Irish Pharmaceutical Healthcare Association

Response by the Research-Based International Biopharmaceutical Industry to the Public Consultation on the White Paper on Enterprise

BACKGROUND

We welcome the opportunity to respond to the consultation process for the White Paper on Enterprise. We acknowledge the Tánaiste, Leo Varadkar TD, for his leadership in taking this initiative. We are conscious that this submission is set against the backdrop of a war in Ukraine. Our industry's focus is on retaining the resilience of supply chains so that people in Ukraine, in Russia and in neighbouring countries continue to get their medicines. The industry's humanitarian response has so far included the donation of over 29 million doses of essential medicines and funding of more than €63 million to NGOs.

In this submission, we will outline where the industry, in Ireland and globally, is situated now, along with ideas and proposals which we hope the Government will deem constructive inputs.

Our industry in Ireland is experiencing a period of sustained growth. The global demand for medicines and vaccines, accelerated by Covid-19, means that manufacturing sites have been operating at or near capacity and more of them have been expanding. Figures from the Central Statistics Office show that the value of exports of medical and pharmaceutical products jumped by 63% in May compared with the same month a year ago. The sector made up 39% of total exports in May. The latest industry jobs tally, from IDA Ireland, is 42,000. Our value-add to the economy is in the tens of billions.

Research, conducted for us in recent weeks by pollsters Ipsos, shows that 53% of the public has a favourable opinion about our industry. That number has remained steady over the past two years. It is up almost 10 points since before the pandemic. We are trusted by 60% of people, almost twice the global average.

For the Government, the spike in demand and productivity, accelerated by Covid-19, has meant more revenues in the form of corporation taxes, payroll taxes and spending power. Overall corporation tax receipts in the first half of this year rose by €3 billion to €8.8 billion, according to the the Government's Summer Economic Statement. Our industry was a key driver of that increase. We agree with the Government's assessment that the public finances must be resilient. The same goes for our industry whose strength now cannot be assumed to be there in the future. We must work together, industry and Government, in ensuring that we have the best possible conditions to draw jobs and investments in research and advanced manufacturing, and to get the best new medicines to patients when they need them.

Our industry fits the 'mega-trends' the Government has identified, given the scale and pace of innovation in medicines. Like other industries, we are buffeted by international policy developments and geopolitical events. These externalities are shaping influences on the operating environment. Our scientists tell us that we live in a 'biocentury', with the discovery of new medicines catalysed by the intersection of a better understanding of human biology and the new tools of technology, artificial intelligence and machine learning. The medicines of the future offer enormous upside - for qualify of life, for length of life, and for jobs and investments. It is critical that we get the policy conditions right to take full advantage of innovation.

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Although our economy is strong now, the global outlook is uncertain, especially with inflation, war in Europe and the ongoing impact of Covid-19. Our industry's footprint is significant - but it must not be taken for granted. Product life cycles, industry consolidation patterns, the draw of emerging markets, skills readiness and sub-optimal speeds of adoption of new medicines in the health services are creating headwinds that could decelerate the pace at which the industry scales into the future. More partnership and structured dialogue between the State and our industry can yield growth opportunities for the country, as well as identifying risks such as a loss of competitiveness or a diminution in standards of care.

This submission sets out ways in which we can work together to achieve our shared potential.

PATIENTS' ACCESS TO INNOVATION

We want an environment where medicines innovation, access and affordability co-exist. The environment for reimbursement continues to be a key factor for global decision-makers when weighing locations for investments in research and production. Ireland's record on reimbursement, both in process efficiency and funding, has been poor.

Although pre-dating the Government's most recent investments, the latest figures to 2020, gathered by health data analysts IQVIA, place Ireland 24th out of 35 countries in Europe reporting data for time to availability of 160 innovative new medicines. Ireland is four months slower to make new cancer medicines available to patients compared to the average across the EU27.

The public expects more. Forty-seven per cent of people believe access to new medicines is too slow, according to a recent survey we commissioned from Ipsos. In the same survey, a significant majority of people valued our industry's science and innovation, as well as our economic contribution.

There has been recent progress. A four-year Framework Agreement on the Supply and Pricing of Medicines has been operating since the start of the year. It is delivering to the State significant savings on older medicines so that investments can continue to be made in new medicines. This Government has provided €80 million for new medicines in the past two Budgets.

These steps will help to consolidate progress in bringing innovation to patients as fast as other countries in Europe with populations and standards of living similar to our own.

1. **Sustained, adequate investment in new medicines**
   The innovation pipeline is strong. Next year, our member companies intend to launch 30 new medicines. These can treat a range of serious medical conditions, including ulcerative colitis, heart disease, lung disease and many forms of cancer. The medicines would be available for the medical care of over 7,000 patients, helping to change their lives for the better. We estimate that the cost of these medicines in 2023 will be €35 million. That is our funding request for Budget 2023.

2. **Reform the reimbursement process**
   There is a demonstrated need for a fitter, faster, more streamlined medicines reimbursement process. All sides have a role in enabling that reform outcome. Our tracking of the process this year shows, for example, that even after a Health Technology Assessment is completed by the

National Centre for Pharmacoeconomics, it is taking over 12 months for a positive reimbursement decision and implementation for patients' access.

SPURRING INNOVATION

As policymakers review the operating environment for our industry under the EU Pharmaceutical Strategy, Ireland must strongly champion innovation as the basis for new jobs, investments, vaccines, treatments and cures. Research and development leads to innovation which leads to first-mover advantage in advanced manufacturing. This is the cycle that supports a jobs-rich industry in Ireland. The wrong policy moves now could damage the cycle of biopharmaceutical innovation. Already, it is at risk. In the 1990s, Europe was the primary destination for research and development. Now, the US occupies that position, with competition intensifying from Asia, US and the UK.

Europe, and Ireland, should aspire to become the home of research, of high-quality jobs and of fast access to innovation. Hundreds of new treatments have emerged from the Paediatric Medicines Regulation (2007) and the Orphan Medicinal Products Regulation (2000). Any moves to weaken these intellectual property rights risk damaging the innovation pipeline and the jobs bonus that goes with it. As the European Commission prepares to table a legislative proposal later this year, we urge these steps to spur innovation.

1. **Boost research and development**
   That means improving regulation, data and clinical trials. We must use new types of clinical trials and real-world evidence, have more dialogue between the regulator, the European Medicines Agency, and the inventor during the development of a treatment, and streamline the regulator's committee structure to enabler faster decision-making. Having a proper data capture and analysis architecture for tracking and measuring health outcomes would create a foundation for personalised healthcare, optimise prescribing patterns and establish 'value' metrics for the pricing of medicines. We support the EU Pharmaceutical Strategy's European Health Data Space which would, it is hoped, create an interoperable data access infrastructure to facilitate secure analysis of data across Europe. We need incentives, at European level, for research in antimicrobial resistance. In Ireland, reforms in the clinical trials process, especially efficiency measures, funding and protected research time in hospitals, are needed to attract more research.

2. **Build strategic autonomy**
   That means backing vital industries like ours. We should keep the jobs, research and manufacturing we have within our own borders, and draw new investments as global competition intensifies. Any policy change must strengthen the capacity of industry and public research bodies to develop more new medicines and vaccines. The intellectual property framework, which has worked well in finding answers for rare diseases, for diseases that affect children and for diseases like cancer, must be tailored to today's science. In part, that means maintaining eligibility criteria and thresholds for orphan incentives. Attracting private funding is vital for innovation. Certainty is key for investors whose risks, often, yield no reward.

3. **Improve access to new medicines**
   Innovation without access is meaningless. The root causes of medicines access challenges are funding shortfalls and the capacity of a health system to adopt innovation at scale and speed. Linking intellectual property incentives to the launch status of medicines is wrong. The industry has committed to file for pricing and reimbursement in all EU countries within two years of

central EU market authorisation. At the national level, we want to see faster decision-making by health systems on the adoption of new medicines.

The decision of the World Trade Organisation in June for a TRIPS waiver on Covid-19 vaccines was disappointing. The cause of global Covid-19 vaccine inequity is not supply. Rather, the causes are logistics, administration and hesitancy. The EU has not yet settled on a position in relation to the possible extension of the waiver to therapeutics after six months. We urge the Government to resist that extension.

COMPETITIVENESS, JOBS AND SKILLS

Our industry is distributed regionally, creating economic activity in communities. We have heritage in manufacturing that spans decades, moving from small-molecule production to advanced manufacturing and now into supply chain and manufacturing for advanced therapeutic medicinal products (ATMPs). A commitment to sustainable environmental practice characterises expansion plans in manufacturing, with wind and solar energy helping to power some sites. Our capacity to keep the production, research and commercial investments we have, and to attract new ones, will depend on how well we can compete in a volatile global trading environment.

These steps will help us to stay competitive for new investments.

1. **Protect global supply chains**

Maintaining diverse global supply chains is vital. We source 76% of active pharmaceutical ingredients from inside Europe. The EU is the world's largest exporter of medicines, with a market share of 64%. We must avoid blunt-instrument policies like 'near-shoring' or 'reshoring' that would jeopardise supply chain resilience. When Covid-19 hit, borders closed, export restrictions arrived and air freight options disappeared. At the same time, demand for some medicines increased exponentially. The global supply chain, with significant parts of it based in Ireland, endured. Patients still got their medicines. As risks emerge over gas supplies, it is vital that, in prioritising our industry as part of the European Gas Demand Reduction Plan, protection is afforded to the entire medicines supply chain.

2. ***Build for skills and future science***

Thousands of medicines are in development, biopharmaceuticals, technology and medical technology are converging, and production is digitalising. All that means new skills are needed to keep pace with innovation and a surging global industry. Artificial intelligence, the internet of things, genomics and cell therapy are part of a healthcare revolution. The accelerated co-design by industry and the State of academic and apprenticeship programmes that meet skills needs now and in the future is vital. The promotion is STEM, along with an interdisciplinary approach to education, is important for our schools. These are considerations for the forthcoming report of the EGFSN. NIBRT, the industry's bioprocessing training institute, is expanding, with a focus on next-generation biologics, digitalisation and ATMPs. Ireland is part of the World Economic Forum's Global Lighthouse Network. The Janssen manufacturing site in Cork is one of three global sustainability lighthouses. The Government should support moves to add more of Ireland's manufacturing sites to the WEF's Global Lighthouse Network, a collection of the world's most advanced factories adopting 4IR technologies.

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ATMPs

Advanced therapeutic medicinal products, otherwise known as cell and gene therapies, are usually one-time treatments that can add months, sometimes years, to a patient's life, replacing a lifetime of treatment. In cancer, haemophilia, SMA Type 1 and ocular diseases, cell and gene therapies offer significant clinical potential. mRNA, used by Pfizer and Moderna in their Covid-19 vaccines, has potential clinical application in the treatment of cancer and other infectious diseases. A limited number of cell and gene therapies are reimbursed for patients in Ireland.

Ireland can be a European leader for testing, manufacturing, supplying and adopting cell and gene therapies. There is significant potential for investing in allogeneic manufacturing, as well as establishing indigenous companies in the area. Through the global business service operations already located here, we can have a role in the digitisation of autologous cell and gene therapy supply chains. Cherrywood in south Dublin is to be the site of a 30,000 sq ft life sciences incubation and acceleration centre, with specialised laboratory, office and collaboration space for more than 100 people. In Dublin's Grange Castle, Takeda has opened a commercial-scale cell therapy production facility, supplying patients in Europe, the US and Canada. Gilead has opened a Global Paediatric Drug Development Centre of Excellence in Dublin's docklands. Pfizer's Grange Castle site is part of the global mRNA vaccine production cycle.

Ireland should build towards an infrastructure to support the location of cell and gene therapy investments across the lifecycle. We need to ensure that there is a national policy for adopting them in the health services.

These steps will help to ensure our potential in ATMPs.

1. A national ATMP adoption policy that draws together proposals for tackling the related strands of assessment, access and reimbursement.
2. Overhaul the information infrastructure to enable real-world evidence collection for targeted therapy areas.
3. Create centres of excellence at certain hospital sites, allied with investment in training and engagement for doctors and patients.
4. Targeted marketing for global industry investments in ATMP supply chain and manufacturing as part of our overall foreign direct investment strategy.

CONCLUSION

Medicines innovation needs a champion in Government. The pace at which science is moving means new treatments, cures and vaccines are on the way, with significant upside for health outcomes and for jobs if we can integrate these new opportunities into our policymaking. Closer collaboration between industry and the State on the operating environment for medicines innovation and investments is the way forward. That happens in other countries in Europe. It has been a feature of our recent relationship through Brexit and Covid-19, as well as in drawing investments, planning for future skills needs and supplying medicines to patients. The opportunity now is to build a permanent bridge, through strategic dialogue, that cements the relationship between policymakers and one of the most consequential industrial sectors. We are ready to take the next steps on an exciting, collaborative journey.

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