

Paul Cullen: What prompted Irish health insurers to make innovative new cancer drugs available to subscribers?

Cancer medicine is undergoing a revolution, with scores of new treatments targeting specific tumours on the way



A graphic of a stomach tumour. Thanks to the internet, patients can keep abreast of latest options for treating their cancers in leading centres in the US and elsewhere. Illustration: Alamy/PA



[Paul Cullen](#)

Sat Jul 1 2023 - 05:00

It's not often that a business offers new benefits to its customers, but doesn't rush to tell them. This has just happened with two companies accounting for half the health insurance market.

Irish Life Health and Laya Healthcare have both decided to make innovative new cancer drugs available to subscribers, though it took a query this week from The Irish Times to establish what was happening.

Using similar language to one another, the insurers separately issued statements explaining that, following a 12-month review of policies, they had decided to make high-cost cancer treatments available to patients once they have been approved by the European Medicines Agency (EMA).

This could shave up to two years off the length of time seriously ill cancer patients, otherwise running out of options, have to wait for access to these medicines.

The two companies have been on the back foot for the past month, since The Irish Times highlighted the yawning gap between their policies on access to cancer treatments, and the policy of the VHI.

Cancer medicine is undergoing a revolution, with scores of new treatments targeting specific tumours on the way. Thanks to the internet, patients can keep abreast of the latest options for treating their cancer in leading centres in the US and elsewhere.

In 2019, VHI took stock of these developments and decided to fast-track availability of these drugs for their patients. These immunotherapies are expensive but are particularly sought-after by patients who have run out of road with existing treatments.

Irish Life and Laya chose not to follow suit, sticking to their policy of waiting for the drugs to be funded under the public system before agreeing to pay for them for their customers.

Over time, the number of new drugs, and the number of indications of these drugs for different cancers, has multiplied. Oncologists, already used to waiting long periods before cancer drugs were approved for public patients, found that even for their private patients, access varied hugely between different insurers. “Patients know these drugs exist. They are proven. They’ve been approved on clinical grounds by the regulatory bodies. But we can’t use them [on Irish Life and Laya patients] until a price has been agreed in the public system, and that can take over two years,” Prof Ray McDermott told me. “A lot of patients will be dead by then.”



Oncologist Prof Ray McDermott: 'Patients know these drugs exist. They are proven. They’ve been approved on clinical grounds by the regulatory bodies'

In desperation, patients and their families resorted to paying for the drugs themselves or through organising fundraisers, he said.

Along with other colleagues, Prof McDermott grew increasingly frustrated at the unfairness involved in delays. His point was illustrated by the case of Mary

O'Loughlin, from Co Wexford, who had been unable to access immunotherapy he recommended because it not funded by the HSE or her insurer, Irish Life. Ms O'Loughlin has a rare form of gastric cancer and has undergone extensive chemotherapy and surgery. The drugs Prof McDermott wants to administer are already indicated for other, more common cancers; her treatment would be funded if she had the same form of cancer in the colon rather than in the stomach.

Both Prof McDermott and Prof John Crown had accused Irish Life and Laya of "hiding behind" the lengthy process for approving drugs for public patients by holding off on funding until the HSE had agreed to reimbursement.

Both companies had referenced the National Centre for Pharmacoeconomics (NCPE) in their decision to withhold funding for the drugs. Yet the NCPE's sole role is to evaluate the cost-effectiveness of medicines for the State, not to adjudicate on how well they work. Cost-effectiveness will always be determined by price, which is why recommendations by the NCPE on any drug are always followed by (often lengthy, always secret) price negotiations between the HSE and the manufacturer. The unspoken approach by the State is to delay in the hope the price asked for will fall over time.

Almost half the population has private health insurance, and half of those people are customers of Irish Life and Laya, so the companies' U-turn will be significant for many patients. That still leaves the wider disparity in access between public and private patients, one that is replicated across the health service.

According to a European pharma industry group, it took on average 567 days from EMA authorisation to availability to patients last year of new innovative medicines in Ireland. That was among the slowest in western Europe, and 100 days longer than it took three years earlier.

Yet Department of Health consultants, in a report published earlier this year, found the HSE process for funding medicines was operating in line with legislation and delivering results "in keeping with international norms". Minister for Health Stephen Donnelly did agree to set up a working group to see how greater transparency and better communications with patients could be effected.

The consultants' report was published three years after it had been completed, nothing more has been heard of the working group and Mr Donnelly says his officials will complete consideration of its recommendations "when resources permit".



Health

Laya and Irish Life customers to get faster access to cancer drugs following policy U-turn

Public patients may now have to wait up to two years longer than all private patients for access to innovative therapies



Irish Life Health and Laya Healthcare say they will provide cover for the treatments as soon as the drugs are clinically approved by the European Medicines Agency

[Paul Cullen](#) Health Editor

Tue Jun 27 2023 - 05:00

Two private health insurers have promised to make innovative new cancer drugs available more quickly to patients, in a significant U-turn in policy.

Irish Life Health and Laya Healthcare say they will provide cover for the treatments as soon as the drugs are clinically approved by the European Medicines Agency (EMA). Up to now, they have generally waited until the HSE decides to reimburse the drugs for public patients, a process that can take several years.

The two companies' change of heart follows revelations in *The Irish Times* earlier this month of the substantial gap between the cover they provide for cancer patients and that provided by VHI Healthcare, which funds the treatments once the EMA has approved them.

Leading oncologists Prof Ray McDermott and Prof John Crown accused Irish Life and Laya of "hiding behind" this lengthy process for approving drugs and denying very sick patients access to proven treatments. The two companies account for about half the private health insurance market.

Laya was “accelerating the approval pathway” for new cancer drugs following a 12-month review of policies and benefits, the company told hospitals in a letter seen by The Irish Times.

While continuing to “accept the guidance” of the National Cancer Control Programme (NCCP) and the National Centre for Pharmacoeconomics (NCPE), it will now cover new, innovative medicines as soon as they have been approved by the EMA.

Cover will be subject to pre-authorisation, meeting clinical criteria and will be reviewed on a case-by-case basis, the company says.



Prof John Crown was one of the two leading oncologists who accused Irish Life and Laya of 'hiding behind' the lengthy process for approving drugs and denying very sick patients access to proven treatments. Photograph: Alan Betson

Irish Life had reviewed its current processes to assess ways to speed up patients' access to drugs not currently approved by the HSE, NCCP or NCPE, the company told The Irish Times.

“On foot of this review, Irish Life Health has decided that it will cover patients for high-cost cancer drugs that have received approval from the EMA,” it said. “Decisions on individual cases will be taken on a case-by-case basis, in consultation with an independent panel of clinical experts who will advise on clinical effectiveness and patient safety.”

Prof McDermott said he was delighted by the change in policy by the two insurers. Mary O’Loughlin, a cancer patient from Boolavogue, Co Wexford, also welcomed the news. She has been unable to access immunotherapy because the drugs Prof McDermott recommends are not funded by the HSE or Irish Life.

Ms O'Loughlin, who has a rare form of gastric cancer, has been given a sixth round of chemotherapy instead and is awaiting a scan to see how that has impacted her disease. "At least I know it's on the way," said Ms O'Loughlin, whose renewed application for access to immunotherapy was refused by Irish Life as recently as two weeks ago.

The changed stance by insurers means public patients are seriously disadvantaged due to the length of time the HSE reimbursement process takes. This is due to the number of intermediate steps involved and the length of time behind-the-scenes price negotiations with drug manufacturers take.

While both Irish Life and Laya maintain they refused only small numbers of patients, Prof Crown said this was because oncologists knew their applications for cover would be refused so there was "no point" in applying for it.

'Dismay' over care home's move to former workhouse

Petition calling on HSE to reopen Galway day care centre signed by 2,500 people

MARESE McDONAGH

Campaigners opposed to the relocation of a "purpose-built" day care centre in Loughrea, Co Galway have written to the Charities Regulator expressing concern that the facility is being moved into "a former workhouse".

In a letter to the regulator, the Loughrea Concerned Citizens group said there was "much dismay" in the community at the plan to move the centre into a former workhouse which feels like "a backward step" when "a bright, airy, purpose-built centre stands just a few yards away".

More than 2,500 people have signed a petition calling on the HSE to immediately reopen the Seven Springs day care centre which closed during lockdown and is now open just one day a week while service users attend the local Loughrea Hotel three days a week.

The Concerned Citizens group say a day care facility was built on the site in 1979 with funding provided by local

such as adapting empty bedrooms and building an extension. "Hiqa never dictated that the day care centre be commandeered," he added. The Seven Springs centre is linked to the nursing home by a glass corridor.

When the day care centre, which pre-Covid was attended by up to 35 people, failed to reopen after lockdown restrictions eased, two protests were held in Loughrea.

Petition
Geraldine Donohue, an Independent member of Galway County Council who organised the protests, said the HSE was "clearly not listening to the 2,500 people who signed the petition".

Kitty Devine, a former assistant director of nursing in St Brendan's, said the HSE proposal was not in line with Mrs Topping's wishes. "I knew Nora Topping. She was a wonderful woman, a former nurse who saw the isolation in rural areas and wanted to do something about it," said the 85-year-old local woman.

Ms Devine said she did not believe Mrs Topping would approve of the plan to move the service into a 150-year-old building "with so many sad memories there".

Local Fine Gael TD Ciarán Cannon who supports the HSE plan said the new facility would be larger than the old Seven Springs centre and would have a substantial outdoor garden and courtyard, something not available in the existing facility.

In a statement, the trustees who include Mr Cannon, said "due to certain ill-informed speculation" they were clarifying their role.

They said the terms of the trust stipulated that it was for the benefit of residents of St Brendan's nursing home or people qualified to be residents.

The HSE confirmed that during the pandemic when the day service closed, the nursing home used that space to ensure compliance with social distancing rules. An "application to vary" the use of this space was submitted and the re-registration reflected that change.

Mr Cannon said the HSE had recently confirmed that if the nursing home lost the Seven Springs space, it would be in breach of the Health Act 2007 "and the continued operation of the CNU [community nursing unit] would be seriously threatened".

Hiqa raised concern about the inadequacy of dining space available

woman Nora Topping now deceased, who they say intended it to be a community facility. This building was demolished when the St Brendan's community nursing unit was built in 2011, and was replaced by the Seven Springs facility.

The HSE confirmed that the Topping Trust, a registered private charitable trust, was "supporting the capital cost" of adapting part of the former workhouse which is also in the St Brendan's campus, as a new day care centre. A spokeswoman said the facility should be completed by late 2023. Tenders have been sought.

Documents

Documents released to the Concerned Citizens group under the Freedom of Information rules show that Hiqa raised concern about the inadequacy of dining space available to St Brendan's residents on a number of occasions.

Retired teacher Mattie Quinn, chairman of the group, said the documents showed that a number of options to address this issue were discussed



'Extremely unfair': Imbalance in health insurance cover for crucial cancer drugs



Paul Cullen
Health Editor

Two cancer patients and two oncologists raise concerns about how customers of private health insurers Irish Life and Laya Healthcare are losing out on access to new cancer treatments

Scores of patients with advanced cancer are losing out on access to the newest and most promising treatments because of their choice of private health insurer.

The plight of public patients forced to wait long periods for access to next-generation therapies is widely acknowledged but a separate access issue has developed over the past four years between customers of the three main health insurers.

In 2019, VHI broke ranks with its rivals by agreeing to fund wider access to cancer treatments for private patients. Irish Life Health and Laya Healthcare, which elected not to follow suit, generally wait for a drug to be approved on the public system before green-lighting it for customers.

Since then, the number of new drugs, and the number of indications of these drugs for different cancers, has multiplied, leading to what oncologists say is a growing disparity in coverage between different providers.

"Existing insurance customers and those considering taking out insurance do need to realise that there is a substantial imbalance in coverage for cancer between VHI and the other two companies," says Prof John Crown.

This is reflected in the experiences of cancer patients who have talked to The Irish Times about the difficulty they have experienced accessing treatment through their insurer.

Mary O'Loughlin, from Boolavogue, Co Wexford, is unable to access immunotherapy to treat her cancer because the drugs her consultant recommends are not funded by the HSE or her private health insurer.

Mary was diagnosed with a rare form of gastric cancer two years ago and has undergone extensive chemotherapy and surgery. Faced with a recurrence of the disease, her oncologist, Prof Ray McDer-

mott, recommended the use of pembrolizumab or nivolumab to treat it. It is "highly likely" her tumour will respond to this form of immunotherapy, he told The Irish Times.

"I was delighted, but then Irish Life said they don't cover it," Mary says. "The VHI will cover it, and the HSE don't want to know about it for certain cancers."

Prof McDermott asks: "What is the benefit in having Irish Life or Laya insurance if you need treatment for metastatic cancer, specifically a drug that has been shown to work and is recommended in all useful guidelines? In my view subscribers should know this when they choose their insurance plan and act accordingly."

Mary is now back on chemotherapy, for which she travels from her home in Co Wexford to St Vincent's hospital in Dublin every second week.

"It's going very hard on me. Chemo is much harder than the immunotherapy - there's awful fatigue, nausea, vomiting, hair loss and a feeling of being generally unwell," she says. "At least I'm having it, but it would have been much better if I could have been given the immunotherapy. I'm wondering why we can't have it in Ireland."

Appealing the decision

She says she didn't have the strength to take up the issue with her insurer but a family member helped her appeal the decision to refuse cover for pembrolizumab.

Irish Life declined the appeal, and also said it "cannot allow" an exception on compassionate grounds.

Ironically, Mary used to be with VHI but was switched by her broker to Irish Life 16 years ago; the broker receives a 3 per cent commission from Irish Life each year. She believes brokers should let clients know "what's definitely not covered" before moving them to another health insurer.

While she could switch back

to VHI next time she is renewing her policy, use of the immunotherapy would not be covered for the first two years under standard health insurance switching terms.

Anita O'Connell believes the refusal of her health insurer, Irish Life, to fund a potentially life-changing treatment for her cancer is "extremely unfair" when it is available through another insurer, VHI.

After the 52-year-old woman was diagnosed with breast cancer in 2018, she was treated with aggressive chemo, surgery and radiotherapy. Her scans were clear for two years

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It's going very hard on me. Chemo is much harder than the immunotherapy - there's awful fatigue, nausea, vomiting, hair loss and a feeling of being generally unwell

but then she experienced back and bone pain and required further treatment.

Prof Crown recommended a course of sacituzumab govitecan (Trodely), a new drug from Gilead Sciences that regulatory bodies in Europe and the US have approved for the treatment of secondary breast cancer. Clinical trials have shown it can slow progression of the disease by several months and extend a person's life by about five months compared with traditional chemotherapy.

However, her insurer, Irish Life, refused to pay for the treatment, on the basis that it is not reimbursed by the HSE.

"I was extremely disappointed and very frustrated," says Anita. "I felt my access to a life-changing drug is dependent on the randomness of the insurance company that my husband happens to be in, through his work."

"Time is not on my side. It is frustrating to think the people making these decisions probably do not have first-hand experience of what it's like to have cancer and to have a time-bomb ticking over your head."

She tried to switch insurance to VHI, which initially said it would fund the treatment but at the last moment told her it would apply a two-year wait period for eligibility because the treatment was considered an upgrade in cover. Staff apologised for the initial misinformation and suggested she might have a case with the insurance Ombudsman but she felt too stressed to take this on at a time when her disease is progressing.

Six-month course

For now, her hopes rest on a decision by the HSE to reimburse the drug, which would trigger coverage by Irish Life and its availability in the public system. The National Centre for Pharmacoeconomics, Ireland (NCPE) ran the rule over the cost-effectiveness of Trodely last March, and found it costs at least €82,000 per patient for a six-month course.

Its review concluded that the drug could be considered for reimbursement "if cost-effectiveness can be improved relative to existing treatments".

This means the drug will be approved if HSE and Gilead can reach agreement on a reduced price. So far this has not happened.

Ireland is not the only country wrestling with these issues: the UK initially rejected Trodely then did a U-turn, while Dutch regulators are holding out for a 75 per cent reduction on the price quoted by the manufacturer.

Mary O'Loughlin of Boolavogue, Co Wexford: her insurer will not meet the cost of the immunotherapy cancer drugs she needs. PHOTOGRAPH: PATRICK BROWNE

"You wonder what all the red tape is for," says Anita. "All this tardiness while people's lives are hanging by a thread. This drug could change my life, and many others."

"I felt they didn't try hard enough to help me. 'Irish Life - we're here to help.' Well, they weren't really there to help at all, to be quite honest with you."

Responding to queries from The Irish Times, Irish Life says it funds treatments that have been approved by the NCPE, the National Cancer Control Programme (NCCP) or the Health Service Executive. The company last week announced an increase in premiums, for the second time this year.

Laya says it "accepts the guidance and direction" of the NCCP, the NCPE and the HSE, "in consultation with medical consultants involved in the treatment of patients".

"There are times when we will approve drugs earlier than HSE-led approvals, where the treatments have been approved by the EMA and are supported by medical evidence."

Acknowledging the frustration experienced by cancer patients, a spokeswoman says the company is "working hard to find ways to influence the speed at which funding decisions are made while upholding the clinical standards and regulatory guidance to ensure maximum patient safety".

VHI says it is committed to ensuring members can avail of the best medically appropriate benefits "in a timely manner".

"We will provide benefit for drugs in accordance with our membership rules and when it is medically necessary for these to be administered in a hospital setting."

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THE IRISH TIMES

GPs warn about risks from cancer test delays

PAUL CULLEN

GPs in Kilkenny have expressed serious concern about the risk to patients from a large backlog in reporting cancer test results in the southeast.

Patients' diagnosis and treatment for cancer could be delayed by the backlog at the pathology lab at University Hospital Waterford, the doctors have warned.

More than 5,000 patients have endured waits for test results of up to six months as a result of staffing shortages at the lab.

After details of the delays emerged in March, the Kilkenny branch of the Irish College of General Practitioners wrote to Health Service Executive (HSE) bosses warning of the potential for "avoidable adverse clinical outcomes".

"The risk of delayed histology reporting for thousands of

patients, for periods between one and six months, raises serious concerns regarding delay in the diagnosis and initiation of appropriate management," according to the letter, seen by The Irish Times.

"Many of these patients will already have experienced other

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More than 5,000 patients have endured waits for test results of up to six months

significant time delays," the letter signed by Dr Justin Kwong, chair of the Kilkenny group, in mid-March states.

"Such a cumulative delay at each stage of the patient journey and ongoing diagnostic uncertainty is a serious patient quality and safety issue, espe-

cially for any person with a cancer diagnosis."

The lab delay is causing doctors additional administrative and clinical workload burdens, Dr Kwong pointed out, thereby exposing them to "increased patient frustration, dissatisfaction and additional microlegal risk".

Dr Kwong called for a "real-time, urgent and ongoing solution" to clear the backlog, and for patients with significantly delayed reports to be notified directly and in writing by the HSE.

The HSE replied last month through Gerard O'Callaghan, chief executive of the South/Southwest Hospital Group, and Declan Lyons, chief executive of the Ireland East Hospital Group, who chair the safety incident management team set up to lead efforts to clear the backlog.

They apologised for "any in-

convenience, anxiety or stress" caused to patients and GPs, and said extra resources had been put in place to clear the backlog, including evening and weekend working at the lab and outsourcing to a retired member of staff.

Last month, The Irish Times asked the South/Southwest Hospital Group a series of detailed questions about the delays, which it declined to an-



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