

NOVEMBER / 2023



MEDICINE SHORTAGES

SYMPTOMS & SOLUTIONS

AZURE
PHARMACEUTICALS

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EXECUTIVE SUMMARY

In February 2021, as the world grappled with the COVID-19 pandemic, an executive order from the United States President reflected the central role stable medicine supply chains have on public healthcare. The response was an acknowledgement of the indispensable role that medicine supply plays to protect public health and patient well-being. When this supply is threatened, the consequences are real.

This realisation came in the context of a pharmaceutical industry intricately woven into the fabric of globalisation, with manufacturers spanning international boundaries for ingredient sourcing, manufacturing, and distribution, most notably for the lower priced off-patent segment of the medicines market. A defining characteristic of the generic market has been the migration of the majority of medicine Active Pharmaceutical Ingredient (API) production to Asia, particularly India and China. This procurement transformation, driven by cost-cutting in response to downward pressure on reimbursement prices, delivered advantages to manufacturers, buyers and consumers. Yet, as we are now experiencing, the concentration of generic pharmaceutical production in a limited number of countries has created a precarious situation with reverberations in the form of severe shortages of essential medications, here in Ireland, the European region, and across the globe.

Delays in drug manufacturing, upended supply chains, over-dependency on too few suppliers, unsustainable pricing models, and changing economic circumstances in the Asian economy combined with immediate consequences. As a result, patients, healthcare

professionals, and healthcare systems are being jeopardised.

In Ireland, the number of medicines out-of-stock have more than doubled in just 12 months - a 107% increase. Two thirds of the entire population have been impacted by medicine shortages. Almost half of patients have experienced shortages for prescription medicines at a pharmacy.¹

In response to the crisis, countries in Europe and elsewhere have responded through a range of policy measures. Portugal, the UK, and Switzerland have taken price related policy measures, paying more to enhance supply. As have Germany, which has also recently turned to stockpiling essential medicines ahead of another expected seasonal peak this winter. Sweden and Denmark, which both use tenders to set reimbursement prices, have deployed price increases to enhance supply of core medicines. Sweden has also introduced specific incentives to bolster antibiotic stock levels.

For a nation like Ireland, the challenges of medicine shortages have unique complexities. Our smaller population and geographic location mean we lack the volume purchasing power of larger countries who are more centrally located. Our dependency on too few suppliers for too many medicines increases risk. Consequently, we find ourselves particularly vulnerable to the fluctuations and disruptions that can afflict global medicine supply chains.

It is therefore no surprise that the medicine shortage crisis we face as a nation has not abated but rather worsened over time, culminating in a crisis point that calls for vital solutions at policy level.

1. Amarach Research commissioned by Azure, 2023

SO, HOW TO **RESPOND?**

The Medicine Shortages Index was launched one year ago to highlight the escalating crisis in the availability of medicines in Ireland. In just 12 months, the number of medicines in shortage in the country has surged from 178 to 347, marking an alarming 88% increase, according to the Index, which uses data from the Health Products Regulatory Authority (HPRA).

In this paper, we are seeking to constructively contribute to addressing this challenge. We have put forward nine specific proposals which can help to alleviate this problem in the immediate and ongoing sense. They are informed by a deep understanding of the local and global medicine landscape and a desire to tackle a problem which continues to hinder our health system.

Ours is just one perspective. There are and should be others. Collaboration is key if we are to effectively address this complex issue. While medicines shortages will persist, we can influence their impact and frequency. We remain ready to play our part.



MEDICINE SHORTAGES IN IRELAND

107%⁺
INCREASE

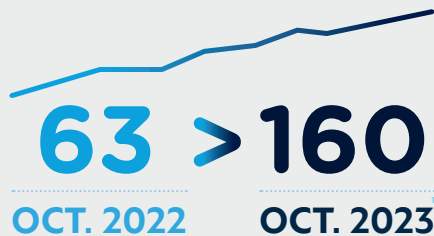
increase in medicine shortages in one year¹



60% of Ireland's population has been affected by medicine shortages.²



Almost 50% of Ireland's population deeply concerned by deteriorating situation²



Number of single source shortages that do not have an exact or similar medicine available.



13 medicines listed on the WHO 'critical medicines' list³

Over-use of unlicensed Exempt Medicinal Products (EMPS) used to cover depth of medicine shortage crisis:

3
MILLION

Around 3 million unlicensed EMPS dispensed in Ireland in 2022⁴

250,000

Around 250,000 patients per month getting unlicensed medicines in Ireland⁴

25
€MILLION

About €25 million spent on unlicensed EMPS in Ireland in 2022⁵

SOURCES:

1. Medicine Shortages Index Azure Pharma (Data taken from HPRA website)
2. Amárach Survey conducted in May 2023 commissioned on behalf of Azure Pharmaceuticals
3. WHO Essential Medicines List 23rd List 2023
4. Data on File – Azure Pharmaceuticals Ltd.
5. HSE response to Parliamentary Question

SYMPTOMS

The Medicine Shortages Index, compiled by Azure using data from the Health Products Regulatory Authority (HPRA), was launched one year ago to highlight the escalating issue of medicines availability in Ireland. We could see through our engagement with pharmacists, patients, and others, that staple medicines, the ones that large swathes of the population depend upon to manage their daily healthcare needs, were becoming increasingly difficult to source.

Now, 12 months on since our first Index, the number of medicines in shortage in the country has surged from 178 to 368, a 107% increase.

A striking contributing factor to the shortages is the number of single source shortages in Ireland, which now stands at over 40% of the total number of medicines in short supply. By contrast, the comparative EU average is 24%. Single source shortages are those medicines that do not have an exact or similar medicine available, pushing patients back to the prescriber (GP or hospital consultant) to have a new prescription issued for an alternative therapy. In such cases, the alternative may be a sub-optimal treatment to that which was initially prescribed.

Recent data underscores the profound impact of medicine shortages on Ireland's population, with 60% of patients reporting difficulties in obtaining their prescribed medications within the past year. Almost half of the population also expressed deep concern about the persistence of this issue into the future.

Throughout the crisis we have seen essential medications, such as the commonly prescribed low dose Aspirin 75mg, which sees approximately four million annual dispensations, unavailable. This dire

scenario extends to other essential medicines used to manage conditions such as high blood pressure, epilepsy, high cholesterol, antibiotics, mental health treatments, and a range of topical treatments.

The consequences of shortages extend to the doors of patients who find themselves grappling with a sense of vulnerability, uncertain if they will receive the medicines they rely on for their health and well-being. What is unequivocal is that this problem is not going away; it is evolving and intensifying, casting a shadow over the resilience of our healthcare system.

Against a backdrop of significant medicine shortages both on a global scale and more significantly within our own borders, it is abundantly clear that the stakeholder response has fallen far short of what is needed to address the current situation and has been lacking any forward-thinking measures. In parallel, evidence indicates an increasing over-dependence on unlicensed medicines (Exempt Medicinal Products or EMPs) which heretofore were used in exceptional cases. What was exceptional however is normalising, with over three million EMP medicine packs dispensed in 2022 at a cost to the State's medicine's budget of over €25 million.

Funding challenges in the Irish healthcare system have, once again, come to the surface. Government's acknowledgment of a significant budget shortfall underscores the considerable strain on the healthcare budget. In tandem, we grapple with ever-increasing demands, demands which will not dissipate.

Concurrently, discussions surrounding budgetary enhancements place a strong emphasis on optimising the value derived from existing expenditures. The Department of Health anticipates medicine expenditure this year of €2.9 billion, more than double what it was just 10 years ago. It estimates €1 in every €8 of funding for health in the public system relates to the pharmaceutical bill. Such realities emphasis

both the importance of extracting maximum value for every euro spent, and the requirement for highly effective planning and management of what is a huge budgetary line item.

Government has acknowledged the role that generic medicines can play in achieving value. The scope to do so is clear. The generic medicine volume level in Ireland stands at 57%. While this represents a major advance from the strikingly low levels of usage pre-2013, we still lag notably behind European volume levels which average at over 70%.

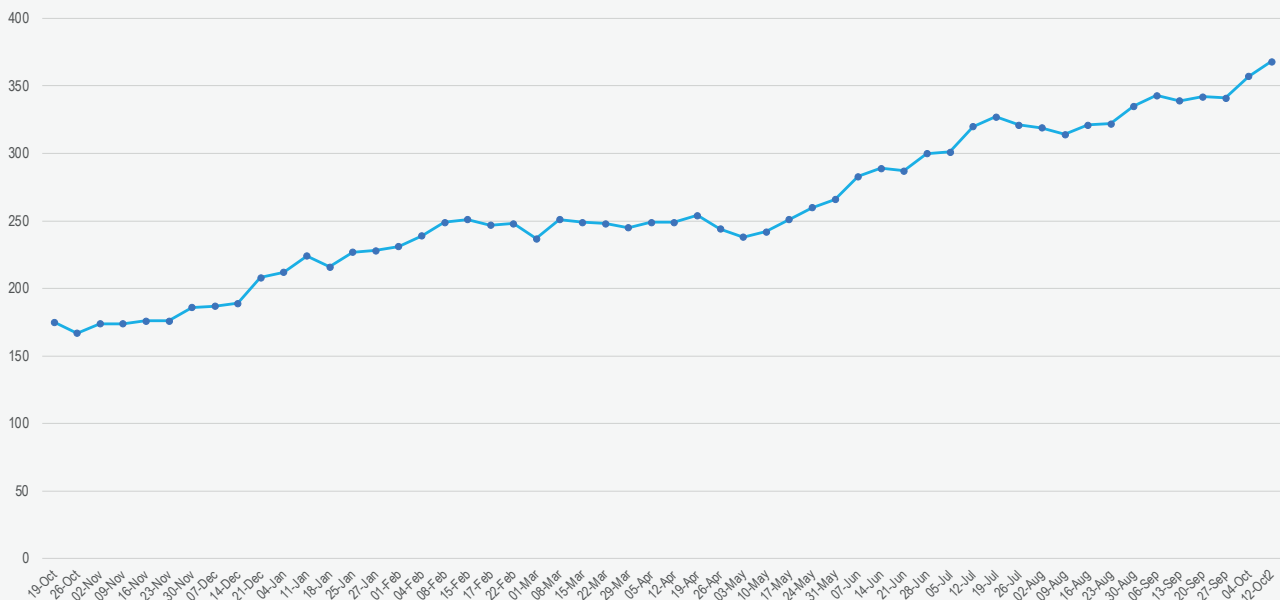
Deriving better value from our medicines budget creates budgetary headroom to fund medicine innovation. However, we need to confront the realities of the changed global landscape. Older generic medicines, the mainstay of patient needs, have seen their business models upended. The prices of these medicines have not even remotely kept pace with inflationary realities. Generic manufacturers,

confronted by uneconomical realities, are beginning to pivot away from supplying low margin medicines to those higher up the value chain. This is at the core of the ongoing medicine shortages issue.

It is time to reset how Ireland meets medicine demands. The landscape has changed. Medicine supply chains have been upended. The number of suppliers for many off-patent medicines is decreasing. Those that remain are often intertwined, compromising independence and in the process, increasing the supply risk. Evidence of first mover advantage is increasingly apparent, with those countries choosing to pay more, procure differently, and deploy their annual budgets more astutely fairing best.

Ireland must respond. Hereunder, we have set out nine ways in which we can.

Number of Medicines Out of Stock since October 2022





SOLUTIONS

In this whitepaper, we present a framework of achievable and practical solutions, grounded in decades of experience, shared insights and a profound commitment to the health and well-being of Irish patients. Through a pragmatic and realistic strategy, we can chart a path towards a healthcare system that not only effectively addresses the challenges presented by medicine shortages but also fortifies its resilience in the supply of medicines.

Here we put forward nine proposed solutions to address the challenge of medicine shortages and supply in Ireland. These proposals reflect our commitment to collaborative working, acknowledging the complexities of the task ahead, and striving for effective solutions that serve to meet this challenge. We aim to present the steps needed toward a more secure future for Ireland's medicine supply.

Our nine proposals are:

1.

ESSENTIAL MEDICINES LIST: introduce an Irish specific essential medicines list (137 countries currently have one, Ireland does not).

2.

MEDICINES INVENTORY SYSTEM: to measure and review medicine dispensing, track trends, enhance transparency and aid forward planning.

3.

USE EXISTING POWERS IN FULL: utilising available mechanisms to ensure sustainable medicine pricing and enhance supply efficiency.

4.

MINIMAL SUPPLIER RULE: implement a directive to broaden supplier diversity, enhancing stability in the supply chain

5.

HPRA FASTTRACK LICENSING STREAM: to expedite the market authorisation for essential medicines, a new HPRA Fasttrack Licensing Stream.

6.

DECOUPLE MANUFACTURER SOURCES: strengthening supply chain resilience by seeking independent manufacturing and API supplier origins.

7.

RED TEAMING IRELAND'S MEDICINE SUPPLY PREPAREDNESS: using real-time simulation techniques, robustly test and assess national supply plan at regular intervals.

8.

PROCUREMENT PARTNERSHIPS WITH OTHER COUNTRIES: Ireland to enter buying partnerships with other similar sized markets to enhance capabilities and savings.

9.

BUFFER STOCK INCENTIVES: commission study to incentivise maintenance of buffer stocks of essential medicines.

PROPOSALS

1.

DEVELOPMENT OF A DEFINED ESSENTIAL MEDICINES LIST.

Introduce an Irish specific Essential Medicines List (EML).

A comprehensive catalogue of medications, EMLs are necessary for maintaining public health and responding to healthcare challenges. EMLs ensure that essential medicines are readily available and accessible to the population while aiding healthcare professionals and the wider system itself to operate effectively and efficiently.

An EML is fundamental to the proper functioning of a healthcare system, especially in resource-constrained settings. It is central to proper proactive planning, acting as an early warning signal and identifying vulnerabilities in the supply chain.

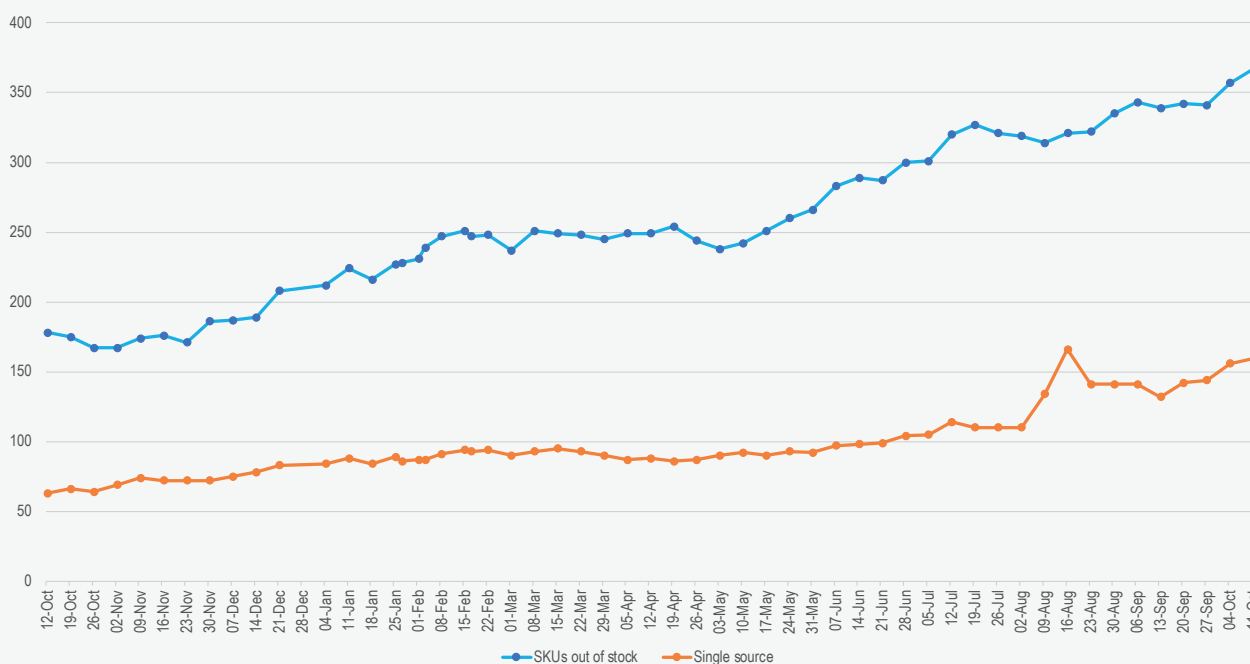
There are currently 137 countries globally that have a published EML. Ireland does not have an EML, making it an outlier. Grippled by the challenges of medicine shortages, many countries have moved to introduce EMLs over the recent period, including the USA in 2020 and France in 2023.

An EML is typically developed and maintained collaboratively by relevant stakeholders, including healthcare professionals, health policy makers, administrators and regulators, medicine manufacturers, health insurers and patient representatives.

An operational framework can be developed which defines what constitutes an essential medicine, one which is adaptable so as to be responsive to where and when supply challenges can present. It can be informed further from data sharing and analysis with other countries, the World Health Organisation's EML (its 23rd EML was published in 2023), and guidance from the European Medicines Agency published in February 2023.

Number of Single Source Shortages since October 2022

Medicines Shortages Index - Single Source average 38%



2.

MEDICINES INVENTORY SYSTEM.

The existence of an EML, as proposed above, provides the foundation which underpins our second proposal - establishing a Medicines Inventory System (MIS) of essential medicines.

If the EML defines essential medicines, the MIS enables us to measure medicine dispensing, track trends, forward plan, and signal watchouts.

The MIS would define and track the:

- Quarterly/annual volume of essential medicines required and dispensed.
- Number of suppliers per essential medicine and number of suppliers needed to meet demand.
- Signal alerts as to where the number of suppliers has dipped to levels which present risks to overall supply.
- Site details of the manufacturer to enhance transparency around of supplier sources.
- Source of the medicine's Active Pharmaceutical Ingredient (API). Where crossover between manufacturer and API source exists, this should also be flagged as lack of independence between these parties presents supply risks.
- Annual spend per medicine.

Such a system would also serve as a stimulant to competition among existing and prospective suppliers who, through the existence of better data, can make more informed and speedier decisions.

3.

USE EXISTING POWERS IN FULL.

A primary reason for medicine shortages are unsustainable, uncompetitive prices. Medicine supplies generally tend to be strongest in countries which pay the best prices.

Under existing legislation (2013 Act), the HSE has existing powers at its disposal which it can deploy to maximum effect in mitigating the ongoing supply challenges:

- Clause 7.3: clause 7.3 of the IPHA Framework Agreement which provides for a price uplift in order to enhance the viability of a medicine in a small market. Such price uplifts are relatively low cost in the context of overall medicine spend. For example, the annual impact of 12 most recently short medicines shows an overall increase of less than €10m if both private and general medicine scheme (GMS) patients are included. For context, we estimate that delays in implementing savings eligible under the IPHA Framework Agreement cost over €10m from May 2022 to May 2023.
- Interchangeable medicines: the HSE also has the option under the Health and Supply of Medicine Act 2013 to set Reference Prices for interchangeable medicines in a timelier fashion and to add medicines to the Interchangeable List at a faster rate once patents have expired. Significant savings are being forgone by the delay in acting these pricing levers which would more than offset any cost increase due to the small number of low-priced medicines that need to have an uplift.
- Hardship Scheme decision time: for existing essential medicines, the HSE is dragging out decisions in relation to applications for price increases under the Hardship Scheme causing

PROPOSALS

manufacturers to withdraw medicines in the worst-case scenario, or reducing the volume they supply to the Irish market and favouring supply to higher priced markets. To address these delays, HSE should apply timely and fair implementation of the Hardship Clause contained within the existing industry Framework Agreements.

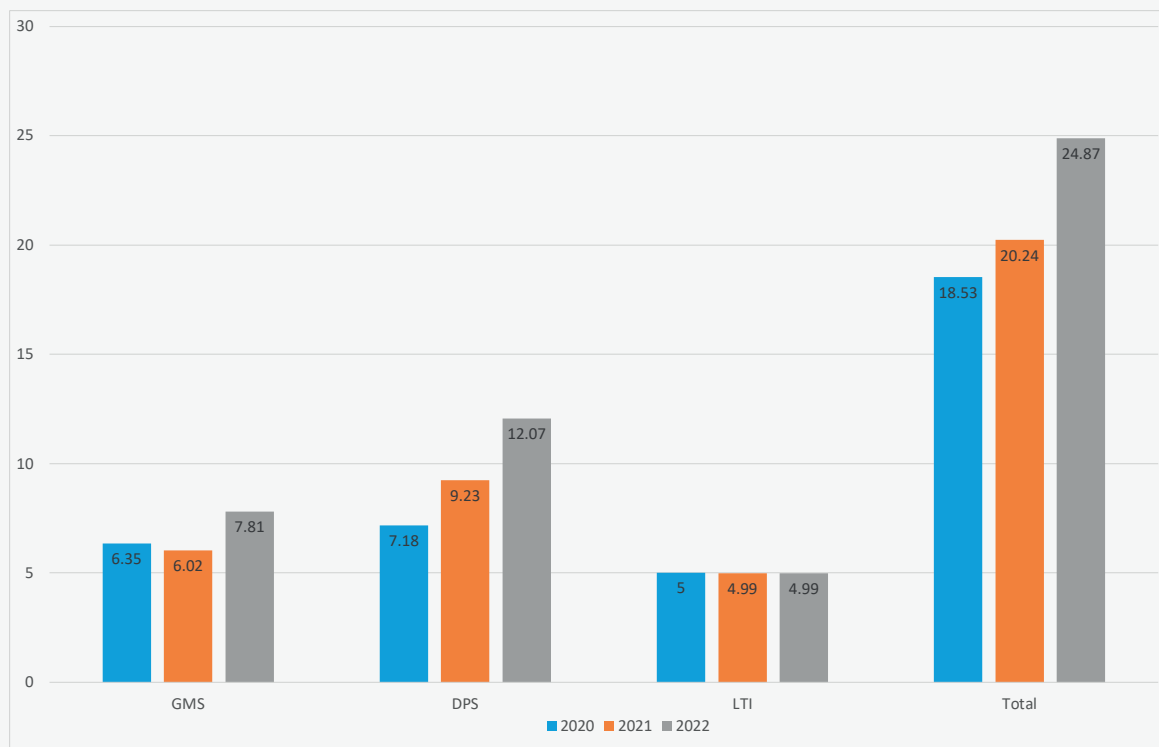
- Apply existing reimbursement methodology to essential medicines: reimbursement of essential medicines that are currently derived from a single source for the Irish market need to be urgently reviewed. The requirement to bring a generic of these to the market at a 60% price reduction versus the brand is a detrimental barrier to competition being brought to the market. Even where the HSE decides to waive this requirement to some lesser percentage, the delays in obtaining reimbursement for new launches are also deterring the sourcing of alternative supplies of medicines that mitigate against future shortages. Increasing reimbursement

to the average of the basket of EU countries using the same methodology, as is currently being applied to all reimbursement decisions including innovation high price medicine, would alleviate supply challenges.

Deployment of these existing powers as outlined would also act as a further budgetary offset as it would decrease the State's growing dependency on the use of unlicensed medicines (Exempt Medicinal Products). Heretofore, unlicensed medicines were used in exceptional cases, but publicly available data is showing this is changing. Apart from the obvious lack of regulatory oversight, an increased use of unlicensed medicines, which now equate to over three million medicine packs dispensed annually, costs more. Most recent data shows that unlicensed medicines cost the State over €25 million in 2022.

State spend on Exempt (Unlicensed) Medicines

€Millions (excl. out of pocket by patient)



4.

**MINIMAL SUPPLIER RULE
IN MEDICINE PROCUREMENT.**

To mitigate medicine supply risk, the State should introduce a rule whereby all essential medicines must have a minimum number of suppliers, wherever patent expiration permits, embedding the rule into any public tendering requests.

Such a model would stimulate competition, reduce existing single source dependencies, and incentivise suppliers to maintain medicine licenses rather than allowing them to lapse.

In order to secure additional sources for essential medicines that are off-patent, current suppliers to the Irish market should be the first port of call. However, many of these are local subsidiaries of large multinationals and are dependent on their internal research and development pipelines which are largely

focused on future off-patent opportunities at a European or global level. It is unlikely that these global players will set aside R&D spend specifically for Irish market demand. Indeed, many of the larger generic companies are reflecting on their future investment with some signalling that their focus may no longer lie in commodity generics, rather in higher priced value-added medicines, including biosimilars.

In the absence of appropriate dossiers, which are the basis for getting a license for a medicine, being available from the larger generic players, there are smaller local suppliers who specialise in sourcing and in-licensing older off-patent medicines.

These companies are well networked and have connections with companies that have no direct presence in Ireland but who are focused on developing difficult-to-source medicines. These companies also work to develop their own dossiers in co-operation with third parties at considerable expense. The cost of developing a dossier could be as high as €250,000, depending on the requirement for bio-equivalence studies and the complexity of the development.

Medicine price comparison (Medicines that have had recurring shortages in Ireland)

Medicine	Strength	Pack Size	IE €	UK €	EU Average €	Treatment for
Paracetamol	500mg tablet	100 pack	1.73	3.05	7.35	Pain
Amoxicillin	500mg capsule	100 pack	16.15	31.75	22.07	Infection
Lorazepam	1g tablet	100 pack	3.77	7.63	11.43	Anxiety
Nitrofurantoin	100mg Caps	30 pack	6.73	13.03	11.91	Urinary tract infection
Amisulpride	200mg	60 pack	31.68	39.08	60.99	Schizophrenia
Clonazepam	0.5mg	100 pack	4.33	35.46	13.59	Epilepsy
Co-Amoxiclav	125/31mg/5ml	100ml	1.38	6.25	4.12	Infection
Tamoxifen	20mg tabs	30 pack	4.58	3.16	9.11	Breast cancer
Alprazolam	0.25mg	100 pack	2.22		8.71	Anxiety
Ipratropium Nebules	250mg/ml x 2ml	20 pack	4.5	7.46	7.95	COPD

5.

HPRA FASTTRACK LICENSING STREAM.

A regulatory reset encompassing the two central pillars governing the medicine market in Ireland - licensing and reimbursement — is timely if we are to meet the ongoing medicine shortages challenge, improve supply resilience, and streamline processes contributing to delays. This reset should provide for the following:

The existing medicine licensing application system must adapt to meet the supply challenge, particularly when it comes to essential medicines. It needs to be responsive to the fluidity of supply risks as they present, adaptable and agile to enhance our collective effort in meeting the challenge.

To this end, we propose the introduction of a new Fasttrack Licensing Stream for essential medicines within the office of the Health Products Regulatory Authority (HPRA) to expedite the market

authorisation for essential medicines. Such a structure would bring efficiencies to the licence application process, with the time saved serving to lessen the duration of shortages and speed-up new supply channels. Such a fast-track stream should have clear operational performance indicators whereby application decisions, subject to license quality, should be concluded within 12 months of submission.

As part of this, HPRA should review the fees charged for such applications. Current fees for applications range from approximately €11,000 up to €45,000 depending on the type and basis of application. In a post-Brexit landscape, the requirement to undertake new bio-equivalence studies to replace a UK reference product with an EU reference product is a significant barrier to sourcing dossiers that do not require a significant investment in order to comply with this new bio-equivalence requirements.

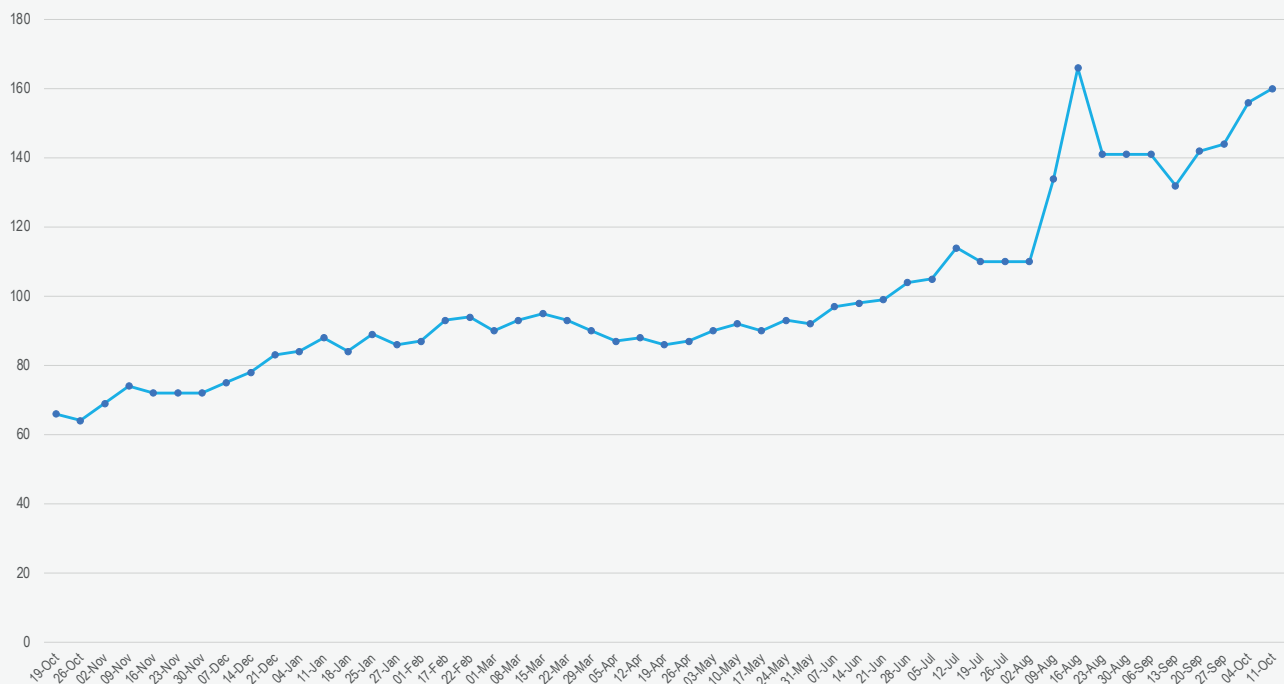
This should be investigated further as to the basis for the requirement, other than the obvious political issue, and whether a derogation could be obtained for certain products that are Essential and in short supply e.g., older antibiotics.

Cost Implications to bring Irish reimbursement prices to EU average
(Medicines that have had recurring shortages):

Medicine	Strength	Pack Size	IE €	EU Average €	Annual Vols	Cost €
Paracetamol	500mg tablet	100 pack	1.73	7.35	1,771,556	3,153,370
Amoxicillin	500mg capsule	100 pack	16.15	22.07	202,000	1,195,840
Lorazepam	1g tablet	100 pack	3.77	11.43	26,000	199,160
Prednisolone	5mg tablet	98 pack	3.06	7.49	66,390	294,108
Clonazepam	0.5mg	100 pack	4.33	13.59	61,000	564,860
Co-Amoxiclav	125/31mg/5ml	100ml	1.38	4.12	43,000	117,820
Tamoxifen	20mg tabs	30 pack	4.58	9.11	71,000	321,630
Doxazosin XL	4mg	28 pack	3.68	8.96	317,000	1,673,760
Alprazolam	0.25mg	100 pack	2.22	8.71	124,000	804,760
Betamethasone	0.10%	30g	1.77	5.75	154,000	612,920
Clarithromycin	250mg	14	2.97	9.72	97,000	654,750
Ipratropium Nebules	250mg/ml x 2ml	20 pack	4.5	7.95	50,000	172,500
TOTAL					3,103,946	9,765,477

Cost assumes all of the packs are dispensed under GMS. Assuming 65% is covered, cost is approx €7.5m to GMS

Cost implications to bring Irish reimbursement prices to EU average



6.

DECOUPLE MANUFACTURER AND API SUPPLIER SOURCES.

Medicine manufacturers traditionally source the Active Pharmaceutical Ingredients (APIs) - the main components of the medicine - from a third-party supplier. To add to the complexity, manufacturing sites may be producing the same medicine for more than one license holder. In periods where supply is constrained, manufacturers may have to decrease or suspend the supply to one license holder in favour of another. API suppliers face similar situations.

More often the decision to supply one customer over another is a factor of the volume on order, and the price being paid by the customer, which is directly linked to the size of the destination market and the price being paid there.

HSE should introduce a requirement to have independent manufacturing sites and ideally separate Active Pharmaceutical Ingredient (API) supply sources. Decoupling in this way would mitigate overall supply risk, particularly in circumstances where the number of suppliers of certain essential medicines are low.

7.

RED TEAMING IRELAND'S MEDICINE PREPAREDNESS.

The multifaceted nature of the medicine shortages issue challenges the thinking of all stakeholders. Collectively, we need to challenge assumptions and probe deeper if we are to navigate through a period which will continue to influence healthcare outcomes for the foreseeable period.

Red teaming - a simulation technique deployed in various fields to robustly assess organisational plans and responses to multidimensional challenges - would deploy real-world scenarios to test the collective preparedness of our national medicine supply chain.

Objective evaluation of each facet of the supply chain and the policies and processes which govern it can help us to better understand, anticipate and mitigate medicine shortages. Through interdisciplinary collaboration, the red teaming would create real-world scenarios, mimic supply chain disruptions, unexpected spikes in demand, and consequential actions of domestic and international supply chain parties. Vulnerabilities in the system could be pinpointed. New, creative solutions which heretofore may not have been considered could be identified.

For example, is Ireland giving due consideration to the increasing practice of 'near-shoring-'western' countries increasing generic medicine manufacturing capacities at home in response to an over-dependency on Asian-based manufacturers and the related economic, resourcing and infrastructure considerations of same?

Are we engaging meaningfully with Irish-based generic manufacturers to fully understand why they are exporting their medicines to international markets rather than supply locally?

Are we leveraging the knowledge of leaders in the local pharma manufacturing community to better understand and respond to the shortages challenge?

Furthermore, diversity of perspectives lends to more comprehensive analysis and in doing so, foster an adaptive culture that is in tune with the ever-changing and uncertain realities of medicine demand and supply.

Micro and macro solutions. For example, increasing manufacturing capacity of generics in Ireland - near shoring. Local manufacturers are currently exporting abroad rather than supply locally given the price advantages.

Consider the local knowledge and expertise we have on pharma manufacturing - are we maximising this knowledge?

The Minister for Health should initiate a red teaming of this matter, appointing individuals with diverse skills, backgrounds, and knowledge to bring varied perspectives to the evaluation process. The process should be systematically undertaken at regular intervals to test national preparedness, providing related insights and recommendations to inform decision-making.

8.

PROCUREMENT PARTNERSHIPS WITH SIMILAR SIZED COUNTRIES.

Looking ahead, particularly in light of the significant repercussions of Brexit, it may be prudent for Ireland to explore potential buying partnerships with other similar sized markets. Collaborative efforts could involve the creation of joint pharmaceutical packs, a strategy that could amplify the volume of Essential Medicines, rendering them more appealing to global players. Given that Ireland shares derogations from EU pharmaceutical legislation with other markets such as Malta, Cyprus and Iceland, a small market pack mutually agreed by all four regulators could be an option for consideration.

This type of international initiative, akin to the 2015 Beneluxa initiative which saw Ireland partner with Belgium, the Netherlands, Luxembourg, and Austria to improve access to medicines, could play a pivotal role in ensuring Ireland's access to essential medicines. Driven by cooperation among nations, such an initiative would not only have the potential to streamline procurement processes and negotiate favourable pricing for critical medicines but can also foster innovation and the development of new treatments.

The 2015 Beneluxa initiative allowed the participants to engage in joint pricing negotiations, horizon scanning for new drugs or competing drugs, joint health technology assessments, and information sharing, resulting in more efficient and transparent process.

9.

BUFFER STOCK INCENTIVES.

Supply problems are worsening as manufacturers choose to supply to those countries who pay better prices. Similar instances arise when it comes to new medicines which are often not launched onto the Irish market due to unsustainable pricing. Both of these factors put pressure on existing stock levels.

The Public Health Agency of Sweden recently ran a pilot project to investigate whether a model with guaranteed reimbursement to the pharmaceutical company can improve access to particularly important antibiotics in the country. Evaluation of the study shows that the studied reimbursement model led to increased access to the antibiotic products in Sweden, earlier than in other comparable European countries.

To examine these factors, the Department of Health should take note of the study undertaken in Sweden and commission the HSE to conduct a preliminary study to develop criteria and guidelines for a new reimbursement model where pharmaceutical companies receive a compensation for maintaining a buffer stock of essential medicines. In keeping with our proposal on partnering with similar sized countries, the preliminary study should also scope the possibility for potential buffer stock collaboration or coordination with other countries. The study when completed should be presented to government for consideration.



ABOUT **AZURE** PHARMACEUTICALS

Azure Pharmaceuticals is “small” Pharma with big ideals - a belief that we can help safeguard supply of the staples of the medicine cabinet. Our commitment is to ensure medicines remain accessible, available, and affordable.

Our portfolio of medicines encompasses a range of therapeutic areas, including cardiovascular health, mental health, and chronic conditions. Our dedication to ethical practices and patient-centred care drives us to draw attention to the crisis in medicine supply in Ireland, devoid of any financial interests. We advocate for better access to essential medicines through sustainable healthcare

SOURCES:

1. Medicine Shortages Index Azure Pharma (Data taken from HPRA website)
2. Amárach Survey conducted in May 2023 commissioned on behalf of Azure Pharmaceuticals
3. WHO Essential Medicines List 23rd List 2023
4. Data on File – Azure Pharmaceuticals Ltd.
5. HSE response to Parliamentary Question
6. Data from Reimbursement Authorities in UK and 7 other EU reimbursement authorities
7. TBC
8. Data on File Azure Pharmaceuticals based on EU reimbursement prices and Irish sales of packs 2023

ACCESSIBLE

AVAILABLE

AFFORDABLE



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PHARMACEUTICALS

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