



Rialtas na hÉireann  
Government of Ireland

# Focus on Biopharmachem

## August 2020



# Biopharmachem

## Description

The Biopharmachem sector encompasses the discovery, development, production and sale of pharmaceutical products, chemicals, and active pharmaceutical ingredients (APIs) and biopharmaceuticals or biologics. The sector includes a mix of large global companies, service providers and smaller operations with complex value chains. Pharmaceuticals are small molecule, chemically manufactured, active substance molecules, for human and veterinary applications. Biopharmaceuticals or biologics are large molecule pharmaceutical drug products manufactured in, extracted from, or semi-synthesised from biological sources. Biologics include monoclonal antibodies, vaccines, recombinant hormones/proteins and new emerging advanced therapeutic medicinal products (ATMPs) also termed cell and gene therapies (CGTs) encompassing cells as therapies, gene therapies and engineered tissues with applications across infectious diseases, oncology, immunology and autoimmune diseases. The biotechnology market consists of the development, manufacturing, and marketing of products based on advanced biotechnology research. Medical and healthcare is a major component of this market. Global Business Services is a growing part of the sector spanning regulatory affairs, virtual clinical trials and medical information.

## Snapshot

Global			Market Size		Growth Forecast			
	Pharmaceuticals <sup>i</sup>		\$1,111.8 billion (2018)		\$1,469.8 billion by 2023, CAGR 5.7% 2018-2023			
	Biopharmaceuticals <sup>ii</sup>		\$186.5 billion (2017)		\$526.0 billion by 2025, CAGR13.8% 2017-2022			
	Biotechnology (Medical/Healthcare) <sup>iii</sup>		\$218bn billion (2017)					
Ireland (Agency)		Exports (2018) <sup>iv</sup>	% of national exports <sup>v</sup>	5-year CAGR of exports (2013-2018)	Employment (2019) <sup>vi</sup>	% of national employment <sup>vii</sup>	5 -year CAGR of employment	DEE (2018) <sup>viii</sup>
	All Agency	€52.4bn	21.5%	9.35%	35,372	1.50%	6.50%	€3.9bn

Irish owned Enterprises	€0.5bn	0.2%	9.26%	3,877	0.16%	5.53%	€0.3bn
Foreign owned enterprises	€51.9bn	21.3%	9.35%	31,495	1.33%	6.63%	€3.6bn

- i. Global Pharmaceuticals, Marketline, March 2019 (Global Medicine outlook predicts that the by 2021, the global pharmaceutical industry is will reach a value of US\$1.5 trillion by 2021, CAGR of 4%-7%.
- ii. Biopharmaceuticals Market by Type - Global Opportunity Analysis and Industry Forecast, 2018-2025, Allied Market Research, July 2018
- iii. Global Biotechnology, Marketline, June 2018
- iv. ABSEI 2018, DBEI – Agency Supported Enterprises only; CSO Data shows exports of €80bn
- v. percentage of national exports is derived using total exports from ABSEI 2018
- vi. AES 2019, DBEI
- vii. National percentages derived using CSO, LFS Q4 2019 figure of 2,361,200
- viii. Direct Economy Expenditure relates to total payroll costs and materials and services sourced from Irish Suppliers

## Pre-COVID-19 Position

***Globally the sector was experiencing high growth rates coupled with downward pressures on costs, advances in technologies, intensified competition and regulation.***

- The USA remains the largest healthcare market in the world, but emerging economies such as China are growing at a significant rate. In 2018 of the top 10 drugs with the highest global sales, 8 were biologics and 2 were oral small molecules.<sup>1</sup>
- Incidence of chronic and non-communicable diseases was increasing globally driven by increased life expectancy, an ageing population and lifestyle. Challenges in treatment of communicable diseases were also resulting from increased urbanisation, climate change and antibiotic resistance. There were also growing trends towards wellness, prevention and early diagnosis.
- Data Analytics capability and the growing demand for information-based medicine is driving more customised therapies. Data analytics is also core to manufacturing excellence.
- Advances in advanced therapeutic medicinal products (ATMPs) is transforming the pharma landscape globally.<sup>2</sup> Gene and cell therapy development is accelerating. Chimeric Antigen Receptor Therapy (CAR-T) is projected to increase at an annualised rate of 51% during time period, 2018-2023.<sup>3</sup>

<sup>1</sup> <https://pharmaintelligence.informa.com/products-and-services/data-and-analysis/datamonitor-healthcare>

<sup>2</sup> <http://www.biopharminternational.com/new-paradigm-drug-development>

<sup>3</sup> 2019 Global life sciences outlook Deloitte

- While the promise of these therapies is very positive challenges related to commercial manufacture and regulation remain. The cost of CAR-T therapy is extremely high presenting challenges to healthcare providers and payers on the Pharmacoeconomics of treatment.
- Competition for Biopharma FDI is intensifying. A number of jurisdictions are investing in NIBRT<sup>4</sup> like centres in ATMP manufacturing. These include a \$70m investment in NIIMBL in the US<sup>5</sup> and a £50m investment in a Cell and Gene Therapy Catapult Centre in the UK<sup>6</sup>.
- The sector is highly regulated. Approval can require many years of clinical trials. Even after the drug is released, it will still be monitored for efficacy and for safety risks. The regulatory process drives the overall costs of development and time taken to deliver new drugs to market.
- Significant up-front RD&I product investment is required, and it can take 10-15 years to bring a product to market. The proportion of products entering the RD&I pipeline that is ultimately approved for commercial use may be as low as one for every 5,000-10,000.
- To support innovation, EU and global regulatory networks are formalising horizon-scanning processes to identify new product types and technologies. The EU has been funding research and innovation in medicines (and other health products) through Horizon 2020 and through the public-private partnership Innovative Medicines Initiative. Funding will continue under Horizon Europe.
- Significant advances in manufacturing technologies are anticipated over the next 5 years. Biopharma 4.0 heralds the onset of digitisation of production requiring companies to understand and implement concepts and technologies around AI, continuous manufacturing, data analytics and 3D printing. There is an increasing trend by biopharma companies in the use of CMOs (contract manufacturers) and CROs (clinical research organisations)
- There was increasing convergence of biopharmaceuticals and medical technologies in drug-device combinations and companion diagnostics. There is a continuing trend among major pharma companies towards M&A, partnering, outsourcing and corporate venturing to source innovation, unlock synergies and realign portfolios, all of which are ultimately focused on increasing shareholder value and wealth.<sup>7</sup>

***Ireland – a leading location for Biopharma manufacturing and an opportunity to develop a leadership position to attract investment in new advanced therapy medicinal products.***

- Ireland has an established mix of large multinationals, start-ups, and high growth SMEs specialising in API, veterinary and human finished product manufacturing, drug discovery, development and delivery, as well as service, regulation, engineering, construction and clinical trial management. There is a strong culture of collaboration and cooperation

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<sup>4</sup> NIBRT is Ireland's National Institute for Bioprocessing Research and Training- a global centre of excellence providing training and research solutions for the biopharmaceutical manufacturing industry.

<sup>5</sup> <https://niimbl.force.com/s/about-niimbl>

<sup>6</sup> <https://ct.catapult.org.uk/>

<sup>7</sup> What's behind the Pharmaceutical Sector's M&A push, McKinsey 2018

between the large multinationals and indigenous Irish companies which include over 100 Enterprise Ireland supported companies.

- The global top 10 Biopharmaceutical companies have a manufacturing presence in Ireland. The Irish life sciences manufacturing sector has grown exponentially in recent years with major investments from companies like Pfizer, Eli Lilly, WuXi, Janssen, MSD, Sanofi, BMS, Alexion, and Allergan<sup>8</sup> who have made significant investments in Ireland which have facilitated the rapid growth of the industry.
- The indigenous sector is highly innovative with companies competing successfully in global markets throughout the world e.g. Alimentary Health, ICON, Chanelle, TopChem, APC. ICON is now one of the top 5 global CROs.
- Ireland's strong international reputation in pharmaceutical manufacturing is largely due to: excellence in manufacturing and regulatory compliance; a highly qualified workforce operating in manufacturing sites that are globally recognised as manufacturing 'process/product' development specialists; competitive corporate taxation rates with competitive R&D tax credits and supports; and a world-class research landscape.
- Biopharmaceuticals were the single largest exporting sector of goods from Ireland, valued at €80bn, 53% total exports in 2019, a 9% increase from 2018. This comprised exports of organic chemicals of €30bn and Medical and pharmaceutical products of €50bn in 2019, an increase of €7bn from 2018.<sup>9</sup> 35% of exports in this sector in 2018 were to the US. The Biopharma Sector is a high value-added sector and a large contributor to corporation tax receipts.<sup>10</sup>
- Exports of chemicals from agency supported firms amounted to €41.9bn in 2017<sup>11</sup>, 20% of total exports from agency supported firms.
- There are a small number of companies engaged in the manufacture of non-pharmaceutical chemical products such as BASF, Henkel etc.
- Ireland is the second largest net exporter of medicinal products and pharmaceuticals from the EU accounting for almost 30% of Ireland's total extra-EU trade, the highest amongst EU countries.<sup>12</sup>
- There has been significant capital investment in excess of €10 billion by the industry in bio-manufacturing operations in Ireland. There are 90 biopharma plants here, all approved by the Health Products Regulatory Authority, of which 40 have also been approved by the FDA, highlighting Ireland's positive regulatory track record.
- The Irish Health Products Regulatory Authority, (HPRA) is highly regarded within the EMEA Network and is one of the European agencies included under the Mutual Recognition Agreement.

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<sup>8</sup> AbbVie to acquire Allergan. Announcement June 2019

<sup>9</sup> CSO, TSA06: Value of Merchandise Trade by Commodity Group, Year and Statistic, commodity groups 51 and 54.

<sup>10</sup> <http://www.audgen.gov.ie/documents/annualreports/2016/report/en/Chapter20.pdf>

<sup>11</sup> ABSEI 2018

<sup>12</sup> Eurostat, 2017

- Ireland is well positioned to be a leader in Pharma 4.0 supported by the National Institute for Bioprocessing Research and Training (NIBRT), the Pharmaceutical Manufacturing Technology Centre (PMTC), the Research Centre for Pharmaceuticals, (SSPC), and Irish Manufacturing Research (IMR).
- Ireland had a highly skilled workforce that achieved critical mass. There are over 30,000 in direct employment in the sector, of which over 60% hold a third level qualification. The sector employed approximately 25% of all PhD graduates currently employed in Irish industry.
- Ireland is seeing a significant development of supply chain management operations supporting the sector, particularly in Dublin. The skills for this services area in many cases are coming from the manufacturing sector.
- Trade and investment policy shifts in the US and international tax developments intensify the need for Ireland to continuously strengthen its competitive advantage for Biopharma investment and to remain a location of choice for innovation and manufacturing.
- Irish companies sourcing chemicals from the UK and Northern Ireland post Brexit may become EU importers with responsibility for the registration, authorisation, notification and other essential safety information requirements for these chemical products arising from specific EU Regulations including the REACH Regulation (Registration, Evaluation and Authorisation of Chemicals), the CLP Regulation (Classification, Labelling and Packaging of Chemicals), the Detergent Regulations and the Rotterdam Regulation.
- In Ireland, access to medicines is governed by the Health (supply and pricing of medical goods) Act 2013 and through the IPHA/HSE Framework Agreement on the Supply and Pricing of Medicines 2016-2020.

## Impact of COVID-19

### GLOBAL

- The COVID-19 pandemic has brought Telehealth and telemedicine into focus as doctors seek to assess patients in the safest way possible. The market is forecast to reach US\$148 billion by 2025.<sup>13</sup>
- The competitive nature of biopharma means that companies usually work on their own to come up with treatments/vaccines. However, with COVID-19, some companies seem to be open to collaboration. Roche, Sanofi, and Johnson & Johnson have all said they will collaborate and share resources and clinical trial data with governments and one another to help increase testing capacity and develop treatments for COVID-19.<sup>14</sup>
- Around the world, there are hundreds of clinical trials under way for potential treatments and vaccines. Experts say there are 133 treatments in development for potential use in the fight against COVID-19. There are eight candidate vaccines in clinical trials and a further 82 in pre-clinical stages of development. In Europe, this progress is underpinned by the EU's robust intellectual property framework – the scaffolding for medicines innovation. It has enabled bold investments in new medicines and many of them are now being tested for their possible use in COVID-19 cases.<sup>15</sup>
- Some pharmaceutical companies have had to slow or stop patient recruitment for clinical trials to reduce the risk to patients who could be exposed to the virus. Some companies are delaying trials and opting not to launch new ones in order to reduce the burden on health care systems.<sup>16</sup>
- Some pharma companies, many who have facilities in Ireland, are supporting efforts in the detection, prevention, and treatment of COVID-19. GSK donated US\$10 million to the WHO and the UN Foundation's COVID-19 Solidarity Response Fund to help prevent, detect and manage the pandemic. The company is expanding vaccines collaborations and evaluating existing medicines to determine whether any could be used beyond current indications. MSD has donated a supply of interferon beta-1a (Rebif) to the French Institut National de la Santé et de la Recherche Médicale following a request for use in a clinical trial. The company has supported China's fight against COVID-19 with multiple donations in cash and in kind to local charities. Takeda is initiating the development of a plasma-derived therapy, designated TAK-888, with the potential to treat hospitalised COVID-19 patients and to prevent infection in frontline healthcare workers. Johnson & Johnson is searching for a vaccine, making existing antivirals available for testing, collaborating with

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<sup>13</sup> [https://biopharmachemireland.ie/Sectors/BPCI/BPCI.nsf/vPages/Newsroom~biopharma-ambition-2020-18-05-2020/\\$file/BPA-Report-Final.pdf](https://biopharmachemireland.ie/Sectors/BPCI/BPCI.nsf/vPages/Newsroom~biopharma-ambition-2020-18-05-2020/$file/BPA-Report-Final.pdf)

<sup>14</sup> <https://sloanreview.mit.edu/article/in-the-face-of-a-pandemic-can-pharma-shift-gears/>, 2020

<sup>15</sup> <https://www.ipha.ie/peoples-behaviour-and-a-belief-in-science-are-turning-the-tide-on-covid-19-writes-bernard-mallee/>, 2020

<sup>16</sup> <https://www2.deloitte.com/us/en/blog/health-care-blog/2020/covid-19-pandemic-could-forever-change-biopharma.html>, 2020

industry partners to screen a library of antiviral molecules, working with health authorities and institutions on research platforms, and providing tools and personal equipment where it can.<sup>17</sup>

## NATIONAL

- The impact on the Biopharma sector has been non-uniform. Companies in the Pharma sector are focused on continued demand for essential products and increasing demand for production related directly to COVID-19 (including vaccines and anti-viral medications). Some companies are also dealing with a demand-side shock in relation to the cancellation of elective surgeries in many countries due to the pandemic. For example, products targeting respiratory conditions are in high demand, however, there is a significant global slowdown in elective procedures.<sup>18</sup>
- The BioPharma and Chemical sectors have stayed operational, with most sites employing remote working for 50% of the workforce. Many critical construction projects were suspended, and some sites have become involved in supplying sanitisers and critical reagents to the HSE.
- The HPRA have been progressive in how they have utilised digital technologies to address the challenges presented by COVID-19, manifesting itself in such initiatives as virtual audits and remote Qualified Persons.
- Shortages in some raw materials is an emerging issue due to the fact that freight costs have significantly increased. Talent development and availability will present a challenge to the biopharma sector due to a less mobile workforce in the medium to short term; investment decisions may be postponed or delayed.<sup>19</sup>
- Companies are making a difference at a community level. Johnson & Johnson is working with the South/South-West Hospital Group on a return-to-normal-care plan that could help some 300,000 patients. Novartis, Eli Lilly and Roche are funding or supplying personal protection equipment to hospitals. Reckitt Benckiser has donated 40,000 anti-bacterial products to the HSE for distribution to hospitals and nursing homes. Roche employees are volunteering as contact tracers, as well as supplying personal protection equipment to local hospitals.<sup>20</sup>

## Issues, Opportunities and Challenges for the Sector

- Throughout the pandemic, Ireland's biopharmaceutical industry has focused on keeping manufacturing operations open and monitoring supply chains to safeguard access to medicines. Companies in Ireland is also working towards a vaccine and a treatment. It is

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<sup>17</sup> <https://www.ipha.ie/what-is-the-biopharmaceutical-industry-doing-in-the-fight-against-covid-19/>, 2020

<sup>18</sup> <https://dbei.gov.ie/en/Publications/Economic-Considerations-for-Reinstating-Economic-Activity.html>, 2020; IDA Ireland

<sup>19</sup> Ibec Reboot & Reimagine, 2020

<sup>20</sup> <https://www.ipha.ie/peoples-behaviour-and-a-belief-in-science-are-turning-the-tide-on-covid-19-writes-bernard-mallee/>, 2020



also supporting Ireland's response to the pandemic by sharing knowledge and expertise, staff, and supplying the health authorities with appropriate resources.<sup>21</sup>

- The next wave of investment by the life sciences sector internationally will include a focus on COVID-19. IDA Ireland and Enterprise Ireland have developed a new grant scheme, the COVID Products Scheme under the EU Temporary Framework, aimed at supporting the research, development, and production of COVID-19 related products in Ireland. The intention of this new Scheme is to accelerate the production of vital medicines and potential vaccines, along with essential equipment, used in the fight against COVID-19. The scheme allows for up to €200m in targeted State support to facilitate the research and development of COVID products, to enable the construction or upgrading of testing and upscaling infrastructures that contribute to the development COVID-19 relevant products, as well as to support the production of products needed to respond to the outbreak. €25 million was committed for the COVID-19 Life Sciences Products Scheme in the July Jobs Stimulus.
- Diversification of supply chains will become an issue after the pandemic.

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<sup>21</sup> <https://www.ipha.ie/ipha-launches-biopharmaceutical-industry-video-montage-for-covid-19-response/>, 2020