

POSTGRAD OPTIONS 2025 10-PAGE PULLOUT

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Pharma firms pressed Ireland to resist EU reforms

New regulations of pharma sector could cost jobs in Ireland, industry warns

Novo Nordisk executive lobbied Fine Gael leader Harris at playground launch

JACK POWER
Europe Correspondent

Pharmaceutical companies were "disappointed and concerned" at the lack of support offered by the Government to the sector as it pushed back against proposed European Union reforms, correspondence shows.

The pharmaceutical industry has waged a huge lobbying campaign over the last two years with a view to watering down proposed regulations for the sector, which it has warned could cost manufacturing jobs in Ireland and Europe.

Correspondence seen by The Irish Times shows several big pharma companies, such as Pfizer, MSD, Novo Nordisk and AstraZeneca, lobbied the Government to join a pro-industry coalition of EU states to push back against the reforms.

The changes seek to speed up the roll-out of new medicines across the EU, particularly to smaller and poorer countries. The reforms aim to do this by attaching strings to the number of years companies can sell new drugs they produce before cheaper generic competitors can enter the market.

The industry has sought to block efforts to cut the minimum number of years of market exclusivity firms enjoy after developing new drugs from eight to six years.

Pharmaceutical companies were "disappointed and concerned" at the position Ireland took during the EU negotiations, the head of AstraZeneca's Irish operation, Alex Wilkes, told the Government in a letter on August 2nd last.

Pfizer's global executive vice-president, Alexandre de Gernay, warned Ireland was "fast becoming an outlier" by not expressing concerns about the proposed reforms.

The June 27th letter was sent to now-Taoiseach Micheál Martin and Tánaiste Simon Harris during the previous government's term.

"The best interests of patients, the industrial vitality of Europe, and Ireland's economic growth hinge on maintaining the integrity of the intellectual property system," the senior Pfizer executive wrote.

The head of Novo Nordisk's Irish operation managed to get the ear of Mr Harris in person during last year's general election campaign. The encounter with Nina Therese Hovland occurred as the Fine Gael leader was unveiling playground equipment at a school in his Wicklow constituency, which had been funded by the Danish pharma company.

In a November 28th letter following up on the encounter in Bray, Ms Hovland said it was "critical" Ireland picked a side in the pharma debate. The Irish Pharmaceutical Healthcare Association, which represents the sector, called for the Government to align with a group of "like-minded" EU states opposing the changes, which includes Germany, Denmark, France, Sweden and Italy.

The proposed reforms could make companies less likely to invest in research to develop new medicines in Europe, the lobby group told Mr Harris, in a letter on April 9th last. The correspondence detailing the lobbying efforts of pharmaceutical companies was released to The Irish Times under the Freedom of Information Act.

The proposed overhaul of regulations governing the sector is still being debated at EU level. A Department of Health spokesman said Ireland wanted the reforms to find "the right balance" between improving access to medicines and supporting industry. US president Donald Trump has spoken about his desire to bring pharma jobs back to the United States.

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Green wave Crowds enjoy the parade

Thousands, from home and abroad, turned up to see the St Patrick's Day Festival Parade make its way through the streets of Dublin yesterday.

Photograph: Alan Betson

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Simon Harris warns of turbulent times ahead during New York visit

Over 300,000 people pile into Dublin to watch parade

Kabin Crew brings a spark to Cork while Limerick aims to become 'more fun'

Finance officials lowered housing forecasts last year

ARTHUR BEESLEY
Current Affairs Editor

The Department of Finance housing unit in October said new home completions for last year were likely to be "similar or below" the 2023 total, weeks before Government candidates fought the election saying a big rise was coming by the end of the year.

Repeated campaign claims that 40,000 new homes would be delivered last year proved drastically wrong when official

data published in January showed annual output dropped to 30,330 homes from 32,525 in 2023.

The figures led the Opposition to accuse Government leaders of misleading voters by making bullish forecasts about increased housing delivery before the November 29th election.

After the disclosure that Department of Housing officials questioned the rate of delivery in August, Department of Finance records add to a growing body of evidence on the extent

of doubt about housing targets in official circles.

A new document has come to light showing an official in the Department of Finance's housing unit indicated in October that a rise in annual output was unlikely last year.

The document was sent to the department's economics division after the Central Statistics Office released housing output figures for the third quarter of the year. That was almost a fortnight before another department document – separate-

ly released last week to Sinn Féin TD Pearse Doherty – drew the same conclusion about last year's output in a submission to then minister for finance Jack Chambers.

"The figures to date are broadly in line with recent revisions to completions forecasts from the Central Bank for 2024, which point to housing output similar or slightly below last year," said the housing unit email of October 24th.

The Central Bank in September said output would drop to

32,000, but government figures continued to insist 40,000 new homes would be built.

Finance officials noted the 32,000 projection from the bank. Completions were down 8.8 per cent in the first half of 2024, but housing starts rose above 51,000 in the 12 months to June.

However, a September 17th note by Department of Finance officials said "the timing of the translation" of such commencements into completions remained uncertain and was "as-

sumed to occur in 2025 and 2026".

The records were released under the Freedom of Information Act.

A spokesman for Mr Chambers, now Minister for Public Expenditure, described the October file as "internal correspondence between officials" preparing the Minister's November update.

"This internal email contains the same wording as the November housing update," said the spokesman.

McGregor 'doesn't speak for Ireland', Tánaiste says

CORMAC McQUINN
Political Correspondent

Remarks made by mixed martial arts fighter Conor McGregor about immigration during a visit to the White House have been criticised by Irish politicians as "wrong" and "outrageous".

McGregor's St Patrick's Day meeting with Donald Trump came after the US president last week identified the Dubliner as his favourite Irish person during a press conference in the Oval Office with Taoiseach Micheál Martin.

Speaking to reporters at the White House yesterday, McGregor claimed "Ireland is at the cusp of potentially losing its Irishness" and that "the illegal immigration racket is running raven".

The Taoiseach later described McGregor's remarks as

"wrong" and said they "do not reflect the spirit of St Patrick's Day, or the views of the people of Ireland".

McGregor later responded to the Taoiseach, telling Sky News that "every available metric has shown that the Government of Ireland currently has failed the people of Ireland".

He suggested Dublin is one of the most dangerous cities in Europe. "I won't speak about him [Mr Martin] personally or throw a jab. I could. I could throw many jabs at them."

Tánaiste Simon Harris said McGregor "doesn't speak for the people of Ireland and has no mandate to do so". Labour leader Ivana Bacik said McGregor's comments were "outrageous and do not reflect the positive diversity of modern Ireland".

McGregor has in recent years suggested he might contest the upcoming Irish

presidential election and has espoused anti-immigrant sentiments.

Last November, a jury in a High Court civil case found he raped Dublin woman Nikita Hand in 2018 and awarded her €248,603 in damages.

McGregor's appeal, aimed at overturning the jury's finding, is due to come before the Court of Appeal this week for the purpose of making directions to progress the matter.

Dublin Rape Crisis Centre chief executive Rachel Morogh said reports of the fighter's meeting with the US president were "shocking" given the civil judgment against him came "only 16 weeks ago".

Footage of the Oval Office meeting shows Mr Trump directing Mr McGregor to a map of the Gulf of Mexico, which he has sought to rename as the Gulf of America.

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Sports Tuesday

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Inside the pharma industry's lobbying campaign to water down reforms



Jack Power
Brussels Correspondent

Pharmaceutical companies are 'disappointed' in Government's stance during EU negotiations

From Government Buildings to the corridors of the European Parliament – and even a playground in Bray, Co Wicklow – the pharmaceutical industry has been quietly waging a massive lobbying campaign.

The aim is to kill key parts of proposed regulations governing the industry, which have been working their way through the European Union's policymaking machine.

Ireland has come under particular pressure to bat for the industry, given the large concentration of pharma giants such as Pfizer, Eli Lilly, MSD, Johnson & Johnson and others with manufacturing plants or other sites in the State.

The European Commission, the EU's executive arm that puts forward new laws, proposed a landmark overhaul of regulations covering the pharmaceutical industry two years ago. The idea was to make access to medicines more equal across Europe. Currently, many new drugs come on stream in some EU states much quicker than others.

Big countries such as Germany and France have traditionally enjoyed near-immediate access to these medicines, while poorer and smaller states in central and eastern Europe can be waiting for years.

Controversially for the industry, Ursula von der Leyen's commission proposed to fix this by tying strings to the number of years that a company maintains exclusivity over new drugs it produces before cheaper generic competitors can enter the market.

Pharmaceutical companies are currently granted at least eight years "protection" over their data from research and clinical trials. When this regulatory data protection runs out, generic producers can then copy the initial homework and start developing their own rival version of the medicine.

The commission wanted to cut the minimum window of protection from eight to six years. Pharma companies would be able to win back more time, for example, by getting an extra two years of protection if they launched their new drug in every EU state.

The changes caused alarm within the pharmaceutical sector. Companies feared their profits would take a hit if generic drugmakers were able to muscle in earlier.

The pharma industry launched a multi-million-euro lobbying campaign, targeting the EU institutions in Brussels and governments in national capitals, to push back against the proposed changes.

Correspondence seen by The Irish Times shows the extensive lobbying effort from pharmaceutical companies aimed at convincing the Government to adopt the industry's position in EU negotiations on the reforms.

Applying pressure

Among those applying pressure were Pfizer, the global pharma giant that employs 5,000 staff in Ireland and is among the biggest contributors to corporate tax receipts the State has come to rely on; Novo Nordisk, the Danish drugmaker that has enjoyed soaring profits on the back of huge demand for its anti-obesity drug Ozempic; and US giant MSD (Merck), which has large plants in Tipperary, Cork, Meath and Dublin.

The industry argued the commission's plan to tie protection over regulatory data to medicine access would not work. Some of the ways the EU executive envisaged firms earning additional years of market exclusivity, such as launching new products in all member states, were far from straightforward, and not always in the gift of the drugmaker.

The changes would make investing in research to develop new medicines more uncertain, companies said.

The Irish Pharmaceutical Healthcare Association (Ipha), which represents the sector, warned this could lead to a 22 per cent drop in new medicines being developed over the coming decade.

"It would be short-sighted to assume that manufacturing jobs in Ireland and Europe as a whole will ultimately be unaffected by a reduction in the incentives to invest," the group told then taoiseach Simon Harris in an April 9th, 2024 letter.

Deb Mangone, head of Pfizer in Ireland, told Harris that the EU legislation had the potential to shape the pharma sector "for the next couple of decades and Ireland with such significant scale will be heavily impacted by this".

In her April 12th, 2024, letter, sent shortly after the Fine Gael leader first became taoiseach, Mangone said Pfizer hoped the government would "continue to advocate for pro-innovation policies that maintain a stable environment for investment".

Lobbying correspondence from MSD to Harris, sent around the same time, called for Ireland not only to seek to oppose any cut to regulatory protection, but to push to "strengthen" intellectual property supports.

The US Chamber of Commerce also got in on the act. Representatives from the powerful business lobby group met officials from the Department of Health and the Department of Enterprise last June. They lobbyists told department officials they had concerns about "the impact of some aspects" of the EU reforms, accord-



■ Ursula von der Leyen, president of the European Commission, and Tánaiste Simon Harris: from Government Buildings to the corridors of the European Parliament, the pharmaceutical industry has been quietly waging a massive lobbying campaign. IMAGE: PAUL SCOTT

ing to minutes of the meeting.

It is understood the Department of Health was keen on the reforms improving access to new medicines. The Department of Enterprise was more supportive of the arguments being made by industry, according to three sources.

While representations were being made to national governments, a parallel lobbying campaign was being waged in Brussels.

After the commission proposed the changes in April 2023, the legislation moved to the European Parliament, where MEPs had to vote on their position.

Industry called on the parliament to set the minimum period of regulatory protection back to eight years. MEPs were warned the proposed changes could result in companies cutting jobs in Europe.

"The pharma lobby, of course they are a little bit aggressive," one source involved in the parliament's negotiations said.

The centre-right European People's Party (EPP), the largest grouping that includes Fine Gael, backed the industry position, while the centre-left Socialists and Democrats and the Greens initially resisted rolling back the reforms.

Pernille Weiss, a centre-right MEP from Denmark who was seen as very supportive of the industry, was one of the lead negotiators. Parliament logs show Weiss had 17 meetings with Novo Nordisk over the course of the year that MEPs were working on the law.

"At the end of the day, it would not matter who from the EPP has the file, because the EPP position is industry-led. They care

66

Given the deep knowledge of our experts, across multiple topics contained within the legislation, it is a legitimate right to share this expertise with MEPs

more about the industry and competitiveness than they do about access for patients," said a source from the second biggest parliament grouping, the centre-left Socialists & Democrats.

Weiss did not respond to requests for comment.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) marshalled the campaign to rework the regulations in parliament.

Internal emails show the industry group frequently drafted rafts of amendments, sending the proposed changes to MEPs to table.

In some cases, MEPs appeared to "copy and paste" the suggested text into amendments they proposed, one source involved in negotiations said.

"Given the deep knowledge of our experts, across multiple topics contained within the pharmaceutical legislation, it is a legitimate right to share this expertise with MEPs," an EFPIA spokeswoman said.

Medicines for Europe, which represents generic producers, also drafted proposed amendments they then circulated to MEPs, emails show.

Adrian van den Hoven, head of the generic drugmaker lobby group, said making technical suggestions to MEPs for amendments was "part of policymaking in Brussels". Politicians were "free to choose what suggestions resonate best with them", he said.

In one December 2023 memo shared with MEPs, Medicines for Europe warned about the direction of travel some were pushing for: to extend, rather than cut,

companies' regulatory protection periods.

"The proposed extensions will have massive cost implications by extending the monopolies for blockbuster drugs well beyond the current legal framework," the memo said.

Negotiators from the various European political groups were working to a tight deadline. There was a rush to vote on the huge piece of legislation before the parliament's term ended last spring.

In the end, a large majority in parliament voted to set the minimum amount of regulatory protection at 7½ years, just six months less than the current period. The vote was seen as a win for the pharma industry and a slap in the face for the commission.

Several sources described the behind-the-scenes lobbying by industry as intense. EFPIA spent between €5.5 million and €6 million on its lobbying operation in 2023, according to filings published on an EU transparency register.

Pfizer, Bayer, Sanofi, Novo Nordisk, MSD, Novartis, Gilead Sciences and GSK all separately reported spending more than €1 million on their EU lobbying operations in the same year.

Vulcan Consulting, the lobbying firm set up by former Fine Gael junior minister Lucinda Creighton, was heavily involved in efforts to lobby Irish MEPs. Filings show Vulcan was paid between €100,000 and €200,000 to lobby for the Irish Pharmaceutical Healthcare Association in 2023.

The sector has made its case to von der Leyen as well. In a September 2024 letter to the commission president, Eucoupe, which represents mid-sized pharma players, said its members needed a "robust, predictable and strong investment and industrial ecosystem".

Compromise

Since the middle of last year, the EU's 27 national governments have been debating the reforms, which explains the lobbying being conducted in capitals across the EU.

Member states, the parliament and commission will have to settle on a compromise, before the reforms are voted into law.

A group of countries, led by Denmark and Germany, are firmly on the side of the pharmaceutical sector in the negotiations. Smaller states in central Europe want to pressure companies to roll out new medicines more widely.

Ireland is sitting in a middle camp between these two groups.

The Danish government has "deep concerns" about cutting the amount of regulatory protection companies have over new drugs, according to an internal paper setting out its position. The proposed changes would make the EU a less attractive place for research and medicine production, it stated.

There is a feeling among pharma companies with big footprints in Ireland that the Government should be in the camp defending the sector, according to multiple sources in the industry. Ireland's decision to "sit on the fence" has been noted, two sources said.

AstraZeneca, which is headquartered in England, told the previous government that pharma companies were "disappointed and concerned" by the position Ireland had taken.

In an August 2nd, 2024 letter, Alex Wilkes, head of the company's Irish office, reiterated the "serious concerns" industry had with the proposals. The correspondence was sent to Minister for Enterprise Peter Burke and the then minister for health Stephen Donnelly.

The friction between the industry and the Government over the EU reforms comes at a particularly sensitive time. The sector accounts for a huge chunk of the billions of euro worth of exports Ireland sells to the United States.

This trade flow – and the jobs created by US pharma companies in manufacturing sites in Ireland – are in the sights of US pres-

ident Donald Trump, who has promised sweeping taxes on such exports.

His hope is that tariffs will pressure companies to reshore intellectual property or manufacturing output from Ireland back to the US.

Oliver O'Connor, head of the lobby group the Irish Pharmaceutical Healthcare Association, said cutting companies' regulatory protection would send the "wrong signal to European and global

investors".

In a June 21st, 2024, letter to the coalition leaders, now Taoiseach Micheál Martin and Tánaiste Simon Harris, O'Connor called for Ireland to join the group of "like-minded" states opposing the changes, which included Germany, Italy, France, Denmark, Sweden and others.

The correspondence was released to The Irish Times, following requests made under the Freedom of Information Act.

Pfizer also ramped up the pressure. The pharma giant's global executive vice-president, Alexandre de Germay, told Harris and Martin that Ireland was "fast becoming an outlier", by not expressing concerns about the reforms.

"The best interests of patients, the industrial vitality of Europe and Ireland's economic growth hinge on maintaining the integrity of the intellectual property system," he wrote in a June 27th letter.

In reply, Harris said that the concerns of industry were understood by the government. Ireland wanted to improve access to medicines, while making sure the sector remained strong and innovative, he said.

The head of Novo Nordisk's Irish operation managed to get the ear of the Fine Gael leader in person, during the general election campaign late last year, in an unlikely setting: a playground in Bray.

Campaign trail

Harris was on the campaign trail unveiling new playground equipment at a school in his Wicklow constituency, which had been funded by the Danish pharma company.

In a November 28th, 2024 letter following up on the encounter, Nina Therese Hovland said it was "critical" that Ireland picked a side in the pharma debate.

A coalition of pro-industry states were signalling their commitment to the sector, she said. What stance Ireland took would be "pivotal to it remaining one of the best places in the world to do business", the Novo Nordisk executive said.

Though the Government has not been as receptive as companies may have expected, it looks like the pharma sector will get its way anyway.

A source involved in current negotiations said a majority of capitals looked likely to agree to back companies getting seven years of regulatory protection, but with the option to earn a further year of cover much easier than had been previously proposed.

One official inside the European Commission reportedly summed up how things were looking during a recent meeting: industry had largely secured what they wanted, the official said.

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