not always the case that innovation, greater competition and more market choice are the right approaches)

- The existence of non-regulatory barriers to innovation, which can severely impede the impact of any activities a regulator may undertake
- The resource investment needed to carry out these activities, which is often more extensive than regulators realise (particularly in the case of innovation testing or international harmonisation) and should be weighed up against other regulatory needs
- The extent to which innovation is already happening in relevant sectors
- The potential risks associated with innovation for consumers, the public and the environment

Routes to impact

We found good evidence that innovation-friendly approaches to regulation can support business-led innovation through two key routes: increasing investment and investor trust in new products, services or business models; and helping participating companies bring their innovations to market (or acquire a license) quicker.

Interviews with businesses and innovators indicated that greater investment and investor confidence could be attributed to several factors including: requirements for innovators to pass certain eligibility criteria and demonstrate due diligence before participating in a particular initiative; closer engagement with regulators (investor confidence was strongly associated with approaches that enabled or required a closer working relationship with the regulator); and evidence the new product, service or business model was viable after testing in a sandbox or testbed-like environment.

Speed was a key feature of all the approaches we have described and was facilitated in a number of different ways. More focused regulatory support either through advice or practical help during participation (for example faster processing of licences) was the main route to impact. Other outcomes such as greater knowledge of the potential regulatory implications of an innovation or lower interjurisdictional barriers were also important.

We found compelling evidence for two other ways in which regulators can indirectly support business-led innovation while significantly benefitting their wider work. Firstly, many regulators are using these approaches to build knowledge and expertise around the needs of innovators, the types of innovations emerging and their potential impacts. This was a strong feature across most of the examples we covered and a core element of several projects. Improved knowledge allowed regulators to adapt or develop new regulatory frameworks that are more robust and can support innovation. It also allowed regulators to improve the quality of service they offered to those seeking advice or help.

Secondly, by developing approaches that are explicitly ‘innovation-enabling’, and creating value in the ways outlined above, regulators were able to increase business trust and facilitate a more open and transparent relationship with many businesses.

Our research turned up some evidence to support other closely connected positive outcomes such as new actors entering different markets, increased competition and a greater number of new ideas that may not have been possible with regulatory support. From the available evidence it was not clear to what extent the approaches presented here have, or could, enable these outcomes. Non-regulatory barriers may still stand in the way of new ideas or new actors achieving success, even after regulatory support.

Finally, we did not find any evidence for increased consumer trust in new products, services and business models or greater public engagement through these initiatives. However, as we did not interview any consumers involved in the examples described here, we were not able to interrogate this area fully.

More robust evidence is needed to fully understand where and how these approaches can enable regulators to both support innovation and fulfil their regulatory objectives. A consistent and robust approach to evaluation, as well as greater requirements for data collection and publication, would be hugely valuable for generating insights across projects and sectors. The evaluation framework for the UK government's Regulators Pioneer's Fund (RPF)[1] and investment in other studies will be an important step in building this evidence base.

[1] The Regulators Pioneer's Fund is a £10 million fund supporting innovative regulator-led projects. The competition's aim is to promote cutting-edge regulatory practices to help make the UK the world's most innovative economy, whilst protecting citizens and the environment.

1. Introduction

Regulation plays a key role in shaping innovation, the development of new sectors and the emergence of new technologies. The development of new products, services and business models is a vital source of economic growth and societal benefit but at the same time can create new forms of public harm and other threats. Regulators, therefore, often have to strike the right balance between enabling innovation and meeting their core objectives (such as maintaining consumer protection or ensuring competition), while there is still uncertainty around the impacts of an innovation. Recent technological developments have only intensified this issue as new technologies, like data and AI, erode sectoral boundaries, scale extremely quickly and allow consumers the ability to do things they have not been able to do in the past.

In its White Paper on Regulation for the Fourth Industrial Revolution, the government set out plans to transform the UK's regulatory system to support innovation while protecting citizens and the environment. Regulators around the world have developed a wide range of approaches to directly support businesses to bring new products or services to market while still delivering on their core objectives. However, little has been done to systematically review these practices, in particular what works in different contexts and the kinds of positive outcomes they can create.

This report presents a detailed study of the different innovation-friendly regulatory approaches being used around the world. By providing practical guidance on how to design and implement these new approaches, as well as surfacing emerging information on their impacts, we hope this report will help regulators to explore how they might better support, or even stimulate, innovation in their respective sectors through future projects.

The aims of this report are to:

- Develop a taxonomy outlining different types of approaches regulators can take to support the development of innovative products, services and business models in a variety of sectors (while delivering on their remits and objectives)
- Synthesise evidence on the outcomes and effectiveness of different approaches
- Provide advice on the efficacy, wider applicability, and benefits and limitations of these innovation-friendly regulatory practices, highlighting best practice and design considerations where possible.

The analysis in this paper draws on academic and policy-related literature and interviews with relevant regulatory bodies and companies.

Background: The shift towards innovation-enabling regulation

Technological developments, fast-changing markets and new players are not only shifting the economic landscape but also creating unique challenges for regulation. Innovations in the digital economy have allowed entirely new players to enter and disrupt existing sectors, created new ways for consumers and businesses to interact, and created new challenges for ensuring public protection.

At the same time, some sectors, such as legal services (The Law Society, 2017) or energy (Ofgem, 2018b), for various reasons (BIS, 2014) have struggled to capture the benefits that disruptive innovation could deliver for customers and the economy. Governments and regulators have found it difficult to keep pace with these developments or know how to intervene to protect the public and allow innovation to flourish.

It is against this backdrop that a new set of innovation-friendly approaches to regulation have started to emerge in recent years. Regulators have devised a variety of approaches to directly support businesses to bring new products or services to market, while at the same time mitigating public harm and delivering on other objectives. Some of these approaches have adapted well-established methods from other sectors; for example, the development of fintech sandboxes and autonomous vehicle testbeds have drawn on the use of clinical trials in health (Walport, 2015). Many regulators are starting to explore business-led innovation as another tool to achieve their statutory objectives.

A few attempts have been made to bring some clarity to these developments, such Nesta's anticipatory regulation framework (Armstrong, Gorst and Rae, 2019) and Deloitte's Future of Regulation toolkit (Eggers, Turley and Kishani, 2018); but beyond the emerging literature on the fintech sector, little robust analysis has been carried out. With interest growing in these techniques, and proliferation in their use, it is particularly important that we understand these approaches better: How do they achieve positive outcomes for regulators and innovators? Where do their limitations lie? Where can they be applied, and how?

Structure of the report

The paper is organised into two further sections. Section 2 describes the methodology undertaken, including literature research, typology development and the qualitative approach applied through interviews and analysis. Section 3 provides the key insights drawn from the five approaches explored, outlining the aims of each approach, examples, practical considerations, benefits and limitations.

2. Methodology

The research methodology of the present study was comprised of three phases:

1. Literature research (grey and white literature)
2. Typology development
3. Semi-structured interviews and analysis

First, we conducted a broad review of the literature on innovation-friendly regulatory approaches. We reviewed academic sources as well as reports by governments, think tanks and consultancies. In addition to the literature describing existing approaches, we also performed an extensive online search focusing on the regulatory bodies of the countries included in the scope of this study and reached out to regional contacts to identify new areas to explore.

Our focus was the identification of regulatory practices (either initiated or led by regulators) that explicitly aim to support emerging product, service or business model innovation. Ideally, we were also looking for practices that could be undertaken through existing regulatory powers without the need for legislative change.

We did not set out to explore the potential impact of certain regulations (such as environmental regulations) on innovation. While this was intended to be a broad inquiry, we limited our work to countries and approaches that could inform the actions of UK regulators and would, therefore, be applicable to a UK context. We did not intend to create a complete list of all existing innovation-friendly regulatory examples but sought to identify as many different types of practice being employed by regulators around the world as we could and use this to develop a taxonomy to better outline the core elements and common themes underlying these practices.

Our search uncovered over 100 relevant examples spanning virtually every sector and representing over 30 countries. The examples we collected were mainly concentrated in nine countries (see appendix II for full list):

- Australia
- Canada
- Denmark
- Hong Kong
- Japan
- Korea
- Singapore
- UK
- USA

This bias reflects the countries where many innovation-friendly regulatory initiatives are concentrated as well as the focus of our search. The reason for our narrowed country focus was twofold: firstly, a key goal of the work was to surface approaches that may be applicable to a UK context, and so we picked countries that may have similar legal structures, regulatory regimes or economies; secondly, previous work has highlighted the existence of many innovation-friendly approaches in a number of these countries (for example Singapore and Japan). Along with these country-specific examples, we also identified several international initiatives.

Perhaps unsurprisingly, certain sectors, such as finance and health, were comparatively over-represented. In the case of the financial sector, this is largely due to the rapid growth of initiatives in this space (fintech sandboxes are live or planned in over 50 jurisdictions see UNSGSA, 2019) and the existence of a small literature base that has already gone a long way in compiling and examining examples from across the globe. While sandboxes and innovation hubs are not exclusive to the financial sector, little analysis has been done to look beyond fintech examples or take a cross sector approach.

Almost all of the examples collected are within highly regulated sectors such as finance, health, energy, food etc. and relate to potentially disruptive technologies such as data, blockchain, drones, robotics or the Internet of Things. The focus on emerging technologies fits with many of the challenges regulators are now having to face. However, it is not clear whether the strong link with highly regulated sectors is a function of a greater need to support innovation in these areas (i.e. complex regulatory systems may limit innovation) or because the strong presence of a regulator results in more regulatory initiatives taking place.

The majority of the initiatives we identified have only been developed in the last five years. Though most of these approaches are not new per se, many are novel in a regulatory context and have, therefore, required important adaptations and innovations.

In the next phase, we developed a typology of these approaches by grouping broadly similar initiatives based on different characteristics. We grouped initiatives primarily using three elements:

1. Activities different approaches encompassed
2. Stated (or implicit) aims of the approach
3. Use of shared language or terms

From this, we produced a typology of five broad categories of innovation-friendly approaches to regulation. Due to the recent proliferation and interest in the use of experiments (often referred to as sandboxes or testbeds) by regulators, we devoted more resources and interviews to the analysis of these approaches.

Semi-structured online interviews were carried out with regulators, government actors and company representatives, with relevant experience of the selected initiatives. The development of the topic guide was informed by the proposed evaluation framework of the Regulators' Pioneer Fund. The interviews were audio-recorded and transcribed. Finally, we analysed the material in search of common themes and salient insights around practices and impacts. Overall, we performed 35 semi-structured interviews, nine with regulators, eight with government actors and 18 with companies which had participated in some form of innovation-friendly regulatory initiative.

It is important to note that many of these company interviews were with businesses that had been through the Financial Conduct Authority's (FCA) fintech sandbox. This was due to several factors including accessibility, availability of information on participants, willingness to participate and the opportunity to interview participants across a number of sandbox cohorts. (A full list of interviewees is available in appendix I).

A note on the availability of evidence on impacts

One of the aims of this project is to identify evidence of positive outcomes resulting from the use of these approaches. As noted in other work (ESMA, 2018), our research uncovered very little in-depth evaluation or quantitative evidence on the impact or outcomes of these initiatives. Where there was evidence, it was mostly anecdotal or case dependent, though very informative.

An important reason for this is undoubtedly the fact that many of these approaches are still fairly new and have not engaged particularly large numbers of businesses. It may only be possible to properly assess or measure potential outcomes after these practices have been in operation for much longer. However, this is only one side of the story. We did not find that regulators had invested significant resources in evaluation or published detailed findings where they may have them.

We wanted to explore whether these initiatives could lead to:

- Greater number of new ideas and innovations
- New types of products, services or business models made possible that might otherwise not have happened
- Innovations brought to market (or licensed) quicker
- Increase in the amount of investment and trust given to innovations
- New businesses entering different markets increasing competition
- Greater consumer confidence and engagement
- Increase in business trust and satisfaction of regulation/regulators

3. Key findings

Five types of innovation-friendly approaches to regulation

The use of innovation-friendly approaches to regulation continues to grow, yet little analysis has been done to map out what is happening and better describe how these approaches may deliver beneficial impacts. To this end, we have sought to collate, describe and analyse what is happening around the world. Through a global search of innovation-friendly approaches to regulation, an extensive literature review and interviews, we have identified five broad types of activities:

1. Providing regulatory advice to innovators
2. Supporting experimentation and testing of innovations
3. Setting regulatory challenges to drive innovation
4. Streamlining regulatory approvals for innovators
5. Collaborating internationally on innovation

Below we outline their aims, the issues they are trying to overcome, how they work and the outcomes they can achieve. Each approach encompasses a different set of drivers and activities. As such, certain approaches tend to be more useful and valuable than others in specific contexts. Resource requirements and the relationship of these approaches to other regulatory goals/activities are also important elements to consider when deciding on the appropriateness of any initiative.

1. Providing regulatory advice to innovators

Aim

These programmes use dedicated innovation teams or contact points to:

- Help innovators or businesses navigate the regulatory system
- Ensure new products, services or business models align with existing regulations or regulatory expectations
- Gather intelligence on new products, services and business models to support future regulatory reform

Description

It is often the complexity of regulatory frameworks rather than any particular regulatory barrier that stands in the way of new products, services or business models being developed and deployed. Startups and small to medium-sized enterprises (SMEs) with limited resources or prior knowledge can find it particularly difficult it to navigate complex regulatory frameworks. Regulatory uncertainty has specifically been cited as a specific reason businesses may delay or decide not to launch an innovative product or service (GAO, 2018). In reality, there are often many more opportunities for innovation under existing regulations than businesses realise, and regulators may underestimate the degree to which this complexity is a barrier.

Advice centres (often called innovation hubs, innovation offices or contact points) provide varying degrees of formal and informal (and usually non-binding) guidance to overcome these issues. The potential benefits of these initiatives include greater investment certainty, less time to bring new ideas to market, greater market competition and greater consumer choice. At the same time, they create scope for regulators to engage with innovations early on, ensure new products or services are compliant with existing regulation and that consumers are protected. An additional benefit of this engagement is the ability of regulators to see and better understand emerging developments within their sector. While advice centres are generally open to different types of businesses (apart from a few that target specific groups such as SMEs), it tends to be startups or new market entrants which predominantly access these programmes in financial sectors (ESMA, 2018).

Examples

Name	Description
UK Medicines and Healthcare products Regulatory Agency (MHRA) Innovation Office	Launched in 2013, the MHRA's Office provides a single point of access to free, expert regulatory guidance. It is a joined-up advice service covering several authorities and offering support on UK and EU regulatory matters, scientific advice, and a specific Regulatory Advice Service for Regenerative Medicine. Its services have been used successfully by large companies, academic institutions and startups.
UK energy regulator, Ofgem's, 'fast, frank feedback'	Ofgem's Innovation Link provides 'fast, frank feedback' to businesses looking to launch new products. The advice offers an informal, non-binding steer regarding the regulatory implications of proposals. It is open to businesses of any size, at any stage of development whose products may benefit consumers. In addition, the service provides an opportunity for the business community to represent their views and offer input that might inform longer-term policy changes.
SME Assist (Australia)	A dedicated service that Therapeutic Goods Administration (part of the Australian Dept of Health) offers to help SMEs, researchers, startups and those unfamiliar with regulation to understand their regulatory and legislative obligations. It includes interactive decision tools, mailing list, documents, videos and workshops.
German Federal Institute for Drugs and Medical Devices, Kick-Off Meetings; Scientific Advice and Pre-submission Meetings	Several advice services are offered to companies and research groups at various stages of development. Kick-off meetings are intended for small, new entrants like startups which have little to no experience with navigating the regulatory landscape and are in the very early stages of development. It helps guide future project development and may thereby support companies, minimising unnecessary mistakes and reducing time and cost. In addition, scientific advice and pre-submission meetings are offered at a later stage and address regulatory and scientific matters regarding the

Name	Description
	development and licensing of medicinal products and medical devices.
Hong Kong Monetary Authority's (HKMA) Fintech Supervisory Chatroom	The HKMA launched a Fintech Supervisory Chatroom in response to a large number of requests from technology companies and other actors in the fintech space, which are not regulated by HKMA. The chatroom has received over 250 requests between December 2017 and February 2019, 70 per cent of which were from tech companies.
Health Canada Device Advice: Pre-Clinical Meetings pilot	The initiative was launched after stakeholder feedback that the criteria for pre-clinical meetings were uncertain. In response, a formal process was set up to allow medical device manufacturers to discuss evidentiary requirements and testing protocol design. The meeting takes place early in the development phase and allows for higher quality submissions and faster regulatory response times (Health Canada, 2018).

Practical considerations

Regulators have seen the need to fulfil their statutory objectives (for example, protecting consumers or encouraging competition) as both a key driver and enabler of these advice centres. General supervisory powers and practices have been cited as sufficient to create and operate these initiatives, which are in many ways a structured approach to existing practices of responding to ad hoc queries (ESMA, 2018). There are many examples of regulatory advice centres across the world in many different sectors, from fintech and energy to data, health and the legal sector. In the fintech sector for example, 33 different jurisdictions have some form of existing or informal 'innovation office' (UNSGSA, 2019).

Different advice centres provide different levels and types of support, depending on their scope and size. Many have dedicated teams (the FCA, for example, has a team of around 15 people) that respond to queries and bring in other expertise where it is needed, while other examples rely on a single coordinator to leverage expertise from across the regulator or sector (ESMA, 2018). In some instances, advice centres have been set up as joint initiatives, particularly where the governance structure splits a single sector or area between several regulators with different but closely aligned remits.

For example, the MHRA's Innovation Office provides access to regulatory information, advice and guidance for organisations developing innovative medicines, medical devices or novel manufacturing processes. It is a single point of access to joined-up regulatory information and guidance from the MHRA, Health Research Authority, Human Fertilisation and Embryology Authority, Human Tissue Authority, National Institute for Health and Care Excellence (NICE) and other related specialists including the Clinical Practice Research Datalink and the National Institute for Biological Standards and Controls (NIBSC) (MHRA n.d). Similar examples can be found in the financial sector where joint innovation hubs have been set up between central banks and financial market authorities in countries such as Belgium and the Netherlands (ESMA, 2018).

There are four basic stages of an information request submitted to the advice centre (adapted from ESMA (2018), including additional material from our wider literature review):

1. **Query submission**: All innovation advice centres have a dedicated contact point such as a phone number, email address, online submission form or other digital interface (for example, the SME assist service provided by Therapeutic Goods Administration, as part of the Australian Department of Health, includes online interactive decision tools). These may be standardised in some way, but the breadth of queries (and types of businesses submitting the query) mean flexibility is important.

   Some regulators also offer opportunities for face to face interactions through workshops. Access to support is sometimes based on eligibility criteria to help regulators assess how they should prioritise their engagement with different businesses. For example, this may relate to how innovative the product, service or business model is; or how clear the potential consumer benefit and need for regulatory support is. While many of the advice services are free of charge, some regulators in the health space charge a fee for in-person consultations.

2. **Developing a response**: Different agencies will have their own processes for deciding how best to develop a response; but in most cases, they will consider the nature of the issue, urgency, complexity and whether any other regulators or agencies need to be involved.

3. **Providing a response and developing a dialogue**: Again, depending on the nature of the query, this may be a simple response detailing regulatory requirements for consideration or the regulator and business may need to work more closely together to resolve more complex issues. These responses are usually given as ‘preliminary’ or non-binding guidance, though advice centres have been set up to provide explicitly binding advice (ESMA, 2018).

4. **Follow-up actions**: Where a new idea may require regulated activities to be carried out, some advice centres will continue to support businesses through any authorisation process. In some instances, this may also mean engagement with other approaches such as related sandboxes or testbed initiatives.

Evidence of impact

Like many of the approaches presented here, a significant number of advice centres are still fairly new and so only have preliminary information on outcomes or impacts. However, as noted elsewhere, few record-keeping or transparency actions have been reported by regulators in relation to innovation advice centres (ESMA, 2018), and where reports or studies have been published, they tend to lack detailed information or evidence on potential impacts. As a result, it is difficult to fully assess the impact of advice centres without more robust evaluation. Limited information is available on who the businesses engaging with innovation advice centres are, how they engage or what happens to them after they have sought support. Most of the available evidence relies on proxy data, such as the number of businesses engaging with the advice centre, user feedback or specific case studies.

Benefits

Four key positive impacts are often cited as an outcome of providing regulatory advice to innovators (based on interviews and literature review):

1. Reduced time and cost to launch innovative products, services or business models
2. Better consumer, public and environmental protection (ensuring innovations comply with existing regulation)
3. Greater number of new ideas and innovations reach the market
4. Increased competition

Reduced time and cost to launch innovative products, services or business models

Advice centres tend to enable large numbers of interactions between businesses/innovators and regulators, far more than any of the other innovation-friendly regulatory approaches also discussed here. For example, the Australian Securities and Investments Commission's innovation hub worked with over 380 organisations between March 2015 and December 2018. After one year of Australia's SME Assist initiative, it had 45,000 visits to the webpage, almost 7,000 uses of their interactive tool, over 500 subscribers to the email list, over 230 answered phone and email queries and over 200 attendees at 'meeting your obligations' workshops (Therapeutic Goods Administration, 2018).

The FCA has worked with over 500 innovative companies through its innovation office, with many going on to become licensed firms (Woolard, 2018). These initiatives also tend to receive strong positive feedback (ESMA, 2018); for example, the 'fast, frank feedback' service, provided by the UK energy regulator Ofgem, gave feedback to almost 100 innovators within its first 10 months and 88 per cent of those surveyed said the advice given was very useful and helped to shape their business model (Taylor, 2017).

While it is not clear to what extent this high level of engagement does lead to a reduced time to market, a greater number of innovations or increased competition, anecdotal evidence (for example from the MHRA's innovation office (MHRA, 2014)) does indicate that advice can overcome significant barriers to launching a new product or service, particularly for smaller businesses.

Better consumer, public and environmental protection

Specific case studies have also reinforced the consumer protection or compliance benefits of early engagement with innovators and innovations (MHRA, 2015), which could be defined as the adoption of a more preventative, rather than reactive, approach to regulation (a common theme through many of the approaches presented here). Advice centres can help to optimise an agency's enforcement efforts, and by resolving potential regulatory issues early in the development phase, they avoid the more significant effort of having to intervene later. This not only helps the regulator but supports companies in pursuing their core activities without making avoidable mistakes.

Additionally, advice centres help create a more open and transparent culture, which paves the way for more fruitful interactions between regulators and regulatees. This is especially true in the case of new market actors.

"*We're having a very open relationship with this new entity who may be more simply looking at how to comply, as opposed to working out how they can get around comply or something like that.*" (Jonathan Hatch, Australian Securities and Investments Commission (ASIC))

Greater number of new ideas reach the market and increased competition

Where data on interactions have been recorded and published, there is some evidence to suggest advice centres may support the entry of new players into established sectors thereby increasing the number of new ideas and competition in that sector. Of all the innovators who engaged with Ofgem's advice centre only 17 per cent were from the energy sector, the rest came from a variety of other areas and actors including digital technology companies and community/municipal groups (Taylor, 2017). It is logical to assume that the sectoral and regulatory knowledge of these new actors is likely to be less than businesses already acting in a particular area, making an advice centre particularly useful; but more evidence is needed to back this up. It is not yet clear from the information available how much advice centres do lead to greater innovation and competition; wider sector studies or surveys will be needed to resolve this, once advice centres have been in operation for longer.

Some evidence from evaluations of the SME Assist programme has shown that awareness of advice centres may not be very high. Only 31 per cent of SMEs surveyed were aware of the support available and of those only 38 per cent had accessed the service. The majority of those who had used the service (between 70-80 per cent) reported that it was easy to use, comprehensive and met their needs (Australian Government Department of Health, 2018).

Knowledge and openness

Other benefits are also highlighted by regulators, particularly the opportunity to build greater knowledge on how a sector is changing and the types of innovations that are appearing. As a result, they report feeling better able to see where they may need to focus future activities. They have also helped improve relationships with businesses by presenting a more innovation-friendly culture, as evidenced by the strong interest and support for innovation hubs (ESMA, 2018). Regulators tend to rate these benefits as particularly important outcomes of using advice centres.

Limitations

Non-binding advice

Many advice centres are only able to give guidance in the form of non-binding advice. The inherent uncertainty around some areas, particularly new or emerging areas with evolving regulatory and legal frameworks, will limit the value of non-binding advice. In circumstances of high uncertainty, businesses may be looking for assured advice to give them the confidence to develop or market new products or services. As a result, it is important that the nature (or potential changing nature) of the guidance being given is clearly articulated.

Support for some businesses over others

While there may be potential for some regulatory capture in the way advice is given, regulators were confident that this is not a significant risk. Advice is equally accessible to everyone and, as a result, some regulators see it as a move towards democratising access to regulatory advice, which especially benefits small companies. Previously, companies would have had to hire legal services to understand regulatory requirements, which small players may find more difficult to afford. Where regulators provide greater support in specific cases, this is usually done based on transparent criteria or public need, particularly where there is greater regulatory uncertainty.

Achieving wider impact

Though many regulators, including those we spoke to, have identified advice centres as an important way to build knowledge, we found few examples of consistent data collection or wider systematic evaluation of the advice requests being made. Where information was recorded, and teams were well resourced, insights could feed into other programmes such as horizon scanning efforts or adapting regulatory frameworks. In general, it is not clear whether this happens through formal or informal processes. Businesses voiced frustration where they felt support was not joined up between adjacent regulators and innovations did not fit neatly into predefined regulatory remits. Coordinated action has also facilitated better information sharing between adjacent or international regulators in the financial sector (ESMA, 2018).

Summary

- Advice centres are predominantly seen by both regulators and businesses as an effective and useful tool.
- They are not limited to particular sectors and could be used in virtually any context.
- On a practical level, to function effectively, advice centres need to be well resourced if they are to offer support in a timely and ongoing manner.
- We have also found coordinated action between adjacent regulators to be important as many innovations are increasingly cross-sectoral in their impact.
- For businesses, advice centres can help overcome a key barrier to innovation: understanding the implications of potentially complex regulatory frameworks on new ideas.
- For regulators, it is an opportunity to gain knowledge, develop a better regulatory or supervisory policy concerning emerging activities, and (perhaps most importantly) it creates a route for preventative action.
- More evidence is needed to identify the extent to which advice helps facilitate quicker market access for new products and services or its impact on market competition.

2. Supporting experimentation and testing of innovations

Aim

Live-testing environments, such as sandboxes or testbeds, can:

- Help innovators or businesses trial novel products, services or business models, in a safe space, before fully accessing the market to test the viability of an innovation
- Ensure novel products, services or business models align with existing regulations or regulatory expectations and do not cause adverse effects (in the areas measured during the trial)
- Facilitate regulatory learning and adaptation in response to innovation

Description

There are instances where it may be unclear how a new (potentially disruptive) product, service or business model may interact with existing regulations (or may affect other regulated sectors) without an opportunity to test it in the real world. Different approaches to experimentation, whether they are called sandboxes, testbeds or living labs, provide regulators and innovators with a controlled and time-limited opportunity to test ideas under live conditions, often with real customers.

The objective of setting up these live experimentation initiatives differs between regulators and sectors. For some, it is to enable innovation and to develop regulation alongside technology development where regulation could be a barrier or does not yet exist. For other initiatives, such as those within the mobility sector, objectives may be to help drive the development of the entire mobility ecosystem or to meet broader policy objectives. For example, Singapore's Land Transport Authority plays a crucial role in building and supporting an entire ecosystem around autonomous mobility, and its live-testing activities serve the purpose of realising the broader objective of meeting some of Singapore's unique challenges around increasing travel demand, shortage of labour, land constraints and an ageing population.

Here, we will focus on regulator-led initiatives that include the live-testing of innovative products, services or business models and involve at least one of the following components:

- Seek to provide clarity to companies about their regulatory obligations through testing new products, services or business models
- Seek to establish/refine the regulatory framework
- Provide temporary regulatory reliefs to testing companies

Examples

Regulatory sandboxes, living labs and testbeds have been developed and deployed in many different sectors in recent years. While much of the focus has been on the financial sector, little has been done to explore the similarities and differences in live-testing approaches across sectors. Before looking in more detail at common themes across all of these examples and the wider applicability of these initiatives, we will provide an introduction to the developments in each sector.

Fintech

Financial regulators were the first to embrace the idea of implementing structured programmes for the controlled monitoring and evaluation of innovative technological solutions. The UK's FCA launched Project Innovate in late 2014 with the aim of encouraging innovation and promoting competition through disruptive technologies. The first regulatory sandbox was established in early 2016 to act as 'a safe space for businesses to test out innovative ideas with real people.'

This model has become the blueprint for similar initiatives around the world, and the fintech sector has seen a proliferation of sandboxes. There are now operational sandboxes in 31 countries, with another nine countries launching programmes soon, and nine more have been proposed (UNSGSA, 2019). Plans for the first multi-jurisdictional sandboxes have also emerged. Spearheaded by the UK's FCA, the Global Financial Innovation Network (GFIN) launched formally in January 2019 and unites 29 organisations that seek to facilitate regulatory collaboration on financial innovation.

Several different technologies are being experimented with in fintech sandboxes around the world, including distributed ledger technologies, biometric authentication, robo-advisers, soft-tokens, remote account opening, etc.

Health

To date, only a very limited number of sandboxes exist in the health sector. For example, the Licensing Experimentation and Adaptation Programme was launched by Singapore's Ministry of Health in 2018. Its goal is to work towards a regulatory framework for telemedicine and mobile medicine services. Such services connect patients to healthcare providers and are already permitted to operate in several other countries. However, they do not fall under the purview of the Singapore health regulator because they run a platform without offering medical services themselves. The aim of the sandbox is to ensure patient safety equal to in-person consultations. In addition, the sandbox allows for experimentation with services that are currently disallowed, such as drug delivery. Companies can apply to join the sandbox and, if accepted, they can feature their participation in their marketing communication and have a direct contact person at the Ministry.

Energy

A higher number of initiatives exist in the energy sector. At least four countries, the United Kingdom, Canada, Singapore and Germany have implemented mechanisms for experimentation in this domain. These sandboxes have different goals and are run by entities with differing mandates. For example, the Singapore Energy Market Authority's sandbox seeks to encourage innovations within the electricity and gas sectors, and a large-scale regulatory experiment underway in Germany is focused exclusively on increasing the proportion of renewable energy sources.

Mobility and transport

There is a higher degree of activity within the mobility sector, especially around mobility on demand (MOD) solutions and connected and autonomous vehicles (CAV). Since the live-testing of mobility innovations emerged simultaneously with, but independent of, regulatory sandboxes, initiatives in this space are often described as living labs or testbeds. An important distinguishing feature of CAV testing initiatives is that they often require legal changes to be implemented to allow for public road testing of autonomous vehicles. Moreover, due to the cross-sectoral nature of CAVs, these initiatives take the form of large-scale public-private partnerships with the joint involvement of actors from government, industry and academia. Notable examples include the Catalan Living Lab, the Singapore Autonomous Vehicle Initiative, GoMentum Station in the US, or the Austrian government's efforts around connected and automated mobility.

Data

Sandboxes have started to emerge that seek to address uncertainties around the use of personal data. These initiatives are cross-sectoral by definition because such questions arise in almost every domain. The beta-phase regulatory sandbox developed by the UK Information Commissioner's Office is open to organisations of any type that deal with challenges around the use of personal data, such as sharing or data protection impact assessment. The Singapore Infocomm Media Development Authority's Data Collaborative Programme offers funding as well as a sandbox environment and targets companies that seek to offer a data-sharing platform as a service.

Thematic and general sandboxes

Thematic sandboxes, which focus on particular technologies, such as blockchain (Lithuanian Central Bank's blockchain LB Chain) or on the promotion of a specific aim within the regulator's remit, such as financial inclusion, have started to appear as well; examples of which include Abu Dhabi Global Market, Bank of Thailand, and Japan's Financial Services Authority (FSA (UNSGSA, 2019).

Finally, a handful of countries have committed to expanding the sandbox principle to a wide range of industries and have made steps to move towards a culture of testing and experimentation. The initiatives include the government of Japan's Regulatory Sandbox, the National Regulatory Sandbox of Malaysia and Germany's Regulatory Test Beds Strategy.

Practical considerations

No changes to existing laws have been required to develop or run these initiatives in most cases (some examples of autonomous vehicle testbeds are an exception) and regulators have noted that general supervisory powers are sufficient in the case of regulatory sandboxes (ESMA, 2018), though regulators often have to ascertain the extent to which existing legislation and regulation allow for flexibility around relevant obligations. In some jurisdictions, regulators and policymakers have outlined the need for 'experimentation acts' to allow and encourage activities like sandboxes. Outcomes-based regulation can make it easier to facilitate testing by removing the need to provide waivers (SRA interview). Generally, companies testing new ideas still have to conform to a broad set of regulatory obligations and have licences to operate.

Statutory objectives, such as promoting competition or consumer protection, often act as the starting point for developing these initiatives. These are often very sector-specific; for example, promoting financial stability or supporting the energy transition towards cleaner energy production. Other regulators have developed these initiatives out of a need to understand and regulate an emerging area, for example, telemedicine.

While regulatory sandboxes, testbeds or living labs can vary greatly, they usually engage in a common subset of activities. These include the provision of individual guidance and advice on navigating regulatory requirements, as well as offering certain temporary regulatory exemptions and restricted licensing. Support is provided in very different ways; for example, some regulators provide a very hands-on approach, engaging with participating companies openly and frequently.

- Initiatives tend to be broad in scope (for example, they are not focused on one part of the financial sector) but some are more narrowly focused on a specific area of innovation, for example, blockchain or telemedicine.
- There are jurisdictional differences regarding what regulatory reliefs regulators are able to provide, as well as the degree to which adjacent regulators collaborate and coordinate (ESMA, 2018).
- Most initiatives are open to incumbents, new entrants and businesses from other sectors (a notable exception is the HKMA's fintech sandbox, which is only open to initiatives intended to be launched in Hong Kong by banks).
- The number of participants involved varies greatly depending on the size of the initiative, the resources regulators have available and the maturity of the programme.

- Similarly, eligibility criteria are largely sector and context dependent though a requirement for truly innovative products or services that have a potential benefit for customers is common.
- Regulators and innovators predominantly co-develop testing requirements on a case-by-case basis.

Testing products vs testing policy

A key distinction between initiatives is the extent to which they include the potential for (or focus on) regulatory adaptation. This distinction has been described in different ways, advisory vs adaptive (Armstrong, Gorst and Rae, 2019) or 'product-testing' vs 'policy-testing' (UNSGSA, 2019). These elements are not necessarily mutually exclusive, but sandboxes and testbeds tend to have a stronger focus on one over the other.

The primary aim of *product-testing initiatives* is to allow companies to test novel products, services and business models before launching, in order to gauge customer uptake, the value of the innovation and ensure that the activities in question comply with existing requirements.

The primary purpose of *policy-testing initiatives* is to identify particular regulations that may impede innovation in some way or new frameworks that need to be developed and use innovation testing environments to develop and evaluate regulatory change. Under this approach, the regulator takes a much more direct role in supporting innovative activities by proactively adapting its supervision or frameworks.

Most of the examples we have identified do both in some way or at least leave open the possibility for regulatory adaptation if a strong case can be made. In practice, however, there have been few examples of regulators actively changing rules except where it is a core purpose of the initiative. For example, the HKMA updated its supervisory guidance on biometric authentication and remote account onboarding in light of tests conducted by banks participating in the sandbox. Similarly, ASIC developed its guide on crypto-assets based on learnings derived from sandbox trials and the exchange with companies through the innovation hub. The relative scarcity of regulatory adaptations could reflect the difficulty of changing individual regulations effectively or that there may be more flexibility under existing regulatory frameworks than is often realised.

Policy-testing focused sandboxes are less common than product-testing initiatives that may include an adaptive/policy-testing element. Notable exceptions include the Monetary Authority of Singapore's sandbox, as well as the Ministry of Health's Licensing Experimentation and Adaptation Programme, which are primarily devoted to evaluating changes to their respective regulatory frameworks.

Policy-testing: importance of timing

It is important for policy-testing initiatives to be focused on a time-horizon that allows companies to benefit from regulatory adaptation. If a given trial serves the sole purpose of informing longer-term policy change, then companies are unlikely to see any benefit in participating, as their primary objective is to launch a successful business, not to inform long-term policy change. If it is impossible for a company to offer their services at the end of a trial because the regulator will only then engage in considering various possible adaptations that might take years to implement, then investing in testing may carry no value to firms. This was a frustration expressed by a few companies developing potentially disruptive innovations.

Timing, technology readiness and the ability to adapt regulation are therefore critical in achieving beneficial alignment of the needs of regulators and innovators. It suggests that only innovations that are sufficiently advanced technologically or in terms of novelty, are ready to be tested with consumers, could create benefits (for consumers/public or environment), and may only need small or easily fulfilled regulatory changes. However, it is worth noting it will not always be possible to assess all of these elements effectively without testing.

The Licensing Experimentation and Adaptation Programme run by the Singapore Ministry of Health is a good example of effective alignment. The sandbox is part of a sweeping reform of the Private Hospitals and Medical Clinics Act which includes a shift from premises-based to service-based licensing. In the context of this reform, the Ministry of Health is running a sandbox to develop a framework for telemedicine and mobile medicine services. These areas were previously not regulated by the Ministry but are technologically ready for large-scale adoption.

Testing initiatives in the mobility sector focusing on CAV may provide further examples to illustrate the role of timing, where the horizon for regulatory adaptation and technology market readiness is longer. These testing initiatives serve the purpose of allowing the two to co-evolve, and both companies and regulators are aligned in their interest in working towards the eventual and gradual rollout of the technology alongside appropriate legal and regulatory frameworks.

Linking testing programmes to broader strategy initiatives

There is also a clear distinction between initiatives that seek to test new innovations that may deliver on elements of their statutory objectives, such as consumer protection or competition, and other programmes that encompass a more strategy-driven approach, linked to broader government objectives or initiatives (such as transitioning to a fully renewable energy supply (Federal Ministry for Economic Affairs and Energy of Germany, 2018)).

Most of the testing initiatives (including all the sandboxes) we have identified fit into the first category. The mobility sector is perhaps most different in this respect (as well as some examples of energy-related initiatives), where live-testing environments aim to serve broader policy goals such as a movement towards a different mobility structure.

For example, the aim of the Singapore Autonomous Vehicle Initiative is to provide a technology platform for the research and development and test-bedding of AV technology solutions. These efforts form parts of Singapore's broader strategy towards attaining a sustainable transport ecosystem, which seeks to reduce reliance on private transport through ride-sharing and mobility on demand, to increase the use of public transport. Other examples of this approach include the Austrian Action Programme on Automated Mobility, as well as GoMentum Station in the United States.

There are several factors that may lead to a more strategically aligned testing programme. These could be sector or context related, for example the complexity, interconnectedness and risks of the innovation in question (such as autonomous vehicles) or linked to the presence of broader government strategies in these areas. Live-testing initiatives in this space tend to have much longer roadmaps, involve a much broader set of stakeholders and include no temporary regulatory reliefs (other than potentially some legal clarifications or adaptations). Instead, they pursue an incremental approach to crafting an overall framework that adequately responds to the complex legal, technological, infrastructural and social requirements of automated mobility. Strategic approaches may be more likely where regulators do not have statutory independence from other parts of government.

Developing an initiative: pre-establishment

A report by the European Supervisory Authorities (ESMA, 2018) recommends that prior to the establishment of a sandbox type initiative, a "rigorous analysis should be carried out to identify the appropriate expertise, powers, processes, and structures required in light of local market conditions and the resources available to the competent authority." From our research, this kind of analysis is not routinely done. Lessons learned from the first two cohorts of Ofgem's sandbox, and a comparative analysis of fintech regulatory sandboxes by the UNSGSA (2019), shows there is a risk of a mismatch between the way regulators seek to support businesses and what those businesses need to innovate.

In this respect, the Lithuanian Central Bank's processes for setting up a blockchain sandbox may be viewed as valuable. The bank conducted a thorough assessment of the technological feasibility and benefits of the concept of a blockchain sandbox and pursues an iterative approach, whereby the sandbox is first piloted at a smaller scale before rolling out for general use. The process involved continuous discussions between the regulator, platform service providers and interested fintech companies. While such extensive prior engagement is costly and time-consuming, it can serve to ensure that the resulting sandbox is maximally fit for purpose.

Support: a hands-off vs hands-on approach

Interviews with companies that participated in the FCA's Regulatory Sandbox highlighted the high support and frequent interactions as a key part of the value of the initiative. Many businesses continued to have informal contact with case officers even after exiting the regulatory programme, providing more long-term, engaged support. According to businesses, which have been through several different sandboxes, this more active, open and engaged approach is far more beneficial. However, it is important to note that this approach is more resource intensive and so there can be a trade-off between investment and the scale of the live-testing initiative.

"The case officer was very helpful. He's very responsive. He executes well in terms of helping us internally with the FCA, linking us up with the right parties, etc. So, my experience is very positive… we have spoken with FCA's peers in Hong Kong and Singapore, etc. My impression is that there, they're much more hands off and they prefer the innovation to foster in the industry first and then bring it to the sandbox." (Vadim Sobolevski, FutureFlow)

In contrast, other regulators have pursued a more hands-off approach, such as the HKMA Fintech Supervisory Sandbox 2.0. The HKMA regulates banks in Hong Kong, and participation in the sandbox is not tied to any strict eligibility criteria, there are no reporting obligations or mandatory minimum requirements beyond ensuring safety and consumer protection. There is no dedicated contact person during the testing period, and the interaction between the regulator and the bank is mostly limited to the creation of the testing protocol.

Regulatory cooperation

Where an innovation may fall between two regulatory regimes, it can be very difficult for a company to participate in a testing space.

"The UK rulebook so to speak says there are two tracks, insurance or consumer finance, but those two don't speak to each other...I personally think it's a pity that let's say the FCA has not more regulatory flexibility which we have seen with other regulators. I think it's in part because we had the split in the UK, as I'm sure you are well aware, between the FCA and the PRA. So,

one is doing the conduct side, one is doing the prudential regulatory side, the venture capital side. If those two are two different authorities, you're probably a bit more limited than others." (Tobias Taupitz, Laka)

Regulatory agency cooperation, like that seen in the MHRA's innovation office, is important where innovation is more likely to cross sectoral, as well as regulatory, boundaries.

Successful approaches have also developed:

- Clear entry criteria, in line with the aims pursued by the sandbox
- Clear communication on timelines and expectations given to companies looking to test
- Provision of clear information about the services and tools, including advice and regulatory reliefs, that are available
- Streamlined application process (for example, request only the pieces of information needed) which maintains enough flexibility
- Due diligence performed on the companies applying
- Adequate safety, consumer protection, cybersecurity and dispute resolution mechanisms are in place
- Disclosure of the trial nature of services to any customers using them during the testing phase

There are four basic stages of testing innovations in a controlled environment through sandboxes, testbeds and living labs:

1. **Application**: Some regulators run these initiatives through cohorts over defined periods while others have an open, ongoing application process. The latter method allows firms to approach the regulator at any time when they are ready to test an idea and is favoured by many regulators as a result. Applications are judged on specific eligibility criteria which normally includes stipulations around the scope of the initiative, how innovative it is, its potential benefits, the level of need for testing and the readiness of the product, service or business model to be tested. When determining how genuinely innovative a proposal is, regulators tend to apply a low bar, at least in the early stages of a sandbox or testbed, and simply try to confirm nothing like this already exists in the market. Innovators may also need to demonstrate that they are able to make any necessary partnerships or secure clients before entering the testing space.
2. **Preparation of licences and design of testing environment**: Regulators work closely with eligible innovators to design the testing space and secure any necessary licences. This is done on a case-by-case basis. This preparation phase can be completed in a matter of weeks.
3. **Testing phase**: Time available for testing varies considerably between different initiatives. Throughout the testing phase, innovators are expected to communicate and share data with the regulator and surface any issues as soon as they arise.
4. **Exit and evaluation**: At the end of the testing phase, a final report is produced (either solely by the business or jointly with the regulator). A plan for removing any limitations and other restrictions can then be put in place. Several interviewees highlighted the importance of the exit strategy: " [It was] very important – we did the sandbox as a route

> to becoming fully authorised. Therefore, the exit process and becoming fully authorised without restriction was of course the most important part for us. The sandbox team made this journey simple and straight-forward." (Myles Milston, Globacap).

Currently, very few sandbox operators have systematic evaluation measures or performance indicators in place.

Evidence of impact

The use of regulatory sandboxes, testbeds and living labs has expanded considerably in recent years. These programmes are still young and have had relatively few participants, so it may still be too early to judge their impact. The FCA's sandbox, one of the longest-running testing spaces, has received 89 companies into its programme since 2016 through four cohorts, each of around 20-30. Resource limitations and the high level of support and interaction provided to participants limits the size of these cohorts. Most of the evidence available is in the form of reported benefits by regulators or businesses. It is worth noting that the breadth and range of innovations being tested, along with other sector and context differences, makes it difficult to provide universal insights. There is also significant variation in operational transparency of different initiatives and their results. Very few regulators offer publicly available information on lessons learned from running these programmes, while others offer summary statistics at most (ESMA, 2018). Notable exceptions include the FCA and Ofgem, which have published reports summarising the insights and learnings derived from their respective sandboxes (Ofgem, 2018a; FCA, 2019b).

Benefits for regulators

More innovation in the market

The extent to which sandboxes, testbeds or living labs have helped enable more innovation is not clear from the evidence available. Based on the number of businesses going through these initiatives, the impact on the market as a whole is likely to be minimal, though the microeconomic impacts (at the scale of an individual business or emerging sector) may be significant.

Risky or novel innovations may particularly benefit from these opportunities. Analysis on fintech sandboxes categorised startups as either competitive (those that are direct challengers to incumbent financial services institutions) or collaborative (those that offer ways to enhance the position of existing market players) and found that the FCA's sandbox had lowered barriers to entry for competitive fintech companies (Bromberg, Godwin and Ramsey, 2017).

Some participating businesses have also commented that participation forced them to think more innovatively:

"In the long run we're probably going to be in a better position since we have been forced to focus more on innovation than we might otherwise have done. We would probably have said, "Yes, that's the long-term vision. Let's focus on that sometime in the future. The regulatory sandbox has given us the possibility to focus on it right now and try out new things, which will fast-track those streams of innovation within the company." (Fractal)

Consumer, public and environmental protection

By working closely with businesses as they develop their innovations, the regulator can better understand the potential risks (and opportunities), guiding businesses to ensure new products or services are aligned with regulation expectations and do not cause any form of obvious

public harm. The positive, transparent and collaborative nature of the relationship between businesses and the regulator is a key route to achieving this.

"I think the very idea of a sandbox is already fantastic. That idea itself is actually allowing a lot of people to deliver telemedicine in a very safe manner." (Dr Siaw Tung Yeng, MaNaDr)

Regulators and businesses greatly valued this transparency, and many seem to have continued informal relationships after exiting the initiative. Regulators and businesses saw this positive relationship as an ongoing opportunity to identify emerging issues earlier and work to resolve them before they became a serious problem and might, therefore, have required punitive action. Companies have also commented that participation led them to adopt better practices which will help them ensure compliance in the future:

"The rigour that we went through in applying and participating in the sandbox was really positive. We've taken the learnings from that and embedded it into our deployment methodologies that we use with our clients. The rigour that you go through to go through the FCA sandbox, is one of the key benefits of the process." (Dan Scholey, Moneyhub)

Experimentation can inform long-term policymaking

A number of regulators have used sandboxes to inform their long-term regulatory strategy to specific issues. Engagement with innovative businesses allows regulators to stay up to date with a changing market, the evolving needs of businesses and recent technological developments.

"...we are able to feel the pulse, what the industry is living with, what problems are we solving, what innovation is out there." (Vytautas Kieras, Lietuvos Energija Sandbox)

The Singapore Ministry of Health sandbox was set up solely for the purpose of helping to craft a legal framework for certain applications that traditionally fell outside the scope of the regulator. The Bank of Lithuania's blockchain sandbox will also serve the purpose of guiding future regulation informed by the experiments, and the HKMA also reported that they had adapted their supervision on several occasions. This is another way in which regulatory agencies can ensure adequate safeguards are in place to protect consumers, while at the same time enabling innovation.

Based on our interviews, regulators are building these insights in two ways:

1. A new rule or principle can be introduced for evaluation by the regulator
2. The regulator may decide to utilise the knowledge gained during testing to create new frameworks based on what it considers best practice.

Nevertheless, comprehensive evidence is still lacking on the ways these initiatives feed into the policymaking process or the positive impacts this has had. The Singapore Ministry of Health sandbox will be a valuable source of learning in both these respects as it continues to 2020.

"...the main outcome we wanted to achieve is to better understand new innovative services by partnering early with industry. This allows us to review an effective, efficient and appropriate way to support innovation, while delivering care that prioritises patient safety and welfare." (Praveen Raj Kumar, Singapore Ministry of Health)

Demonstrates a commitment to innovation and learning

Regulators are often accused of being too slow to respond to emerging innovations. Sandboxes and similar live-testing environments can send a strong message to innovators that the regulator is interested in engaging with cutting-edge developments and working with the private sector to support a flourishing ecosystem. This, in turn, may help support wider investment in innovation and may be particularly important in sectors or contexts where there are cultural barriers to innovation.

"As Singapore's regulatory framework transitions from a premises-based to a services-based approach, healthcare services like telemedicine will be regulated. While there is potential value of telemedicine for our system (e.g. follow-up for simple chronic conditions), Singaporeans are generally cautious when it comes to new health modalities and there is a need to increase adoption for such use cases. Through the sandbox programme, we were able to provide more assurance to the public that the providers within the sandbox and the modality itself was safe (i.e. a legitimising effect). For providers, the sandbox gave them the opportunity to work with us to better understand the use cases, risks, potential benefits of telemedicine, and co-create the future regulatory regime. This gave them the assurance that their models would transition seamlessly into the new regulatory regime. In short, the sandbox has helped to grow a telemedicine ecosystem that is safe, of good quality and in-line with our national healthcare objectives." (Praveen Raj Kumar, Singapore Ministry of Health)

Benefits for innovators

Quicker entry to market

One of the most significant reported benefits of these initiatives is the ability to test ideas and get them to market quicker. This could lead to greater competition and consumer choice. Within testing environments, innovators can better understand the newly developed product or service from a business and consumer point of view as well as a regulatory one before fully launching. This is particularly important where entirely novel products or services are being developed. The transition from application and acceptance to participation in the testing phase can be completed very quickly (often a matter of a few weeks), including acquiring any necessary licences.

While it is true that sandbox or testbed licences (or exemptions) can be provided very quickly, our interviews indicated that in some circumstances there might, in fact, be a time cost for participating in the initiative. This negative impact was viewed as acceptable in light of the other benefits the sandbox offered, mainly ensuring compliance, investor confidence, building a relationship with the regulator and helping shape relevant future regulations.

"We tempered our innovation whilst within the sandbox. We turned things down to eight...we were moving so fast in comparison to many others and we had a lot more understanding and experience of decentralised systems, decentralised finance, cryptocurrency, blockchain activity than many around the table, that we needed to make sacrifices and compromises in our vision so that we could actually execute. Thankfully the regulatory team is very bright and they came up the curve really fast." (Ben Whitby, Tokencard)

Reduced regulatory uncertainty

For all of the companies we interviewed, participation in the initiative offered a greater level of regulatory understanding and, therefore, certainty. It also improved communication routes between the innovator and regulator on an ongoing basis even after exit from the initiative (only where regulatory agencies took a more hands-on approach). This created a more

sustained sense of regulatory certainty for both companies and investors. An open dialogue and greater transparency could reduce the likelihood of severe penalties should an issue arise if it is clear the business is acting responsibly.

Legitimacy and investor confidence

Being part of these initiatives has given innovators a 'stamp of legitimacy' in the eyes of others in the industry, particularly investors or potential partners and clients. This is especially true in the case of innovations which fall outside of existing regulatory frameworks or which are deemed to be potentially high risk. Being associated with a regulatory sandbox or testbed helps instil a level of trust and can be seen as an indication that the business is actively looking to ensure compliance and customer value.

"We're very early in the evolution of Cryptoassets, very few traditional firms wanted to work with us, those that did agree to work with us said 'We're saying yes because we believe you're being transparent, you're trying to do the right thing, and the FCA accepting you into the sandbox is a very strong indicator and evidence of you trying to do the right thing'." (Ben Whitby, Tokencard)

Some of the businesses we interviewed were directed to a sandbox type initiative, for this reason, demonstrating a wider sector appreciation for these testing environments and the role of the regulator in building confidence (FCA, 2017).

"The most beneficial part would be more or less legitimising our service... I think the main benefit of being a member is that MoH did endorse us to say that they have looked through our processes and they feel that it is safe enough as an option to seek healthcare if you really need to." (Dr Kevin Kok, Doctor Anywhere)

"...the sandbox is quite effective in the sense that it's a very safe way for the regulator to put you on the map and to signal to the industry what is reasonably interesting and relevant. But at the same time,...it's very difficult to generate traction in the industry without first having some sort of traction in the regulatory side." (Vadim Sobolevski, FutureFlow)

Limitations

Cost implications

One of the potential limitations of live experimentation initiatives is the high resource costs they require both in terms of time and money. Some early analysis also suggests that the cost and effort involved in launching and operating a sandbox are often underestimated by regulators; and that at least one goal, the promotion of financial inclusion, is better served by more traditional regulatory mechanisms (UNSGSA, 2019). Some interviewees have also questioned the merits of this approach and its wider worth in providing public value, especially compared to other approaches such as advice centres, which are comparatively less resource intensive.

"With respect to testing innovation, there seems to be a high 'asymmetry' between the people in the administration who are responsible for granting special permits, e.g. in licensing authorities on the State level, and the project managers [regulators]. In many cases there is for example a high uncertainty on legal, safety and liability issues." (Dr Kai Hielscher, Federal Ministry for Economic Affairs and Energy)

Legitimacy label: misunderstood market signals and PR-stunts

Existing literature has highlighted that sandbox (or testbed or living lab) participation may signal to consumers, or the wider industry, that the regulator 'approves' of a certain business or product, whereas the business has only been given temporary exemption to test the quality and regulatory compliance of an innovation.

To avoid this risk, ESMA recommends that appropriate disclosures to consumers should be required, as well as creating clarity on the issue that the regulator bears no legal responsibility as it is merely monitoring the testing. Some have suggested that perceived legitimacy could become the main reason companies participate as a way of getting ahead (Kelly, 2018). However, we did not find any evidence of this and do not see it as a major risk as eligibility criteria should ensure only appropriate businesses and innovations participate.

Success beyond the trial

There is no guarantee an innovation will be successful beyond the sandbox or testbed. This may be more likely in the case of entirely novel products, services or business models. Here other barriers may stand in the way of success.

"...it's all very well going to a sandbox and having temporary permissions to do something a bit different, but once those temporary permissions go away you're potentially sat in limbo with a great idea that helps our customers that you can't execute, because we can't change legislation fast enough, addressing this would be a good enhancement to the process." (Dan Scholey, MoneyHub)

"It's nearly impossible to open a bank account, nearly impossible to get an underwriter to want to underwrite your product, which is why Etherisc ceased the FCA sandbox process and will not be in the UK... it's just basically finding the common ground that is a challenge just because you are a blockchain-based technology." (Luis Novella, Vivat/Etherisc)

Non-regulatory barriers to innovation

In some sectors, particularly where large-scale and complex infrastructures or legacy systems exist, regulation may not be the main barrier to innovation. In some contexts, the regulator is only one part of a wider system that includes key elements that sit outside of the regulator's control, such as industry codes and culture. A clear example of this is the UK energy sector:

"It's very rare that some radical new model is blocked by one line of rules. [...] The things that block these things are a complex web of rules, norms and attitudes, not just in the regulator and innovative business, but in potential partners […] the rule also dictates how the system works […] So, while it's accurate to say that a rule is the cause of it, changing the rule does not change the infrastructure. And changing infrastructure often involves really big investment." (Daniel Kirk, Ofgem)

In these cases, creating more flexibility for innovation would require not just changes to the rules and regulations but also significant investment to adapt existing infrastructure, coordinated action with a range of stakeholders (whose incentives tend not to involve change) and cultural shifts. These kinds of issues may be relevant in some form to every sector but are likely to be more significant where there are high infrastructure costs, well-established incumbent businesses, a need for long-term investments and existing complicated structures, for example in transport or areas of telecommunications.

Representative testing

Concerns have been raised as to whether testing provides a good enough representation of the impacts an innovation might have once it is fully integrated into the market (Kelly, 2018). Understandably, it is in the interest of companies to test their innovations in a lower-risk way.

"Our first use case is cover for high-end bicycles. So, we deliberately chose a test case where we would not burn through millions and millions of pounds if it goes wrong. In that case, worst case, maybe the bill would have been £20,000 if we had too many claims, right? So, we designed it that way, so it can be contained." (Tobias Taupitz, Laka)

Dispositional market advantage

Another concern is the positional advantage gained by companies in a sandbox, which benefit from close cooperation and direct support from the regulator. By providing insights from the sandbox or testbed to the wider community through other channels such as advice centres or reports, regulators tended to see these approaches as a way of enhancing their wider support offer. Here public documents describing the authority's policies and lessons learned are particularly important but not prioritised enough (ESMA, 2018).

Summary

- Experimentation and the live-testing of innovative technologies are becoming increasingly widespread in sectors, including fintech, mobility, data, health, and energy.
- These methods allow regulators to understand and reduce the risks of emerging innovations, ensure compliance, and work towards improved regulatory frameworks.
- The specifics of running a testing initiative will be heavily dependent on sectoral and jurisdictional characteristics.
- Testing can bring about several positive outcomes, such as allowing new market entrants to gauge demand for their services, ensure regulatory compliance/alignment, increase investor confidence, and contribute to the development of adaptive regulatory frameworks.
- In addition, experimentation may support other statutory objectives or broader policy goals. For example, improving market competition in the case of the FCA, or Ofgem's objective to promote security and sustainability of the energy supply for present and future generations.
- Experimentation can contribute to the creation of a more open and transparent relationship between regulators and regulated organisations.
- It can also be resource intensive, and regulators should carefully assess whether it is the most appropriate means to achieve their objectives.

3. Streamlining regulatory approvals for innovators

Aim

Streamlining approval processes:

- Help innovators or businesses with new products or services achieve full market access faster by providing alternative routes to authorisation
- Lessen the initial regulatory burden for innovations where there is an unmet need or a strong potential for consumer benefit in a critical area like health.

Description

A variety of mechanisms have been developed to speed up market authorisation of novel products or services, particularly in the health sector. These include long-running fast-track pathways for pharmaceutical products and initiatives such as the Food and Drug Administration's (FDA) De Novo classification process for innovative medical devices and software. These mechanisms share similarities with experimentation initiatives, such as regulatory sandboxes, but differ in several important ways.

Unlike regulatory sandboxes or testbeds, they are not designed as experiments, i.e. they do not include any provision for a specific, safe testing space or post-testing evaluation before any necessary approval. Instead, they provide full market access through faster alternative approval processes, often with post-market monitoring or different evidence requirements. Experimentation in a regulatory setting is also more open-ended and does not tend to focus on a specific regulatory barrier; whereas, these mechanisms are designed to overcome clear and specific regulatory barriers to innovation around authorisation.

These initiatives tend to be used where there are high unmet needs due, at least in part, to existing regulatory barriers and the regulator, therefore, may need different approaches to balance risk and innovation effectively. One of the first examples introduced in the US was via the Orphan Drug Act of 1983, which established several incentives for pharmaceutical companies, including fast-track approval of drugs for rare diseases. In line with the Act, the Humanitarian Device Exemption programme was introduced by the US FDA in 1990, exempting certain medical device-based therapies intended for rare diseases from the requirement of establishing a reasonable assurance of effectiveness (FDA, n.d).

The FDA's De Novo classification process, first developed in 1997 and updated more recently, is an attempt to overcome the negative impacts its predicate-based system (comparing new devices or designs against existing devices) can have on innovation by providing alternative means to classify low-risk, novel medical devices or software. These and other measures since have sought to shorten drug and medical device development and review, and manufacturers are sometimes allowed to combine multiple expedited pathways to speed up the process further.

More recently, a number of new designation systems have been introduced by major health and medicine regulators in the USA, the EU and Japan. These regulatory and legislative initiatives often give regulators the power to approve treatments with less rigorous assessment in the case of high, unmet clinical need, such as for serious and life-threatening conditions, where the new therapy promises a significant improvement on available treatments. In these cases, surrogate measures of efficacy may be used, which provide 'reasonable indications' of benefit. In addition, post-market surveillance and subsequent trials are required to establish efficacy.

Manufacturers participating in facilitated pathway programmes benefit from mechanisms, such as early meetings with the regulators, extensive support on the design of trials, expedited review, a cross-disciplinary project lead, and the involvement of senior managers and review staff (Darrow, Avorn and Kesselheim, 2018).

Examples

Initiative	Description
UK - Accelerated Access Collaborative Pathway (AAC)	Launched in 2018, the AAC is an initiative hosted by the National Institute for Health and Care Excellence. It brings together a range of actors across government and industry to facilitate a number of acceleration activities to speed innovative products to market. The AAC's activities include the creation of an accelerated pathway to market, as well as horizon scanning to identify highly transformative innovations. The 'breakthrough' designation of the accelerated pathway is focused on "affordable products which can dramatically improve efficiency, fill an unmet need or make a step change in patient outcomes." (Department of Health, 2017). The expectation is that innovations may reach patients up to four years earlier, and it is anticipated that around five products will go on the accelerated pathway each year. A key consideration has been affordability by the NHS, and the programme has been designed to be cost neutral.
Swissmedic - Fast-track authorisation procedure	Swissmedic's Fast-track procedure is intended for novel treatments of conditions where existing therapies are unavailable or unsatisfactory, the condition is serious and life-threatening, and high therapeutic benefit is expected. The evidentiary requirement for reviews on the fast-track procedure does not differ from the standard route, and the acceleration is achieved through "the targeted planning of resources", which involves direct and frequent engagement and advice sessions between the regulator and the firm (Swissmedic, 2019).
FDA De Novo classification	Unlike the rules-based classification schemes used in Europe, Brazil and other markets, medical devices in the US are classified using a predicate-based system. The FDA uses this system to classify medical devices as Class I, II or III based on increasing risk to the patient or user. The De Novo classification pathway functions as an alternative means of classifying low- to moderate-risk devices. Traditionally, these devices were automatically classified as class III devices, after the FDA determined that they were not substantially equivalent to an existing product. The De Novo process provides a pathway to classify novel medical devices where available evidence provides reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device.

Initiative	Description
	The FDA allowed the marketing of one of the first artificial intelligence-based devices, to detect certain diabetes-related eye problems in this case, after reviewing under the De Novo premarket pathway (FDA 2018b). Announced in August 2017, as part of the Digital Health Innovation Action Plan, the software Pre-certification (Pre-Cert) Pilot Programme, will help inform the development of a regulatory model that provides streamlined and efficient regulatory oversight of software-based medical devices developed by manufacturers which have demonstrated a robust culture of quality and organisational excellence, and who are committed to monitoring real-world performance of their products once they reach the US market. The Pre-Cert program is tied to the De Novo classification system and is being piloted as another approach for ensuring the safety and effectiveness of new devices (particularly software-based systems).
FDA Breakthrough Therapy Designation System	Introduced in 2012, Breakthrough Designation is the FDA's 6th instrument to expedite drug development. Eligibility criteria include the existence of preliminary clinical evidence showing how the drug may have substantial improvement on at least one clinically significant endpoint compared to available therapies. The designation allows drug approval to proceed on the basis of fewer, smaller or shorter clinical trials and with recourse to less than well-established surrogate endpoints.
Japan - Strategy of SAKIGAKE	Launched in 2015, the strategy includes two priority pillars, the SAKIGAKE Designation System and the Scheme for Rapid Authorisation of Unapproved Drugs. The designation system seeks to promote research and development in Japan, as the country has a considerable drug approval lag compared to other major regions. The criteria for receiving the designation include showing prominent effectiveness based on non-clinical studies or phase I or II trials, as well as a commitment to making a premarket application firstly in Japan or simultaneously in other countries and Japan (Kondo et al., 2017). Substantial post-marketing safety measures are also involved, such as extended re-examination periods. The specific benefits of SAKIGAKE designation include shortened review from 12 to 6 months, potentially longer market exclusivity and a 10-20 per cent pricing premium if the pharmaceutical is proven to be highly useful. The rapid authorisation scheme seeks to facilitate access to drugs unapproved in the EU/US if certain conditions are met, such as, finalising a phase III trial in Japan, or showing promising published clinical data.

Initiative	Description
Hong Kong Insurance Authority Fast-Track Approval system	Introduced in 2017, new insurers, mostly tech companies, with an innovative business model, who own and operate only digital distribution channels can apply for authorisation and receive consideration in a dedicated queue. To mitigate the risks, applicants must establish a partnership with an existing traditional insurance company. The first such fast-track insurer licence was announced in December 2018.

Practical considerations

Due to the compressed timeframes and increased resource requirements of reviewing facilitated pathway applications, they can represent a major increase in workload for regulators. Therefore, authorities have to prioritise applications that are most closely aligned with their regulatory objectives.

Depending on the jurisdiction, the specific regulator's remit, and the mechanisms used to accelerate and support approval, some facilitated pathways need legislative action in order to be implemented. For example, in the case of the FDA, Accelerated Approval regulations and the Fast Track process were formalised by the agency itself, on the basis of existing powers, while the most recent Breakthrough Designation, the Priority Review designation, and the Orphan Designation came about via congressional activity.

Ongoing monitoring and real-world data

Many of these approaches require some level of post-authorisation monitoring, especially where there are less stringent requirements for impact evidence prior to authorisation. Therefore, mechanisms must be put in place to monitor the real-world performance of products effectively. When creating such mechanisms, regulators must consider the kinds of real-world data that can meaningfully inform evaluations of a product's performance and its conformity with requirements.

This kind of monitoring may be particularly critical for software and AI-based systems where models may be regularly optimised based on new data. Such monitoring is meant to ensure continued safety, effectiveness and performance as AI-based tools evolve (FDA, 2019).

Evidence of impact

There are a few different approaches to streamlining authorisation in a number of different areas of healthcare and a handful in other sectors. Some initiatives are relatively new or have been fairly recently updated so evidence on impact may be limited. For example, while the De Novo pathway was set up in 1997, recent changes and improvements (for example, to review times) have only recently been put in place, as well as the increased focus on software-based devices.

The use of streamlining regulatory approvals has been most extensively studied in the pharmaceutical sector. Here, it is important to keep in mind that several the limitations highlighted below are predominantly associated with the way these approaches have been

applied, or misapplied, in relation to drug approvals and underlying issues in that sector[2]. These insights provide lessons for other sectors that may consider utilising these approaches.

Benefits

A faster route to market for low-risk or 'critical' products

Initiatives can drastically cut the time taken for low-risk innovative products to reach the market. This can be a competitive advantage for companies developing novel products; for example, the FDA is one of the first regulators in the world to authorise an artificial intelligence-based diagnosis device (for detecting certain diabetes-related eye problems). In safety-critical areas like healthcare, novelty can be a significant barrier to market entry without extensive evidence of impact and efficacy.

Incentivising innovation

Initiatives may serve as strong incentives for companies to pursue innovation by reducing the costs and time associated with bringing new products, particularly drugs, to market. Many initiatives also provide longer exclusivity periods where applicable. The development times on facilitated pathways are sometimes dramatically shorter than standard periods (Darrow, Avorn, and Kesselheim, 2014).

The Japanese SAKIGAKE designation system has been successful in helping to address the country's lag in introducing new therapies that had already been approved in Europe or the US. An increasing number of companies are deciding to launch in Japan first or at the same time as in other major markets (McCalister, 2017).

However, it is difficult to assess the overall impact of facilitated pathways on innovation in these markets. An extensive review showed that the rate of pharmaceutical innovation measured in the production of new molecular entities has been largely constant over the period 1950-2009 (Munos, 2009).

Unmet needs

These initiatives can help bring a larger number of new products to market in potentially underserved but critical areas faster. For example, they have been used to help higher numbers of new pharmaceuticals reach the market, especially for patients with rare diseases and life-threatening conditions (Damle et al., 2017).

Limitations

Resources needed for post-market analysis

Heavy reliance on post-market surveillance will add additional burdens for regulatory agencies. Greater resources will be needed to effectively monitor developments as they happen in the 'wild'.

Enforcement

[2] There are a number of structural issues affecting the development of new drugs, that colour existing evaluations of the facilitated pathway approach. Many argue the industry has, to a considerable extent, avoided the pursuit of 'disruptive innovations' (Pantelli and Edwards, 2018) and focused on 'me-too' drugs, which do not provide substantial improvement on existing products (Naci, Carter and Mossialos, 2015).

After pre-certification and product launch, if issues were to arise, agencies might have limited enforcement powers or delays in recalling a product, meaning potentially increased public exposure to potential risk.

Legitimacy label

Certification may result in consumer confidence based on the expectation that marketed products have received rigorous assessment when that will not have been the case (Lee and Kesselheim, 2018).

Perception of safety

Facilitation of approvals involves striking a delicate balance between meeting consumer/patient needs while ensuring adequate safeguards and quality. Designations that confer an aura of innovativeness, such as 'breakthrough therapy', even before the real outcomes have been sufficiently verified may exacerbate demand. There can be increased public pressure to approve such products, putting public safety at risk. Acting on a safety issue post-approval may turn out to be very difficult (Darrow, Avorn and Kesselheim, 2014).

While the above analysis is primarily focused on pharmaceuticals, similar issues around the move towards faster review times, lowered evidentiary standards and the trade-offs between speed of access, product quality and public benefit have been raised in relation to medical devices (Kramer, Xu and Kesselheim, 2012; Janetos et al., 2018) and advanced biological treatments as well (De Grandis, Brass and Petersen, 2018).

Favouring established actors

Although facilitation is intended to support new ideas and market entrants, conditions and requirements may not favour emerging actors. For example, the Hong Kong Insurance Authority's Fast Track process requires that new players partner with established organisations.

Measures of innovativeness and public benefit

In deciding which products or services should be included in a facilitated pathway, there are challenges around how to define and measure innovativeness or potential public benefit. In the case of drugs development, this is particularly difficult where a person's quality of life may be at stake. Naci, Carter and Mossialos (2015) distinguish among several possible measures associated with new drug approvals such as technological and pharmacological novelty, the number of patents associated with new medicines, and clinical superiority over existing alternatives.

Overuse of facilitated pathways for drug deployment

An analysis of FDA drug approval trends from 1987-2014 has shown that newly approved drugs are associated with an increasing number of expedited review mechanisms. This suggests that, despite the original motivation that expedited streams should support innovative, or first-in-class drugs, the trend seems to be driven by less innovative applications (Kesselheim et al., 2015). Similarly, a cross-sectional study spanning the period from 1995 to 2016 assessed Health Canada's use of expedited pathways and has shown that around 30 per cent of applications went through such a pathway; however, these fail to predict major therapeutic gains reliably. Consequently, the study suggested that the continued use of such pathways should be re-evaluated (Lexchin, 2018).

However, there may be considerable national differences with regard to the utilisation of expedited pathways, as demonstrated by the example of the Swiss regulator. According to its 2017 annual report, Swissmedic received 287 applications for first authorisations of, and major variations to, innovative medicinal products, out of which 32 were approved during the same year, and only seven qualified for the fast-track procedure, which is a considerably lower proportion than in many other jurisdictions (Swissmedic, 2017). This suggests that agencies utilise fast-track processes in very different ways that warrant further comparative analysis.

Lower standards in drug development

Concerns have also been raised about the apparent tendency towards the use of increasingly flexible evidentiary standards to grant access to expedited review processes, such as the use of surrogate endpoints, as well as smaller and fewer studies, which may pose risks (De Grandis, Brass and Petersen, 2018). For example, evidence suggests that pharmaceuticals going through an expedited pathway are associated with a significantly higher rate of subsequent safety issues and even withdrawals than drugs on standard pathways (Kesselheim and Darrow, 2014). Unfortunately, despite the long-standing existence of expedited pathways, there has not been sufficient gathering of post-marketing confirmatory trial data (Darrow, Avorn, and Kesselheim, 2014) and the reliability of real-world data is also disputed (Santos Rutschman, 2017).

Summary

Approaches to streamlining approvals may be appropriate for regulators with a licensing and permission-granting responsibility. We have observed three forms of streamlining:

- *Increased resource allocation*, whereby an agency decides to prioritise certain applications by devoting more support and services, without modifying the set of criteria they have to meet
- *Alternative evidentiary standards* involve the lowering or alteration of criteria that an application has to meet in order to acquire the agency's approval
- *Acceleration of limited licences* involves granting a limited authorisation, which may be appropriate to new (tech) entrants to a market, who are carrying out a small subset of regulated activities and where monitoring can be easily implemented

The most important positive impact of fast-tracking is that it may bring innovative new solutions to consumers more quickly, thereby also helping regulators to meet their objectives.

Existing examples of fast-track procedures in the pharmaceutical sector reveal limitations, including overuse of fast-tracking, a higher incidence of post-marketing safety issues and a lack of efficacy in identifying which applications are appropriate for acceleration.

4. Setting regulatory challenges to drive innovation

Aim

Challenges can help regulators:

1. Direct or stimulate innovation towards a specific challenge or outcome as an alternative way for regulators to meet their objectives and respond to key risks or market failures;
2. Facilitate regulatory learning and adaptation in response to innovation.

Description

Where market forces may fail to address significant problems (for example, fairer access to products or services, or bigger issues such as climate change) that affect a regulator's ability to fulfil their obligations, a more proactive approach may be needed. Challenge-driven initiatives can be an effective approach of stimulating and directing innovation towards a particular challenge, which could be a market failure or gap, bigger societal challenges or the opportunity to create new types of consumer/public benefit.

The challenge methodology offers regulators the opportunity to play "a more active role in driving innovation" (FCA, 2018) and can potentially deliver several benefits. Challenge-driven initiatives are particularly suited to solving problems that share some key characteristics (Ballantyne, 2014):

- Problems that are clearly defined so that there is a clear and unambiguous goal for innovators
- Problems that would benefit from new ideas and innovators; for instance, because the sector is fairly inert or there is a related field that is much more dynamic
- Problems where additional attention and support could plausibly accelerate progress
- Problems where the solution could thrive in the market

Challenge prizes (a form of challenge-driven initiatives that provides a cash 'prize' incentive) have been used for several centuries, and they are a well-established method for driving innovation in the public and private sector. Several more recent national policy initiatives have been set up to encourage the use of challenges by government agencies (for example, Impact Canada and Challenges.gov). There are very few examples of challenges being used in a regulatory context, and the examples that we have identified have only been developed very recently. While discussing challenge-driven approaches, we refer to initiatives instigated or led by regulators that have a clearly defined and measurable problem statement(s) or challenge and an open call for participation.

Examples

Initiative	Aims	Description
Legal Access Challenge	Stimulate AI-powered innovations that could serve to widen access to justice	As part of the RPF, the UK's Solicitors Regulatory Authority is developing a challenge to stimulate innovations in the area of AI-powered legal advice and to inform the regulator's approach to these new technologies. The project is about to be launched, and it is hoped it will not only lead to some exciting access to justice solutions but also help stimulate innovation in a technology-inert sector.
Green FinTech	Develop and support	The FinTech Challenge is a pilot approach for the UK financial regulator's FCA Innovate programme and involves the FCA

Initiative	Aims	Description
Challenge (FCA, 2018a)	financial products or services designed to respond to the challenges of climate change	taking a more active role in driving innovation in an area where there are clear benefits for UK consumers and markets. The pilot FinTech Challenge will focus on firms developing innovative solutions to assist in the UK's transition to a greener economy. The initiative will seek green solutions that need specific regulatory support to bring their proposition to market. The challenge will provide support to a selection of firms developing innovative products and services and is open to startups, incumbents and technology providers. Examples of green solutions include: • Supporting capital flows/investment towards green products and services • Driving efficiency in the issuance, distribution or adoption of green products • Managing climate-related risk posed to market participants • Environmental impact measurement • Delivering new green financial products
Open Up Challenge (Nesta, n.d.)	Develop new products that support UK SMEs as part of the open banking initiative	In 2016, the Competition and Markets Authority (CMA) proposed the introduction of a common open banking standard across the largest banks as a remedy for ongoing issues in the UK retail banking market. Open banking enables third parties to access a bank customer's accounts, with the customer's permission, to access the customer's data and initiate payments on their behalf. The Open Up Challenge is part of the same remedy package and provides financial incentives for third parties to develop useful innovations that build on open banking functionality, rewarding the most impactful. The challenge provides participants with anonymised data from the banks to support their product development, proactively encouraging experimentation by innovators, enabling them to test new products and services that will help achieve the overall goals of greater innovation and competition. The UK's pioneering role in implementing open banking is being followed by several other countries, including Australia, Canada, Germany and Mexico. The Challenge awarded £4.5m in equity-free funding to 25 financial technology companies.

Initiative	Aims	Description
LabCFTC (Commodity Futures Trading Commission (CFTC), 2018)	(In development)	LabCFTC, the US CFTC's fintech initiative, is requesting public input to gather ideas and topics for innovation competitions to advance the agency's fintech goals. LabCFTC Director Daniel Gorfine. *"Our ultimate goal is to focus the energy of America's innovators on ways to improve our agency and our markets so that we can keep pace with a rapidly digitizing world."* This initiative is possible through the Science Prize Competition Act (2015), that allows government agencies and regulators to hold competitions and award prizes, such as non-monetary prizes and prizes in partnership with external organisations, to stimulate innovation designed to advance the goals of different government agencies.

Practical considerations

As with advice centres and innovation testing spaces, no changes to existing laws have been required to develop or run these initiatives, and regulators are similarly able to leverage their general supervisory powers. Where challenge-driven initiatives may include a testing or experimentation element, they can function in the same way as a sandbox or testbed. Two of the examples we identified are directly linked to existing innovation testing spaces (the FCA's Green FinTech Challenge and the SRA's Legal Access Challenge). Initiatives may differ in several ways; for example, some may provide more extensive support at various stages or employ the use of financial and non-financial incentives ('prizes'). Below, we discuss three important practical considerations when developing a challenge-driven initiative:

- Basis and focus for the challenge
- Participation and eligibility criteria
- Support provisions and incentivising participation

Basis and focus for the challenge

As a challenge-driven initiative requires regulators to take a more proactive approach to innovation, defining a specific outcome that will shape the market, it is crucial that there is a strong regulatory basis for running the challenge and the area upon which it focuses. For most regulators, this is a different way of operating as the FCA have highlighted:

"This involves taking a view on areas where financial services markets could benefit most from innovation, and actively encouraging the development of creative, market led solutions in that space. To date, we have been values and sector neutral in our selection criteria of firms that we work with." (FCA)

Regulatory agencies need to carefully consider whether they are comfortable taking an approach that predominantly focuses on one area and the companies operating in that area. If the regulator decides to explore this method, then the next stage is to identify an appropriate

focus area where innovation could most benefit the relevant market or consumers/public. High-risk issues or market failures have been highlighted as an important catalyst in the development of several initiatives. For example, the Open Up Challenge was part of a set of remedies introduced by the CMA to overcome persistent market failures in the UK's retail banking sector.

"This work is not about social policy or political objectives; it is about better delivering our statutory objectives, and using innovation as a more efficient remedy tool within the FCA's decision-making framework (i.e. utilising innovation as a remedy to harm or "markets not working as well as they could")." (FCA)

The basis for the Green FinTech Challenge

For the FCA increasing competition and consumer benefit provided a basis for developing the Green FinTech challenge.

"The Green FinTech Challenge aligns with the FCA's statutory objective to promote competition. There is potential for consumer benefit arising from more competition and innovation in this space." (FCA)

The focus on green finance and innovation related to climate change emerged from an identification of critical risks to the financial sector and changing consumer needs. As Andrew Bailey has laid out "*Our Mission explains that we aim to act where we add the most public value, and so we must take into account the ways markets are likely to develop and users' changing needs.*" (FCA, 2018b) This covers a range of issues and drivers of change, of which climate change and increasing consumer demand for 'green' financial services products are a key part. There is also a recognition that continuing political and policy shifts around climate change will have a major impact on financial markets and products.

The challenge will provide support to businesses developing innovative products or services that assist in the UK's transition to a greener economy (FCA, 2018b). These green solutions include areas such as:

- Supporting capital flows or investment towards green products and services
- Driving efficiency in the issuance, distribution or adoption of green products
- Managing climate-related risk posed to market participants
- Environmental impact measurement
- Delivering new green financial products

The FCA sees this approach as an opportunity to drive innovation in an area where they believe there is a clear benefit to UK consumers and financial markets. *"We have not seen many green finance firms within Innovate in the past... Through the FinTech challenge, we see an opportunity to more effectively support business and market needs, through shining a light on issues where innovation has the potential to deliver maximum benefit to UK markets and consumers."* (FCA)

The basis for the Legal Access Challenge

For the SRA, the incentive to develop a more proactive approach grew out of three important observations. Firstly, despite running other innovation-enabling programmes (an advice centre

and sandbox) they had not seen the same kinds of new ideas or disruptive innovations emerge in the legal sector as other sectors such as fintech.

"We hope to see more and different types of innovation in that space, but at the moment the firms that are in there are only really testing new practising arrangements...They're just ahead of where our regulation is going anyway, so I would argue they are not examples of disruptive technological innovations." (Emma Tunley, SRA)

This *"disconnect between what they could do and what they want to do"* (Emma Tunley, SRA) likely stems principally from the culture of the sector, how business pricing and models work and the structure of the market. The challenge was, therefore, an opportunity to help stimulate innovation that may come from outside the sector and overcome these cultural issues to increase the range of new ideas in the market, improve competition and provide consumers with new services (and, therefore, benefit).

Secondly, new unregulated AI-enabled advice systems have started to appear, such as the do-not-pay chatbot (donotpay.com, n.d.): *"one of the issues that's coming out of the work is around concerns about the quality assurance of AI. Even if it's information, but certainly when it's flipping into legal advice, it is whether consumers trust that advice, where's the quality assurance..."* (Emma Tunley, SRA)

Lastly, access to legal services has been identified as a key risk in the SRA's ability to meet its regulatory outcomes (SRA, n.d.). Cuts to legal aid (Gilbert, 2018) have heightened this problem in recent years, and the market is yet to deliver new products or services to respond to consumer needs.

Participation and eligibility criteria

All the examples referenced are open to incumbents and new or non-traditional sector entrants. These may be participants from anywhere in the world. A key feature of challenge-driven initiatives is that they open up the problem to new players and create the conditions for solutions to be put forward from non-traditional or unusual places (Ballantyne, 2014). Based on their experience with a sandbox and advice centre, the SRA expect much of the innovation they will see through the challenge to come from outside the traditional legal sector.

"I think there are some, but a limited number of particularly innovative or disruptive business models in the legal sector. Going forward, I think disruptive change is particularly going to come from the technology companies working along-side law firms." (Emma Tunley, SRA)

As with innovation testing spaces, eligibility criteria tend to cover innovativeness, potential impact and relationship to the challenge.

Support provisions and incentivising participation

The level and types of support provided as part of a challenge can be very different. Some non-regulatory challenges take a very hands-off approach: setting the challenge and waiting to see what innovations emerge. On the other hand, challenges can provide very high levels of support in a similar way to incubators or accelerators. Some include both financial and non-financial support either throughout the process or at specific stages, potentially with a final 'prize' being awarded to the winner or winners (the innovations that best solve the challenge). Prizes, both financial and non-financial, can help incentivise participation but are usually only nominally more valuable than the overall support provided (Gök, 2013).

The Open Up Challenge and the Legal Access Challenge have provided additional support through the use of development grants as well as access to expertise and regulatory assistance to ensure innovators are adequately supported. Support from the Information Commissioner's Office will be an important part of the Legal Access Challenge as personal data will be a fundamental part of the solutions being developed. These accelerator type activities are particularly useful in supporting companies in the early stage of their development (Hathaway, 2016; Bound and Miller, 2013).

All the examples we have identified provide an opportunity to test innovations in a real-world environment with real customers, in close partnership with the regulator. In this way, a challenge initiative could be one part of a wider regulatory package. For example, the FCA will provide access to existing support facilities already available through the Innovate programme, namely:

- A dedicated Innovate Adviser
- Authorisation support
- Live market testing in the sandbox
- Guidance and informal steers

There are five basic stages of running a challenge-driven initiative:

1. **Defining a challenge**: A focus for the challenge will have to be developed that fits with the broader objectives of the regulator.
2. **Application**: An open application process based on set eligibility criteria that cover stipulations around the scope of the innovation and its aims. Challenges are usually open to earlier stage ideas though there may be requirements related to how developed the concept is or where the business currently operates.
3. **Preparation of licences and design of testing environment**: Where testing will be required, the same kinds of preparations and limitations apply as they do to innovation testing spaces.
4. **Challenge and testing phase**: Development and testing phase can include different types of support or action, from mentoring, advice and expertise to financial support. This phase commonly has a specific time limit.
5. **Assessment and judging**: A challenge may end with a demonstration of the innovations being developed, and a judging panel made up of independent experts may decide on a set of 'winners'. The judges will evaluate the participants on several elements; how innovative the solution is, impact on addressing the challenge and other design considerations.

Evidence of impact

As all these initiatives have only been established relatively recently, and most are yet to launch, there is little evidence available on the impacts of these programmes on their stated goals or a regulator's other statutory objectives. The benefits discussed here are potential benefits as perceived by regulators undertaking these initiatives.

Benefits

Actively stimulates and promotes innovation

This is one of the few regulatory approaches we have identified that aims to stimulate and promote innovation rather than enabling innovation already happening. While this is primarily focused on the specific defined challenge, regulators indicated they expected there to be spillover effects, supporting a wider culture of innovation. For the SRA, this is an opportunity to drive more innovation in the legal sector as a whole; for the Green FinTech Challenge, it is an opportunity to support the growth of an important area of the financial sector. As with other innovation-friendly approaches, this is expected to lead to increased competition, consumer benefit, and potentially increased investment and trust in areas which have been underfunded or not prioritised in the past.

Guides the development of new areas

This approach allows regulators to work closely with the emerging products and services early in their development (especially those that sit on the boundaries of their remit) and create the right regulatory frameworks that balance the need for consumer protection against the need for innovation and flexibility. In this way, challenge-driven initiatives can mirror policy-testing sandboxes such as the Licensing Experimentation and Adaptation Programme in Singapore.

"While the project covers a critical risk area we have identified – improving access to legal services – so is firmly in our regulatory remit, the methodology also appears to offer an important opportunity to explore early on whether emerging developments such as automated legal services that may currently sit outside our current regulatory perimeter will have important implications for our ability to regulate effectively going forward" (Emma Tunley, SRA)

Direct innovation towards important challenges

Challenge-driven initiatives tie the innovation they promote to a particular problem or public good. For innovators, it can be a clear signal that this is a valuable emerging area to focus on, and there is the opportunity to help shape those future regulatory frameworks.

"This work is not about social policy or political objectives; it is about better delivering our statutory objectives and using innovation as a more efficient remedy tool within the FCA's decision-making framework (i.e. utilising innovation as a remedy to harm or "markets not working as well as they could")." (FCA)

Other outcomes for regulators

As with other approaches, regulators can use challenge-driven initiatives to build greater knowledge around innovation and new areas, which is particularly important if they are likely to have a disruptive effect on the sector. By acting in a more proactive way, it may also help build better relationships with new actors, enhancing the profile of the regulator as open and innovation enabling.

The use of challenge-driven initiatives outside of a regulatory context has also identified this method as an effective means of (Ballantyne, 2014):

- Bringing new products and services to market
- Engaging a wider network of innovators
- Gathering new information on an issue
- Identifying new types of innovation
- Building the capacity of new innovators and supporting their entry into the market

Limitations

Market distortion

Challenge-driven approaches are only one way a regulator may go about addressing a market failure. As it requires regulators to play a more active role in shaping the market (or a new market) and will focus on market actors developing innovations related to the challenge, it may lead to greater market distortions than other mechanisms. However, as initiatives aim to do this in a way that promotes wider innovation, and therefore competition in a particular area, it should not preferentially favour any particular subset of businesses (unless, for example, the project focused on an area where only incumbent businesses were able to act).

The examples that we have identified have all ensured the scope and criteria for participation opens the possibility of involvement to a large array of businesses and innovators. Regulators developing these projects have also identified the broader application of lessons learned during the process as a way of providing support back to the wider sector through advice or new regulatory frameworks. More analysis and evaluation will be needed to assess how effective and appropriate this approach is (in different contexts) over other mechanisms of resolving market failures.

The continued success of new products, services or markets without further support

In creating markets in new areas, for example around open banking, or directing innovation towards a particular outcome, there is no guarantee that the products or services will continue to flourish outside of the regulatory initiative. Consumer and investor confidence will be needed for a new market to grow. The growth of green fintech businesses or AI legal advice systems will also depend on many other actors, political choices and other socio-economic drivers. However, the regulator is in an important position to provide legitimacy and signal where they see a need for innovation.

Relationship with government policy

The focus of the challenge may be closely connected to other government policies or initiatives. Care is, therefore, needed in how those challenges are defined to ensure independence from the government but also reflect the direction of travel. Some of the areas already identified by regulators for challenges are potentially highly political. Political changes and shifts in policies could impact initiatives in the future, though this does not alter the fact that the challenge may relate to a key risk area that the regulator has to deal with, such as climate change.

Summary

- Regulators are beginning to use challenges as a way to drive innovation and address critical risks or market failures in a way that traditional regulatory action may not be able to.
- It provides an opportunity for regulators to engage with emerging activities that may be coming in from outside the sector.
- Utilising these types of initiatives will depend on the regulator's openness to play a more proactive role in shaping markets and innovation.
- Careful consideration needs to be given to the focus of the challenge and levels of support provided to participants.
- The potentially close relationship with policy and political agendas may limit where challenges could be used, and this type of market shaping may not be seen as attractive in certain circumstances.
- The nascent nature of these initiatives means little evidence currently exists on their impacts.

5. Collaborating internationally on innovation

Aim

International agreements or regulatory harmonisation can:

1. Help innovative firms navigate different jurisdictions and interact with regulators to test and bring novel products, services or business models to market quickly in several countries at the same time
2. Reduce international regulatory barriers or burdens to innovation
3. Support cross-border information sharing, regulatory learning and adaptation in response to innovation

Description

Regulatory frameworks can differ significantly across countries, and it can be extremely difficult for businesses or innovators to navigate jurisdictional complexities. Harmonisation efforts may take the form of bilateral, regional or international agreements, whereby aligned regulatory requirements are crafted to reduce the costs of compliance, increase market access for innovation and drive consumer benefit. Harmonisation initiatives may take a variety of forms, including binding norms that have a supranational scope, such as EU regulations; softer instruments, like best-practice guides that national agencies may adapt to local specifics; or more informal networks.

There is a long history of international harmonisation initiatives; here, we focus on recent efforts to develop programmes that focus on cross-border regulatory approaches that support innovation such as a network of cross-border regulatory sandboxes (GFIN, 2018).

For the purposes of this report, we distinguish between three main approaches to international collaboration, which are not mutually exclusive and can be employed simultaneously.

1. Work-sharing, where regulators collaborate across borders to expedite an authorisation process and bring products to several markets simultaneously
2. Harmonisation, where multiple countries work towards creating a harmonised set of rules and standards, which creates certainty, predictability and larger market access to companies
3. Collective experimentation, where multiple jurisdictions collaborate on the facilitation of cross-border testing of innovative products

Examples

Initiative	Description
Global Financial Innovation Network	The GFIN seeks to provide a more efficient way for innovative firms to interact with regulators, helping them navigate between countries as they look to scale new ideas, facilitated through cross-border testing. The GFIN builds on the FCA's early 2018 proposal to establish a global sandbox. It was formally launched in January 2019 by an international group of financial regulators and related organisations, including the FCA.
Fintech Bridges	Fintech Bridges are bilateral regulatory cooperation agreements that enable information sharing among regulators regarding financial services and emerging trends within this field, together with regulatory concerns (Fekete, 2018). The aim is to foster fintech beyond the borders of a country, and towards international implementation (Goodman, 2018). The bridges allow companies to scale internationally through access to other markets. They are cooperation platforms which concern governments, regulators and the private sector (Goodman, 2018). The first bridge was established in 2016 between the UK and Singapore (Fekete, 2018). There are currently 47 fintech bridges implemented across the world, between multiple jurisdictions (KAE, 2019), and in 2018, the first global study on the then 46 fintech bridges was launched, which provides a more concrete understanding of the impact of these initiatives (Irish Tech News, 2018).
US-Japan Medical Device Harmonization by Doing (HBD)	In December 2003, government, academia, and industry in Japan and the United States jointly started activities in order to harmonise US-Japan regulations pertaining to the approval of cardiovascular devices. Since the first meeting in December 2003, a series of think tank-type meetings have been held, and a working group has been established to develop a single, global clinical trial protocol for cardiovascular devices. In addition, another workgroup is devoted to the standardisation of information available in post-market data registries, and "reducing

Initiative	Description
	manufacturers' premarket data requirements by using post-market data." (FDA, 2018a).
International Medical Device Regulators Forum (IMDRF)	Established in 2011, the IMDRF is a voluntary group of medical device regulatory agencies working towards global harmonisation. Among its work items are medical device cybersecurity, clinical evaluation, personalised medical devices, and good regulatory review practices.
Australia-Canada-Singapore-Switzerland Consortium (ACSS Consortium, 2019)	The ACSS was formed in 2007 by four 'like-minded' regulatory authorities to work towards greater alignment and collaboration. The aim is to enhance the efficiency of regulatory systems by building synergies and sharing knowledge among participating authorities. The ACSS has two working groups, one on New Chemical Entities, and one on Generic Medicines. Both working groups have launched innovative work-sharing trials for coordinated assessment across multiple jurisdictions. The pilots are expected to provide valuable knowledge about the use of foreign assessments by regulatory bodies, thereby reducing regulatory burdens and bringing products faster to more markets.
EU cooperative intelligent transport systems (C-ITS) Regulation	In March 2019, the European Union adopted a new set of rules regarding cooperative intelligent transport systems (C-ITS). The rules establish minimum legal requirements for interoperability between the different cooperative systems used, thereby creating legal certainty for manufacturers about the expectations their products will have to meet (European Commission, 2019).

Practical considerations

Agreeing, arranging and maintaining international regulatory initiatives or harmonisation is a significant undertaking, and there are a number of important practical considerations to take into account.

Clear guidelines on individual jurisdictional effort

Individual members taking part in the agreements, cross-border experimentation initiatives and regulatory harmonisation processes, must be proactive in their efforts within their jurisdictions. Within GFIN (FCA, 2019a), each regulator is responsible for overseeing testing in their jurisdiction, and that appropriate safeguards are in place.

Clear guidelines on the nature of the collaboration

In establishing an initiative, it is also necessary to pin down how participating regulators will collaborate. In the first consultation paper proposing the setup of GFIN (2018), three foundations for the collaboration are described: a network of regulators promoting information exchange, collaboration between regulators on key policy questions and cross-border trials.

In the FinTech Bridge agreement drawn up between Australia (ASIC) and the UK (FCA) (Treasury of the government of Australia, 2018) there are four pillars of collaboration:

1. **Government-to-government**: To discuss fintech policy as it relates to each jurisdiction.
2. **Regulator-to-regulator**: Regulators will facilitate the testing of innovations between the jurisdictions, through a referral mechanism for firms wanting to enter the other's market. The authorities are to work towards quicker processing of licensing for businesses already licensed or authorised in the other jurisdiction.
3. **Trade and investment**: Governments support companies entering either market.
4. **Business-to-business**: Governments support active engagement between the fintech industries in the respective countries.

Evidence of impact

Several of the examples discussed in this report are still in the pilot phase or are yet to be launched. Therefore, little data is available about these initiatives' outcomes, but various types of benefits appear to be emerging.

Benefits

Shared understanding and common terms of reference

International harmonisation initiatives can be highly successful in creating a shared understanding, as well as common guidelines and definitions for multiple regulatory jurisdictions. For example, the IMDRF's guidelines on the definition, quality management, risk categorisation and clinical evaluation of software as a medical device product has become an important reference for regulators and manufacturers around the world (FDA, 2017). Although such guides might need local adaptations to be implemented, they provide a common 'frame of reference' that supports industry and innovation by creating clarity on key regulatory expectations.

Information exchange

Collaboration between regulatory agencies facilitates knowledge sharing and better equips regulators to successfully respond to challenges that similar agencies may have already encountered. Both the GFIN and FinTech Bridges programmes aim to promote information exchange within their networks and between jurisdictions to keep up with market trends and innovation developments.

Concurrent market accessibility

Faster market access and a reduction of the regulatory burden for licensing or approval (for example, by only needing to submit one application) are an important benefit of these initiatives. Harmonised regulatory requirements directly translate into financial savings for companies and resources that could then be put back into research and development activities or other business functions. The distributed workload among multiple regulators can lead to faster decisions and market accessibility in several jurisdictions, leading to the faster dissemination of innovations (Zuekeng and Seoane-Vazquez, 2017). The Australian-UK FinTech Bridges initiative specifically includes faster licensing/authorisation as a core role of the regulator-to-regulator collaboration (Treasury of the Government of Australia, 2018).

Attracting foreign investment and talent

Initiatives such as the FinTech Bridges programme can provide benefits through encouraging and enabling greater foreign investment in priority markets and by allowing companies to scale faster (Kocianski and Toplin, 2016). For companies, it may also be a way to attract new talent (Goodman, 2018).

Higher quality products and services

Harmonised requirements, especially data and knowledge sharing among regulators, can play an important role in improving the quality of products. Relying on a larger pool of data gathered from multiple jurisdictions has the potential to reveal more flaws, mistakes and inefficiencies, which can then be corrected and improved. Examples include more effective pharmacovigilance as well as fintech trials conducted in a global sandbox.

Meeting consumer needs

Harmonisation can directly benefit consumers by allowing them earlier access to products and services. This is well illustrated in Japan where there used to be a serious ‘drug lag’, and pharmaceuticals already approved in the EU and the US appeared on the Japanese market several years later. A series of measures which included strong international harmonisation efforts have helped to significantly reduce Japan’s drug lag, thereby benefiting patients and potentially saving lives.

Limitations

Below we identify a number of risks that might accompany international regulatory harmonisation initiatives.

Barriers to international collaboration

While international collaboration and harmonisation initiatives aim to overcome regulatory divergence, there are many instances where differences in culture or regulatory systems may be too large to develop common frameworks. Unless harmonisation initiatives are sufficiently broad in geographical scope, they may result in regional silos that could grow progressively distant from and incompatible with each other.

Power asymmetry

Countries with larger and more developed economies might exert an undue influence on the framing and creation of norms, rules and guidelines (Knaack, 2015; Goldbach 2018a, b) during these collaborations, though it is worth noting these dynamics can also be seen outside of international harmonisation projects.

Convergence or competition?

While regulatory convergence and cooperation might have significant benefits, it could reduce the scope of regulatory innovation by creating entrenched, complex and slow-moving systems that are difficult to adapt to quickly changing circumstances and developments, thereby representing a form of regulatory lock-in. On the other hand, lack of collaboration might induce a race to the bottom whereby jurisdictions compete on imposing the least number of safeguards and controls in order to maximise short-term gain. These risks may be avoided by striving for a flexible mix of regulatory competition and collaboration (Esty and Geradin, 2000).

Summary

- International collaboration plays an increasingly important role in meeting the challenges of emerging technologies and the demands of a globalised economy. Such efforts can help spread the global benefits and impacts of emerging innovations.

- International collaborations may exist at the bilateral, regional or international level and provide benefits to regulators and consumers alike.

- Collaborations may aim to reduce barriers to market entry and promote the scale up of companies beyond their borders, which can both enable and stimulate innovation development.

- We have identified three different ways in which regulators can work together to facilitate innovation: 1) work-sharing, 2) harmonisation and 3) collective experimentation.

- It may be more difficult to create cross-border collaborations and harmonise between partners, whose regulatory landscapes and whose regulators work very differently in a given sector.

- Collaborations can reduce the time it takes to bring innovations to international markets, harmonisation can create legal certainty and support the industry by reducing the burden of compliance with multiple sets of regulatory criteria, while international experimentation can allow companies to scale more quickly, attract more investment and talent and create international regulatory frameworks

- Collaborations can be difficult to implement if the regulatory landscapes are too varied and may be influenced by power asymmetries among participating countries

- There may be a risk of regulatory 'lock-in', whereby expensive and time-consuming efforts aimed at harmonising and aligning regulations may lead to lost opportunities of innovation development through regulatory competition

4. Conclusions

In trying to support innovation and the development of new sectors and fulfil their objectives, regulators have begun to develop new approaches that better align these two aims. In many ways, regulators are starting to see promoting business-led innovation as a potential tool to deliver their objectives, whether that be market competition, sustainability or protecting the public. But how much do the approaches allow regulators to achieve these goals and what kinds of positive outcome can they deliver? Our analysis has identified a number of important routes to impact.

Routes to impact

We found good evidence that innovation-friendly approaches to regulation can support business-led innovation through two key routes; increasing investment and investor trust in new products, services or business models, and helping participating companies bring their innovations to market (or acquire a license) quicker.

Interviews with businesses and innovators indicated that greater investment and investor confidence could be attributed to several factors including requirements for innovators to pass certain eligibility criteria and demonstrate due diligence before participating in a particular initiative, closer engagement with regulators (investor confidence was strongly associated with approaches that enabled or required a closer working relationship with the regulator) and evidence the new product, service or business model was viable after testing in a sandbox or testbed like environment.

Speed was a key feature of all the approaches we have described and was facilitated in a number of different ways across different approaches. More focused regulatory support either through advice or practical help during participation (for example faster processing of licences) was the main route to impact. Other outcomes such as greater knowledge of the potential regulatory implications of an innovation or lower interjurisdictional barriers were also important.

We found compelling evidence for two other ways in which regulators can indirectly support business-led innovation while significantly benefitting their wider work. Firstly, many regulators are using these approaches to build knowledge and expertise around the needs of innovators, the types of innovations emerging and their potential impacts. This was a strong feature across a majority of examples we uncovered and a core element of several projects. Improved knowledge allowed regulators to adapt or develop new regulatory frameworks that are more robust and can support innovation. It also allowed regulators to improve the quality of service they offered to those seeking advice or help.

Secondly, by developing approaches that are explicitly ‘innovation-enabling’, and creating value in the ways outlined above, regulators were able to increase business trust and facilitate a more open and transparent relationship with many businesses.

Our research turned up some evidence to support other closely connected positive outcomes such as new actors entering different markets, increased competition and a greater number of new ideas that may not have been possible with regulatory support. From the available evidence it was not clear to what extent the approaches presented here have, or could, enable these outcomes. Non-regulatory barriers may still stand in the way of new ideas or new actors achieving success, even after regulatory support.

Finally, we did not find any evidence for increased consumer trust in new products, services and business models or greater public engagement through these initiatives. However, as we did not interview any consumers involved in the examples described here, we were not able to interrogate this area fully.

While most of the activities we have described could be used in virtually any context, we found that their usefulness and impact will depend on several important considerations:

- The scope of the regulator(s) involved, including their objectives and culture
- The role innovation can play in meeting those objectives (it is certainly not always the case that innovation, greater competition and greater market choice are the right solutions)
- The existence of non-regulatory barriers to innovation, which can severely impede any activities a regulator may undertake (particularly innovation testing and challenge-driven initiatives)
- The resource investment needed to carry out these activities, which is often more extensive than regulators realise (particularly in the case of innovation testing or international harmonisation) and should be weighed up against other regulatory needs
- The extent to which innovation is already happening in relevant sectors; where there is little happening, a challenge approach may be more applicable, but where there is already plenty of market-led innovation occurring, other approaches may be more effective
- The potential risks for consumers, the public and the environment that are associated with the types of innovation being enabled

One of the main findings from this research is the limited extent to which evidence is available (or exists) on the impacts of using different innovation-friendly regulatory approaches. This is partly due to the recent emergence of many of these practices, but a consistent lack of investment in robust evaluation and transparency is a predominant factor. Greater future effort and investment are needed to fill these gaps, of which the planned evaluation of the RPF will be an important step. As further work is done to evaluate these approaches in greater depth, it will be possible to more definitively state which activities are necessary to achieve the outcomes regulators desire in different contexts. It is also likely that as regulators continue to embrace new methods, new types of innovation-friendly approaches will start to appear that have not been described here.

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Appendix I: List of interviewees

In the team's research, representatives from- companies which are/were part of the innovation-friendly regulatory initiatives, and regulatory bodies and other administrative bodies (private companies, governments, consultancies, etc.) running or contributing to these initiatives, were interviewed. The interviewees are listed below and categorised according to the aforementioned groups. The person is mentioned together with the organisation or institutional body the person works for- as well as with the associated innovation-friendly regulatory initiative. Interviewees who have wished to remain anonymous, are referred to as N.N.I. (name not included).

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- Kirk, Daniel (Ofgem), Ofgem Regulatory Sandbox

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- Knight, Chris (Digital Jersey), Digital Jersey Digital Health Sandbox
- Russ, Martin (AustriaTech), Austria Automated Mobility
- Stewart, Louis (Sacramento City), Autonomous Transportation Open Standards Lab
- Stubelius, Andreas (Swedish Energy Agency), Cleantech Hubs Sweden
- Tarbunas, Paulius (Tieto Lietuva Consultancy), LBChain Blockchain Sandbox

Appendix II: List of countries / administrations where examples were identified

- Austria
- Belgium
- Bermuda
- Canada
- Denmark
- Estonia
- EU
- France
- Germany
- Hong Kong
- Hungary
- Ireland
- Italy
- Japan
- Korea
- Lithuania
- Malaysia
- Malta
- Netherlands
- New Zealand
- Norway
- Poland
- Portugal
- Rwanda
- Singapore

- Spain
- Sweden
- Switzerland
- UK
- USA

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