cytiva

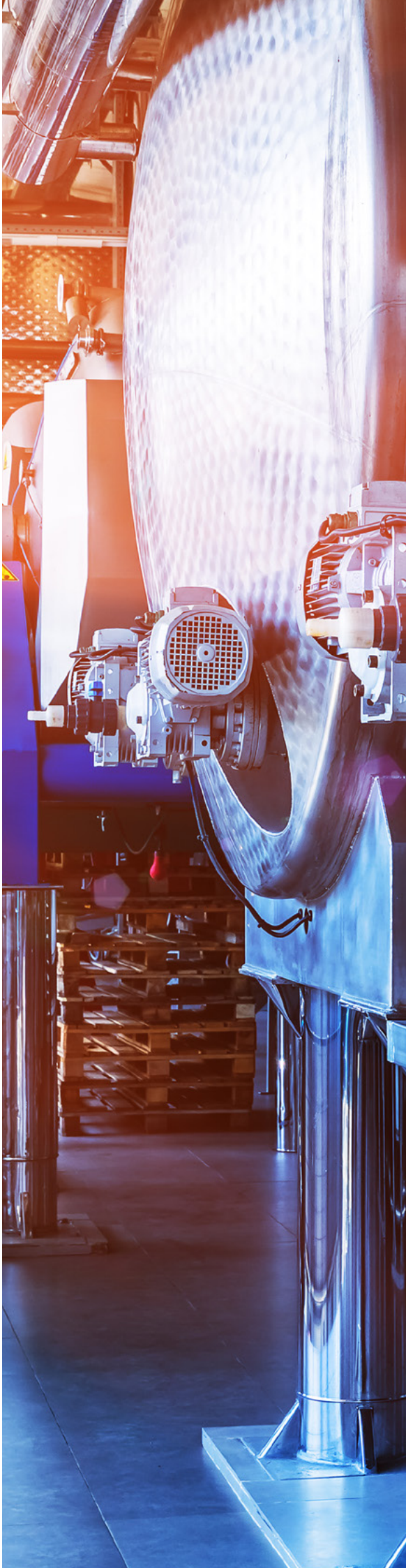
BIOPHARMA 2021: THE RESILIENCE RETHINK

In an age of crisis, can the biopharma industry withstand global shocks?

FT MARKETING SERVICES

This research was conducted by Longitude, a Financial Times group company and part of FT Marketing Services.

CONTENTS



FOREWORD
BY EMMANUEL LIGNER

Today, biomolecules save the world. That has rarely been clearer. As a key player in the biopharma industry, we decided to find out how our sector can help make that happen.

We wanted to understand how biopharma leaders rate themselves in terms of what is going well, where pain points are, and how different parts of the sector can join forces to improve this most crucial of industries.

Our Global Biopharma Resilience Index is the first of its kind to put a number on the strength of, and confidence in, the biopharma industry. We asked 1000 senior pharma executives and healthcare policymakers across 20 countries about five areas: supply chain resilience, access to talent, strength of the R&D ecosystem, manufacturing agility, and the extent to which government policy and regulation supports the industry in helping to serve more patients worldwide. The Index gives us a deep and comprehensive view, country by country, of how biopharma is doing. In the following pages you can explore the findings in detail.

Some of the results are not a surprise — the low score in talent, for instance, which has always been a difficult area for the industry. But there are some less predictable results. Russia, Spain and South Korea, for example, score highly, demonstrating the investment that has happened in those countries and some good government policy. Then there is the strong performance of government policy and regulation — probably affected by the critical role played by policymakers and regulators in the quest for Covid-19 vaccines and therapies.

In addition to the quantitative research, we also hosted in-depth interviews and panel discussions with 10 leading thinkers, policymakers and academics in the biopharma space (see page xx for the full line-up of interviewees). Each of these experts took the time to share their views on the research findings and how the industry can strengthen its performance, and you will find their insights throughout this report.

We hope that the Global Biopharma Resilience Index, by giving us a clear view of the industry's challenges and opportunities, will become a platform for further debate as the world emerges from this period of crisis and uncertainty. Our ambition is that this kind of collaboration will help the industry to chart a course to the futureand ultimately provide better outcomes for patients. It might even save the world.

EMMANUEL LIGNER
President and CEO, Cytiva

RESEARCH METHODOLOGY

Quantitative research

The Cytiva Global Biopharma Resilience Index is built using data from a survey of 1,165 respondents across 20 countries, with 95% of responses coming from pharma and biopharma executives and 5% from healthcare policymakers. The research was carried out by Cytiva in partnership with Longitude, a Financial Times company, in October and November 2020. Of the survey sample, 40% were director level or above, and one-third (33%) were from organisations with annual revenues of more than $1bn.

The index results are based on 19 different performance indicators across five different pillars. These indicators (or questions) and pillars are:

1 Supply chain resilience

- How prone is a country to drug shortages?
- How much dependence is there on imports?
- How effective is the country at boosting supply when there are shortages?
- How easily can suppliers be switched?

2 Talent pool

- Can talent be sourced easily?
- How much dependence is there on imports?
- Is there sufficient education and training to nurture talent?
- How friendly are labour regulations towards accessing talent overseas?

3 R&D ecosystem

- Are partners readily available in the ecosystem?
- How sufficient are existing R&D capabilities?
- Is there healthy cooperation among industry actors to drive innovation?
- How supportive was the R&D ecosystem in responding to the Covid-19 pandemic?

4 Manufacturing agility

- Is the existing manufacturing capacity sufficient to meet current needs?
- What impediments are there to manufacturing with agility?
- How effective are contract manufacturing organisations in terms of quality, adaptability and speed?
- How open has the manufacturing process been to tech adoption?

5 Government policy and regulation

- How effective are government agencies in ensuring industry resilience?
- What policies are in place to promote industry integrity?
- How much funding is available?

Survey respondents were scored out of 10 based on their responses to these questions, with a score of 10 indicating excellent performance and a score of 0 indicating complete failure.

The scores were then aggregated and averaged to provide an overall index score for each country, as well as individual scores for each of the five pillars. The scores act as a proxy for the resilience of the biopharma industry overall, and in each of the five areas.

Expert interviews

In addition to the survey, we also hosted in-depth interviews with 10 leading biopharma experts. We would like to thank the following individuals for participating in the research:

Steve Bates, chief executive, UK Bioindustry Association

Jerry Cacia, head of global technical development, Roche

Dr Chris Chen, chief executive, WuXi Biologics

Roberto Gradnik, a physician and the chief executive of biotech start-up Ixaltis

Adrian van den Hoven, director general, Medicines for Europe

Kiran Mazumdar-Shaw, executive chairperson, Biocon

Martin Meeson, chief executive, Fujifilm Diosynth Biotechnologies

Clive Page, professor of pharmacology, King's College London

Arleen Paulino, senior vice president of global manufacturing, Amgen

John Rim, CEO, Samsung Biologics

INTRODUCING THE GLOBAL BIOPHARMA RESILIENCE INDEX

At no point in the modern era have the health and resilience of the biopharma industry been more crucial. But 2020 revealed some uncomfortable truths about a sector that has become a globalised system of production, trade and distribution. Are the benefits of a global supply chain now outweighed by overdependence on a small group of countries for essential medicines and active ingredients?

In April 2020, as a fear of critical drugs shortages took hold a month after Europe was plunged into panic by a rapid surge of coronavirus cases, Stella Kyriakides, the European Union's health commissioner, urged the bloc to "reduce our dependency on other countries".[1] The previous month, authorities in India — the world's largest provider of generic medicines — had ordered the country's pharmaceutical firms to stop exporting 26 drugs and drug ingredients.[2]

A top priority for biopharma

Constraints in air freight[3] and blockages to talent have come as a shock for the biopharma industry. That is hardly surprising, as it is accustomed to a sprawling network of processes to get everything from generics to biosimilars and other biologics to the market.

"There is huge political interest in this," says Adrian van den Hoven, director general of Medicines for Europe. "Any politician, minister of health or minister of industry you speak to will say, 'This is a top priority. I want to be resilient'."

But van den Hoven also points out that there is a "struggle to understand" where the pain points across the sector are, let alone how the public and private sectors can address them. "The difficulty is in saying, 'What do you do to actually make supply chains resilient, or ensure more investment in manufacturing?'," he says. "What other things can you pursue?"

So just how prepared are countries and their respective biopharma industries to meet a soaring demand for critical drugs?

Introducing the Global Biopharma Resilience Index

To assess the strength of the global industry and its capabilities, Cytiva has created the Global Biopharma Resilience Index. Based on data from a survey of 1,165 pharma and biopharma executives and healthcare policymakers from 20 countries, the index scores and ranks 20 countries on five factors — or pillars:

1. Supply chain resilience
2. Access to talent
3. Strength of the R&D ecosystem
4. Quality and agility of manufacturing processes
5. Effectiveness of government policy in supporting the industry

The overall index score for each country acts as a proxy for the strength of its biopharma industry.

[1] https://www.ft.com/content/c30eb13a-f49e-4d42-b2a8-1c6f70bb4d55
[2] https://www.nytimes.com/2020/03/03/business/coronavirus-india-drugs.html
[3] https://www.ft.com/content/79a02264-6edc-11ea-89df-41bea055720b

THE INCOME DIVIDE: RESILIENCE BY COUNTRY

Of the 20 countries included in the index, the US came out on top with an index score of 7.12, with Switzerland (7.08) and the UK (7.01) in second and third place. Towards the bottom were Indonesia (5.91), Thailand (5.93) and South Africa (5.95).

Perhaps unsurprisingly, the scores show a clear divide between the high-income economies and the upper-middle-income to lower-middle-income economies (as defined by the World Bank). However, when we plot the index scores by gross national income (GNI) per capita (see chart 1), a more nuanced picture emerges.

The top-right-hand quadrant of chart 1 highlights the US and Switzerland as clear leaders when it comes to both GNI and index scores. This indicates that their biopharma industries are thriving and their populations are unlikely to experience shortages of essential medications.

In contrast, the bottom-left-hand quadrant of the chart reveals a group of 'at risk' countries, which fall into the lower-income categories and also have lower index scores. Many of these countries have large populations — Indonesia and Brazil, for example, with more than 200 million people each — which means that greater swathes of people are at risk of not having access to vital drugs in the event of serious disruption to their nation's biopharma sector.

Meet the outperformers

Yet despite having relatively low GNIs per capita, some countries' biopharma resilience matches that of countries in the high-income group. As the bottom-right-hand quadrant of the chart shows, India, China and Russia score high on the index compared with other countries in the same income bracket. This suggests that their biopharma industries are thriving.

What can the biopharma industry learn from these outperformers?

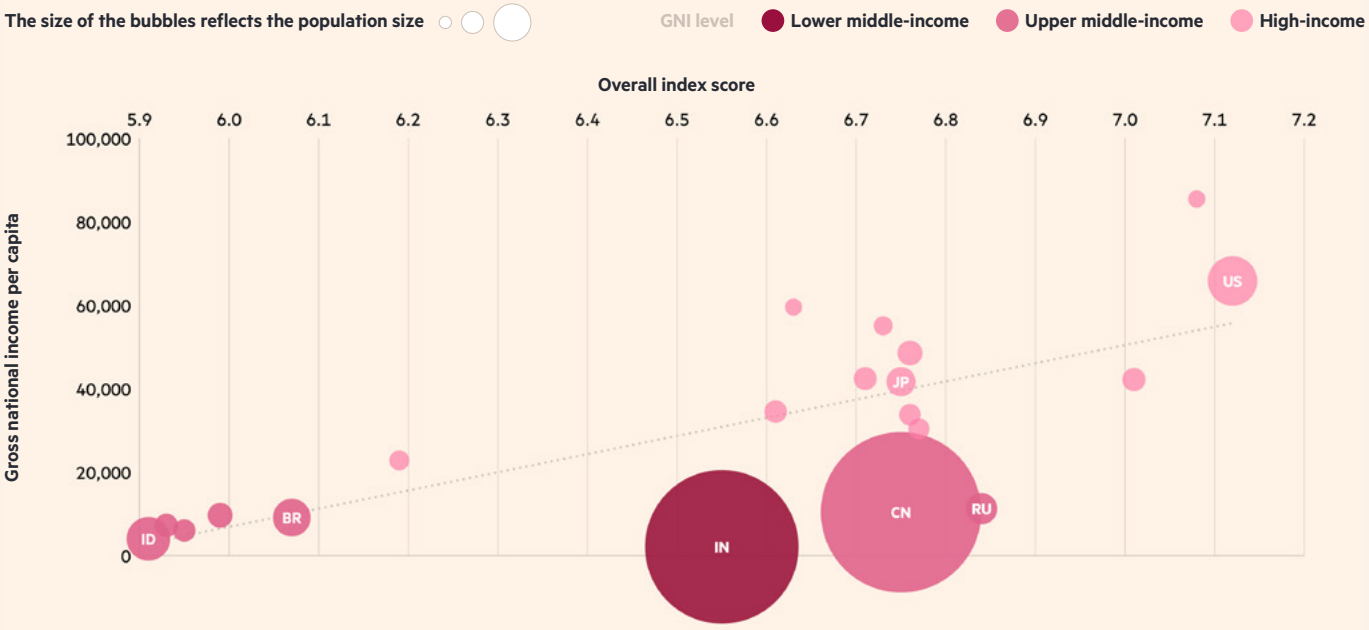
Kiran Mazumdar-Shaw, the chairperson and founder of Biocon, India's largest listed biopharmaceutical firm by revenue, believes that India's approach to developing biopharmaceuticals provides a template for supply chain resilience that other countries can follow.

"I think companies need to be global in their business models," she says. "Today, India is able to cater to large populations in low- and middle-income countries because of our high-volume, low-value approach, which is really inbuilt in everything we do. Whether it is vaccines, generic medicines, or biologic drugs, we are building our business at scale. In contrast, if you look at what is happening in the US and Europe, in terms of delays in vaccine supplies or shortages of vaccines, it is largely attributable to western models of catering to the needs of small populations."

Today, India is able to cater to large populations in low- and middle-income countries because of our high-volume, low-value approach, which is really inbuilt in everything we do.

KIRAN MAZUMDAR-SHAW, CHAIRPERSON AND FOUNDER, BIOCON

CHART 1: INDEX SCORES BY GNI PER CAPITA

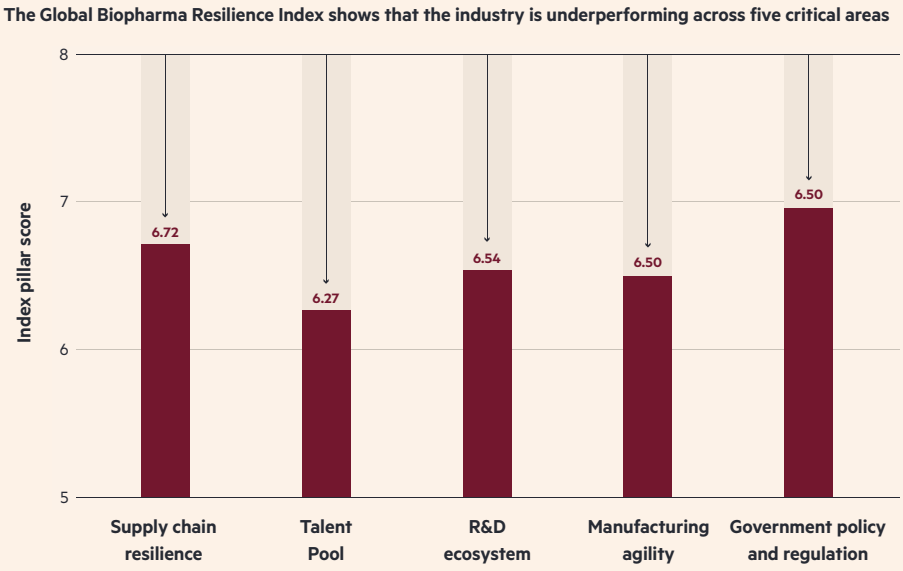


Scores in detail: Where is the biopharma industry strongest and weakest?

Looking at the index results by pillar (see chart 2) allows us to identify where the biopharma industry is strongest and where countries need to improve. Strengthening performance across the pillars will help to address some of the imbalances shown in chart 1, and ultimately increase the availability of essential medicines while speeding up the development of novel treatments.

The industry's weakest area is the talent pool, which has the biggest gap below the mean (see chart 2). That is a symptom of the lockdown restrictions that are limiting how far industry leaders can cast their net to find skilled workers. Where will their future workforce come from?

CHART 2: THE GLOBAL BIOPHARMA RESILIENCE INDEX SCORES BY PILLAR



WHAT DO THE SCORES MEAN?

A score of 10 would indicate:

Supply chain resilience

- Biopharma supply chain is resilient enough to meet the global demand for medications, without shortages
- World is not overly dependent on a small number of countries to produce essential medicines
- Biopharma supply chain is highly agile, and suppliers can be switched quickly if necessary

Talent pool

- Biopharma industry is able to easily source the talent it needs — in particular, specialist digital and technical talent
- The cost of talent remains affordable for all countries
- Education and training is sufficient to nurture talent
- Flexible labour regulations make it easy to source talent from other regions

R&D ecosystem

- Biopharma industry has a strong culture of collaboration, and companies can easily find partners to work with them on R&D
- All aspects of biopharma ecosystem have sufficiently strong R&D capability
- The biopharma R&D ecosystem is able to rapidly collaborate in response to global emergencies, such as Covid-19

Manufacturing agility

- Biopharma manufacturing capability is strong enough to meet global demand for essential medications
- The industry has access to contract manufacturing organisations that excel in quality, speed and adaptability
- Emerging technologies - such as AI and automation - are being adopted to continuously improve biopharma manufacturing

Government policy and regulation

- Agencies responsible for drug approval excel across the following areas: speed, technical capacity, openness to innovation, and cost-effectiveness
- Governments are implementing policies that support the biopharma industry (such as tax and trade policies, and IP laws)
- Funding for start-ups is sufficient to drive growth and innovation in the biopharma industry

The survey responses show that the industry has ample scope to improve in other areas, too: manufacturing agility is another pillar where most countries are below the mean, and the R&D ecosystem manages little better. There are also weaknesses in collaboration and innovation that could put security at risk.

"We synthesise so many materials, and therefore our suppliers are critical. That is why we have such strong partnerships with our suppliers — because they are crucial to the products we manufacture for patients. We want to make sure that there are strong partnerships across the ecosystem: not just between the companies producing medicines, but also with their suppliers and the individuals that develop the technologies required to produce the medicines."

JERRY CACIA, HEAD OF GLOBAL TECHNICAL DEVELOPMENT, ROCHE

The Covid effect

The relatively low index scores may come as a surprise after globally coordinated efforts produced multiple Covid-19 vaccines in record times. But that outcome is the exception rather than the rule. According to van den Hoven, part of the challenge is in regulatory approval: efforts to get biologics manufacturing sites up and running in the US and Europe, for example, often go through long, drawn-out procedures before getting the green light. But the pandemic has shown that governments can act quickly.

"During Covid, there were some rapid procedures, just because the governments wanted additional scale," he says. "So they accelerated certain approval procedures by using more IT tools or gave temporary approvals for example under emergency use rules for some medicines like dexamethasone."

It is not all bad news. Despite the severe headwinds of 2020, the supply chain scores higher than the mean, as does government policy and regulation — traditionally an obstacle. Accelerated rollouts of vaccines are likely to have signalled to the industry that it can, to some extent, count on policymakers when the stakes are high.

For some countries, the pandemic has also highlighted a need to scale up domestic biopharma manufacturing. "It is not that we should be reducing globalisation, but we should make sure we have sufficient capacity to help biopharma companies build locally in the UK and then become global distributors of medicines when they have found something that works," says Clive Page, professor of pharmacology at King's College London.

"Over the next 10 years, I think there will be a big push to scale up biopharma manufacturing in the UK — enabling us to take innovations forward and make sure we retain better control over them."

Over the past two decades, biopharma has taken full advantage of the revolution in global supply chain management, leading to many benefits for patients. However, the Cytiva research shows that, faced with Covid-19, policymakers and biopharma executives no longer see this approach as resilient.

In this report, we go into each of the five pillars in more depth to unearth the challenges and opportunities faced by this most crucial of industries.

GLOBAL OR LOCAL? BIOPHARMA'S SUPPLY CHAIN CHALLENGE

In a letter to doctors on New Year's Eve, the UK's chief medical officers made an important point about the Covid-19 vaccination programme: "Vaccine shortage is a reality that cannot be wished away".[4]

For the profession, the message was a reminder that challenges were still to come, despite the emergence of multiple vaccines. For biopharma industry observers, meanwhile, the chief medical officers' warning was a symptom of a perennial issue.

The biopharma industry has grown increasingly dependent on a global supply chain for the manufacturing and distribution of medicines. This has driven cost efficiencies through economies of scale, but it also makes it vulnerable to bottlenecks.

A complex tangle of processes across multiple countries vastly increases the potential for pain points in the biopharma supply chain, and these have knock-on effects that ultimately delay production. In a pandemic, that is both more likely and more catastrophic.

At this critical point, how is the supply chain performing? The Global Biopharma Resilience Index suggest a mixed picture.

Drug shortages are common

While 50% of executives and policymakers in the survey say their country never experiences shortages of critical medicines such as insulin, this drops to 26% for more specialised areas such as oncology biologics. Respondents from countries with a lower GNI per capita — Indonesia and Thailand, for instance — are more likely to report shortages. For example, 32% of respondents in Indonesia say that their country experiences shortages of oncology biologics more than once a year, compared with none in Switzerland and just 4% in the US.

Meanwhile 51% of executives say that drug shortages increased in their domestic market during the pandemic, although 33% say that the issue had been increasing over the past five years. This points to underlying issues around supply chain resilience, which have been exacerbated — but not caused — by the pandemic.

Part of the problem of supply chain security is the reliance on others. About half of the executives and policymakers surveyed (47%) say their country is moderately or highly dependent on the import of drugs, which illustrates the sheer expanse of the drug production and delivery process.

China and India in particular have become the epicentres of production for the generics and active pharmaceutical ingredients (APIs) that form so much of the industry's output. Any breakdown in the supply chain here would create serious problems.[5]

"I think even before the current crisis companies were rethinking their supply chains. They were moving away from really extreme globalisation."

ROBERTO GRADNIK, A PHYSICIAN AND THE CHIEF EXECUTIVE OF BIOTECH START-UP IXALTIS

[4] https://www.gov.uk/government/publications/letter-to-the-profession-from-the-uk-chief-medical-officers-on-the-uk-covid-19-vaccination-programmes/letter-to-the-profession-from-the-uk-chief-medical-officers-regarding-the-uk-covid-19-vaccination-programmes

[5] https://www.bain.com/insights/a-strategy-to-make-pharma-supply-chains-more-resilient

Six in 10 executives (59%) say that the era of offshoring drug manufacturing to low-cost countries is over, and 67% say that the manufacturing of biopharma staples such as biologics would dramatically increase in their own countries over the next three years.

The need to build resilience at home is not just an imperative for countries with a lower GNI per capita. Countries such as Switzerland and the US — among the top five countries for supply chain resilience (see chart 3) — acknowledge that they are vulnerable to scarcity. Figures from the US Food & Drug Administration, for example, show that the US currently has more than 100 drugs in short supply;[6] that includes opioid active ingredient morphine sulfate, a key painkiller ingredient, and pindolol tablets used on patients with hypertension.

These shortfalls are a concern. And although the Global Biopharma Resilience Index indicates that the biopharma supply chain performs better than other aspects of the industry (see chart 2 at the beginning of this report), there are still a number of areas that need improvement.

The way the industry addresses this weakness will vary from country to country. But increasing domestic production while securing stronger networks with suppliers globally could give it the agility it needs to keep operations running smoothly.

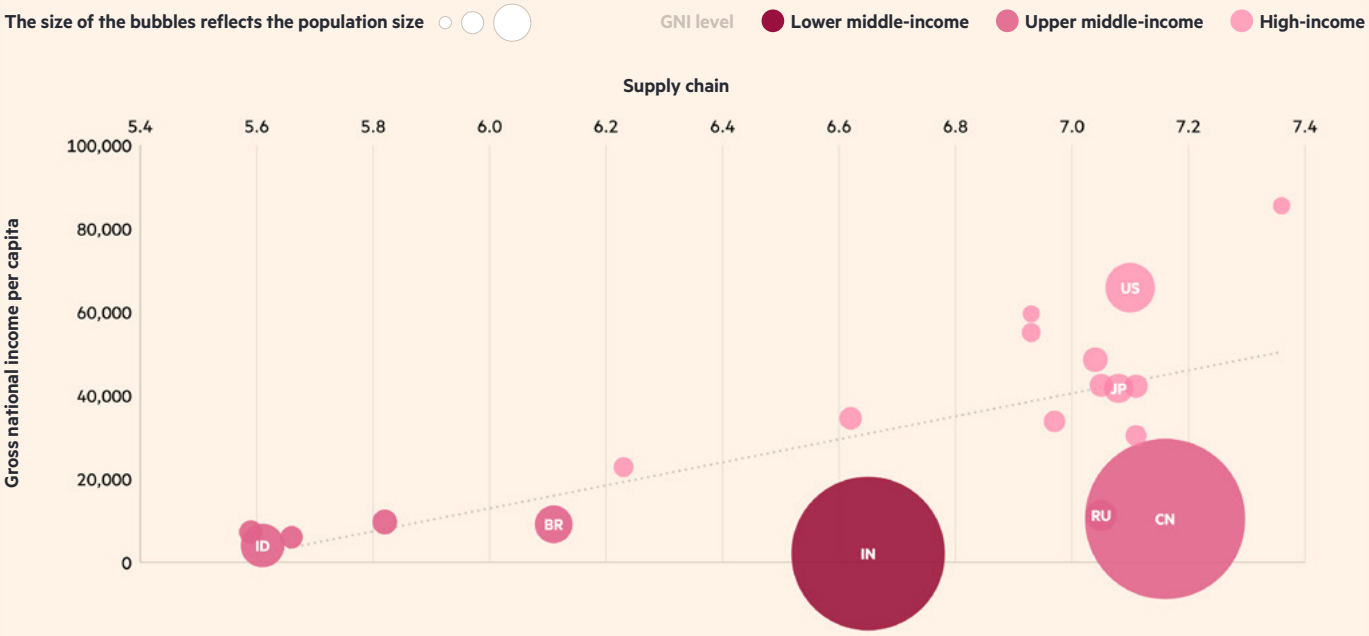
Take Chinese firm WuXi Biologics, for example. With about a decade of experience in the manufacturing portion of the supply chain, the company has rapidly become a key partner for the pharma giants. 'Dr Chris Chen, WuXi Biologics' chief executive, is acutely aware of the risks to global supply chains brought on by Covid-19, but he is of the view that these global bases need reinforcement, while domestic operations are enhanced.

"We are building a very significant facility in Ireland, we have also purchased two facilities in Germany, and we are building a facility in the US," says Chen. "There will still be a global supply chain. There will be some efforts to build local supply chains, but it may not be that easy."

Martin Meeson, chief executive of Fujifilm Diosynth Biotechnologies, believes that some elements of the supply chain, such as packaging, can benefit from localisation. But he also advocates for stronger global collaboration. "The cost of building a biopharma facility is in the billions," he says. "And it would certainly not be economically viable for every country to try to put such a facility in place. It would be far more efficient for the world if the level of collaboration that we currently see within the pharma industry is mirrored in the way that the governments interact, in order to use resources efficiently."

[6] https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

CHART 3: COUNTRIES WITH A LOWER GNI PER CAPITA HAVE FRAGILE SUPPLY CHAINS



The biopharma supply chain on the ground

In a conversation with Adrian van den Hoven, director general of Medicines for Europe, which represents the generic and biosimilars industries, and a closer look at Swiss healthcare giant Roche, we find out how supply chain challenges are playing out in biopharma vs generics, and what industry leaders expect to change in the future.

In conversation with
ADRIAN VAN DEN HOVEN
Director general, Medicines for Europe

How do the supply chain challenges faced by the biopharma industry compare with those seen in traditional pharmaceuticals?

Most of the recent issues in supply chain risks and drug shortages relate to traditional (chemical) pharmaceuticals. This is mainly because production of traditional pharmaceuticals is heavily concentrated in a small number of regions — for example specific provinces in India and China, or in Northern Italy for Europe — and high levels of consolidation can create risks around security of supply.

But this is far less of an issue in biopharma supply chains, because biopharma supply chains tend to be more vertically integrated and have more of the production steps centralised in one location, to make them easier to control. Outsourcing parts of biopharma production to other locations is therefore much less common and Europe has invested quite heavily in local biopharma production in recent years.

How are the supply chain challenges likely to change over the next few years?

Biopharmaceutical supply chains have not yet seen the same levels of consolidation as traditional pharma supply chains, but I believe this is likely to happen soon. This is mainly due to the rise of biosimilars, demand for which has been steadily increasing over the past decade.

As with generics, governments are starting to pursue commodity type pricing for biosimilars, to try and get the absolute lowest possible price. This price dynamic started in Europe, and it is likely to lead to the consolidation of the biopharma production chain within both Europe and Asia. The challenge for governments is that, as well as wanting to lower the cost of biopharmaceuticals, they want security of supply. In particular, during the pandemic it has been a huge advantage to have certain types of drugs produced in Europe. The dual need for lower prices and security of supply is a difficult challenge for the industry to square.

Which countries are likely to become the biggest exporters of biopharmaceuticals?

At the moment, there are a relatively limited number of countries that are exporting biopharmaceuticals. It is limited to the US, Europe, South Korea and Singapore. However, China and India are getting close to reaching the standards required for exporting biopharmaceuticals — and when this happens there is likely to be a lot of consolidation in the biopharma market.

In my view, there is a much more coherent link between the regulatory process and the manufacturing process in the biopharma industry than in traditional pharma, and this may make it slightly more challenging for China and India to break into the market. We will see how effective they are in the next couple of years.

A closer look

Building a world-class supply chain at Roche

For Jerry Cacia, the key to navigating supply chain difficulties has been to reinforce industry collaboration.

Roche's head of global technical development recognises the challenges that have led to increased localisation — "to make sure the supply of critical medicines is secure for each country".

But Cacia says that this should not cause a total abandonment of the global system. "In some cases, it makes perfect sense to localise manufacturing — parts of your supply chain," he says. "In other cases I would argue that it does not make sense, because these are very complex processes and frankly the costs will be really high."

Roche's success with manufacturing networks, says Cacia, has come from not having the supply chain "purely relegated to a specific country or region" for APIs, but through close relationships with suppliers that act as a pillar of support. It was able to "mobilise very quickly" to join forces with US biotech firm Regeneron, for instance, to support its production of a Covid-19 antibody treatment.[7] In a world without global supply chains, this kind of urgent collaboration would be much more difficult.

[7] https://www.roche.com/media/releases/med-cor-2020-08-19.htm

BIOPHARMA REACHES FOR HOMEGROWN TALENT

In the weeks running up to the rollout of the Covid-19 vaccine developed by the University of Oxford and pharma giant AstraZeneca, the UK's NHS England gave it a codename. It was dubbed the 'Talent vaccine'.[8]

The label is likely to have been in recognition of what Sarah Gilbert, professor of vaccinology at the university, describes as a "multinational effort"[9] in which a global pool of talent came together to work towards a common goal.

But it is uncertain how likely it is that a similar initiative could be driven by talent in other regions of the world. Many countries have struggled to foster a strong base of local talent — either through a lack of guidance for students emerging from STEM subjects at university, or by falling prey to a brain drain effect as promising young scientists and technicians in low- to middle-income countries flock to markets that offer more lucrative opportunities.

Though talent is vital to all industries, it is particularly so for pharma and biopharma because of the sector's complexity, making a shallow pool of local talent a real issue.

"Biopharmaceutical production is extremely specialised," says Adrian van den Hoven, director general of Medicines for Europe. "You need specialist biochemists, engineers, even people with a lot of IT skills."

So just how reliable is the biopharma talent pool, and can the industry ensure it has access to the people with the skills it so desperately needs long into the future?

The Global Biopharma Resilience Index presents an unsettling picture of the anxieties surrounding pharma's access to talent, which emerges in the index as the area where the industry is weakest (see chart 2 at the beginning of this report).

An expensive business

The idea that talent is freely available and easy to source only resonates with some of the survey respondents, and a quarter say the opposite:

25% say that the sourcing of talent in technology, manufacturing and R&D is a substantial or very substantial challenge.

Part of that challenge stems from just how expensive sourcing talent has become. More than 50% of executives and policymakers in the research say that the cost of talent has become a key issue in their country in recent years as expectations of benefits and remuneration have soared. The industry's shift to more specific areas means greater demand for a limited supply of highly sought after skillsets, and local companies in lower-income countries face stiff competition from big multinational firms in high-income countries because of the kind of incentives they can offer.

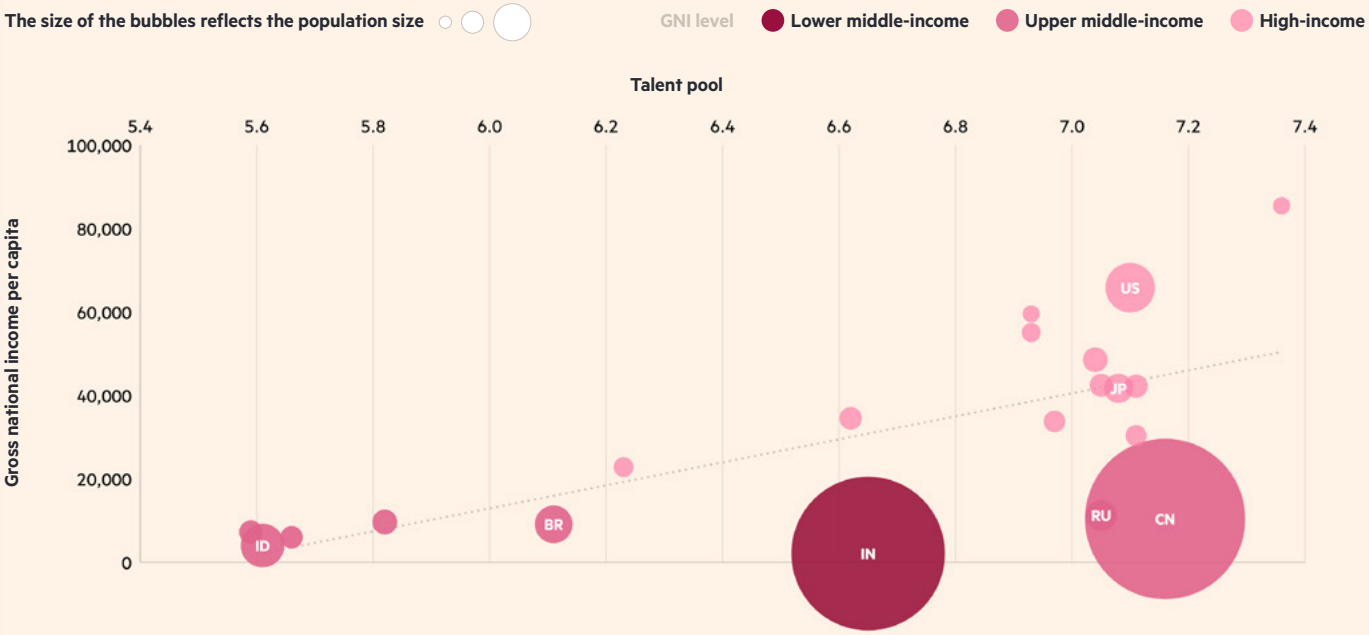
Japanese respondents are having the hardest time with talent costs, with an index score of 4.26 out of a possible 10. But the countries that lead the index overall — the US, the UK (both 4.55) and Switzerland (4.33) — do not fare much better (see chart 4).

Bureaucracy is another challenge. Rigid labour regulations appear to be a sticking point when it comes to accessing the right workers: just one in five respondents say that domestic policies around the use of foreign talent are "very flexible". Respondents in Germany and South Africa reported the greatest challenges with regulation, scoring 6.36 and 6.31 in the index respectively.

This issue comes at a time when a rise in economic nationalism marks a shift away from a global order to one that puts domestic interests first. But unless countries can train the right people at home, cost and bureaucracy are going to become even more of a challenge.

[8] https://www.reuters.com/article/uk-health-coronavirus-britain-vaccines-idUKKBN27Y27V
[9] https://www.ox.ac.uk/news/2020-11-23-oxford-university-breakthrough-global-covid-19-vaccine

CHART 4: COUNTRIES WITH A LOWER GNI PER CAPITA ARE MORE LIKELY TO STRUGGLE TO ACCESS TALENT



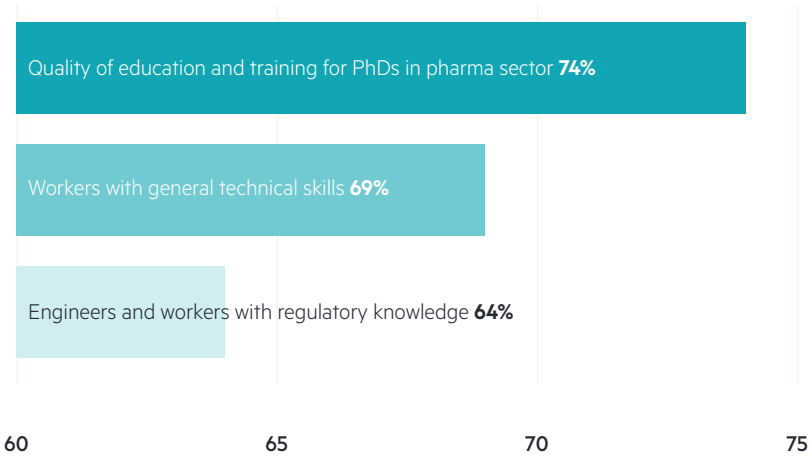
Home improvements

The way respondents feel about the quality of education and training in their own countries varies according to the level of expertise in question.

About three-quarters of respondents (74%) say they are confident in the quality of education and training for PhDs in the pharma sector. But only 69% say they are confident in workers with general technical skills, and 64% in engineers and workers with regulatory knowledge.

It is a clear sign that the talent generated in academia for research and development roles is of a high calibre, but more could be done to bring other areas of industry up to standard.

RESPONDENTS' CONFIDENCE IN QUALITY OF EDUCATION AND TRAINING



The biopharma talent pool on the ground

We speak to senior leaders at pharma giant Amgen and biotech powerhouse Samsung Biologics to find out more about talent risk and to hear what they are doing to secure the best workers.

In conversation with

ARLEEN PAULINO

Senior vice president of global manufacturing, Amgen

What has Amgen done to improve its access to talent?

Talent is always a challenge and an opportunity for us, and we are definitely seeing that with the growth in the biopharma space there is a war for talent.

In many of the regions where Amgen is located, we have formed partnerships with local universities to help ensure that students are ready to take on a role in our industry once they have completed their courses. We find that this is a very important way of strengthening the talent pipeline.

We also work with trade organisations to figure out whether there are programmes we could put in place, such as internships, to help individuals working in other industries to transition into the biopharma industry.

What kind of transferable skills can be valuable in biopharma?

Biopharma manufacturing increasingly requires advanced digital skills, which can be hard to find. There are a lot of workers in the digital space — in gaming, for example — that have the type of skills we need.

So we are looking at how we can help those individuals to make that connection and apply their talent in biopharma. I think that there will increasingly be a convergence of disciplines that are necessary to take the biopharma products of the future forward

And are there any skills that are particularly difficult to source?

Amgen's facilities are highly automated, and we often struggle to recruit automation engineers. They are very difficult to come by, so we are now thinking about how we can build the right curriculum to develop these skills.

A closer look

Powering the future of Samsung, one training course at a time

To keep a business empire running at full speed, talent is a priority. So Samsung Biologics, the biotech division of South Korea's largest conglomerate, has taken control of training.

In July 2020, it signed a memorandum of understanding alongside the country's government to establish a bioprocessing centre that would help to foster talent for a highly skilled element of the industry.

The facility, which is modelled on a similar research institute in Ireland called the National Institute for Bioprocessing Research and Training, will help companies gain greater visibility of the talent they need. But Samsung Biologics is also stressing the need to train people as early as possible.

According to John Rim, the company's chief executive, it is working with a local university to provide two weeks of training to fifth-year pharmacy students at its Biotech Academy training facility.

"We also provide consultancy to another local university regarding their bioprocessing training curriculum and their training facility set-up," says Rim.

Samsung Biologics is involved in South Korea's Covid-19 response, so that pipeline of talent is crucial. The company is planning a $2bn plant at its industrial hub in Incheon, with a launch scheduled for 2022 — and will need the best people to ensure its success.

Ambitious plans need ambitious people on the ground, and according to Rim the industry's most resilient players will recognise this. "Although we operate on a global scale," he says, "We remain dedicated to helping the local biopharma industry continue to thrive."

BIOPHARMA R&D NEEDS MORE COLLABORATION

Of all the lessons for Big Pharma from the Covid-19 pandemic, there is one that is likely to endure. The industry has experienced remarkable success by working in a way that is surprisingly unusual: collaboration.

Biopharma's usual drug-development process involves a whole cast of characters — from research scientists at discovery phases and clinical trials to distributors and regulators laying the ground for commercialisation. But the kind of collaboration that happened in research and development (R&D) over the past year is a rarity.

Covid-19 Vaccines Global Access (COVAX), an initiative aimed at ensuring equitable access to vaccines, brought together 190 economies to turbocharge an immunisation drive.[10] And industry operators that either would not cross paths or are usually competitors have also shown they can work together when the moment calls for it: Pfizer and BioNTech, AstraZeneca and the University of Oxford, Sanofi and GlaxoSmithKline (GSK).

Now, it is up to the industry to continue that momentum and ensure that this vibrant R&D ecosystem lives on. But there is some work to do. The Global Biopharma Resilience Index shows that the R&D ecosystem falls short on performance — it is an area that needs urgent attention.

An inconsistent approach

2020 showed that there is a real willingness among institutes to work together to fight Covid-19, but the broader picture shows that partnership is still a challenge elsewhere.

Although 44% of respondents to the research believe that both traditional pharma and biopharma firms have a widespread culture of cooperation and open innovation, just 34% believe the same about private companies, 32% about academic institutions, and less than 30% about contract research organisations and government think tanks.

That patchwork culture of cooperation has made it difficult for many to find the right people to work with: just a small minority of executives at pharma firms say it is not a challenge to partner on R&D with private companies (25%), government think tanks (14%) and contract research organisations (14%).

Missed opportunities

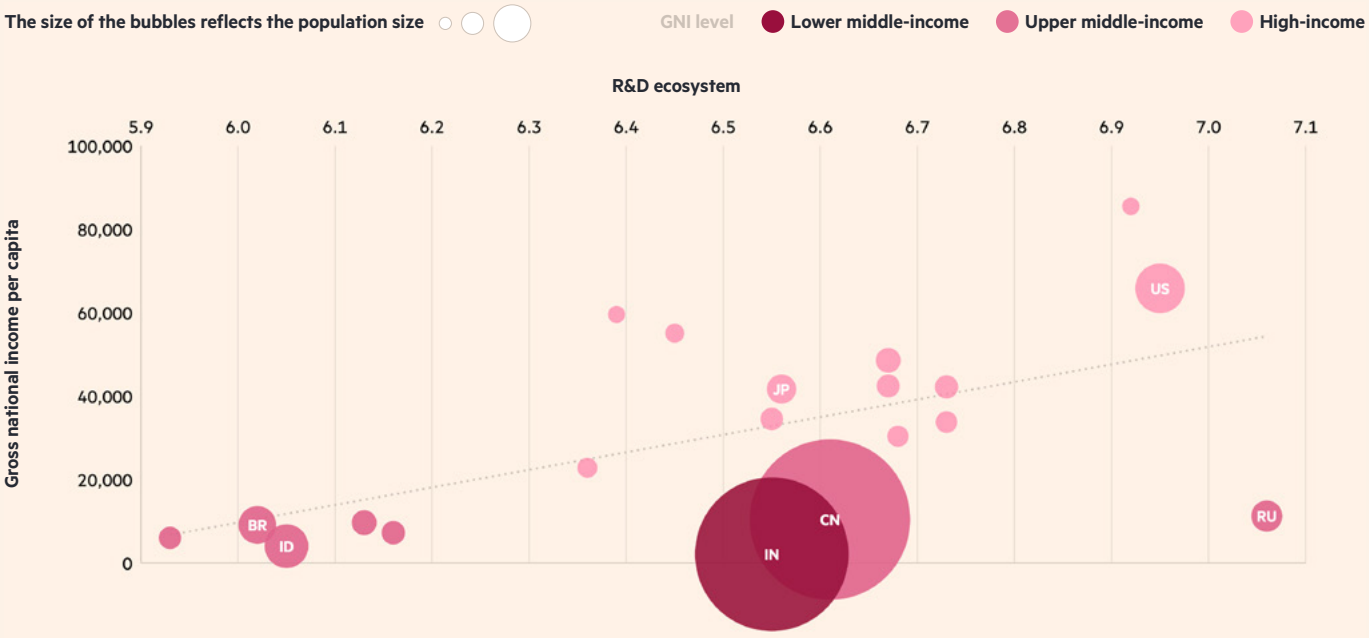
Martin Meeson, chief executive of Fujifilm Diosynth Biotechnologies, recognises these shortfalls, and says that there is "always the ability to collaborate more".

"We can make things," he says. "But we need to know two things before we do: what do you want us to make, and do we have the components we need to make it? This is an essential part of being engaged and committed to collaboration."

Meeson adds that the countries that nurture their R&D, education and infrastructure investment will be "ahead as we move forward". For many countries, this will be a problem.

[10] https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021

CHART 5: COUNTRIES WITH A LOWER GNI PER CAPITA ARE LESS LIKELY TO REPORT THAT THEY HAVE A HIGHLY COLLABORATIVE R&D ECOSYSTEM FOR BIOPHARMA



Of the 20 countries surveyed, many with a relatively high GNI per capita — Singapore, Australia, Japan and Italy, for example — fall short of some countries with much lower GNI per capita, such as Russia, China, India and South Korea. This suggests that sufficient investment has not gone into the R&D ecosystem, or that existing resources are not being used as effectively as possible.

Many of these countries have led innovation in the highly complex space of biotech, so they have reason to be cautious about granting access to their sensitive intellectual property. In the case of Russia, which emerged as the highest scoring country on this pillar, respondents felt that the country's ecosystem made a really good job of its response to the Covid-19 pandemic.

There are some positive signs in the index. Two-thirds of executives (66%) say the response to Covid-19 by their country's R&D ecosystem has been good, which reflects the immense R&D done across continents to battle the pandemic. And most executives rate the capabilities of pharma and biopharma organisations in their countries as being among the best in the world, highlighting their confidence in standout organisations.

But the picture from the index is clear: the industry is too reluctant to partner up to ensure its ecosystem thrives as a unified whole, with many of the world's higher-income countries falling short of where they should be. It does not have to be this way.

Strategic relationships make a better industry

WuXi Biologics acts as a bridge across all aspects of the development process, helping connect the dots across the ecosystem to ensure the effective and efficient delivery of drugs.

"Every relationship we build is very strategic," says Dr Chris Chen, the company's chief executive. "Our business model is when a company has an idea of a drug, we start to work with them, and then when they need a large amount of manufacturing, we work with them, and when the product gets to the end of its cycle we still help them."

The company played an instrumental role, for example, in a $250m investment made by pharma giant GSK into Vir Biotechnology in April 2020 as part of a collaborative effort to accelerate Covid-19 antibodies into clinical trials.[11] This shows how a joined-up approach can really support drug development while fostering closer relationships for the long term by allowing trust to build between partners.

There are other initiatives that are gaining traction. Martin Meeson points to the Biophorum group, which takes a hive-mind approach to solving challenges.

"During the pandemic we joined forces with a wider group of pharma industries to improve communication with the regulatory agencies around virtual inspections," he says. "We are trying to speak with them in a more consolidated way and really streamline that process. This type of collaboration makes the whole industry better."

Roberto Gradnik agrees. His firm Ixaltis is a start-up specialising in genitourinary and renal diseases, so it needs to be able to work with high-level experts. With global guidelines aligning more, for example, he says there is ample opportunity for companies to run development programmes that span multiple countries, speeding up timelines while allowing companies to draw on the expertise of a greater number of experts.

"Even China and the FDA [the US Food and Drug Administration] are working more closely together," he says.

The benefits of this kind of collaboration will become more apparent. "We believe in partnerships because they can help you grow much faster — you can share the risk and reward," says Biocon's executive chairperson Kiran Mazumdar-Shaw. "And I think for a smaller company, the investment needs get shared, and that helps you grow faster." As examples, Mazumdar-Shaw points to Biocon's partnerships beyond its Indian headquarters — with the likes of German pharma firm Sandoz.

[11] https://www.fiercebiotech.com/biotech/vir-gsk-s-covid-19-antibody-starts-rapid-race-through-clinic

The biopharma R&D ecosystem on the ground

To understand how the industry is grappling with these different forces shaping the R&D ecosystem, we spoke to a pharma trade body in the UK.

A closer look

How to maintain a position at the forefront of R&D

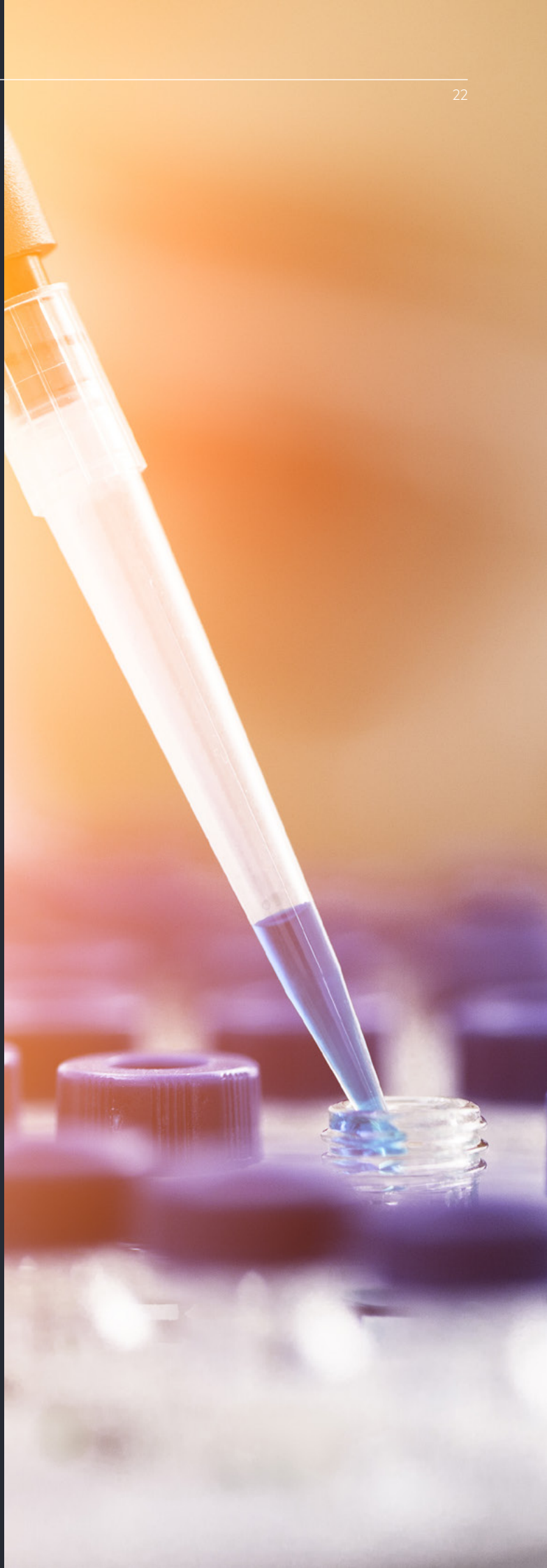
As the chief executive of the UK Bioindustry Association, Steve Bates is committed to driving innovation. Established more than 25 years ago, the trade body aims to ensure that the UK continues to be a global leader in R&D, with strong links between laboratories and the market the key focus. Bates's job is to make this a reality.

"I strive for the UK to be the best place in the world to start, develop and grow a global life science business," he says.

One area he points to as an example of the UK's success is what he describes as "long-term stability". Sustained investment over a number of years — coupled with, for example, R&D tax credits and an integrated healthcare system — has produced a favourable environment in which innovation can flourish. That supportive foundation is key. "We always have to make sure that we are globally competitive on policy," he says.

Although the pandemic made many aspects of operations more difficult, Bates takes the view that the "virtualisation of the world" over the past year has boosted global collaboration because people now know how easily they can connect remotely.

"The ability to transfer ideas around the world is one of the things that makes pharmaceutical products move most rapidly," says Bates. "I think we should defend and support that capability."



SHIFTING BIOPHARMA'S MANUFACTURING INTO THE FAST LANE

In May 2020, as the US's Covid-19 death toll fast approached 100,000,[12] a sense of urgency swept through Washington DC's policymakers as it became clear that action was needed — sooner rather than later.

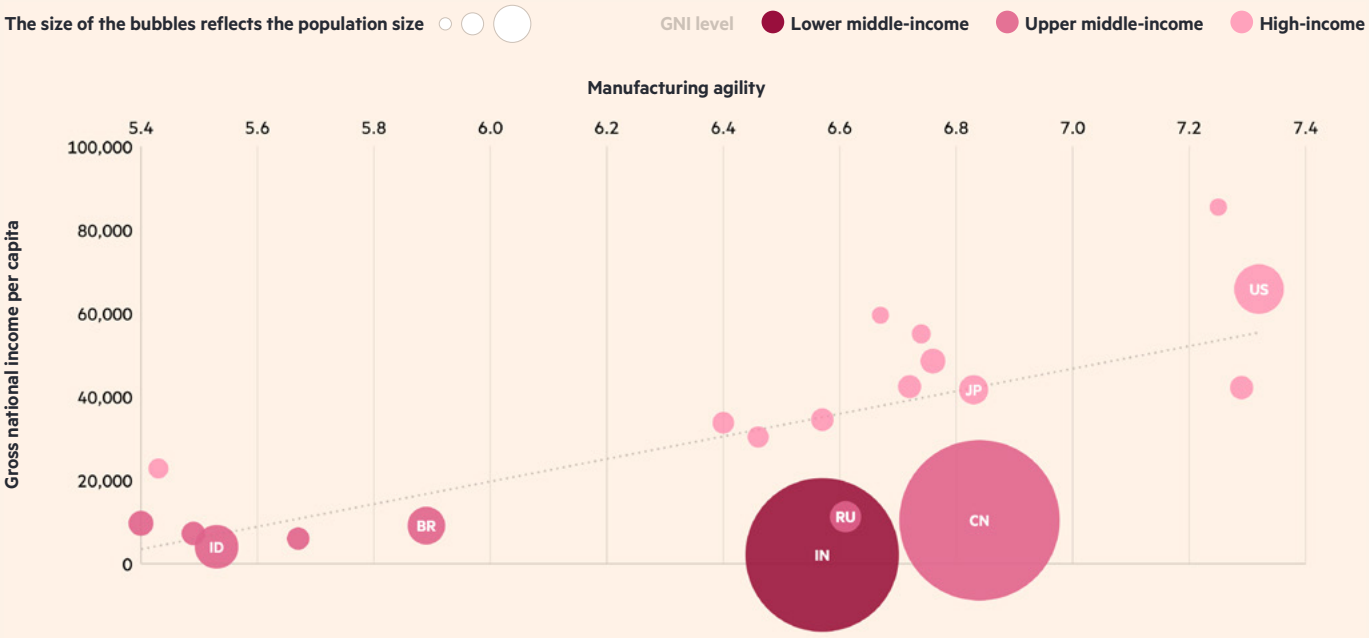
Enter Operation Warp Speed. The programme, launched in tandem with the private sector in order to overcome the pandemic, was named as such in recognition of the fact that anything less than a rapid response was not an option. Among its many objectives, some of Operation Warp Speed's most critical goals were related to manufacturing and distributing vaccines as quickly and safely as possible.[13]

As the past year has shown, the ability to be both malleable and swift is a powerful asset in the face of virulent diseases, but it also helps to ensure sufficient preparedness in case of another public health shock.

The industry has shown that it can move with speed on manufacturing, but the Global Biopharma Resilience Index suggests that that is not always the case.

[12] https://www.theguardian.com/us-news/2020/may/15/trump-coronavirus-warp-speed-vaccine-white-house
[13] https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/

CHART 6: MANUFACTURING AGILITY INDEX SCORES BY GNI PER CAPITA



Domestic capacity at risk

There is a clear bright spot in the index: manufacturing agility. As we would expect, many high-income countries did well here, with the likes of the US, UK and Switzerland all scoring more than seven out of 10 on this index pillar (see chart 6), but many lower- to middle-income countries, such as China, India and Russia, proved that they could keep pace too.

But there are some areas that need work. Domestic pharma firms have some doubts about their capacity to meet their own nation's needs for a number of drugs, scoring less than five out of 10 on this index indicator. Take insulin and vaccines, for example.

Respondents say they would only be able to meet 75% of local needs in the event of a surge in demand, and that drops to just 58% for other biopharmaceuticals.

This highlights the lack of capacity and speed with which countries can currently respond to demand fluctuations.

Pharma and biopharma executives recognise this weakness. Fewer than 3 in 10 describe the manufacturing processes of their organisation as something that offers a competitive advantage, and increases in manufacturing agility emerge as the number one priority for firms.

But to achieve this goal there are impediments in domestic markets that need to be addressed. Among the top three outlined by executives are a lack of skills within companies to drive the manufacturing speed desired, geopolitical developments that could impact the rollout of a drug and crucially, a lack of agility among suppliers.

Picking up the pace

Perhaps the most important suppliers for pharma and biopharma firms are the contract manufacturing organisations or contract development and manufacturing organisations (CMOs or CDMOs). These are external firms to which pharma and biopharma businesses can outsource critical stages of drug development and manufacturing.

One solution to concerns about speed has been the rise of firms that can work with CMOs to offer rapidly scalable manufacturing facilities that reduce the need for a large upfront investment, enabling a much quicker process — particularly in smaller countries where that might not be feasible.

However, just a quarter of executives rated CMOs as being "very good" on adaptability and cost-effectiveness, despite a generally positive sentiment towards their performance (in the index, CMO performance scored 7.39 out of 10). This shows that if CMOs and pharma firms can work in tandem to adapt facilities for the manufacture of one drug or vaccine to another, it would help to drive down costs and shorten a process that can otherwise create significant delays. It also suggests that manufacturers will need to develop their own scalable and flexible facilities to meet demand — even when they are not expecting it.

"We are looking at transforming the entire manufacturing process. If you look at the chemicals and petroleum industry, all manufacturing is continuous, but the pharma industry is batch processed," says WuXi Biologics' Dr Chris Chen. "So we believe the next stage is to go from batch to continuous.

If you look at the petroleum industry, if they went to batch processing they would go bankrupt because they have to rely on very high efficiency."

Executives are keen for more innovative technologies too. Less than one in five are in strong agreement with the idea that frontier technologies such as artificial intelligence are being widely adopted in a widespread way to support the automation of certain processes that could speed things up.

Overall, the index findings lay a clear roadmap for pharma and biopharma firms looking to bring agility that want to make their manufacturing operations more agile: think strategically about the role of rapidly scalable operations that reduce upfront costs, and be bolder with adopting technology.

Manufacturing agility on the ground

Of course, many firms have taken a lead on these changes already, and that includes pharma giants Samsung Biologics and Amgen. We sit down with each of them to find out how they have achieved manufacturing agility, and what lessons the wider industry can take away.

In conversation with
JOHN RIM
Chief executive of Samsung Biologics

How important is technology in accelerating stages of drug development and manufacturing?

Innovative technologies are becoming increasingly important. We are committed to adopting cutting-edge technologies that can help expedite the drug development and manufacturing process.

We are continuously looking for ways to implement new technologies to enhance, improve, and optimise our processes. Ultimately, we aim to deliver optimised efficiency. The industry is going through a digital transformation and it's important that companies are ready to embrace new practices.

What are you doing to improve industry readiness and agility?

Samsung Biologics has recently begun construction for its new facility, Plant 4. Also known as the Super Plant, it will be the most ambitious project to date.

It is designed to be fully flexible and with our experienced engineers, it can be optimised to accommodate various client requests and the changing requirements of the industry, ensuring the shortest turnaround time.

Which technologies do you plan to invest in?

We have begun a Quality Digital Transformation Initiative, which will be completed by the time Plant 4 is operational. The digitalised quality initiative will give our clients live, 24/7 access to computerised systems related to their campaigns, and regulatory authorities will have full remote access to documentation, including quality records.

A closer look

How Amgen stays agile

Arleen Paulino has reason to be proud of Amgen. "We have served every patient, every time, because we have not had a shortage," she says.

As senior vice president of global manufacturing at the Californian biotech firm, Paulino has been central to that achievement, with what she describes as a "very programmatic approach to resilience" in manufacturing. So what is the secret?

"As part of developing our processes and our manufacturing operations, we're constantly looking for ways to be more agile with technology," she says. "Can you implement technologies that drive your productivity and your processes so that you can miniaturise, if you will, the operations?"

The benefits to being proactive on technology primarily relate to efficiency. Firstly, Paulino explains, it helps to find ways of reducing footprint in a way that "translates into improved costs and speed". Secondly, it helps Amgen to find ways to scale up facilities faster.

The company also takes a proactive approach during manufacturing towards its inventory, maintaining both ample operational safety stock, and strategic safety stock of its drugs, and monitoring levels very closely.

"For example, if it takes three months to recover from a specific incident, we may choose to say, 'Well, let's maintain six months of inventory to give ourselves room'," says Paulino.

Agility, then, is as much about responding with speed as it is about ensuring emergency reserves are available when they are needed.

MAKING POLICY WORK FOR THE BIOPHARMA INDUSTRY

How does a world-leading pharma company make sure it is delivering the drugs its patients really need, when they need them? For Roche, part of the answer to that question lies in its commitment to an open dialogue with regulators.

"The regulators are in a position where they see a lot of things we don't, because they have the benefit of seeing what's coming in from everywhere," says Jerry Cacia. "We learn as we interact with them."

Governments often clash with the private sector on policy, but the pharma and biopharma industry has fostered a healthy relationship with regulators in its bid to ensure the supply of safe, life-saving medicines to people the world over.

The rapid rollout of Covid-19 vaccines is a case in point. Vaccines often take close to a decade to reach the market after years of clinical trials, safety checks and approval processes, but this time certain regulatory mechanisms have allowed much faster authorisation.

Making regulation work for biopharma

In Singapore, for example, the Health Sciences Authority approved interim authorisation of the mRNA vaccine developed by US pharma giant Moderna under what is known as the Pandemic Special Access Route, which allows for an adaptable, rapid response to an emergency.[14] China's medical products regulator, meanwhile, has approved vaccines for public use in a similar way, allowing the likes of Beijing-based Sinovac Life Sciences to race towards its goal of producing more than one billion doses annually.[15]

"I give nothing but praise and credit to the regulators of our industry, because they have been very flexible with companies that are doing the right thing," says Cacia. "We see this happening globally, and it is really important that it continues."

Cacia's sentiment resonates with many. In the Global Biopharma Resilience Index, no pillar fares as well as government policy and regulation.

Roche is a key producer of biologics, and it has taken the lead in manufacturing these specialised drugs through an information-sharing process with regulatory bodies globally. This has made sure that there are no blind spots in its understanding of everything from safety to demand.

Resilience at home is a priority

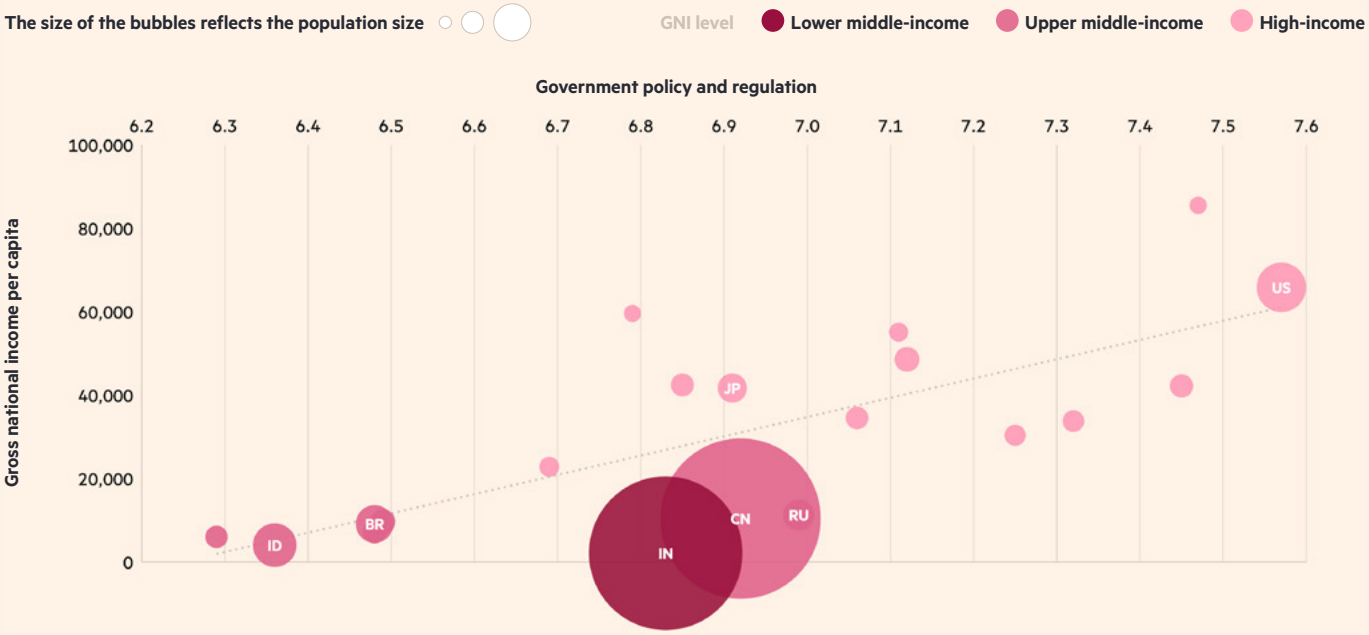
Policy support is not just limited to work that is dictated by demand in a globalised system: 65% of executives in the research say that their country is pursuing policies that actively encourage domestic research and development (R&D) and manufacturing. Domestic resilience is a priority for governments.

Policymakers recognise the value of R&D and manufacturing carried out locally. About two-thirds of executives say that laws in their own country related to intellectual property rights and protection are effective in helping them develop and produce new drugs. When drugs are produced locally, regulators seem to understand firms' commercial imperatives: 63% of the respondents say that their country's trade and tax policies are not an impediment to the export of drugs.

But there are areas where policy could do more. Among these is funding for start-ups and other pioneers. Less than 20% of respondents say that public funding, as well as private funding, is "very supportive" of start-ups. And 21% say that state funding of research at public institutions fails to translate to improved drug production outcomes.

[14] https://markets.ft.com/data/announce/detail?dockey=600-202102030925BIZWIRE_USPRX____BW5600-1
[15] https://www.reuters.com/article/us-health-coronavirus-vaccine-sinovac/china-approves-sinovac-biotech-covid-19-vaccine-for-general-public-use-idUKKBN2A60AY

CHART 7: REGULATORS IN COUNTRIES WITH A LOWER GNI PER CAPITA ARE MANAGING TO KEEP PACE WITH HIGHER-INCOME COUNTERPARTS



How to make regulation work for everyone

Regulation strengths are not limited to countries with a high GNI per capita (see chart 7). China, Russia and India, which are countries with a lower GNI per capita than other countries surveyed, managed to stay level on their index score with the likes of France, Japan and Singapore.

According to WuXi Biologics' Dr Chris Chen, there was once a "disconnect" between China and other regulatory bodies that was difficult for companies to navigate. That has almost vanished, he says.

"Regulatory reform means that right now, China is very close to the global regulatory system, but five to 10 years ago it was very different," says Chen. "You almost had to do two sets of work: you did all your research for China, and you did additional research for US and Europe. That disconnect is pretty much gone."

For Biocon's Kiran Mazumdar-Shaw, the pandemic has showcased activity that indicated how versatile regulators and companies can be when they work together. But she believes that more could be done to ensure this applies to the industry as a whole — particularly for smaller companies that may be deterred from going to market because, she suggests, "It is just too expensive to take an idea from lab to market".

"We should go beyond Covid-19 to apply these various models that evolved during the pandemic, to bring drug development or vaccine development or diagnostic development from lab to market very, very rapidly," says Mazumdar-Shaw.

"If you were to compress regulatory timelines, then that lab-to-market journey becomes much easier and less expensive."

In Mazumdar-Shaw's view, regulation needs a "common sense" approach. She points to harmonisation of regulatory systems as one obvious improvement. Chen agrees, and says he hopes there will one day be a "global, uniform regulatory system".

Recent years have seen an increase in harmony, with organisations able to follow technical guidelines from a more commonly shared set of rules, but there continue to be differences in approvals from country to country.

In conversation with

CLIVE PAGE

Professor of pharmacology at King's College London

We sat down with Clive Page to find out what a "common sense" approach to policy might look like in the UK, and what practical steps would help to ensure that policy works for all.

How do you set up policy to encourage companies to scale up in the domestic market?

There has been plenty of encouragement to get innovation off the ground. There are grants and lots of schemes if you are an academic or a small company.

But once it gets to a certain point, then you have to partner with a big organisation. And there are very few of them left in the UK that are really UK companies. You are inevitably going to have to scour the globe for the best deal for your shareholders or your institution.

What should the UK do to ensure that companies can scale up over the long term?

We should be making sure we have sufficient capacity to help companies build locally in the UK. And then we have to help them become global distributors of medicines when they have found something that works.

At the moment, we are really good at the first bit, but then we sell it off too cheaply. So I think the scale-up agenda that people are talking about — getting manufacturing and the right expertise to take innovations forward in the UK — actually makes sure that we retain better control over companies. Looking at the next 10 years, I think this is important.

WHAT DOES THE FUTURE HOLD FOR BIOPHARMA?

The research highlights five areas where countries are focusing their efforts to boost the resilience of their biopharma sectors.

The work of the pharma and biopharma sectors to produce Covid-19 vaccines in record times has been a bright spot in the response to the pandemic. It showed that the industry can step up to the plate when it has to.

But the Cytiva Biopharma Resilience Index shows that there is plenty more to do to ensure the resilience of drug development beyond Covid-19. Here are five ways for countries to boost the resilience of their biopharma sectors as they look to 2021 and beyond.

1 Re-evaluate the supply chain

The industry's traditional model of drug development and manufacturing has, for the most part, made sure that countries can get by. But given some of the pain points revealed by the pandemic and our index results, getting by is not enough. One way to improve performance is to use emerging technologies to transform the supply chain.

Martin Meeson, chief executive of Fujifilm Diosynth Biotechnologies, explains how revamping the supply chain is a key area of focus for his company, given its specialty as a global contract development and manufacturing organisation (CDMO). He gives the example of continuous manufacturing, which can offer "significantly increased output for reduced amount of usage of resources" compared with the more modular industry standard of batch processing.

Meeson also stresses that biopharma companies must continue to emphasise efficiency throughout this transformation.

> "We have to make sure that every time we do something, we are maximising the output from the resources that we are using."
>
> MARTIN MEESON, CHIEF EXECUTIVE, FUJIFILM DIOSYNTH BIOTECHNOLOGIES

2 Invest judiciously in localised production

The pandemic has driven a step-change in how the biopharma industry approaches certain issues – from expediating drug approval processes through to localising the production of certain pharmaceuticals. The experts we spoke to believe it's critical that the industry doesn't lose sight of these lessons as the world emerges from the crisis.

"The pandemic has really pushed governments to think differently," says Mary Blenn, vice president of global supply chain at Cytiva. "They want localised production. They want more control. They've got an obligation to protect the people living in their countries. But it's important to recognise that there's a balance between having everything done within your country, which can drive inefficiency, versus having certain things done locally."

Blenn believes that executives' desire to be self-reliant by becoming more localised, for example, necessitates a mindset that is willing to "pivot, innovate, accelerate". Localising the industry by bolstering talent pools, expanding manufacturing capacity and fostering a collaborative R&D ecosystem could make countries more versatile globally and locally.

Stanley Erck, president and chief executive of US pharma firm Novavax, also recognises the drive towards localisation: "We've all been surprised by the demands on supply chain and understanding how we can respond to that. Novavax started with zero manufacturing sites in January of last year, and now we have eight manufacturing sites in seven different countries. We use product like we never would have, as well as supplies of raw materials that we never would have forecast a year ago."

3 Improve clarity and collaboration around industry-wide goals

There are few industries as competitive as pharma and biopharma, which has made working on projects together a rare occurrence. But to make sure countries are secure and have sufficient supplies of critical medicines in the coming years, governments need to foster a strong culture of collaboration across the biopharma ecosystem.

"Who would have thought that GSK and Sanofi would work hand in hand to develop a vaccine," says Emmanuel Ligner, president and chief executive of Cytiva. "Or that Eli Lilly, needing some capacity, would tap into Roche."

It's unrealistic to expect that this type of corporate partnership will continue indefinitely. But governments can help to improve collaboration between biopharma firms, academia, and other industry bodies through providing transparency around industry-wide goals and what's required at a regional level – whether this is related to improving supply chain resilience, strengthening manufacturing processes or transforming policy. "Let's make sure that there is a very clear view of what is needed and where," says Ligner. "Not only in terms of customers, but also in terms of geographical location."

Collaboration will also help organisations with talent. The industry's increasing digitisation and use of data, for example, demands new skills from areas that may not be native to pharma and biopharma. The industry will need to look outside itself for partners.

"We are competing with the IT sector, but having said that, I think this is also about collaboration and partnerships with IT companies," says Kiran Mazumdar-Shaw, executive chairperson of Indian pharma giant Biocon. "That is how we are solving the problem."

4 Accelerate regulatory pathways where appropriate

Out of the five pillars of the Cytiva Biopharma Resilience Index, government policy and regulation emerged as the strongest — a vote of confidence in how they responded to the Covid-19 pandemic.

Biocon's Mazumdar-Shaw says that "warp speed" regulatory pathways allowed Covid-19 vaccines to be developed much more quickly than they otherwise would. But she says that with "common sense" — the simplification of regulatory requirements, for example — a streamlining of the lab-to-market process could be extended to other products.

> "If we could make a vaccine in nine months, I do not see why we cannot make drugs and other important medicines in that kind of time. Why are we denying patients access to new medicines just because we have such archaic regulatory systems and pathways? That is what I mean by common sense."
>
> KIRAN MAZUMDAR-SHAW, EXECUTIVE CHAIRPERSON, BIOCON

5 Make flexible manufacturing a priority

Expediating drug approval processes isn't the only area in which regulators can drive change. Stanley Erck believes they can also play a vital role in enabling more flexible manufacturing processes: "I think it's absolutely crucial for manufacturing to be both agile and flexible. Regulators don't always allow you to change manufacturing processes easily, but we really need the ability to do this."

Mazumdar-Shaw agrees: "With data science, analytics, sensors and the kind of means that we have today to show compatibility, I'm sure we can simplify regulations and make manufacturing far more efficient. I think we need to revisit a lot of our manufacturing processes and really focus on how quickly we can pivot to move the process from one product to another. That is what is going enable us to improve the agility of biopharma manufacturing."

Manufacturing agility and flexibility are also critical for biopharma R&D company Akesobio. "We have quite a few products in the development stage, but we cannot build a factory for just one compound," explains Michelle Xia, Akesobio's president and CEO. "So, manufacturing flexibility is very important for us,"

These five actions will help pharma and biopharma industries to continue taking giant steps towards securing the resilience of countries — beyond the achievements of 2020. As Emmanuel Ligner puts it: "We should never forget what we are learning right now."


cytiva


FT
MARKETING
SERVICES