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Review of High-Tech Drug Expenditure

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Paper Summary

1. This paper focuses on High-Tech Drug (HTD) expenditure, a State pharmaceutical procurement and dispensing arrangement for patients with health needs initially met in the hospital setting.
2. Expenditure and activity in the scheme are reviewed in the context of broader pharmaceutical and health activity nationally. HTD expenditure indicators and dynamics are set out, such as average treatment costs by age, sex and disease profile. The key drivers of HTD expenditure since 2012 are disaggregated and analysed.
3. The gross Exchequer impact of new drug introductions on HTD expenditure is reviewed and quantified. Whilst subject to assumptions, the *marginal* effect of new drug introductions is also estimated.
4. The proportion of non-patented generic and biosimilar medicines (non-originator medicines) in the HTD arrangement is set out. The average cost differential between originator and non-originator treatments is examined, and the success of two recent HSE non-originator promotion campaigns is detailed.
5. Policy questions such as the process through which new drugs are introduced and the exchequer impact of the arrangement are discussed, while potential cost containment measures and next steps are also explored.

Key Findings

1. State expenditure on pharmaceuticals has grown from €1.3bn in 2012 to €2.3bn in 2020, an average of 4% or €54m growth each year since 2012.
2. At a component-level the primary driver of this growth is the High-Tech Drug arrangement, which has grown at an average of 11% or €63m year-on-year, from €379m in 2012 to €794m in 2020.
3. The total number of patients funded by HTD expenditure has consistently grown in the years from 2012 to 2019, from a base of fifty-seven thousand patients in 2012 to eighty-nine thousand in 2019, an average year-on-year growth of 6.9%.
4. As the unit prices of drugs generally cannot increase due to agreement with industry, the primary driver of HTD expenditure is the introduction of new higher cost medicines, and growth in patient volume. This growth is partially offset by agreed price reductions with industry and by the introduction of cost reducing treatments, which are most often generic or biosimilar options.

Estimated HTD Cost Driver Impact 2012 - 2021

Cost Driver	Proportional Impact on Annual Expenditure	% of Total Growth Drivers	Average Annual Impact (€)	2012-2020 Marginal Effect
Population Growth	+1.5%	13%	+€8.4m	+€60.6m
Additional Patient Volume Growth	+5.4%	49%	+€30.6m	+€220.1m
Proportional Growth in Higher Cost Treatment Areas	+0.2%	2%	+€1.3m	+€9.4m
New Drug Introductions	+4.0%	36%	+€22.5m	+€161.6m
- of which Cost Incurring	*+6.3%*	*56%*	*+€35.5m*	*+€255.2m*
- of which Cost Reducing	*-2.3%*	*-21%*	*-€13.0m*	*-€93.6m*
Total	**+11.2%**	**100%**	**+€62.9m**	**+€451.7m**

5. The dominant treatment areas in terms of expenditure are Rheumatoid Arthritis and Cancer, both of which are associated with large patient volumes and above median annual treatment costs (approximately €12,700 and €13,500 per patient per annum respectively). While the average annual cost of treating Rheumatoid

Arthritis has begun to fall due to the adoption of non-originator drugs, the cost of treating Cancer continues to rise exponentially.

6. Recent years have seen increases in the number of extremely high-cost treatments (>€100,000 per annum), however for most of these the impact on overall expenditure is significantly mitigated by small patient volumes.

7. The HSE campaign to promote biosimilar alternatives in the Rheumatoid Arthritis space have yielded significant savings.

8. There is a notable trend towards increasingly complex pharmaceutical pricing arrangements between governments and the pharmaceutical industry subject to non-disclosure agreements that compromise the ability to perform an accurate cross-country comparison of pharmaceutical prices. This is advantageous from the perspective of the pharmaceutical industry, as it reduces States' ability to evaluate comparative value for money across other jurisdictions.

Steps Forward/Policy Considerations

1. The High-Tech Drug Arrangement provides treatments for serious and complex illnesses such as Cystic Fibrosis, Cancer and Rheumatoid Arthritis. While continued investment in novel treatment options is required to ensure adequate treatment of these illnesses, cost containment measures must also be considered so that expenditures remain sustainable and good value for money is achieved.

2. Based on the analysis of the data presented in Section 2 and options emerging from the policy literature, a number of possible cost containment measures could be considered in an Irish context.

    a) The Department of Health, DPER and the HSE could work to consolidate and further incorporate forecasting of multi-year expenditure commitments arising from potential allocations for investment in new medicines.

    b) Improvements to existing agreements with Industry which provide more favourable pricing terms to the Exchequer, supporting greater patient access to these drugs.

    c) Over the medium-term, the State could consider measures to promote international cooperation in pharmaceutical policy, including greater information sharing on pharmaceutical pricing and ultimately, where desirable, joint procurement. While it is too early to be definitive, the joint procurement of COVID vaccines through the EU demonstrates the potential application of this approach. Additionally, the desirability of enhanced European co-operation is highlighted in the recent EU Commission pharmaceutical strategy. This may provide the best means of overcoming the anti-transparency practices promoted by industry.

    d) Policies to promote the usage of generic and biosimilar medicines, including chemical-based prescribing, mandatory generic substitution, gainshare initiatives and the publication of a biosimilar strategy. These policies would have patient safety and prescribing practice implications, and their design must be cognisant of both.

    e) Changes to the Quality Adjusted Life Year Threshold (currently €45,000) in the drug approval process, resulting in a greater requirement for cost effectiveness from new drugs if they are to be reimbursed by State expenditure.

3. Some of the cost containment measures considered in the paper may prove challenging to implement in practice, especially where patient accessibility could be impacted by a policy change.

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Introduction

In recent years rising pharmaceutical expenditures have become an issue of significant policy discussion in and among European and OECD countries. This growth is itself a product of complex interrelated factors, reflecting policy and non-policy changes over the last few decades including: rising average treatment costs, the availability of new higher priced treatments driven by unprecedented levels of industry investment in new medicine pipelines, demographic aging, increases in the prevalence of chronic health conditions, and the erosion of price containment measures due to increasing complexity and reduced transparency of pricing and reimbursement processes between States and industry.[1]

This paper reviews the High-Tech Drug arrangement, the pharmaceutical expenditure line in Ireland which has seen by far the largest year on year increases in expenditure, growing from €380m in 2012[2] to just under €1bn in 2021, a 2.6 times increase in nine years. There are 3 basic reasons for the faster growth in HTD expenditure versus other pharmaceutical expenditure lines:

1. The High-Tech arrangement covers a category of medicines associated with higher treatment costs, i.e. treatments for serious, complex, or chronic conditions, as opposed to more general medicines such as anti-microbial and pain reduction.
2. As implied by the name, the HTD arrangement tends to cover medicines which are more technologically advanced. This means many of the technologies remain under patent and the lack of competition implies higher prices.
3. Pricing arrangements in place with industry are set so that unit prices may not increase, and will instead fall based on the prices paid in comparator countries. This means manufacturers typically set higher prices for new medicines coming to market in order to achieve a desired return on investment. The HTD arrangement receives many new medicines and therefore is subject to cost pressure as a result.

The HTD arrangement was initiated in 1996 to facilitate the dispensing of High-Tech Drugs at the community pharmacy level.[3] In more recent years, the HTD arrangement has become of particular interest from a policy perspective due to its significant rate of growth which has raised concerns around funding sustainability. A number of high-profile reimbursement decisions which have been taken in recent years have related to HTD pharmaceuticals procured by the HSE.[4]

This paper was drafted as part of Spending Review 2021. The data employed in this analysis was obtained from two main sources: overall pharmaceutical expenditure figures were derived from regular internal reports produced by the Primary Care Reimbursement Service in the HSE. The data underpinning the detailed analysis of the HTD arrangement was provided by PCRS via the IGEES Unit in the Department of Health. This is composed of individual transaction data generated at the pharmacy level for the payment of pharmacy fees. These data, covering the years 2012-2020 included information relating to the date of transaction, the pharmaceutical provided (brand name and chemical name) and an anonymised unique patient identifier. Additional patient information, such as sex and date of birth was also made available for patients who are present in the GMS, LTI or DPS schemes. The construction of the dataset was an extensive process, with sourcing and linkage of the data taking place over several months. The use of this dataset constitutes a step

[1] (OECD, 2018), (OECD, 2017), PCRS management reports.
[2] The dataset available for analysis contains observations from 2012 onwards.
[3] See the HSE website for a description of pharmaceutical sub-schemes including the HTD expenditure.
[4] https://www.irishtimes.com/opinion/governments-will-struggle-to-pay-for-high-tech-drugs-1.3048728

forward in data-driven policymaking in healthcare, with the combined dataset being one of the largest held by the Department of Health.

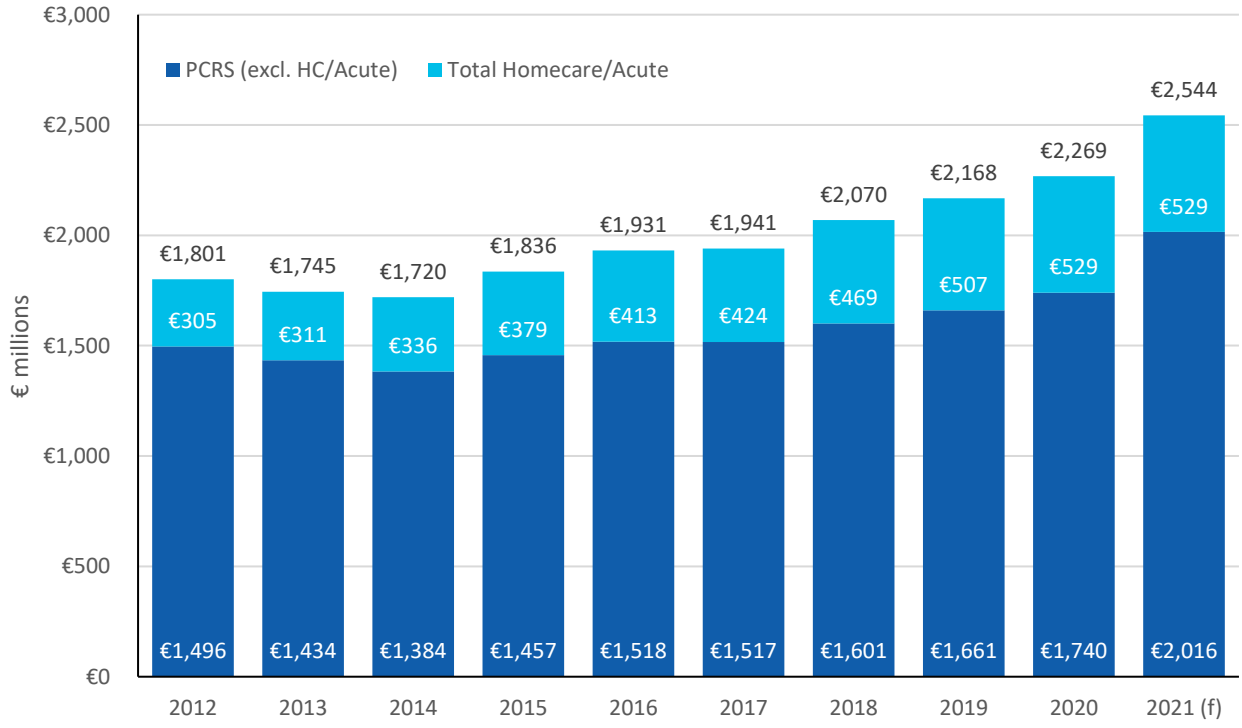
1. Pharmaceutical Expenditure Context

1.1. Overall State Pharmaceutical Expenditure

In Ireland a large majority[5] of expenditure on pharmaceuticals is covered or subsidised by the National Exchequer through State pharmaceutical arrangements administered by the Department of Health and Health Service Executive. Pharmaceutical items are dispensed though a number of avenues and are grouped into arrangements depending on the classification of the pharmaceutical in question.

The majority of State pharmaceutical expenditure is done centrally via the HSE Primary Care Reimbursement Service (PCRS). Another portion however is procured and paid for disparately through hospitals and other health services (a subset of this however is reimbursed through PCRS). The complexity and fact that spend is spread across several areas poses a challenge to accurately tracking total pharmaceutical spend. Figure 1 below sets out the estimated State pharmaceutical spend across PCRS and Hospitals/Homecare; additionally, it should be noted that a smaller amount of pharma spend takes place across remaining health areas e.g., Mental Health. This remnant expenditure was estimated at around €80m in 2020.

Figure 1. 2019 PCRS & Acute Pharmaceutical Expenditure 2012-2021 (forecast)



Source: PCRS Reports / Author Calculations

As depicted above, State pharmaceutical expenditure through PCRS and Homecare/Hospitals is estimated to be almost €2.6bn in 2021 – a 47% increase since 2014. Adding in the estimated remnant expenditure from the various other community health areas, it can be noted that total State expenditure on pharmaceuticals in 2021 is expected to be in excess of this €2.6bn estimate.

[5] It is estimated around three quarters of 2018 private and public pharmaceutical expenditure in Ireland was via the State Exchequer. Calculation based on Total Spend per capita OECD figures, compared with State spend.

1.2. Expenditure by Health Arrangement

While overall State pharmaceutical expenditure has increased each year since 2012, the trend is less clear on a per arrangement basis with reductions in some arrangements being offset by larger increases in others. The General Medical Scheme (GMS) is the arrangement through which pharmaceuticals for people covered by a general means tested Medical Card are reimbursed.[7] GMS is formerly the largest pharmaceutical expenditure area prior to 2018 and has seen an average reduction of €17m or 2% year on year since 2012, with expenditure plateauing in recent years. The decline in GMS expenditure from 2012 was likely driven by a number of factors including a gradual fall-off in medical card numbers in the mid-late 2010s, prescribing control programmes such as Versatis/Diabetic Test Strips, and controlled access. The more recent rise in GMS expenditure has likely been driven by recent changes to the eligibility threshold for Medical Cards for over 70s, and the automatic rollover of some medical cards at the onset of the COVID-19 pandemic.

Figure 2. PCRS & Acute Pharmaceutical Expenditure 2012-21

€m	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021 (f)[6]	Average YoY 2012-21	
GMS	€914	€845	€750	€704	€689	€649	€619	€618	€643	€763	**-€17**	**-2%**
High-Tech	€379	€425	€468	€520	€578	€616	€709	€747	€794	€939	**+€62**	**+11%**
LTI	€104	€93	€111	€158	€176	€181	€199	€216	€235	€231	**+€14**	**+9%**
DPS[7]	€80	€53	€35	€54	€54	€51	€54	€61	€67	€62	**-€2**	**-3%**
NDMS	€0	€7	€12	€38	€45	€65	€67	€86	€76	€106	**+€12**	**+40%**
Other PCRS	€19	€21	€23	€33	€37	€39	€47	€51	€51	€52	**+€4**	**+12%**
Total PCRS	€1,496	€1,444	€1,400	€1,507	€1,579	€1,599	€1,693	€1,778	€1,867	€2,153	**+€73**	**+4%**
Minus HC/Acute	€0	€10	€16	€51	€61	€82	€92	€117	€127	€138	**+€16**	**+39%**
PCRS (excl. HC/Acute)	€1,496	€1,434	€1,384	€1,457	€1,518	€1,517	€1,601	€1,661	€1,740	€2,016	**+€58**	**+3%**
Total HC/Acute	€305	€311	€336	€379	€413	€424	€469	€507	€529	€529	**+€25**	**+6%**
Total	**€1,801**	**€1,745**	**€1,720**	**€1,836**	**€1,931**	**€1,941**	**€2,070**	**€2,168**	**€2,269**	**€2,544**	**+€83**	**+4%**

Source: PCRS Reports/Author forecast

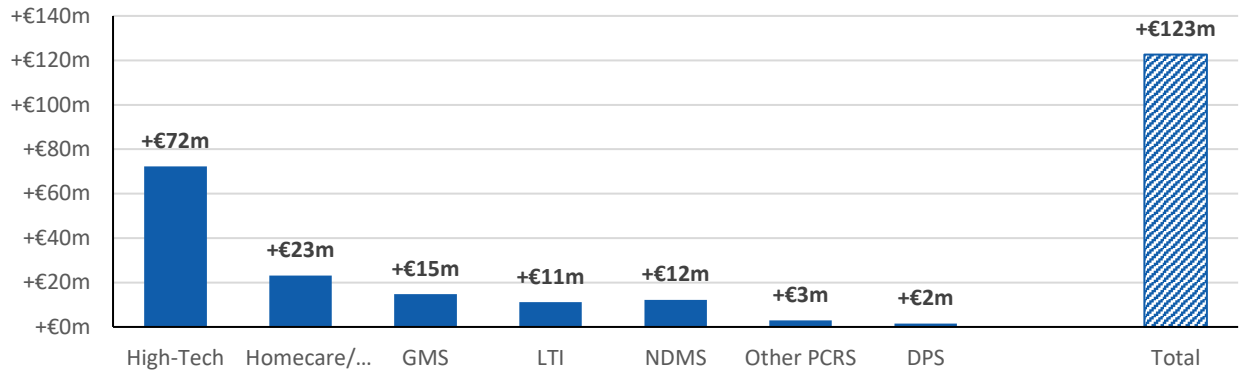
Expenditure on the Long-Term Illness (LTI) arrangement has increased considerably over the period from 2012-21. LTI shares some characteristics with the HTD arrangement in that it is an arrangement for the provision of pharmaceuticals for complex and often chronic conditions.

The Drugs Payment Scheme (DPS) has also seen an average reduction over the period. This scheme is unique however in that it is a scheme for reimbursement of any individual/household whose private expenditure on pharmaceuticals exceeds a given threshold. A significant driver of the expenditure reductions in DPS is due to policy decisions to increase the expenditure threshold following the financial crisis of the early 2010s.

[6] The 2021 Forecast includes the expenditure impact resulting from a change in eligibility criteria for an over 70s medical card. As a result, these Figures are not directly comparable to the 2020 Figures.

[7] DPS is distinct from other arrangements, as an arrangement which effectively subsidises household expenditure on pharmaceuticals rather than providing medicines, with or without a patient fee.

Figure 3. Average Year-on-Year Growth by Pharmaceutical Arrangement 2016-2021



Source: PCRS Reports / Author Calculations

1.3. High Tech Drug Arrangement – Rationale for Investment & Health Technology Assessment

While the large and consistent growth in expenditure in the High-Tech Drug arrangement primarily motivated this review, it is important to also outline the rationale for investment in the arrangement. Since its inception in 1996, the High-Tech Drug Arrangement has been designed to fund equitable access to innovative, precision medicines for illnesses that otherwise would have limited treatment options[8]. Medicines funded under the arrangement are in most cases targeted towards debilitating illnesses such as Rheumatoid Arthritis, Cancer, Cystic Fibrosis, Multiple Sclerosis among others (a full breakdown of expenditure by illness in the High-Tech Drug Arrangement is available in Figure 16). Given the trends observed, it is likely that High-Tech specialty medicines will continue to be an important part of overall pharmaceutical spend. Internationally the number of new medicines approved each year is on the rise, with pharmaceutical companies increasingly targeting the development of treatments for rare illnesses (known as orphan drugs) (OECD, 2018).

While the innovations offered by these new drugs can offer real improvements in health outcomes, the relatively low numbers of users results in higher treatment costs. However, the high prices of these medicines is not necessarily associated with a large increase in clinical benefits. In many cases, the prices of medicines used for severe conditions can become disconnected from the health benefits that they bring to patients, owing to the strong desire to see these illnesses treated (OECD, 2018).

Recognizing the contrasting priorities of access to healthcare and affordability in this context, many countries have pursued a system of Health Technology Assessment (HTA) to determine what medical interventions should be funded through state expenditure (OECD, 2015). In Ireland, Health Technology Assessment is carried out by the National Centre for Pharmacoeconomics (NCPE) in collaboration with the HSE Corporate Pharmaceutical Unit.[9] While the benefits of new medications can be diverse, the NCPE attempts to establish a standardised measure of health improvement offered by a given drug known as a Quality Adjusted Life Year ("QALY"). A QALY incorporates both the additional years of life provided by a drug, and the quality of life provided during those extra years. For example, one QALY constitutes one year of life at perfect health, or two or more years of life at less than perfect health. This QALY measure is then compared with the cost of the

[8] Crucially, the HTD Arrangement allows for the provision of drugs to patients in a community setting, alleviating pressure on Outpatient Departments in hospitals.
[9] http://www.ncpe.ie/about/

technology under assessment[10], allowing for a comparison of the cost effectiveness of all drugs independent of the specific illness they treat. The NCPE recommendations are based around a threshold for cost effectiveness, in general recommending for reimbursement drugs that offer benefits of one QALY per €45,000 spend or less (HIQA, 2014).[11]

Box 1: High-Level Description of the Reimbursement Process for Pharmaceuticals in Ireland

The decision of whether a pharmaceutical entering the market will be eligible for reimbursement through PCRS (in essence, paid for or subsidised by the State) is taken by the HSE. The criteria governing this decision are set out in the Health (Pricing and Supply of Medical Goods) Act 2013[12]; these include patient safety, cost-effectiveness, whether its approval would represent the appropriate use of pharmaceutical items, and the appropriate use of financial resources.

1. Drug receives market approval

The European Medicines Agency is responsible for the scientific evaluation of centralised market authorisation for medicines in the European Union. To evaluate the medicines, the European Marketing Agency is provided with data on the medicine including what patients it is proposed to treat, the quality of the medicine, its compliance with international requirements for laboratory testing and the benefits observed in the treatment group at whom the medicine is aimed. Medicines are assessed on the basis of a consideration of benefit and risk, with medicines that present an overall positive balance between benefits and risks at a population level likely to be granted market approval. Once granted approval from the EMA and HPRA, the medicine is then legally allowed to be used in Ireland.

2. NCPE Review

Following market approval, a pharmaceutical company then will apply for reimbursement. This is a multi-stage process, with the first stage involving a review by the NCPE. The NCPE conducts an analysis of the drug's efficacy performance (effectiveness in controlled tests) and compares this to the ex-factory price listed by the manufacturer. On this information the NCPE makes a determination as to whether the drug represents value for money, and thus, given all associated costs to the wider Health system, whether it should be reimbursed by the HSE.

3. Decision taken by HSE

After an NCPE recommendation is made, the pharmaceutical reimbursement decision is then evaluated by HSE officials. The HSE drugs group gives further consideration to reimbursement, with the final decision being made by the HSE Executive Management Team. The Executive Management Team makes a decision on reimbursement based several criteria, as follows:

a) The health needs of the public;
b) The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services;
c) the proposed costs, benefits and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks;
d) the potential or actual budget impact of the item or listed item;
e) the clinical need for the item or listed item;
f) the appropriate level of clinical supervision required in relation to the item to ensure patient safety;

[10] The Incremental Cost Effectiveness Ratio ("ICER") for pharmaceuticals under evaluation also incorporates the cost of foregone health interventions, e.g scans, outpatient appointments, blood tests as well as cost offsets such as a reduction in attendances to a hospital for a given illness.
[11] It should be noted that there is no fixed cost effectiveness threshold for medications to be accepted for reimbursement, and other factors also play a role in determining reimbursement decisions.
[12] Full act available here.

g) the efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies), and;
h) the resources available to the Executive.

While a formal threshold for cost effectiveness forms part of the decision making process on the reimbursement of a drug, in practice it appears that other criteria often predominate.

A number of criticisms of the current QALY threshold, and its application in decision making, have emerged. For example, O'Mahony and Coughlan (2016) note that the threshold has no empirical basis, and is likely to exceed the equivalent value per QALY threshold applied in the UK. More substantively though is the degree to which this threshold is exceeded in reimbursement decisions, with the authors highlighting how several high-profile drugs have been approved in spite of the threshold as it stands. As argued further in O'Mahony (2021), drugs may be ultimately approved even if their cost effectiveness as a health intervention is poor due to the political sensitivities surrounding drug approvals for identifiable patient groups.

Figure 4: Top 10 Ingredients in High-Tech Drug Arrangement by Cost, 53% of 2019 Expenditure

No.	Ingredient	% Total expenditure 2019	Cost per QALY (illustrative, NCPE estimates)	Indication/Illness Treated
1.	Adalimumab	15.1%	No Pharmacoeconomic Evaluation Available	Rheumatoid Arthritis[13]
2.	Ivacaftor And Lumacaftor	11.7%	€449,035/QALY	Cystic Fibrosis[14]
3.	Etanercept	6.0%	No Pharmacoeconomic Evaluation Available	Rheumatoid Arthritis[15]
4.	Ustekinumab	4.9%	Approved following confidential negotiations for Crohn's Disease, Approved for reimbursement for Psoriasis.	Psoriasis[16] & Crohn's Disease[17]
5.	Lenalidomide	4.3%	Approved following confidential negotiations	Myeloma[18]
6.	Fingolimod	3.3%	€58,572/QALY	Multiple Sclerosis[19]
7.	Secukinumab	2.7%	€68,000 – €80,000/QALY	Plaque Psoriasis, psoriatic Rheumatoid Arthritis[20]
8.	Golimumab	2.7%	€26,727/QALY	Rheumatoid Arthritis[21]
9.	Ibrutinib	2.3%	€82,786/QALY	Leukaemia[22]
10.	Abiraterone	2.2%	€135,454/QALY	Prostate Cancer[23]

[13] http://www.ncpe.ie/drugs/adalimumab-humira/
[14] http://www.ncpe.ie/wp-content/uploads/2012/08/Ivacaftor-Summary.pdf
[15] http://www.ncpe.ie/drugs/etanercept-benepali/
[16] http://www.ncpe.ie/wp-content/uploads/2012/03/Ustekinumab-Stelara-summary.pdf
[17] http://www.ncpe.ie/drugs/ustekinumab-stelara-2/
[18] http://www.ncpe.ie/drugs/lenalidomide-revlimid/
[19] http://www.ncpe.ie/wp-content/uploads/2012/03/Fingolimod-Gilenya-summary.pdf
[20] http://www.ncpe.ie/wp-content/uploads/2015/09/Secukinumab-Summary.pdf
[21] http://www.ncpe.ie/wp-content/uploads/2010/05/Golimumab-summary-revised-price-June-2010.pdf
[22] http://www.ncpe.ie/wp-content/uploads/2014/06/Ibrutinib-Imbruvica-CLL-Summary-2015.pdf
[23] http://www.ncpe.ie/wp-content/uploads/2012/05/Abiraterone-Zytiga-Summary.pdf

Figure 4 illustrates the discrepancy in the application of the threshold. Taking a sample of the top 10 medicines funded under the High-Tech Drug arrangement (comprising 53% of total expenditure in 2019) and comparing the Cost per QALY benefit of these medicines reveals the frequency with which the threshold is exceeded. Out of the ten medicines considered, five have costs per QALY in excess of the specified threshold. Evaluation of the final cost effectiveness of these drugs is obscured by the frequency with which they are subject to commercially confidential pricing, with several of the drugs considered likely having lower final prices as a result of confidential pricing arrangements.[24]

In all, two considerations emerge from this analysis. The first is that there is a strong rationale for investment in high-tech drugs. Many of the medicines funded by the arrangement target illnesses which are high impact, delivering proven patient benefits and in some cases providing treatment for illnesses with otherwise limited alternatives. Because of these demonstrated patient benefits, decisions on the reimbursement of these medications are difficult and can be subject to significant political pressure. The second is that the clinical benefits offered by these innovative medications come at a significant cost, with the high prices of many drugs funded under the High-Tech Drug Arrangement posing a difficult challenge for reconciling the competing aims of maximising accessibility while ensuring affordability. Policymakers will need to be aware of this challenge, with some measures aiming to contain costs also having the potential to impact the degree to which treatment is provided for these illnesses.

2. Analysis of High-Tech Drug Activity and Expenditure

2.1. Methodology

This basis for this analysis were multiple administrative datasets provided by PCRS/HSE and facilitated by DoH IGEES. Extensive engagement between DoH and HSE officials was required to facilitate the full use of this dataset, with pharmaceutical price, rebate and wholesaler mark-up data obtained over an iterative process. Data recording each individual purchase of High-Tech drugs in community pharmacies was also obtained, listing 5.3m separate transactions between 2012 and 2020. Finally, anonymised patient information was obtained to enable analysis of the demographic characteristics for recipients of the HTD arrangement, necessitating correspondence with the Data Protection Commissioner; these enabled unique patient counts and the linking of information on patient sex, age, and region. The use of this dataset constitutes a positive step in the use of administrative data informed policymaking in Irish healthcare policy, with the combined dataset being one of the largest held by the Department of Health.

The base data was dated transaction information for payments to pharmacists for dispensing and care services to HTD patients, which stipulated the patient ID and pharmaceutical dispensed. While the HTD arrangement does not keep detailed information relating to patient characteristics, this information is captured in the GMS, LTI and DPS. Around 75% of the patients in the HTD arrangement were also in at least one of these other arrangements, thus information on sex, location and illness could be linked to the HTD data for a good majority of transactions. Pricing information was also provided by the PCRS: list prices for each item are available online[25]; information relating to the specific VAT for each drug was provided, as was the wholesaler mark-up. The general rebate was then subtracted as was the additional rebate provided under the Patient Access Scheme which applies to a small minority of generally high-cost drugs. From this the assumed net cost to the

[24] Many drugs included in the HTD Arrangement are approved post commercial negotiations on the basis of confidential pricing. This means that the ICER/Cost per QALY for some drugs would be improved relative to the initial price at which these drugs were assessed.

[25] https://www.hse.ie/eng/staff/pcrs/online-services/list-of-prescribable-high-tech-medicines-april-2021.pdf

State[26] was calculated. Finally, information relating to the manufacturer, the Anatomical Therapeutic Classification ("ATC"), Originator status, patent expiration date, and primary indication for each drug was sourced from a number of sources online, such as the HIQA, EMA and the UK Drugs website medicines.org.uk.[27]

2.2. Data Constraints

While the data offers an unprecedented level of granularity on HTD arrangement dynamics, some constraints remain.

- There is an absence of data in relation to patient outcomes. While we can assume a patient has left the arrangement if a long interval has passed between transactions, the reason for leaving is not known – whether it is due to successful treatment, transfer to a treatment option in another pharmaceutical arrangement, or patient death.
- The profiling of patient time in arrangement was complicated by the nine year timeframe. The true time in arrangement for patients who were in the arrangement before January 2012 or after December 2020 cannot be known. Additional analysis was conducted to examine the effect of this constraint.
- As the data requested for this analysis relates only to the HTD arrangement, interactions between it and other arrangements cannot be profiled.
- Dispensing Fees for drugs are excluded from the analysis as this data is not readily available.

2.3. Cost Structure & Budget Performance

Total HTD expenditure in made up of a number of components, the largest of which is the manufacturer's payment for the purchase of the physical medicine, also known as the list price or ex-factory cost; this however is offset by rebate payments returned to the HSE from manufacturers. There are three main rebate types:

- The first is a general 5.5% rebate paid across most medicines;
- The second is a drug specific rebate negotiated on a drug by drug basis through the Patient Access Scheme (PAS rebate);
- Finally, a small number of medicines are capped in terms of expenditure, meaning rebates will apply to 100% of all payments to manufacturers above a negotiated level.

On top of manufacturer's payments, the HSE pays VAT at a rate of 23% of the list price on some but not all drugs in the HTD arrangement. Additionally, a wholesaler mark-up of 8% of list price is provided to wholesalers across the board for each drug in the arrangement. The estimated breakdown of these payments in nominal terms is given in Figure 5 below and illustrated for 2020 in Figure 6.

[26] Savings on other services as a result of drugs expenditure is not included in the calculation of this net position, although is detailed in HTA reports.

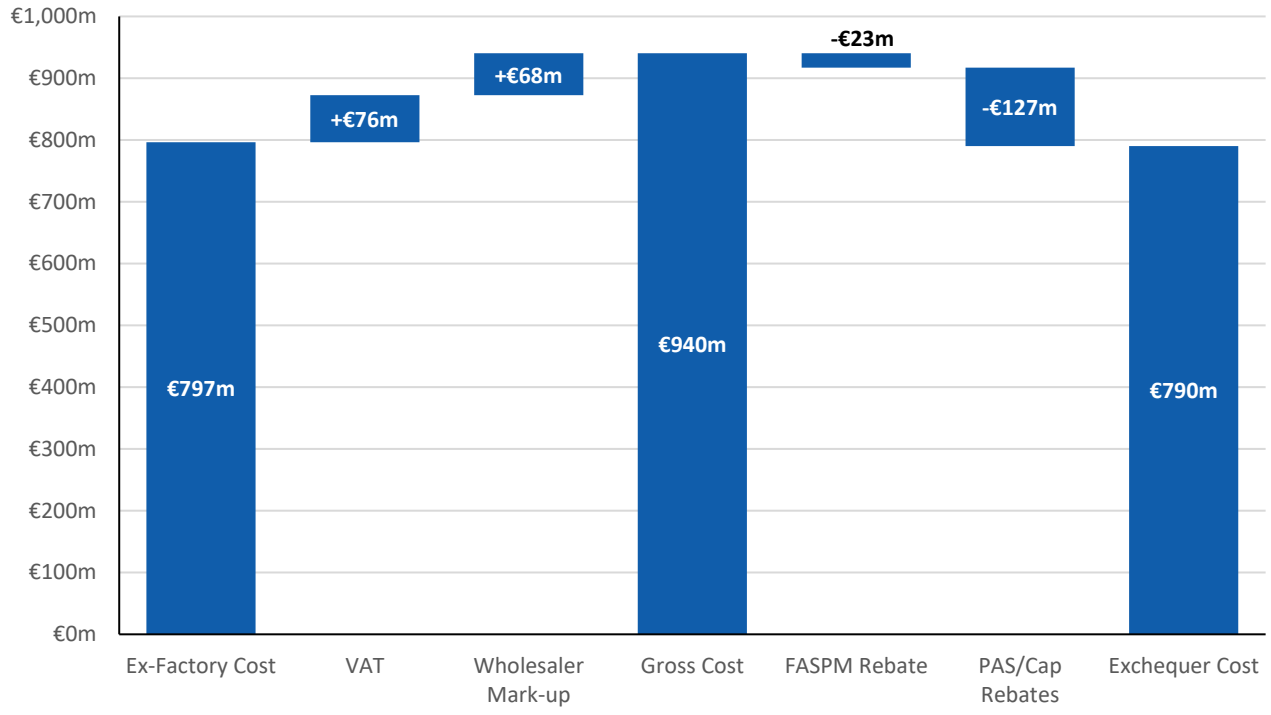
[27] https://www.hiqa.ie/; https://www.ema.europa.eu/en; https://www.medicines.org.uk/

Figure 5. Cost Structure of HTD Expenditure 2012-2020

Year	Ex-Factory Cost	VAT	Wholesaler Mark-up	Industry Agreement Rebate	PAS Rebate/Caps	Exchequer/ Actual Cost
2012	€284m	€42m	€24m	-€11m	-€0m	€339m
2013	€334m	€46m	€28m	-€12m	-€6m	€389m
2014	€376m	€49m	€32m	-€12m	-€11m	€434m
2015	€421m	€56m	€36m	-€13m	-€16m	€484m
2016	€474m	€62m	€40m	-€16m	-€20m	€541m
2017	€543m	€66m	€46m	-€18m	-€22m	€614m
2018	€655m	€72m	€56m	-€20m	-€48m	€714m
2019	€736m	€73m	€63m	-€19m	-€96m	€758m
2020	€797m	€76m	€68m	-€23m	-€127m	€790m

Source: Author Constructed Dataset (Base Data PCRS)

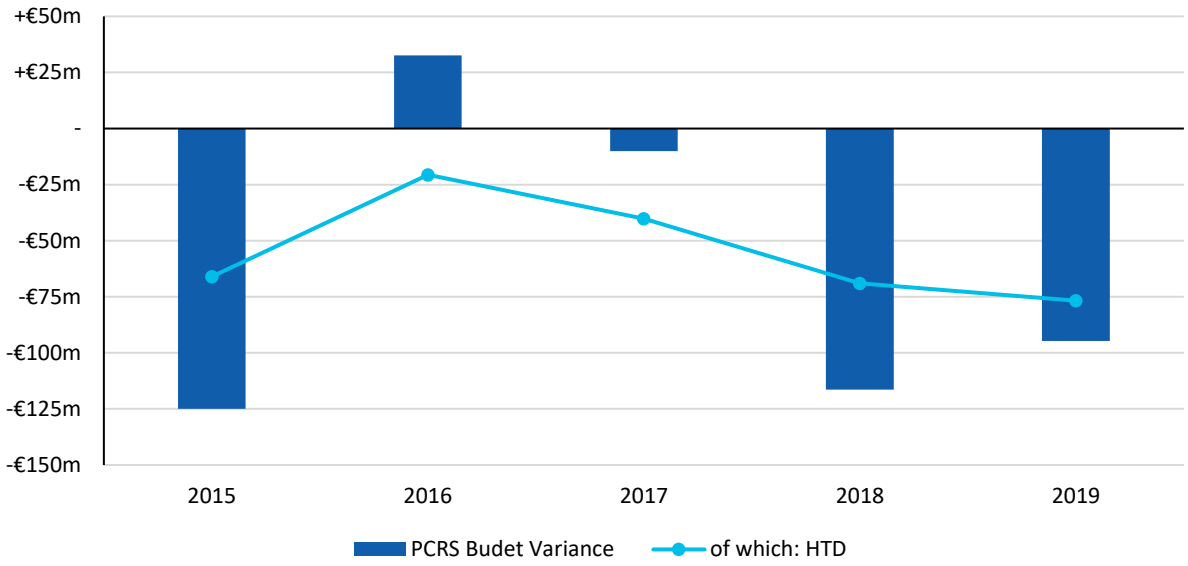
Figure 6. HTD Cost Structure 2020



Source: Author Constructed Dataset (Base Data PCRS)

In relation to annual performance against budget, HTD in recent years has consistently exceeded expected profiles to a greater extent than any other arrangement. While high growth was projected, the actual growth has generally exceeded the available budget provided for the Arrangement. Given the quantum of expenditure now in the HTD arrangement, relatively small underestimations of growth can have a significant budgetary impact.

Figure 7. PCRS and HTD Budget Variance 2015-2019[28]



Source: HSE Management Data Reports (November/December)

2.4. HTD Expenditure and Participation

As demonstrated below, HTD expenditure has increased significantly between 2012 and 2020, at an average of 11% per annum. As a consequence of this growth expenditure has more than doubled over the period from under €400m in 2012 to over €800m as of 2020. As shown in Figure 8. The rate of growth has fluctuated considerably, from a peak of 16% expenditure growth in 2018, to just 4% in 2020.

Figure 8. HTD Expenditure

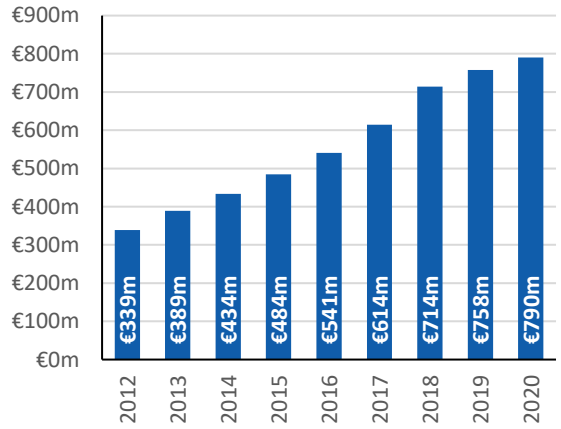
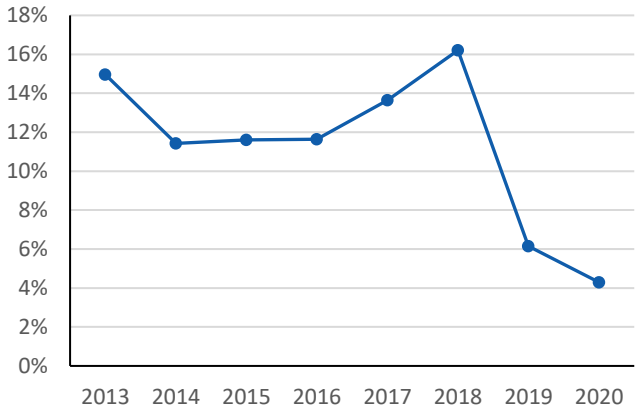


Figure 9. YoY HTD Expenditure Growth



Source: Author Constructed Dataset (Base Data PCRS)

While this rate of annual growth is extreme, it is partly explained by rising patient volumes. The total number of patients in the HTD arrangement has consistently grown in the years from 2012 to 2019, from a base of fifty-seven thousand patients in 2012 to eighty-nine thousand in 2019, an average year-on-year growth of 6.5%. The base of 'existing patients' (here defined as those who were in the arrangement in a given year, and also in it the prior year) has been growing at an annual rate of 8% whereas the number of 'new patients', i.e those entering the arrangement who were not in it the year prior has been growing at a slightly lower rate of

[28] new IPHA Agreement mid-2016 led to the budget surplus in that year.

6% per year. Both the new patient and existing patient cohorts are expanding, therefore contributing to overall growth in the arrangement. This rate of growth vastly outstrips general population growth, which has increased from less than half of 1% to 1.3% over the same period. Given the limitations of the data it is not possible to ascertain the portion of patients who are 'genuinely' new, as opposed to those who may have migrated to the HTD arrangement from another arrangement. In the absence of data the observed volume growth could be driven by:

- Increases in disease prevalence;
- Increases in the life expectancy of patients as a result of new treatments;
- Changes to diagnosis and prescribing behaviour

Figure 10. HTD Patient Participation

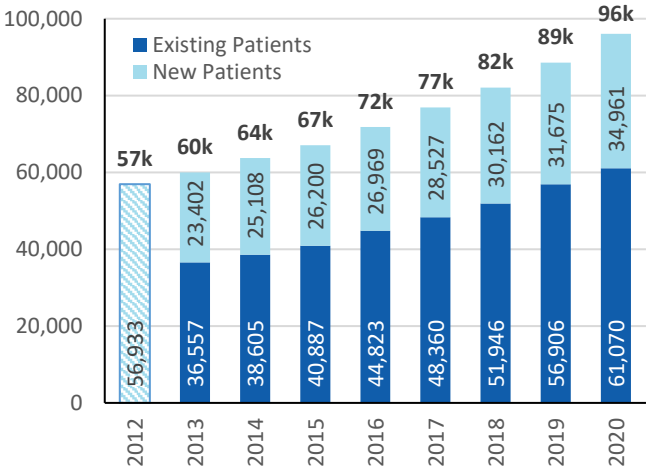
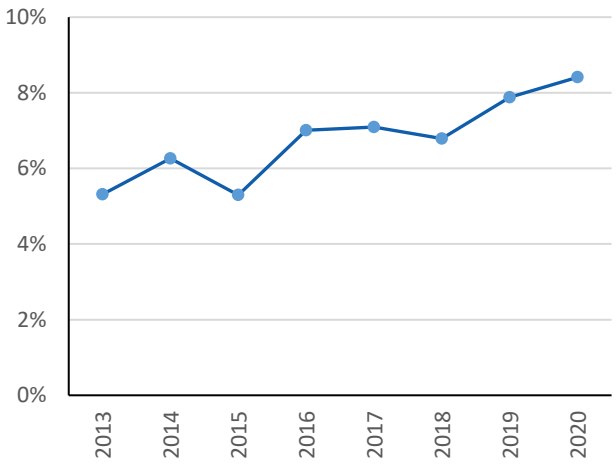


Figure 11. YoY HTD Patient Growth



Source: Author Constructed Dataset (Base Data PCRS)

Controlling for patient growth we can see that both the average and median patient costs are increasing. The average annual patient cost has risen from €6,000 per annum in 2012 to €9,000 in 2020. The median annual cost has also increased over the period from €2,500 in 2012 to €3,500 in 2020, peaking at over €4,000 in 2019. The significant gap between average and median values points to a heavily skewed annual patient cost, with a small number of patients receiving treatment at an extremely high cost; further, the increasing gap between average and median over time indicates that expenditure on patient treatment is becoming increasingly focussed on high cost treatments, skewing expenditure towards these groups.

Figure 12. HTD Average/Median Annual Patient Cost

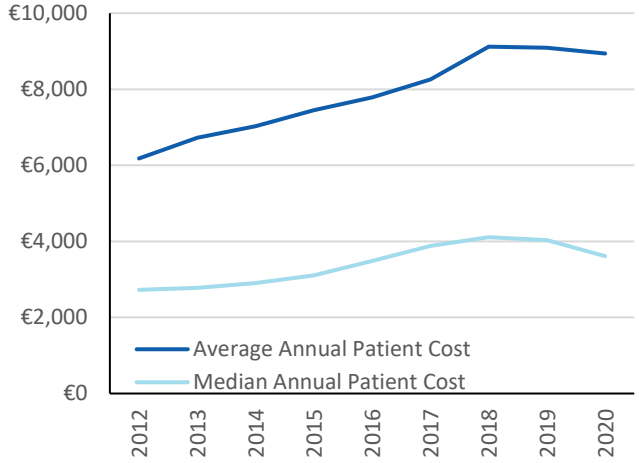
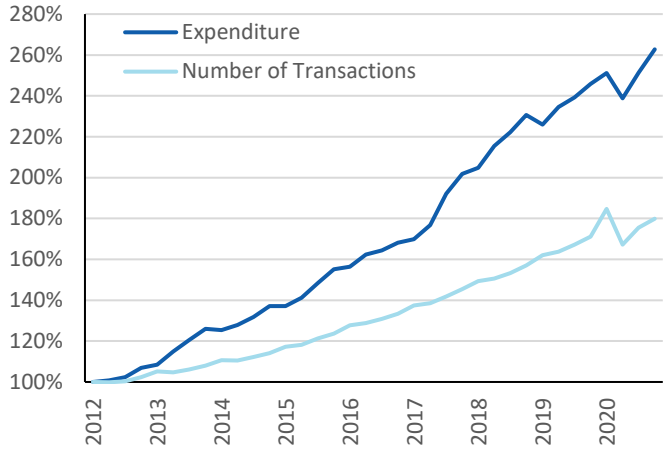


Figure 13. HTD Cost/Transactions (2012 Index)



Source: Author Constructed Dataset (Base Data PCRS)

This increasing average cost relative to transactions is illustrated above in Figure 12. While the number of transactions in 2020 rose to 179% of 2012, total expenditure in 2020 is 263% of the 2012 level. This illustrates that while patient volume is a driver of expenditure, there are also price effects (from new drug approvals and offsetting revisions to the prices of existing drugs) which are increasing expenditure above pure volume growth.

A final consideration in relation to participation is the average duration spent in the arrangement by patients. As shown below, a majority of patients who enter the HTD arrangement exit within a year. Those who remain in the arrangement beyond a year however have relatively even chances of exiting any time up to three or four years later. As noted earlier, the data is necessarily constrained by the fact that all those who were in the arrangement at beginning 2012 are assumed to have entered then, and equally those who were in the arrangement at the end of 2020 are assumed to have left at that point. While this is a limiting factor Figure 15 compares the duration distribution by year and finds it to be relatively consistent in spite of these constraints. This issue could be revisited in future reviews, with the benefit of a wider timeframe of view.

Figure 14. Average Patient Duration in HTD expenditure

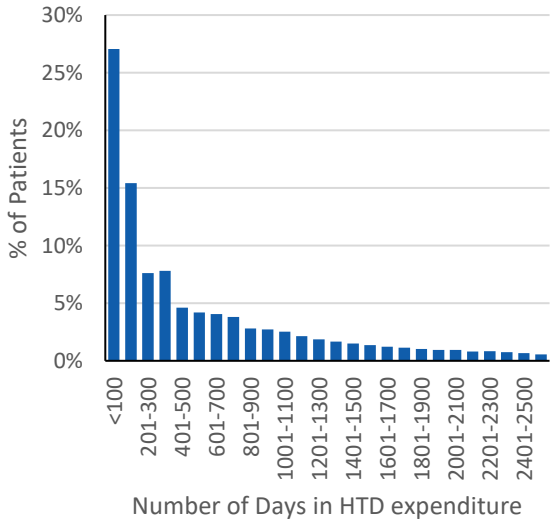
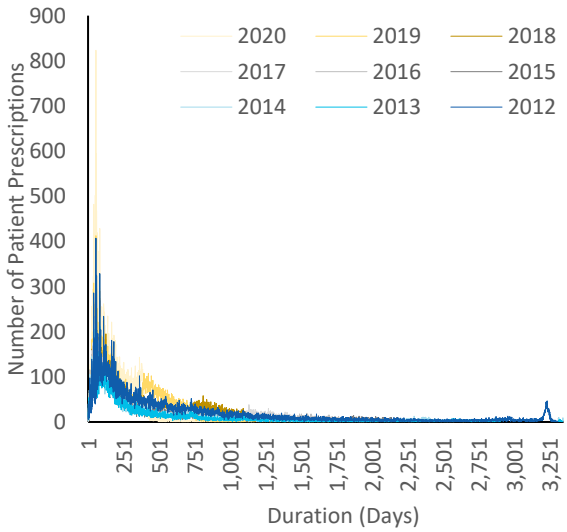


Figure 15. Prescription Duration by Year of Start (2012-2020)



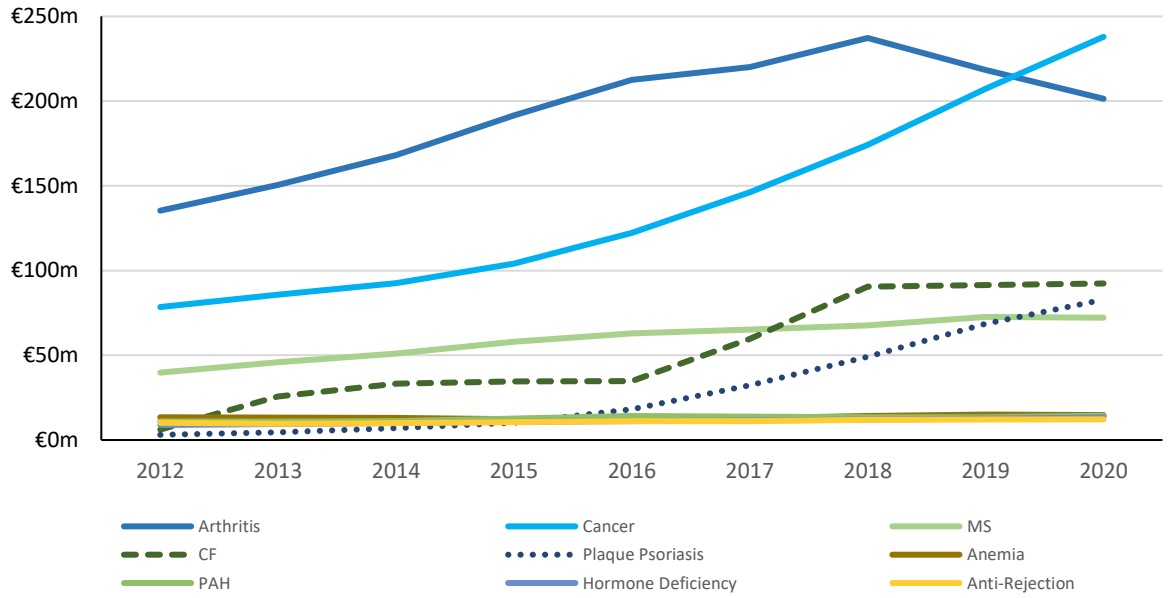
Source: Author Constructed Dataset (Base Data PCRS)

2.5. Pharmaceutical Indication

Total HTD expenditure varies significantly across pharmaceutical indications (drug treatment areas). Between 2012 and 2018 the largest indication spend was in the area of Rheumatoid Arthritis treatment, which increased from €135m to €237m per year over this period, an annual average growth rate of 5.5%. As will be discussed later, the Rheumatoid Arthritis trend is notable in that overall expenditure has reduced since 2018 – the 2012 to 2018 growth rate by contrast was around 10% per annum. Partially due to this reduction in Rheumatoid Arthritis spend, expenditure on Cancer drugs has now become the largest expenditure area in the HTD arrangement. Cancer expenditure has grown at 15% per year over this period, a pace of growth which is accelerating year-on-year, and far ahead of patient growth averaging 5% per annum. The two indications of Rheumatoid Arthritis and Cancer[29] taken together account for over one half of the total HTD expenditure in 2020 at 55%, having decreased as a proportion of overall spend from 63% in 2012.

The third largest indication expenditure area in 2020 was Cystic Fibrosis, which has grown in spend by an average of 40% over the 2012-2020 period. The key determinant of this growth as illustrated by Figure 16 is a jump in 2017 and onwards driven by the introduction of the pharmaceutical Orkambi.

Figure 16. HTD Expenditure by Primary Indication (2012-2020)

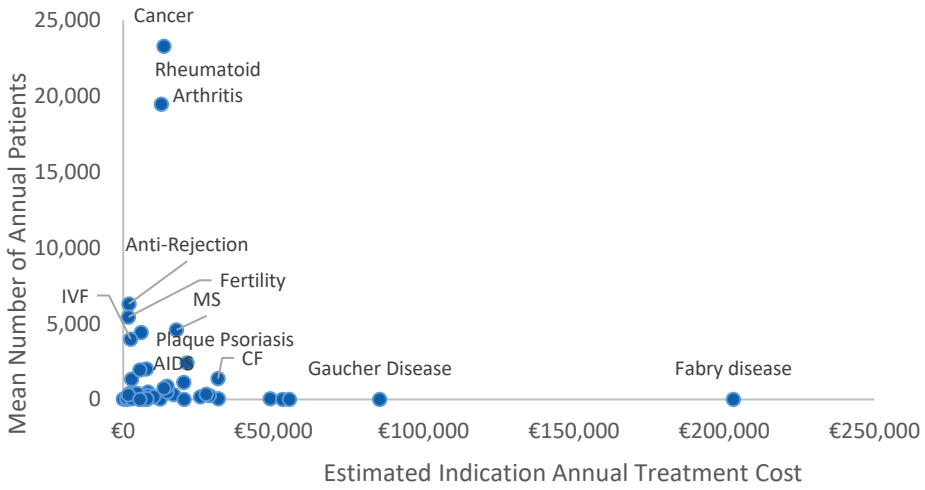


Source: Author Constructed Dataset (Base Data PCRS)

As shown in Figure 17, High cost indications tend to be confined to those with low patient numbers. Cancer and Rheumatoid Arthritis meanwhile make up the majority of HTD expenditure, with treatment costs for both being in excess of the median indication cost in the arrangement (at around €13,000 per annum). Furthermore, the prevalence of these diseases, which have an average of 20,000 – 23,000 patients a year in the HTD arrangement means that overall expenditure is highest in these areas.

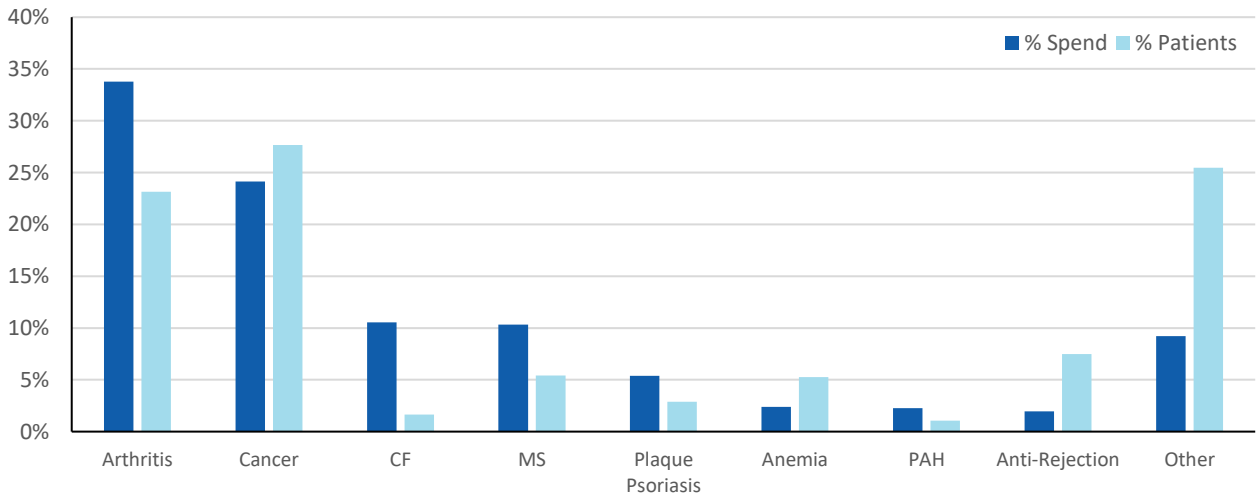
[29] Most of the new drug Oncology spend has occurred within the National Drugs Management Scheme (NDMS).

Figure 17. Primary Indication Area by Av. Number of Annual Patients and Estimated Annual Treatment Cost (2012-2020)



Source: Author Constructed Dataset (Base Data PCRS)

Figure 18. HTD % Spend & % Patients by Primary Indication 2012-2020

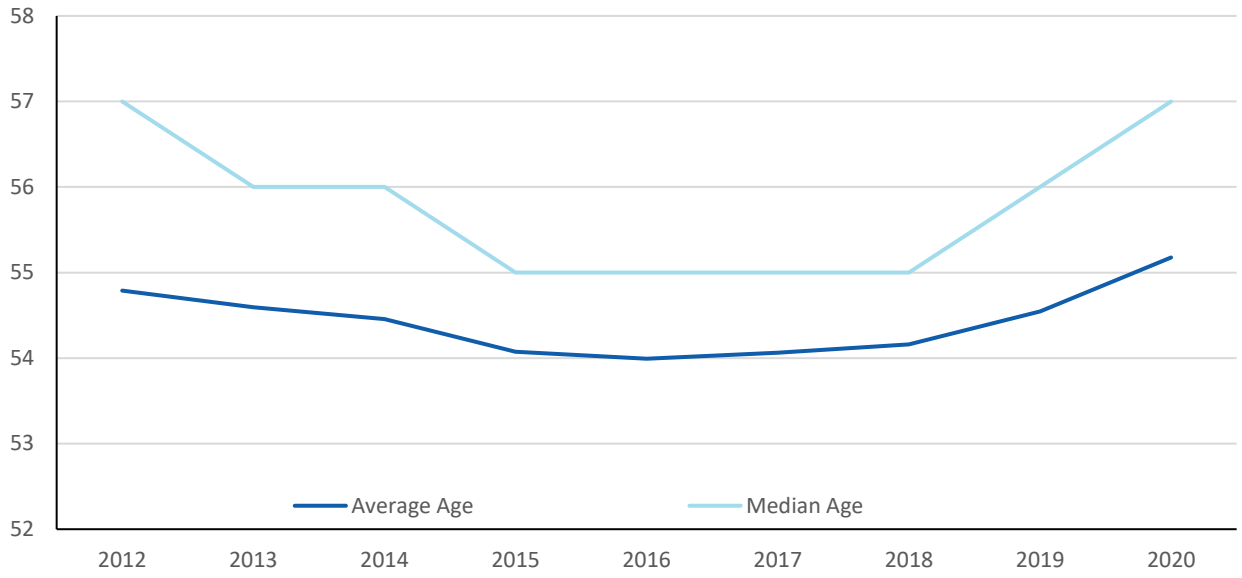


Source: Author Constructed Dataset (Base Data PCRS)

2.6. Demographic Analysis

Pharmaceutical expenditure is often associated with demographic variables such as patient age. This association is grounded in the observation that different age cohorts often require different levels of care, with more care required the older the patient. While the HTD arrangement is notably different from other pharmaceutical arrangements in that the pharmaceuticals dispensed through it are for indications which are not expressly age-related, the primary indication expenditure areas of Rheumatoid Arthritis and Cancer are diseases that are strongly and positively correlated with age. Given that demographic aging is occurring in the general population, this opens up the possibility that aging may be a dominant factor in HTD expenditure growth. Looking first at the age profile of HTD patients between 2012 and 2020 in Figure 19, we do not see the clear upward trajectory in average patient age over time that might be expected. Average HTD patient age falls from around 55 in 2012 to 54 in 2016, at which point it trends back upward to 55 in 2020. The median age over this period is around one year higher, indicating that the average is being pulled down by a few young outliers.

Figure 19. HTD Average/Median Patient Age 2012-2020



Source: Author Constructed Dataset (Base Data PCRS

Considering how expenditure occurs over the HTD patient age distribution as shown in Figure 20 below, the percentage of spend and the percentage of patients map quite closely as might be expected. Notable deviations between the two lines are due to the changing average cost of treatment by age.

- At the youngest ages for example spend outpaces patients due to the disproportionate number of young CF patients and the relatively high cost of CF treatment.
- For patients ranging from 30-39, the percentage of patients jumps without a similar movement in percentage of spend; this is due primarily to women seeking treatment for fertility, a treatment area which is well below average treatment cost in the HTD arrangement.
- Among 40s to late 70s the primary difference in pharmaceutical profile is higher rates of Cancer medicines, which are above average price, thus lifting expenditure relative to patient volume.
- Finally, the group aged 80+ maps quite closely to proportion of spend, however they are slightly below average cost due to the lower representation of auto-immune prescriptions.

Figure 20. % Spend/Patients by Age

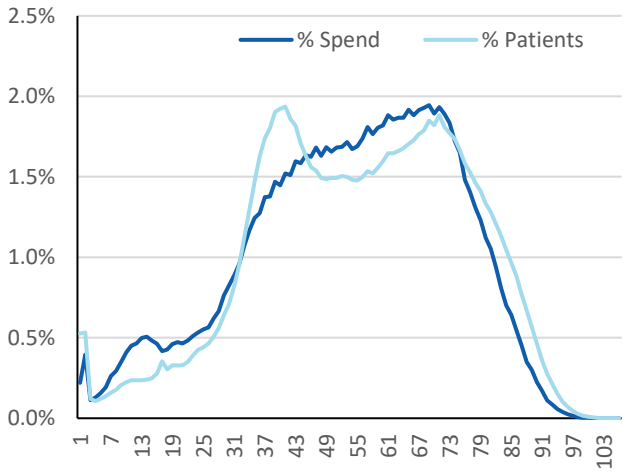
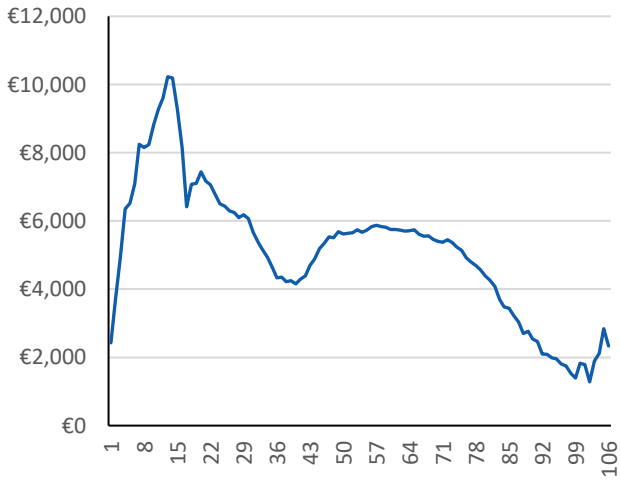


Figure 21. Average Annual Treatment Cost by Age



Source: Author Constructed Dataset (Base Data PCRS)

While patient sex is not detached from healthcare needs, trends in the data are less visible than with age. The proportion of expenditure and patient representation are relatively evenly split. As illustrated in Figure 25, the average cost of treatment for males rises faster over time than for females. This is likely due to the presence of below-average cost reproductive medicines in the arrangement. While it was not possible to dig deeper as sub-types of cancer were not included, part of the gap may also be due to different prices for medicines for cancer generally associated with either males or females e.g. breast cancer/prostate cancer.

Figure 22. % Spend by Sex

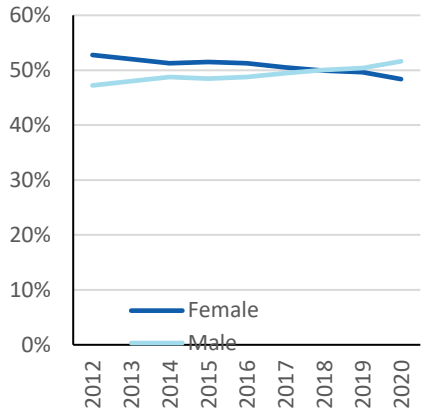


Figure 23. % Patients by Sex

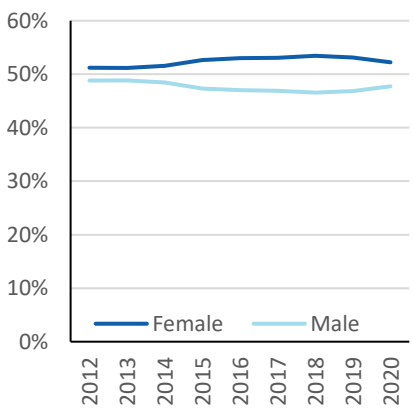
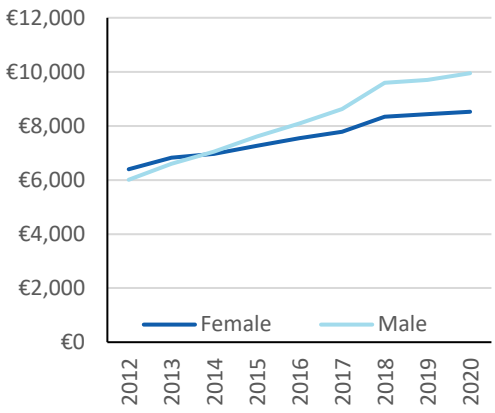


Figure 24. Average Annual Cost by Sex



Source: Author Constructed Dataset (Base Data PCRS)

2.7. Originator/Non-Originator (Generic or Biosimilar) Medicines

Figure 25. % Expenditure/Transaction by Originator Status 2012-20

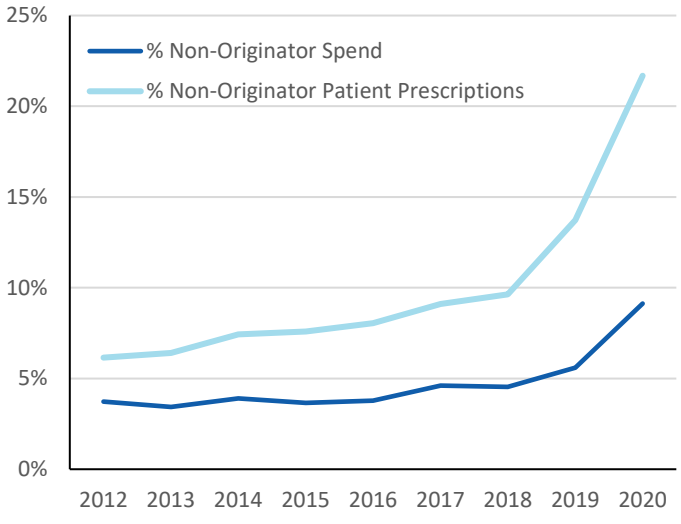
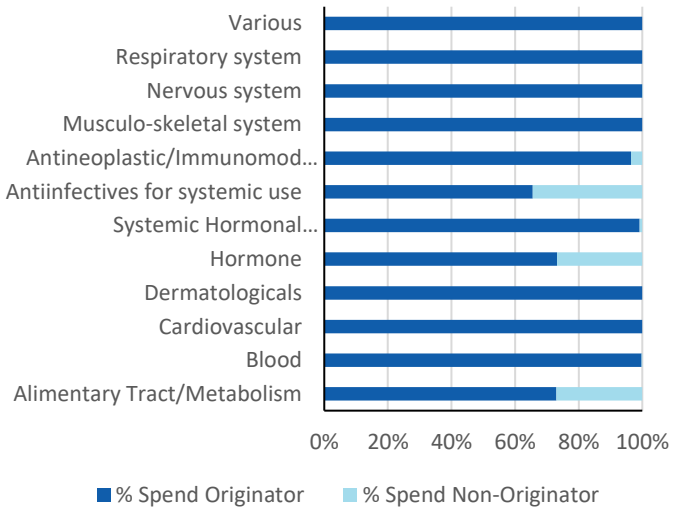


Figure 26. % Spend by Classification/Originator Status 2012-20



Source: Author Constructed Dataset (Base Data PCRS)

Just over 20% of the HTD spend is on non-originators (biosimilar[30] or generic), a significant increase from 2012 illustrated in Figure 25. While HTD expenditure data clearly outlines the scope to increase the use of non-originators, this may be limited in practice depending on the availability of lower cost alternatives. Where non-originator alternatives are present within the HTD arrangement they are on average 77% of the cost their branded alternative based on 2020 prices.

It should be noted however that:

1. While non-originator medicines are generally cheaper than their branded counterparts, there are some instances in the dataset where the price of an originator and non-originator medicine are closely aligned, or where the originator costs less than the non-originator alternative, meaning no significant saving would accrue from switching to a non-originator option. In some instances, this could be due to the loss of exclusivity clauses under the Industry Agreement discussed further in Section 3.2.
2. There are a significant number of classifications in the HTD arrangement where the totality of the spend is concentrated in the originator, this could be due to a lack of alternatives either in the Irish market or generally.

[30] "*A biosimilar medicine is a biological medicine that is very similar to an original biological medicine. The original biological medicine is called the reference medicine. Every new biosimilar medicine must work the same way as the reference medicine. The active substance of a biosimilar medicine and its reference medicine is essentially the same biological substance, but there will be small differences between them. This is because the active substance in a biological medicine is complex and varies naturally. Like its reference medicine, the biosimilar medicine will vary slightly from batch to batch. This is carefully controlled and monitored so the biosimilar medicine will be as safe and effective as its reference medicine." – Health Products Regulatory Authority*

2.8. New Drug Entries

As previously explained, unit prices are not subject to upward movement, as mandated by the Framework Agreement on the Price and Supply of Medicines between the State and main industry body IPHA. This means that upward average cost pressure is a product of the change of the basket of pharmaceuticals purchased each year versus the previous one. While changes may take place within the existing basket (i.e. higher cost medicines growing as a proportion of the existing basket), new drug introductions with comparatively higher prices appear to be the driving force behind average patient cost growth.

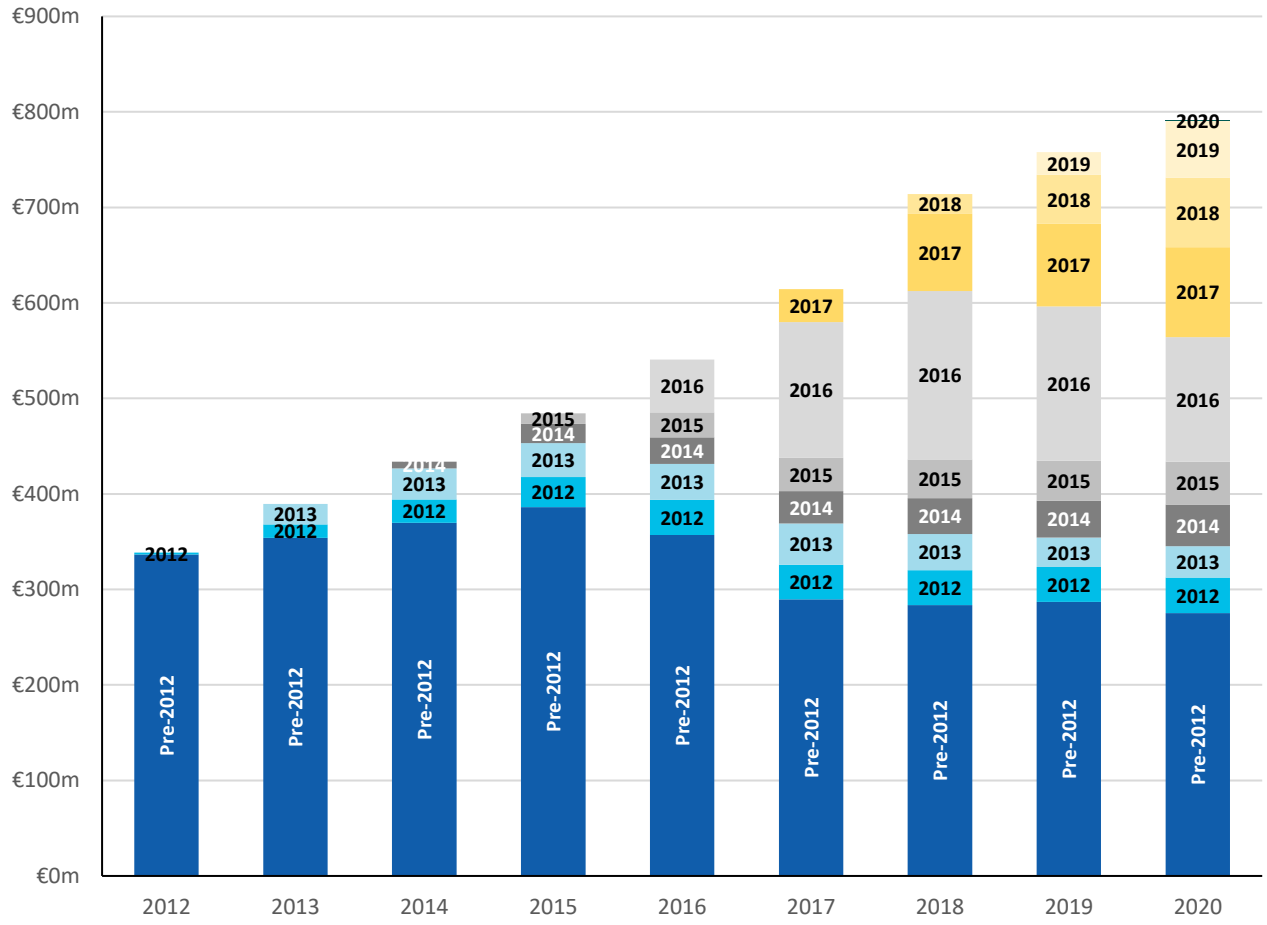
Expenditure from 2012-2020 broken down by the year of introduction is set out in Figure 27 and Figure 28. For example, as highlighted in orange in Figure 27 below, investment in new drugs in 2016 was €55m (cost introduced in 2016 and cost accrued in 2016). Expenditure on that same basket of drugs (introduced in 2016) increased to €142m in 2017 and €176m in 2018 before declining to €162m in 2019 and €131m in 2020. In total over the 5 years post introduction, expenditure on these drugs was €666m versus a first-year cost of just €55m.

Figure 27. Drug Entry and Cost Accrued by Year

Year Entered Arrangement	Year Cost Accrued (€m)									
	2012	2013	2014	2015	2016	2017	2018	2019	2020	TOTAL
1996	17.0	15.1	14.1	13.0	11.5	9.7	8.8	8.1	7.7	**104.9**
1997	4.1	4.0	4.0	4.0	3.4	3.0	3.1	3.1	3.1	**31.9**
1998	16.2	12.0	11.3	11.1	10.7	10.4	10.4	10.3	10.1	**102.7**
1999	3.3	2.9	2.5	2.2	1.9	1.6	1.4	1.3	1.2	**18.2**
2000	8.5	8.1	7.7	6.6	4.8	3.1	2.2	2.2	1.7	**44.9**
2001	7.0	6.7	5.8	4.8	1.7	0.5	0.3	0.3	0.2	**27.2**
2002	13.5	12.7	12.2	11.9	11.7	10.9	10.6	10.5	11.1	**105.0**
2003	34.7	31.3	28.3	20.2	15.3	7.1	4.5	3.8	3.5	**148.6**
2004	23.2	22.4	22.3	19.3	15.9	11.4	9.4	8.5	7.4	**139.7**
2005	4.7	4.9	4.9	5.0	5.4	5.7	6.0	6.5	6.5	**49.6**
2006	36.9	33.4	31.3	30.1	28.0	20.7	17.9	15.7	10.7	**224.7**
2007	74.0	83.9	96.5	108.1	84.7	43.0	35.3	41.5	46.7	**613.7**
2008	7.9	6.9	6.8	6.9	6.9	6.4	6.6	6.4	6.6	**61.5**
2009	42.2	49.2	54.0	58.9	62.6	55.7	55.8	53.6	37.6	**469.4**
2010	24.7	31.8	37.8	44.3	49.6	57.4	67.3	74.7	82.5	**470.2**
2011	18.6	28.7	30.2	39.5	43.3	43.2	43.8	40.8	38.7	**326.9**
2012	2.1	14.1	24.2	31.7	36.7	36.1	36.7	36.3	37.0	**254.9**
2013		21.4	32.6	35.6	37.8	43.4	37.9	31.0	32.7	**272.4**
2014			7.2	20.1	27.8	33.6	37.5	38.5	43.9	**208.6**
2015				10.9	26.0	34.9	40.7	41.9	44.6	**199.0**
2016					55.3	142.2	176.0	161.6	130.6	**665.7**
2017						34.5	80.9	86.3	94.0	**295.8**
2018							20.7	51.2	72.9	**144.8**
2019								23.8	59.2	**83.0**
2020									0.1	**0.1**
TOTAL	**338.7**	**389.4**	**433.9**	**484.3**	**540.6**	**614.3**	**713.9**	**757.9**	**790.4**	**5063.5**

Source: Author Constructed Dataset (Base Data PCRS)

Figure 28. Composition of HTD Expenditure by Year Pharmaceutical Added to Scheme



Source: Author Constructed Dataset (Base Data PCRS)

The challenges associated with these non-linear impacts of new drugs investment are set-out in section 3.4.

2.9. Expenditure Drivers Analysis

Assessing the counterfactual impact of expenditure drivers is a core motivation of this research. While the area is highly complex meaning many different types of drivers could theoretically be identified, for the purposes of developing a useful perspective of HTD expenditure growth a simplified model of expenditure growth has been developed. This model seeks to separate and evaluate the identified drivers of expenditure in isolation by looking at each potential driver and estimating the impact of zero growth in this driver versus what is actually observed. The identified drivers are as follows:

1. Patient volume growth. As noted previously the number of patients in the HTD arrangement has grown at between 5% and 8% year-on-year between 2012 and 2020. Taking the average patient cost for each year and applying that to 2012 patient volume, we see that total expenditure over the nine year period would be 33% lower had zero patient volume growth occurred over the period. For illustrative purposes this has been separated out from general population growth, which was around 1.5% per year over the period.
2. Additional expenditure could result from a change in the basket of drugs being consumed, separate from new drug introductions. For example, the growth of a given illness in a high cost treatment area which outpaces total patient volume growth would necessarily result in higher rates of expenditure.

Taking the proportion of treatment areas observed in 2012 and applying the respective annual average patient cost for that treatment area, we can see that expenditure would be 1% lower had the proportional patient volume remained at 2012.

3. New drug introductions. The introduction of new drugs creates additional treatment options for patients. In some cases, the new therapy will be more expensive than the previous treatment, and in others the new treatment will be cost saving. By observing patient switches, i.e. large numbers of patients migrating to a new treatment within a limited timeframe, counterfactual treatment costs were estimated. In cases where a new treatment was more expensive than the previous treatment (cost-incurring introduction) it was found that the costs were around 30% higher than they would have been had no cost-incurring introductions been made. Considering cost reducing introductions meanwhile, it was found that actual costs were 11% lower than they would have been had no cost reducing introductions been made.

Assessing the proportional impact of the above drivers, and projecting this to the observed average annual growth rate of 11.1% per annum, the effects were quantified as per below:

Cost Driver	Proportional Impact on Annual Expenditure	% of Total Growth Drivers	Average Annual Impact (€)	2012-2020 Marginal Effect
Population Growth	+1.5%	13%	+€8.4m	+€60.6m
Additional Patient Volume Growth	+5.4%	49%	+€30.6m	+€220.1m
Proportional Growth in Higher Cost Treatment Areas	+0.2%	2%	+€1.3m	+€9.4m
New Drug Introductions	+4.0%	36%	+€22.5m	+€161.6m
- of which Cost Incurring	*+6.3%*	*56%*	*+€35.5m*	*+€255.2m*
- of which Cost Reducing	*-2.3%*	*-21%*	*-€13.0m*	*-€93.6m*
Total	**+11.2%**	**100%**	**+€62.9m**	**+€451.7m**

3. Policy Discussion – Potential Measures to Contain Pharmaceutical Expenditure

3.1. Introduction

The analysis provided in this paper makes clear the difficult policy problem that the High-Tech Drug arrangement presents. On the one hand, it is clearly desirable to utilise new, innovative medicines to treat conditions such as Cancer, Rheumatoid Arthritis and Cystic Fibrosis which otherwise would be subject to much less effective treatment. On the other hand, the cost of these specialty medicines is large[31], with our analysis identifying an average of 11% expenditure growth over the last decade resulting from increases in the price and volume of drugs reimbursed.

In light of this challenge, it is necessary to discuss possible routes to contain the cost of the HTD arrangement to ensure long-run expenditure sustainability while being conscious of maximising accessibility for patients to the drugs covered under the arrangement.

Based on the analysis of the data presented in Section 2 and options emerging from the policy literature, a number of possible cost containment measures could be considered in an Irish context:

1. **Industry agreements,** (e.g., ESRI (2013), (Gorecki P. K., 2018), (Connors, 2017))
2. **International cooperation facilitating information sharing and joint procurement,** (e.g. OECD (2017), (European Commission, 2020))
3. **Improved multi-year expenditure budgeting and management for new drug approvals,** (PCRS data & Lamrock et al. (2020))
4. **Continued adoption of Generic & Biosimilar medicines where these are cheaper than Originator options,** (e.g., OECD (2018), (OECD, 2017), (Connors, 2017), HSE Medicines Management Programme)
5. **Reduction in the State's willingness to pay for pharmaceuticals through adjustment of the Quality Adjusted Life Year threshold.** (e.g. (O'Mahony & Coughlan, 2016), (O'Mahony, 2021), (Gorecki P. K., 2017)

These are discussed in turn below:

3.2. Industry Agreements

One of the primary mechanisms for controlling pharmaceutical costs is through agreements on pricing and supply with industry (Connors, 2017). Such agreements have been in place since the 1960s. The most recent arrangement was agreed in July 2016 for a period of four years, and extended due to COVID19. A subsequent arrangement is in the process of negotiation.

This Framework Agreement on the Price and Supply of Medicines (the FASPM, also known as the "IPHA Agreement") signed between the State and industry in 2016 is estimated to have delivered savings in excess of €750m, roughly in line with ex-ante projections made in to 2016 (or a 7% cost reduction versus no agreement and no unilateral pricing measures taken by the State) over the lifetime of the agreement. The arrangement contained four broad cost-effecting levers, as set out in Figure 29 below.[32] The estimated savings arising from the deal are outlined in Figure 30 by major category.

[31] While expenditure on pharmaceuticals can reduce medical costs in other areas, the overall costs of drugs relative to other health interventions still appears to be high.

[32] Full text of the agreement is available here.

Figure 29. Description of Cost Effecting Clauses of 2016 FASPM Agreement

Area	Clause	Description
General Pricing	5.1	Unit prices will not increase over the term of the arrangement.
	5.2	Unit prices will annually be realigned downward to the average of 14 comparator countries, where the average is lower than the Irish list price.
Chemical Loss of Exclusivity	7	Upon the launch of a non-originator chemical medicine, the originator list price will reduce by 50%.
Biologic Loss of Exclusivity	8.1.1	Upon the launch of a non-originator biosimilar medicine, the originator list price will reduce by 20%.
	8.1.3	A rebate of 12.5% of the list price will be paid by the manufacturer to the HSE for non-exclusive branded biologic medicines.
General Rebate	9	A refund of 5.25% of the list price (growing to 5.5%) will be repaid to the HSE.

Regarding the savings achieved, it should be noted for clarity that the impact of list-price elements (clauses 5.2, 7 and 8) are calculated cumulatively over the course of the arrangement (i.e. a saving of €1 in 2016 due to a list price reduction results in a saving of €4 by 2020); this contrasts with the usual expenditure management framework which focuses on annual base expenditure. Based on an unpublished analytical exercise undertaken by PCRS, approximately €230m of the 2016 Agreement savings were derived from mechanisms rolled over from previous agreements:

a) The State already enjoyed rebates of 4% but it is the entire rebate figure, not just the increase to 5.25%/5.5% that is captured in the overall savings target.

b) Similarly, the State benefitted from an alignment of ex-factory prices in 2012 based on a basket of EU countries, but the savings target from the last agreement does not reference savings previously achieved through this exercise and thus overemphasises the marginal impact.

Figure 30. Estimated Savings of 2016 Agreement

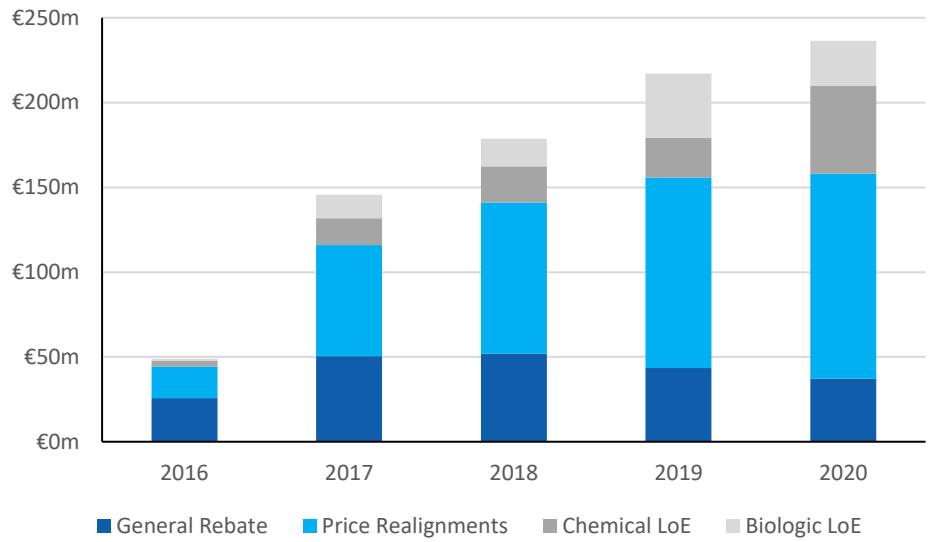
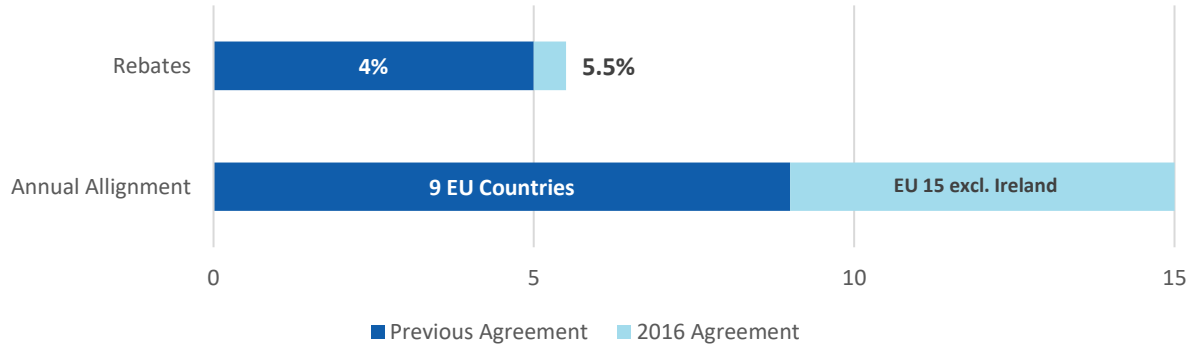


Figure 31. Current Agreement Vs Previous Agreement



External Reference Pricing, where prices of a pharmaceutical in one or several countries is used as a benchmark price for the purpose of setting an agreed price is common in many jurisdictions. The use of External Reference Pricing in many countries results in a significant amount of interdependence of pricing across borders. One way in which manufactures seek to maximise their profits is by launching in higher income countries who generally have a higher willingness to pay for new medicines, thereby anchoring the price at a higher level from the outset, which goes on to inform prices elsewhere; this is known as a launch sequence strategy. Traditionally Ireland has often been an early adopter of new pharmaceuticals, and (prior to the 2016 arrangement) it was widely understood to receive these pharmaceuticals at relatively high prices (Gorecki P. K., Nolan, Brick, & Lyons, 2012), however this early adoption has reduced in recent years[33] in part due to health budgetary pressures.

While the true value of agreements cannot be known in the absence of a counterfactual no-agreement situation, (whereby the State would presumably employ unilateral cost control measures under the Health Act) the State may continue to use industry agreements to the extent that they represent the preferable option of containing drugs expenditure growth. As the comparative benefits of existing agreement clauses weaken over time, and new drug investment decisions are made, improvements in the terms of the agreement should be sought, with potential recourse to alternative arrangements where these are not forthcoming. Additionally, the State may consider developing agreements with other industry representatives rather than only the main industry representative group in order to encourage more holistic arrangements which promote appropriate competition and clinician choice.

3.3. International Cooperation

Greater International cooperation in the evaluation and procurement of medicines could improve transparency in the sector and address some of the challenges associated with their high cost. In particular, information sharing and joint procurement has the potential to "rebalance the negotiating powers of payers [States] and manufacturers in the pharmaceutical sector" (OECD, 2017).

In recent years manufacturers have pursued complex price, rebate and cap measures which are subject to non-disclosure agreements, a trend witnessed both in Ireland and internationally (see PAS Rebate/CAP column in Figure. 6), (OECD, 2017). At the individual national level this results in a lower *effective* price paid for pharmaceuticals while retaining a high list price, thereby debilitating the effect of international reference pricing and compromising the ability for states to perform an accurate cross-country comparison of actual prices. As this trend continues, and complex pricing and reimbursement systems become more embedded, the need for price transparency in pharmaceuticals becomes more necessary to resolve this issue. As set out

[33] According to Pharmaceutical Industry reporting Available here.

in Vogler & Patterson (2017): "Economic theory, and evidence from a few real-life cases, suggests that price transparency supports better-informed decisions and thus improves the negotiating position of purchasers."

International cooperation therefore offers a potential solution to this issue (OECD, 2017). If the actual costs paid for pharmaceuticals are known between countries, then market distortions arising from imperfect information and the monopoly power of exclusive suppliers are reduced. In theory, this would allow for greater bargaining power on the part of states, enabling them to negotiate lower pharmaceutical prices overall. An extension of this strategy would be the use of joint procurement (pooled procurement) between states for pharmaceuticals, taking full advantage of the strengthened negotiating position that would emerge from this arrangement. Recent experiences of German, Dutch and Austrian cooperation in hospital pharmaceuticals procurement found that "cost reductions can be achieved for all participating bodies in this enhanced European cooperation for health procurement" (Espín, et al., 2016). While not a conclusive finding, the benefits of joint procurement are also reflected in the European Union's recent experience in the joint procurement of COVID19 vaccines, with the EU obtaining vaccines at a price far lower than many other countries (BMJ, 2021). In general, the larger European market would also likely improve the negotiating position of member states in the event of joint procurement, as highlighted by the OECD;

"*a single large buyer is in a better position to exert market power than a number of dispersed smaller buyers (Kesselheim et al., 2016; MHS and WHO, 2012).*" (OECD, 2017)"[34]

There has been some progress in the provision of better international cooperation in pharmaceutical policy. Ireland is currently one of five members of the Beneluxa initiative, a forum allowing for information sharing on pharmaceutical pricing and reimbursement as well as cooperation in other areas such as Horizon Scanning and Health Technology Assessment. The recently published European Commission Pharmaceutical Strategy (European Commission, 2020) provides an avenue for further increasing international cooperation in this area. The strategy endorses greater information sharing for pharmaceutical policy, including for public procurement and the production cost of pharmaceuticals. It outlines the potential of joint procurement in pharmaceuticals between EU member states and offers a forum for improving dialogue on issues such as R&D transparency, pharmaceutical affordability, and Health Technology Assessment.

Overall, enhancement and deepening of international cooperation with European partner states could have a significant impact on long-term pharmaceutical expenditure, with greater information sharing and joint procurement improving the prices paid for pharmaceuticals with limited impacts on accessibility.

3.4. Multi-Year Expenditure Budgeting of New Drug Approvals

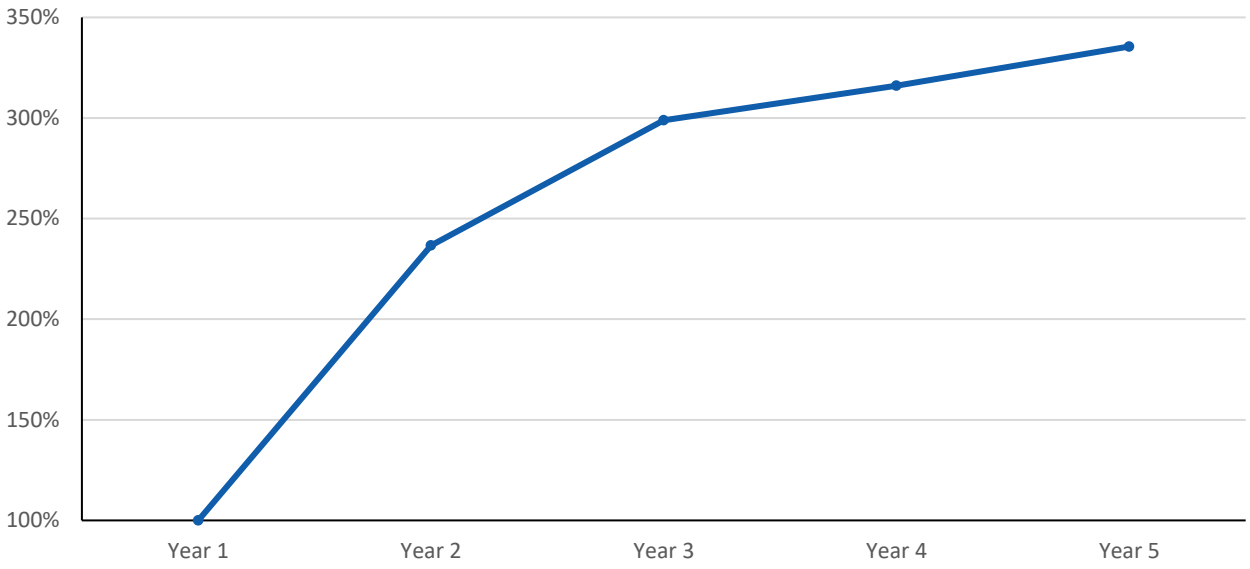
The impact of new development funding provided as part of successive budgets has contributed significantly to the overall increase in PCRS drug expenditure in recent years.

In general, the multi-year Exchequer impact of new drug introductions is not adequately taken into account when approval and reimbursement decisions are initially being made. This leads to an apparent disconnect between first year and longer-term costs for drugs, resulting in higher than anticipated overall pharmaceutical costs on a per drug basis[35] especially for High-Tech drugs. This is also reflected in the official budgetary impact models submitted to the NCPE as part of the drug approval process, with Lamrock et al. (2020) finding that these budgetary impact models have limited accuracy in predicting realised utilisation of a drug.

Figure 32. Average 5-Year Cost Trajectory of New Introductions as % of Yr1 Cost (2013-2020)

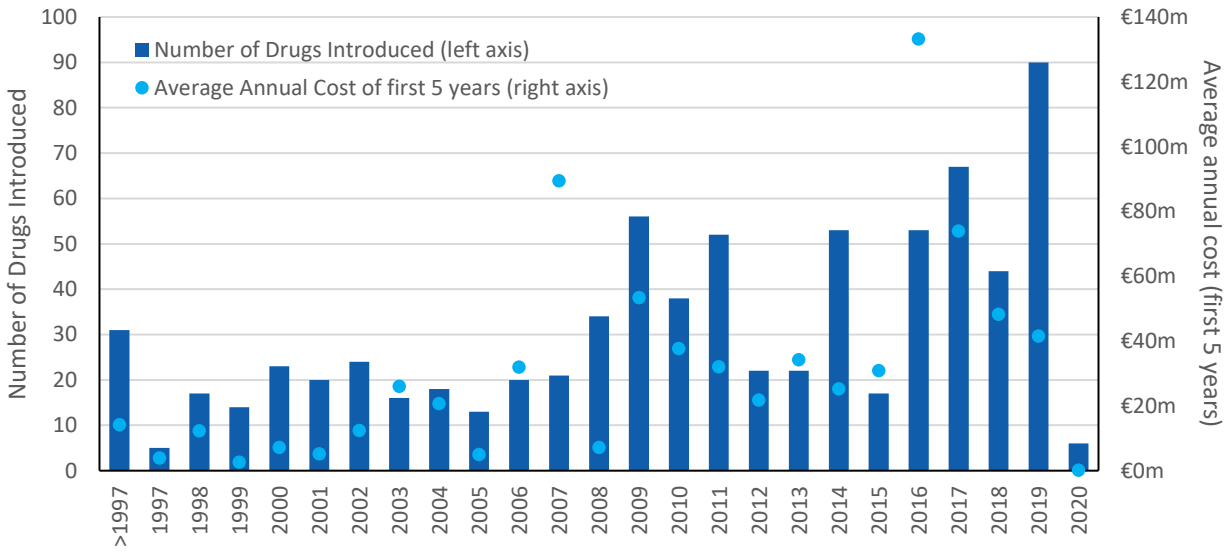
[34] *New Health Technologies: Managing Access Value and Sustainability* Available here

[35] As mentioned, in some cases pharmaceutical expenditure can offset expenditure on other health interventions, including other pharmaceuticals. This means that this may not be systematically true in every case.



Source: Author Constructed Dataset (Base Data PCRS)

Figure 33. New Drug Introductions and Average Annual of First 5 Year Cost



Source: Author Constructed Dataset (Base Data PCRS)

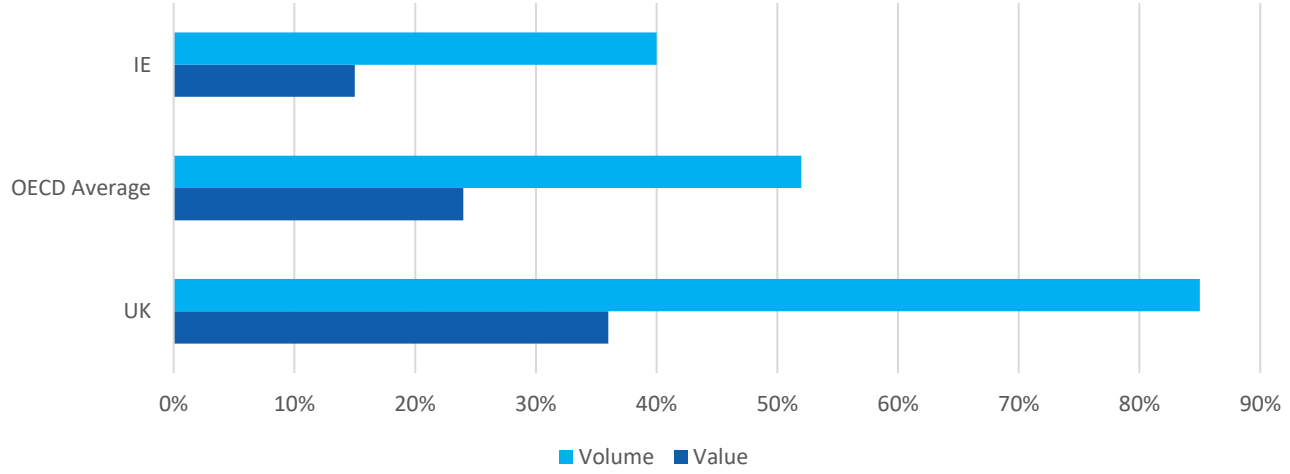
Figure 33 outlines the number of new drug introductions per year versus their associated 5-year cost. As can be seen, there is wide variation between the number of drugs introduced in a given year and the respective 5-year costs of these drugs. This can make it difficult to anticipate the development of expenditure in relation to the drugs being introduced in a given year, leading to persistent issues in forecasting and budgeting of long run costs.

In light of this issue, further consideration of the multi-year sustainability of new drugs introductions should be provided, with the cost of a drug introduction over a long-time horizon being considered before being approved for reimbursement. Joint cooperation between the Department of Health, Department of Public Expenditure and Reform and the HSE on the budgeting of multi-year expenditure commitments arising from new drug approvals would be effective in remedying this issue, with an awareness of long-run costs necessitating better budgetary management in this context.

3.5. Non-Originator Medicines (Generic & Biosimilar Medicines)

Non-originator medicines are medicines which are produced and distributed without patent protection. Promotion of the use of quality assured generic medicines is a method of managing pharmaceutical prices, as generic medicines generally have lower prices than their branded counterparts. On the surface, Ireland's usage of generics in terms of value and volume is significantly behind UK and OECD counterparts.

Figure 34. Generic Market Share Ireland vs OECD



Generic Market Share	Value	Volume
IE	15%	40%
UK	36%	85%
OECD Average	24%	52%

Source: OECD Economic Surveys Ireland 2020

As highlighted by Figure 34, only 15% of expenditure on pharmaceuticals in Ireland is on generic medications, compared to 24% in the OECD overall, and 36% in the UK. Similarly, 40% of medicines prescribed in Ireland are generics, versus 52% in the OECD and 85% in the UK.

The low level of generic usage in Ireland versus other countries is a concern as it likely results in a higher than average spend on pharmaceuticals for the same clinical benefit. Figure 35 illustrates this issue, providing the difference in price of the top ten branded and generic medications sorted by total expenditure.[36]

[36] Where a generic is available, HSE PCRS advise that the penetration rate is >70%. This reporting from OECD may be reflecting the Irish market being less attractive for generic launches (due to size/volume factors).

Figure 35. Originator vs Non-Originator Price Differences (Top 10 drugs by Gross Expenditure where an originator alternative exists)

Non-Proprietary Name	Primary Indication	Originator Estimated 2020 Av. Patient Cost	Non-Originator Estimated 2020 Av. Patient Cost	Price Difference Non-Originator vs Originator)
Adalimumab	Rheumatoid Arthritis	€11,175	€4,776	-57%
Etanercept	Rheumatoid Arthritis	€8,485	€6,358	-25%
Somatropin	Hormone Deficiency	€3,631	€4,313	19%
Teriparatide	Osteoporosis	€4,579	€3,591	-22%
Tobramycin	CF	€9,473	€9,274	-2%
Imatinib	Cancer	€16,877	€11,253	-33%
Leuprorelin	Cancer	€1,575	€1,451	-8%
Triptorelin	Cancer	€1,753	€1,459	-17%
Follitropin Alfa	IVF	€3,951	€4,544	15%
Sildenafil	PAH	€2,230	€2,438	9%
Tadalafil	PAH	€5,778	€5,385	-7%
Average		**€6,319**	**€4,986**	**-21%**

Source: Author Constructed Dataset (Base Data PCRS)

The significant difference in annual prices on a molecule basis (as opposed to marketed item) between many originator and non-originator medications is illustrated in Figure 35 above. Based on estimated annualised 2020 patient costs, while some prices are similar across originator and non-originator medications, in general the price of originator medications is higher than their non-originator counterparts, with an average price difference of 21% between branded and generic drugs. In instances where the non-originator is more expensive than the originator versions, this is often driven by the presence of a particularly cheap item which pull the average originator molecule price downward. Across the whole High-Tech drug dataset, the story is similar with an average price difference of 23% identified between originator and non-originator drugs on 2020 prices. It should be noted that this comparison occurs after the 20%[37]/50% reduction in the price of the originator following the introduction of a biosimilar/generic to the market under the FASPM agreement; without this price reduction the difference in price between originator and non-originator medicines would be significantly greater. In general, this analysis highlights the policy importance of non-originator usage in Ireland as a mechanism to reduce expenditure without impacting the clinical benefits to patients, albeit limited in many cases by the lack of non-originator alternatives.

In addition to techniques already employed by the HSE to promote use of best value treatment options, there are a number of potential options that Ireland could pursue to increase generic usage. In terms of international recommendations, the OECD (2017) identifies two policies which have proved effective in improving generic utilisation:

1) **Mandatory Generic Drug Substitution –** describes a policy whereby pharmacists are obliged to substitute a generic for a branded medication when dispensing medicines.

2) **Chemical Based Prescribing -** encourages or obliges clinicians to prescribe medicines utilising their chemical or International Non-proprietary Name, thereby encouraging generic uptake.

Because these policies remove or limit clinician discretion on whether an originator or non-originator medication is used, their implementation in practice may prove controversial. In the case of biologic pharmaceuticals this is particularly the case, as in some case non-originator medications are perceived as less

[37] Plus an additional 12.5% rebate.

clinically effective than their branded counterparts. While these policies would likely prove effective in increasing generic uptake, this improvement would need to be balanced with the potential impact on prescriber autonomy and patient safety.

In terms of Irish policy, the most notable policy used in recent years to promote greater usage of non-originator medicines has been Gain-share initiatives highlighted in Box 2.[38] This initiative has yielded significant saving when implemented at a national level for certain pharmaceuticals, such as in the case of Adalimumab where in excess of €50m euros has been saved to date as a result of gain-share promotion.

Figure 36. Upcoming Patent Expiries & Associated 2020 Spend

Drug Name	Illness Treated	2020 Spend	Loss of Exclusivity Date
Revlimid	Cancer	€43,869,233	18/06/2022
Ofev	Idiopathic Pulmonary Fibrosis	€6,098,444	20/12/2025
Sutent	Cancer	€4,292,939	14/02/2021
Nexavar	Cancer	€1,480,113	20/07/2021
Vargatef	Cancer	€1,479,507	08/10/2025
Votrient	Cancer	€1,034,554	15/06/2025
Zydelig	Cancer	€984,127	11/05/2025
Bosulif	Cancer	€780,653	22/09/2024
Inlyta	Cancer	€661,433	29/06/2025
Tyverb	Cancer	€355,393	11/06/2023
		€61,114,130	

Source: Author Constructed Dataset (Base Data PCRS)

The continuing loss of the exclusivity of medications over time means that efforts to foster market competition and increase non-originator usage where it is more cost-effective must be continually managed and renewed. Figure 36 provides an overview of upcoming patent expiries within the High-Tech Drug Arrangement; over the next five years, drugs making up over €60m of annual expenditure in the arrangement will lose exclusivity. Should Loss of Exclusivity list price reductions be maintained in the next State-Industy pricing and supply agreement, savings will automatically accrue on the originator spend; additional savings may also be available from switches to competitor non-originator therapies. In general, there is a continuous need to both encourage multiple treatment options to compete in the Irish market, and to grow the volume of non-originator alternatives used in Ireland to ensure that cost savings in this area are maximised.

In terms of pricing of non-exclusive medications, the industry agreement between the Irish Government and the IPHA for 2016-2021 contains specific provisions for pricing of generic medicines, as follows;

- *"On 1 August 2016 each existing such medicine shall be reduced to 50 per cent of the original price set by the HSE for a new medicine;*
- *If a medicine becomes patent-expired, non-exclusive medicine after 1 August 2016, then it shall also be reduced in price by 50 per cent of its original price.*

[38] The gain share arrangement is available to consultant-led teams to fund service delivery or enhancement, when they initiate a patient on, or switch them to a BVB medicine

In effect, this means that branded medications become more competitive from a price perspective with their generic counterparts upon the introduction of a generic into the Irish market. Though this can represent significant savings on pharmaceutical spend in the short term, the long run impact of this agreement may negatively impact generic uptake. Because the financial incentive to switch to a generic is reduced, more patients may continue to take a comparatively expensive branded medication even after the introduction of a cheaper alternative. The agreement thus may reduce competition In Ireland, as the financial incentive for introducing a generic is muted if spending on the branded alternative remains high.

It should also be noted that the potential for savings may be offset by 'well timed' new market launches of reformulated medicines with improved efficacy; this is an understood tactic of the pharmaceutical industry to avoid profit losses from loss of exclusivity.

An important component of increasing non-originator usage in Ireland is to encourage the greater use of biosimilar[39] medications. Since 2017, the Department of Health has been engaged in public consultation activities and the exploration and implementation of a number of operational policy levers to increase awareness and facilitate the use of biosimilar medicines. At an operational level, the HSE's Acute Hospitals Drugs Management Programme has a biosimilar strategy in place since 2017, which is making considerable progress using a collaborative approach with hospital pharmacists and clinical teams to bring about changes in prescribing practice. Hospitals are working towards a HSE targeted minimum prescribing rate for biosimilars of 50%. The HSE is also working on identifying barriers to the prescribing of biosimilars, with a specific focus on education and support. It is seeking to increase understanding of biosimilars through targeted presentations to clinicians and hospitals. This is proving promising, for example the prescribing rate for the biosimilar drug Infliximab increased from 5% in 2017 to 40% in 2018. The HSE's Medicines Management Programme (MMP), incorporating the Preferred Drugs initiative, is overseeing the implementation of a number of actions to bring about greater value for the taxpayer through cost-effective provision of medicines. These measures include the designation of preferred products with a focus on high-cost prescribing areas, in particular optimising the use of biosimilars.

Box 2: Biosimilars Case Study: Best-Value Biologic: Rheumatoid Arthritis:

The case study of biosimilar substitution for the treatment of Rheumatoid Arthritis illustrates the potential wider effectiveness of greater biosimilar utilisation. Biosimilar substitution in this case was facilitated by a Gain-share initiative, also demonstrating the impact that these arrangements can have on non-originator uptake.

Context:

For several years prior to HSE intervention, spend on Adalimumab (Humira) and Etanercept (Enbrel) had been increasing consistently over time, peaking at €205m in 2018.[40] Despite the addition of appropriate Biosimilar to the HSE's reimbursement list[41] negligible uptake was noted.

Best-Value Biological Medicines:

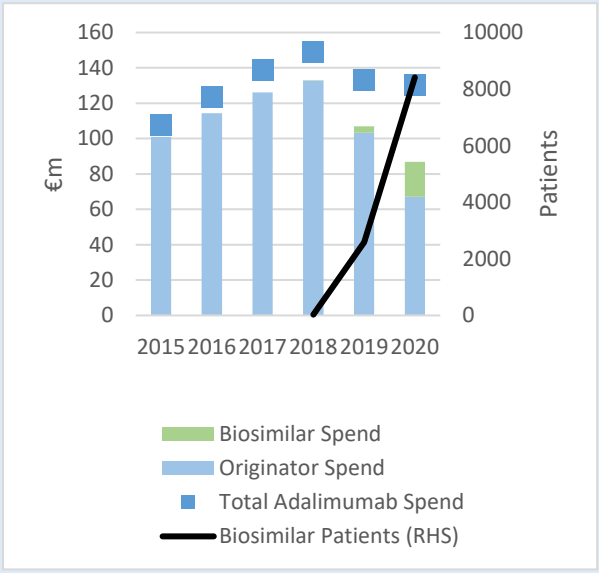
In May 2019, the HSE Medicines Management Programme completed the evaluation process for the identification of the best-value biological (BVB) medicines for TNF-α inhibitors on the High-Tech Drug

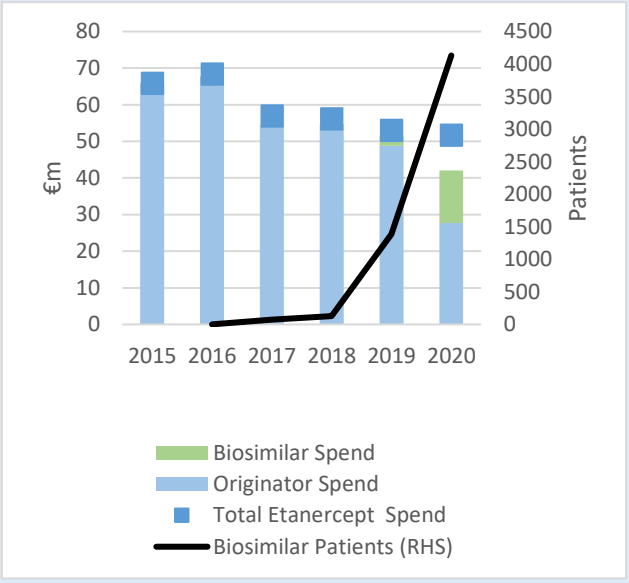
[39] Biosimilar medications are medications that are highly chemically similar to a reference biological medicine.
[40] Humira loss market exclusivity on October 16th 2018.
[41] (Adalimumab – Nov 2018, Etanercept – Sept 2016).

arrangements. The MMP recommended that all new patients being initiated on a biological medicine containing a TNF-α inhibitor should be prescribed one of the BVB medicines. Patients currently on adalimumab or etanercept were to considered for substitution to a BVB medicine when their next repeat prescription was issued.

Gainshare & Impact:

To supplement traditional engagements (information campaigns etc) with clinicians, in June 2019 the HSE introduced a system of gain-share to encourage the prescribing of the BVB medicines. By the end of 2020 the proportion of patients and corresponding spend on the biosimilars had increased significantly, yielding a large saving relative to prior government spend on branded pharmaceuticals for this treatment.





While pockets of progress encouraging the use of biosimilars are positive, overall biosimilar uptake in Ireland remains suppressed. In general, Ireland lags significantly behind comparator countries for biosimilar penetration, with the OECD (2018) recognising a divergence between Ireland and other OECD countries in terms of biosimilar market share. As a first step, efforts should be refocused on the publication of a Biosimilar strategy backed with appropriate targets, performance indicators and milestones**.** Inspiration can be taken from successful initiatives in other countries, such as the launched UK biosimilar policy aiming to have 90% of all newly presenting patients and 80% of all current patients switch to a biosimilar where available (NHS, 2017).

3.6. Changes to the Quality Adjusted Life Year Threshold

The formal requirement for Cost Effectiveness Analysis of drug introductions was first introduced in 2006 with an informal threshold of €45,000 per QALY. In 2008, this same informal threshold was revised downwards to €20,000 per QALY, before being reintroduced at its €45,000 per QALY level in 2012 (Gorecki P. K., Nolan, Brick, & Lyons, 2012). In 2012, the threshold became more explicit, becoming an official consideration for approval of reimbursement of new drugs in Ireland. Despite these changes it remains unclear what the formal basis is for the level at which the QALY threshold has been set.

In the absence of a formal basis for the QALY threshold, the option exists to alter the threshold to achieve a stricter cost effectiveness criterion for new drug introductions. This would have the effect of requiring at approval stage that new drugs provide better clinical benefits for their associated cost. This would further

prioritise State expenditure towards drugs that are the most cost effective, producing an associated reduction in expenditure on less effective, more expensive pharmaceuticals.

A second option for containing pharmaceutical spending in this context is a stricter application of the current threshold, with drugs exceeding the threshold value being potentially ineligible for reimbursement by the government. If imposed in a more rigorous fashion, the threshold would allow for the prioritisation of drugs that offer the best value to society in terms of clinical outcomes and cost. This may also mean that pharmaceutical suppliers would be more willing to reduce the prices of drugs that do not meet the threshold value, as otherwise they will be excluded from State funding.

Several authors have written in support of changes to the QALY threshold in Ireland. For example, Gorecki (2017) argues that the current method of determining the availability and pricing of medicines in Ireland results in too large of a share of healthcare expenditure being allocated to medicines, worsening healthcare outcomes in aggregate. O'Mahony and Coughlan (2016) argue that the threshold as it stands offers a weak barrier to cost-ineffective healthcare interventions. In addition, the current threshold level of €45,000 per QALY has no clearly verifiable empirical basis which can subject to review.

To further illustrate how a threshold of €45,000 per QALY compares to other healthcare interventions in Ireland, analysis by Chen et al. (2018) compares the cost per QALY of 20 waiting list procedures to this threshold. They find that out of the 20 procedures considered, 17 were more cost effective than €45,000 per QALY, with 14 out of 20 falling below €20,000 per QALY. For example, hip replacement and knee replacement come out as significantly more cost effective than some drugs-based interventions, costing just €1,800 and €2,700 per QALY respectively. In spite of the relative cost efficiency of these procedures, there remains significant unmet demand for these interventions, with between 1,500 and 2,000 persons currently waiting for these procedures in Ireland. This illustrates the trade-offs between the provision of different forms of healthcare intervention in the context of a constrained budget. The paper also highlights the potential for non-drugs-based interventions in certain care areas, with colon cancer screening providing benefits at €600 per QALY due to prevented illness.

While the advantages of the imposition of a strict QALY threshold are apparent, the impact of this policy option on accessibility cannot be ignored. In the main, this would likely curtail or eliminate funding for innovative medicines treating high-profile illnesses such as the ones shown in Figure 4. While these drugs are less cost effective than other healthcare interventions in general, the withdrawal of funding for these specific medications would likely have a severe impact on the patients that are currently receiving them. One option to reduce this impact is to only apply this threshold change going forward. If applied prospectively then the impact on individuals currently receiving treatment under the arrangement would be diminished although the problem of access would remain for potential future recipients.

4. Next Steps & Conclusion

4.1. Next Steps

While the cumulative analysis of the High-tech drug arrangement contained in the paper offers a unique examination of the arrangement to date, the research programme also led to the identification of a number of additional issues suitable for further inquiry:

- PCRS or the NCPE should aim to provide summary metrics on pharmaceutical reimbursement and approval decisions so that this information can be systemised and collected as a database. At present, information related to the clinical effectiveness, cost and net budget impact of drugs collected at the appraisal stage of a new drug introduction is not available in a format suitable for data analysis. While metrics for individual drugs can be obtained, an aggregation of these metrics into an administrative database would facilitate better understanding and further analysis. In particular, the net budgetary impact of these drugs, currently collected when a drug is first appraised by the NCPE, could be compared to their final ex-post budgetary cost thereby allowing for better long-run forecasting of the budgetary impact of a drug.
- The structure of the approvals process could change to facilitate approval on an ongoing basis rather than only when a drug is first introduced. This would enable the cost effectiveness of a drug to be reconsidered when significant inputs such as price or clinical effectiveness change. This would enable a more systematic approach to drug investment, as policymakers would have better, more up to date information to inform decisions on the reimbursement of a given pharmaceutical.
- Administrators of the High-Tech Drug arrangement could endeavour to collect information on patient outcomes related to the arrangement, allowing for a much clearer examination of the value for money offered by this healthcare intervention. This would also allow for further analysis in the context of appraisal as the reason for a patient's cessation with the arrangement would be known.

4.2. Conclusion:

In conclusion, this paper has reviewed in detail activity and policy matters related to the High-Tech Drug arrangement, outlining the underlying pharmaceutical context, the main drivers and trends in the arrangement, and options for managing spend on the arrangement going forward.

The compilation and analysis of highly detailed patient data in this paper is novel, illustrating an approach that other authors may be able to follow in the future.

A primary finding from the analysis is that expenditure on High-tech drugs has grown at an exceptional rate, averaging 11% per annum between 2012 and 2020, far ahead of the 6% patient volume growth experienced per year on the arrangement.

While the drugs funded by the arrangement constitute treatment options for various rare and impactful illnesses, the large and continuing expenditure growth in the arrangement prompts concerns around the long-run sustainability of this spend.

In light of this development, the paper offers a number of different policy options for consideration for containing the spend on pharmaceuticals, including Industry Agreement, International Cooperation, Improved Budgetary Forecasting, Promotion of Generic and Biosimilar medicines, and changes to the Cost Effectiveness Threshold applied to new drug introductions.

Appendix

Glossary

AMPI: Association of Medical Pharmaceutical Manufacturers of Ireland

ATC: Anatomical Therapeutic Chemical classification (further info)

Beneluxa: An international pharmaceutical cooperation initiative on pharmaceuticals

Biologic: A pharmaceutical produced using biological (as opposed to chemical) technology

Biosimilar: An alternative unpatented formulation of an originator biologic pharmaceutical

DoH: Department of Health

DPER: Department of Public Expenditure and Reform

DPS: Drugs Payment Scheme

FASPM: The Framework Agreement for the Supply and Pricing of Medicines – a State/Industry arrangement

GMS: General Medical Services (Scheme)

HPRA: Health Products Regulatory Authority

HSE: Health Service Executive

HTA: Health Technology Assessment

HTD: High Tech Drugs (Arrangement)

ICER: Incremental Cost Effectiveness Ratio

Indication: The illness/therapeutic area a specific pharmaceutical is designed to treat

IPHA: Irish Pharmaceutical Healthcare Association

LTI: Long Term Illness scheme

PAS: Patient Access Scheme (a system of drug specific rebates to permit patient access despite high list prices)

PCRS: Primary Care Reimbursement Service (part of the HSE)

Originator/Non-Originator: The original patent protected version of a medicine/unpatented alternative

NCPE: National Centre for Pharmacoeconomics

NDMS: National Drugs Management Scheme

QALY: Quality Adjusted Life Year

Description of PCRS Arrangements

Drugs Payment Scheme (DPS) The Drugs Payment Scheme (DPS) provides for payment to the Pharmacist for the supply of medicines to individuals and families where the threshold of €134, effective from 1st January 2018, has been exceeded in a calendar month. In order to avail of the Drugs Payment Scheme a person or family must register for the Scheme with the HSE PCRS. Drugs, medicines and appliances currently reimbursable under the Scheme are listed on the HSE website. Other items which were reimbursable under the Drug Cost Subsidisation Scheme and Refund of Drugs Scheme continue, in certain circumstances, to be reimbursable under the Drugs Payment Scheme.

Long Term Illness Arrangement (LTI) On approval by the Health Service Executive, persons who suffer from one or more of a schedule of illnesses are entitled to obtain, without charge, irrespective of income, necessary drugs/medicines and/or appliances under the LTI Arrangement.

European Economic Area (EEA)

Residents from one of the other states of the European Economic Area, with established eligibility, who require emergency general practitioner services while on a temporary visit to the State are entitled to receive from a General Practitioner a GMS prescription form for necessary medication and to have such medication dispensed in a Pharmacy that has entered into an agreement with the Health Service Executive within the State.

High Tech Arrangements (HT)

Arrangements are in place for the supply and dispensing of High Tech medicines through Community Pharmacists. Such medicines are generally only prescribed or initiated in hospital and would include items such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy or hormonal therapy. The medicines are purchased by the Health Service Executive and supplied through Community Pharmacists for which Pharmacists are paid a patient care fee. The cost of the medicines and patient care fees are paid by the Primary Care Reimbursement Service.

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To ensure accuracy and methodological rigour, the author engaged in the following quality assurance process.

☑ Internal/Departmental
- ☑ Line management
- ☑ Other divisions/sections
- ☑ Management Board

☑ External
- ☑ Other Government Department
- ☑ Clinical / Operational Agencies
- ☑ Spending Review Steering group