Tithe an Oireachtais

An Comhchoiste um Shláinte agus Leanaí

Tuarascáil ar an gCostas a bhaineann le Drugaí ar Oideas in Éirinn

Deireadh Fómhair 2015

Houses of the Oireachtas
Joint Committee on Health and Children

Report on the Cost of Prescription Drugs in Ireland

October 2015
Chairman’s Foreword

As part of its 2015 Work Programme, the Joint Committee on Health and Children identified the cost of prescription drugs as a major issue. Given that health budgets are limited, the cost of drugs and prescriptions is a priority for all European States.

In Ireland, increased demand for prescription drugs and new treatments means there is an ongoing need to deliver meaningful value for money on the drug treatment budget. The scale of the budget involved is significant. For example, in 2014, €1.8bn out of a total Irish health budget of €12.4bn (14.5%) was spent on drug treatment. Long-term rising costs are attributed to factors such as:

- increased use of prescription drugs;
- demographic trends;
- the development of high-tech drug treatments.

The Health Service Executive (HSE) operates a reimbursement model with the pharmaceutical industry. Patients can also incur additional charges for prescription drugs. Moreover, there is an awareness among Irish consumers that some prescription drugs are available more cheaply abroad. Therefore the Committee wished to consider whether the State and individual patients pay a fair price for prescription drugs, in comparison with their European counterparts.

In this Report, the Committee suggests recommendations which it believes could enhance the effectiveness of the drug reference pricing system, and encourage changes in prescriber behaviour. The report is timely, given that the current agreement (2012 – 2015) between the HSE and the pharmaceutical industry is due for renewal.

The HSE points to significant progress in cutting the overall cost, which fell from almost €2bn in 2012 to €1.8bn in 2014. Although collaboration between the health service and the pharmaceutical industry has yielded savings, the Committee believes that there is scope to make further progress in this area. Balanced against this, the Committee also recognises the need for security of supply.

Given the importance of this topic, the Committee held a number of hearings on 5 March and 12 March 2015.
The Committee heard evidence from a range of stakeholders representing branded and generic pharmaceuticals, the Irish Pharmacy Union (IPU), the HSE, the Irish Pharmaceutical Healthcare Association (IPHA), the Association of Pharmaceutical Manufacturers in Ireland (APMI) and Professor Colum Dunne of the University of Limerick.

We are grateful for the participation of representatives from the Department of Health and the HSE, who briefed the Committee. I would like to express our appreciation to all those who participated in the Committee deliberations.

It should be noted that the Committee was extremely disappointed to receive communications from one pharmaceutical company which declined to participate in the Committee meetings.

The Committee benefited greatly from the input of the Library and Research Service in its preparation for hearings and this Report. I commend this Report to both Houses of the Oireachtas with a request that it be debated in both Houses at an early date.

Jerry Buttimer, T.D.
Chairman
Joint Committee on Health and Children
# Joint Committee on Health and Children

## 31st Dáil Members of the Joint Committee on Health and Children

<table>
<thead>
<tr>
<th>Catherine Byrne TD</th>
<th>Clara Conway TD</th>
<th>Joe Costello TD</th>
<th>Clare Daly TD</th>
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<tr>
<td>(Fine Gael)</td>
<td>VICE CHAIR (Labour)</td>
<td>(Labour)</td>
<td>(Independent)</td>
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<tr>
<td>Regina Doherty TD</td>
<td>Peter Fitzpatrick TD</td>
<td>Seamus Healy TD</td>
<td>Billy Kelleher TD</td>
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<td>(Fine Gael)</td>
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<td>(Independent - WUAG)</td>
<td>(Fianna Fáil)</td>
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<td>Eamonn Maloney TD</td>
<td>Sandra McLellan TD</td>
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<td>Mary Mitchell O’Connor TD</td>
<td>Dan Neville TD</td>
<td>Caolmghín Ó Caoláin TD</td>
<td>Robert Troy TD</td>
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</table>
| Senator Colm Burke  
(Fine Gael) | Senator Thomas Byrne  
(Fianna Fáil) | Senator John Crown  
(Independent) | Senator John Gilroy  
(Labour) |
|-----------------|-----------------|-----------------|-----------------|
| Senator Imelda Henry  
(Fine Gael) | Senator Jillian Van Turnhout  
(Independent) |
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Summary of Conclusions and Recommendations

1. The Pricing Mechanism

1.1 Consideration should be given as to whether the ‘average price’ methodology is the most cost effective option, given that it is the acknowledged ‘starting point’ for negotiations on pricing.

1.2 The Committee notes that the ESRI’s 2012 recommendations in relation to a mid-point review of the Agreement, were not implemented.

1.3 With regard to the basket of countries used in average-price calculations, the Committee recommends that the Minister should consider expanding to 15 the number of countries used for calculating the average, to ensure that lower cost countries are included.

1.4 In cases where average prices are based on a small sample size, the Minister should consider ensuring that any new model includes an automatic annual review mechanism to ensure value for money.

2: Parallel Trade and Export Controls

3.1 The HSE and the Department of Health need to maintain strong surveillance on the impact of national drug price policy on the drug supply.

3.2 The HSE should clarify whether a contingency plan has been prepared should drug shortages arise, and if so, whether this includes consideration of certain export controls (similar to those adopted by Spain and other countries).

3.3 The Department and the HSE should examine the feasibility of introducing concessionary pricing, as a more flexible way of adjusting prices of individual products, where supply is an issue.

3: Study on maintaining supply of medicines

The Committee recommends that the Government commission a future-focused assessment of the challenges posed by pricing, supply and demand for pharmaceuticals in Ireland.

The proposed study would take stock of progress achieved under the Health (Pricing and Supply of Medical Goods) Act 2013, and map out possible future options including the potential for co-ordinated action with EU partners on joint procurement and parallel trading.

4: Clarity over review of pricing mechanism

4.1 The Committee recognises the need for private negotiations between stakeholders in line with standard industry practice.
Joint Committee on Health and Children

However, having regard to the successor 2015 – 2018 Agreement, the Committee recommends that greater clarity and transparency is needed with regard to its terms.¹

4.2 Consideration should be given to publishing the drug reference pricing model which underpins any new Agreement, including justification for the chosen model.

4.3 The Committee recommends the publication of baseline price comparisons for all EU member states on an annual basis.

5: State/Industry agreement regarding ‘savings/cost reduction’ figures

5.1 A more frequent publication of data on cost savings merits consideration. This would allow appropriate scrutiny by all stakeholders, including the Select Committee on Health and Children as part of its financial scrutiny of Estimates of Expenditure by the Department of Health.

5.2 The Committee recommends that consideration be given to including a number of key performance indicators for drug price savings under a new Agreement. This should be broken down by various measures including on-patent and generic substitution, and expenditure on high-tech drugs.

6: Potential additional cost savings

The HSE and the Department of Health should consider responding to the proposal by Teva Pharmaceuticals, including the suggested €113m cost savings, incorporating measures such as generic alternatives and cost-effective prescribing.

7: Feasibility of an Irish Medicines Service and Medicine Use Reviews

7.1 The Committee recommends that the feasibility of establishing an Irish Medicines Service. The introduction of Medicine Use Reviews (MURs), where patients with long-term illness, jointly review their prescriptions on a regular basis, merits examination.

7.2 The Minister should also consider what other steps can be taken to enhance the role of the pharmacist in the provision of primary care to patients.

8: Bio-similars and the High-Tech molecules

8.1 It is necessary to clarify if the Government expects to introduce legislation to enable the interchangeable prescription of biosimilar pharmaceuticals to Irish patients, or whether any consultations have been held to assess any likely regulatory impacts of such measures. The inclusion of high-tech ‘molecules’ (i.e. bio-similar) on the High Tech Drug (HTD) scheme may merit consideration as one possible solution to future cost control.

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8.2 The potential application of a financial incentive mechanism for pharmacists to supply generic versions of products on the HTD scheme, considering the increasing expenditure on this scheme, should be assessed.

9: Development of a single web-based resource for patients and awareness campaign

Misinformation on generic drugs may potentially threaten patient safety and should be comprehensively addressed through a reliable and accessible patient-focused resource.

9.1 An accessible and comprehensive website and comparator tool should be developed and promoted to provide both prescribers and patients with information on all available pharmaceutical products in Ireland, similar to the role of the website ‘Understand Generics’. Such a portal would represent an additional resource for patients and not seek to replace or replicate the role or advice of the community pharmacist or local GP.

9.2 A further awareness campaign, focused in particular on the efficacy of treatment by generics, should also be actively promoted by the HSE in partnership with pharmaceutical representatives, the Irish Pharmacy Union and the Irish College of General Practitioners.

10: Prescribing patterns

10.1 A detailed study is required on the matter of rational prescribing and prescribing patterns in Ireland. This could be conducted under the auspices of the HSE’s Medicine Management Programme which already incorporates a strong, collaborative working relationship with the Irish College of General Practitioners (ICGP).

10.2 In the interests of transparency and informing patients and prescribers alike, the HSE’s Medicines Management Programme could consider providing regular written updates to the Joint Committee on Health and Children to ensure progress can be monitored and sustained.

11: Expanding the role of the community pharmacist

11.1 Considering the wide knowledge possessed by community pharmacists and their proximity to patients, a detailed analysis of the potential to expand their role by delegating drug prescription authority to them, merits further consideration.

11.2 The Committee supports the re-classification by the Health Products Regulatory Authority (HPRA) of a wider range of medicines from ‘prescription-only’ to over-the-counter (OTC) medicines, in line with best practice in other EU countries.

12: Standard pricing templates

In the interests of ensuring a high-level of public transparency, and to inform patients and enhance consumer choice, the display of a standard template detailing the dispensing fee and mark-up fees of community pharmacists merits consideration by the Pharmaceutical Society of Ireland.
Joint Committee on Health and Children

13: Community Pharmacies and Alternative Business Models
The Committee fully acknowledges the important role of community pharmacists in educating patients on generics and suitable pharmaceutical products. The whole-of-service approach provided by community pharmacists is essential in meeting individual patients’ changing medical needs.

The Joint Committee also welcomes the emergence of new models of pharmacy, which can help promote competition, increase generic substitution levels, and provide new services to patients.

14: Pharmaceutical packaging
Generic manufacturers should take appropriate account of packaging similarities between their products and the branded or off-patent equivalent in order to minimise possibilities of confusion for patients.
Introduction: Policy Context

This section highlights three strategic issues which impact on public health policy and the cost of prescription drugs:

a) Demographic Change:

In common with most European countries, demographic change acts as a key long-term driver of demand in the Irish health service. As Irish citizens benefit from higher standards of living and access to better medical treatment, they are living longer.

This is confirmed by Central Statistics Office (CSO) projections. The demographic old-age dependency ratio (people aged 65 or above relative to those aged 15 – 64) is projected to increase from 11.6% in 2011 to 25.19% in 2046.²

This represents a long-term increase of 117% in our older population (as shown in Table 1 below).

Table 1:

<table>
<thead>
<tr>
<th>Year</th>
<th>65 and Over</th>
<th>All Ages</th>
<th>% of Total 65 +</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>458.9</td>
<td>4,133.8</td>
<td>11.10</td>
</tr>
<tr>
<td>2006</td>
<td>467.9</td>
<td>4,239.8</td>
<td>11.04</td>
</tr>
<tr>
<td>2007</td>
<td>471.1</td>
<td>4,375.8</td>
<td>10.77</td>
</tr>
<tr>
<td>2008</td>
<td>483.8</td>
<td>4,485.1</td>
<td>10.79</td>
</tr>
<tr>
<td>2009</td>
<td>498.9</td>
<td>4,533.4</td>
<td>11.00</td>
</tr>
<tr>
<td>2010</td>
<td>515</td>
<td>4,554.8</td>
<td>11.31</td>
</tr>
<tr>
<td>2011</td>
<td>531.6</td>
<td>4,574.9</td>
<td>11.62</td>
</tr>
<tr>
<td>2031</td>
<td>991.0</td>
<td>5,187.4</td>
<td>19.10</td>
</tr>
<tr>
<td>2036</td>
<td>1,131.1</td>
<td>5,337.4</td>
<td>21.19</td>
</tr>
<tr>
<td>2041</td>
<td>1,276.3</td>
<td>5,491.0</td>
<td>23.24</td>
</tr>
<tr>
<td>2046</td>
<td>1,419.3</td>
<td>5,635.2</td>
<td>25.19</td>
</tr>
</tbody>
</table>

An ageing population will have significant implications for the future of how we deliver public healthcare. This was confirmed by Fergal Goodman of the HSE, during the Committee hearings, when he stated:

“Much of this increased longevity is attributable to advances in medical science and in the treatments available, including drug treatments. As well as bringing very clear benefits to individuals and to society generally, increased life expectancy means that as people live longer, they are likely to do so with an increasing burden of chronic disease.

Therefore, despite the success of policies aimed at controlling drug costs, we need to continue the efforts to maximise the benefit to individuals and society of the medicines used in Ireland, and in a way which is affordable for all concerned.”

A number of stakeholders emphasised the potential consequences of an ageing population. A recent study by researchers at Cork Institute of Technology concluded that Ireland’s population growth, coupled with an increase in the coverage and claims rate will ultimately necessitate other policy actions (e.g. income eligibility adjustments, etc.).

During the Committee hearings, Sandra Gannon of Teva (a generics manufacturer), also identified the main impacts of these changes on demand for drug treatments:

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3 “Patterns and Determinants of Healthcare Utilisation in Ireland”
(2013: The Irish Longitudinal Study on Ageing, Lincoln Place, Trinity College Dublin 2)
Joint Committee on Health and Children

...50% of the population now have two or more chronic diseases. Some 61% of all adults are overweight or obese. The HSE has stated that within five years the incidence of chronic disease will increase by a further 40%. The numbers with heart disease, the killer of the largest number of Irish people, will grow by another 31%.

Some 30,000 new patients will be diagnosed with cancer every year between now and 2020. The Irish longitudinal study on ageing, TILDA, also confirms this fact that a “combination of population growth and ageing will increase demands for treatments by between a quarter and a third by 2026, if current approaches to treatment continue”.

b) Investment in high-tech drugs

In spite of HSE achievements in reducing drug treatment costs over time, the cost of high-tech drugs increased by 59% between 2009 and 2014. The revolution in genetics and bio-technology means that some life-limiting illnesses and rare diseases can be targeted by new treatments. Pharmaceutical companies are investing heavily in R&D to develop drug combinations tailored to treat illnesses affecting relatively small groups of people.

In Irish public discourse, there is a higher expectation of timely access to innovative, high-tech drugs. However, international pharmaceutical companies have also been criticised for their pricing policies, and a perceived failure to make some high-tech drugs available at affordable prices.

By way of example, the Committee hearings on drug pricing considered the lack of a long-term agreement between Alexion Pharmaceuticals and the HSE on the provision of Exulizumab (sold commercially as Soliris), a treatment for rare blood diseases, at an affordable price. At an estimated total cost of €33m over five years, Soliris is one of the most expensive drugs in the world. The Committee expressed disappointment at the refusal by Alexion to attend the Committee meetings.

c) Current Expenditure Levels

Although the Committee acknowledges that the current agreements between representatives of the pharmaceutical companies and the health service achieved savings, these are small in relative terms. For example, the 2012 – 2015 agreement with the IPHA included projected savings of €400m. In the context of a total annual health spend of over €1.8bn, this represents an annual saving of approximately 6%. The most recent EU / IMF report acknowledged progress but stated that:

Ireland has made progress in containing the cost of pharmaceuticals, but the ability of measures added to the Memorandum of Understanding late in the programme to deliver further savings mostly remains dependent on post-programme actions.  

From a Committee perspective, therefore, there is scope for further action.

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4 Ex post evaluation of the economic adjustment programme for Ireland (2010-2013)
Joint Committee on Health and Children

Key Issues

- The Primary Care Reimbursement Service (PCRS) scheme administers drug payments to medical practitioners. This funding falls under various State schemes, primarily the General Medical Services (GMS, or medical card) scheme.

- The scale of the budget involved in reimbursement schemes is significant. In 2014, €1.8bn out of a total Irish health budget of €12.4bn (14.5%) was spent on State reimbursements on medicines and appliances. The number of prescribed medicines increased substantially from 32 million items in 2000 to 74 million items (+125%) in 2013.

- Ireland benchmarks its prices against a ‘basket’ of nine countries: Austria, Belgium, Denmark, Finland, France, Germany, the Netherlands, Spain and the UK, using the average price in each country, where available.

- Since the early 1970s, the State negotiated successive agreements to ensure continuity of supply for a full range of medicines, that the State receives good value for money, and that a stable framework exists between the pharmaceutical industry and the State.

- Historically, the prices of both patented and generic pharmaceuticals have been higher in Ireland than in its European counterparts.

- Generic penetration is low in Ireland, but has increased significantly in recent years with the share of generics reaching nearly 70% in some cases under the GMS scheme.

- As the prices for generics and patented pharmaceuticals were until recently coupled together, this did not translate into cost reductions for the State. However, significant changes regarding the pricing of generic pharmaceuticals were set down in legislation under the Health (Pricing and Supply of Medical Goods) Act 2013 which commenced in June 2013.

- Under the EU-IMF Programme, Ireland was required to take concerted action to reduce the cost of drugs, and to increase the use of generic drugs.

- The Economic and Social Research Institute (ESRI) was commissioned by the HSE to produce a report entitled ‘Ireland: Pharmaceutical Prices, Prescribing Practices and Usage of Generics in a Comparative Context’ in June 2013, building upon an earlier report ‘Delivery of Pharmaceuticals in Ireland – Getting a Bigger Bang for the Buck’.

- The Programme for Government (PfG) between Fine Gael and the Labour Party includes a commitment to reduce the State’s pharmaceuticals bill and the cost to individual patients though drug reference pricing and greater generic substitution.

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5 According to the HSE’s Primary Care Reimbursement Service (PCRS) Statistical Analysis of Claims and Payments (2013), the State through the PCRS scheme made payments to GPs, pharmacists, dentists and optometrists totalling €2.51 billion in 2013.

6 IPHA (2011) IPHA Submission to the ESRI, July 2011.

7 Published in January 2012 and revised August 2013.
The terms ‘patented’, ‘off-patent’ and ‘generics’ are used to denote different categories of pharmaceuticals, as summarised in Table 2 below.

### Table 2: Summary of different types of pharmaceuticals

<table>
<thead>
<tr>
<th></th>
<th>Patented</th>
<th>Off-patent</th>
<th>Off-patent / Generics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Brand name / patented (‘originator’*) drugs without a generic equivalent (manufactured by large multinational firms).</td>
<td>Patented drugs (contested / patent holder licenses a number of manufacturers)</td>
<td>Off-patent drugs (i.e. patent has expired). or generics with the same active ingredient, strength and dosage form. Generics can be branded or unbranded.</td>
</tr>
<tr>
<td><strong>Single source in-patent pharmaceuticals</strong></td>
<td>Multiple source in-patent pharmaceuticals</td>
<td>Single source off-patent pharmaceuticals</td>
<td>Multiple source off-patent pharmaceuticals</td>
</tr>
</tbody>
</table>

* see glossary of this Report for definition of ‘originator’

- The price of pharmaceuticals in Ireland is determined by agreements between the State (represented by the HSE and the Department of Health) and the IPHA and the APMI. The IPHA represents the major research-based pharmaceutical companies that provide patented products. The APMI represents generic manufacturers.

- The State has attempted to contain the cost of pharmaceuticals through a number of measures. Under the *Financial Emergency Measures in the Public Interest (FEMPI) Act 2009*, the wholesale mark-up paid on medicines was reduced from 17.6% to 10%, and the retail mark-up paid on items provided under the Drugs Payment and Long Term Illness schemes reduced from 50% to 20%.

- The State has also achieved reductions in the overall cost through renewed IPHA/APMI agreements. Taken together these measures are estimated to have generated cost reductions to the State of €768 million between 2006 and 2014 (€250m in 2006-2010, €250m in 2010-2011, €120m in 2013 and €148m in 2014). Referring to different comparisons, the HSE also stated that since 2006, €1.5bn in cumulative savings has been achieved from all agreements.

- However, over the period of the current agreement, several of the most widely prescribed products dropped off patent due to the ‘patent cliff’, resulting in significant savings for the State. This trend is likely to continue. It is unclear to what extent savings cited under the current agreement can be attributed to such changes.

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The current agreements (IPHA/APMI) are due to continue until November 2015, and may be extended, pending successful renegotiation of a successor. Although there is a provision under the current State / IPHA agreement (2012 – 2015) for a mid-term review, this did not take place. Also, the current agreement does not set out annual targets for savings.

The aim of the *Health (Pricing and Supply of Medical Goods) Act 2013* is to reduce drug prices. Under the Act, the HSE may determine the price of patented pharmaceuticals using seven criteria just one of which is price. Under Section 21 (2), these criteria include equivalent relevant prices in other EU Member States where the item is marketed, the prices of substitute items, the potential budget impact, and resources available to the HSE.

Irish prescribing patterns also play a major role in determining the cost of pharmaceutical expenditure to the State. At present, competition for generics takes place between manufacturers in the form of discounts off the reimbursement price set by the State to the pharmacist. However, a major challenge in encouraging generic take-up is that there is no similar financial incentive for GPs or hospital doctors to modify prescribing practice.

Importantly, research by Dunne et al confirms that patients trust their doctor to a greater extent than pharmacists when it comes to advice on prescribing generics. Attempts by the HSE to tackle the incentive issue, for example through the HSE’s ‘preferred drug initiative’ have yielded some cost reductions, but alternative strategies are needed.

A summary of key issues that arise in relation to the cost of pharmaceuticals in Ireland are summarised in Table 3 (below) of this Report.

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1. Main issues raised at stakeholder hearings

This introduction summarises the main issues raised at two stakeholder hearings held on 5 March and 12 March 2015 on the topic of Cost of Prescription Pharmaceuticals in Ireland by the Joint Committee on Heath and Children (the Committee).

Prescription-only pharmaceuticals are defined by the Health Products Regulatory Authority (HPRA)\(^{11}\) as those “…which require medical supervision and [are] available only with a doctor’s or dentist’s prescription, and dispensed through pharmacies”. Such pharmaceuticals are generally dispensed to patients by community pharmacists (and to a lesser extent, hospital doctors) and reimbursed by the State.

Related but separate issues such as non-prescription pharmaceuticals e.g. over-the-counter drugs (OTCs) or pharmaceutical expenditure in private hospitals by cash-paying patients are not dealt with in this Committee Report.

The stakeholders / witnesses present for the two hearings were as follows:

Table 4: Joint Committee hearings – stakeholders / witnesses present

<table>
<thead>
<tr>
<th>5 March</th>
<th>12 March</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kathy Maher, President and Darragh O’Loughlin, Secretary-General, Irish Pharmacy Union (IPU)</td>
<td>John Hennessy - National Director, Primary Care Division, HSE</td>
</tr>
<tr>
<td>Dr Leisha Daly, President and Oliver O’Connor, Chief Executive, Irish Pharmaceutical Healthcare Association (IPHA)</td>
<td>Shaun Flanagan – MPSI, Chief Pharmacist, Corporate Pharmaceutical Unit, HSE</td>
</tr>
<tr>
<td>Sandra Gannon, General Manager and Aideen Kenny, Head of Commercial Operations, Teva Pharmaceuticals Ireland</td>
<td>Patrick Burke - Assistant National Director, Primary Care Reimbursement Service, HSE</td>
</tr>
<tr>
<td>Shane O’ Sullivan, Chief Executive, Healthwave</td>
<td>Professor Michael Barry - Clinical Lead for the Medicines Management Programme</td>
</tr>
<tr>
<td>Martin Gallagher, President, Association of Pharmaceutical Manufacturers in Ireland (APMI)</td>
<td>Fergal Goodman - Assistant Secretary, Department of Health</td>
</tr>
<tr>
<td>Professor Colum Dunne, Foundation Chair &amp; Director of Research, Graduate Entry Medical School, University of Limerick</td>
<td>Teresa Cody - Principal Officer, Primary Care Division, Department of Health</td>
</tr>
</tbody>
</table>

\(^{11}\) The HPRA was previously known as the Irish Medicines Board (IMB) prior to a name change in July 2014. A glossary is available on the HPRA’s website here.
2. Stakeholder Hearings and Recommendations

The following is a thematic summary of the main arguments put forward at the public hearings and corresponding key issues identified by the Library & Research Service on behalf of the Committee.

2.1 The pricing mechanism

The price setting mechanism, agreed between the State and the pharmaceutical industry, is key to understanding Irish drug pricing.

Average Price Model

Ireland sets prices via multi-annual State / IPHA / APMI agreements, benchmarked on the average price in a basket of nine EU countries. In the context of the pricing mechanism used, the HSE stated the following at the Committee hearing on 12 March:

“On the rationale for using the basket of nine countries, the original basket contained five countries. In 2006 there was a long negotiation. I was not involved, but I understand the negotiators reported directly to a Cabinet sub-committee. At that point it was agreed that the basket would be increased from five to nine countries. Austria, Belgium, Finland and Spain were added and regarded as lower price countries — that is what is coming out in the recent data we have received — than the countries that had been included in the previous basket.”

However, the price outcome can vary significantly depending on whether a median or mean average model is used\(^\text{12}\), whether data from all nine countries is available, or whether the calculation is based on a smaller sub-set of countries.

The Committee also noted that the ESRI’s 2012 report\(^\text{13}\) recommended that the maximum ex-factory price for patented drugs “should be the lowest price of the basket of nine Member States”\(^\text{14}\).

Finally, Ireland’s basket of nine countries is not the common option used by other countries when calculating reimbursement prices.

Table 5 below offers a summary of arrangements in EU countries in terms of the benchmarking methods employed\(^\text{15}\). It confirms that four countries opt for ‘free pricing’ models, with agreements directly with manufactures based on specified prices, as practiced in Denmark, Slovenia, Sweden and the UK.

A minority of countries, including Ireland, base their price calculations on a small basket of countries. A significant number of other EU countries choose to base their prices on a much larger basket of countries.

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\(^{12}\) A mean average is computed by adding up all the values and dividing that score by the number of values, A median average can be computed by listing all numbers in ascending order and then locating the number in the centre of that distribution.


\(^{14}\) Ibid, Recommendation 4.2.

\(^{15}\) Derived from Table 2, p. 16 of Pharmaceutical Pricing Policies in Europe, Gesundheit Österreich FP 2014.
Joint Committee on Health and Children

Table 5

<table>
<thead>
<tr>
<th>No. of Countries in Basket</th>
<th>No. of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&gt;3 &lt;= 9</td>
<td>14</td>
</tr>
<tr>
<td>&gt;9 &lt;= 20</td>
<td>6</td>
</tr>
<tr>
<td>&gt;20 &lt;=30</td>
<td>6</td>
</tr>
<tr>
<td>Free Pricing</td>
<td>4</td>
</tr>
</tbody>
</table>

Graph 2

Country Baskets used in External Price Referencing by EU Country

Note 1: Graph presents the Country Baskets in 31 Countries.
Note 2: Four countries are not included in Graph as they use a ‘free pricing model’: they are UK, Sweden, Denmark, Slovakia.
Source: Data derived from Table 2, p. 16 of Pharmaceutical Pricing Policies in Europe, Gesundheit Österreich FP 2014.16

During Committee hearings, Deputy Keller outlined the possible implications of the current approach when he stated:

“...If a company applies for reimbursement of its on-patent new drug, the nine European countries are used as a basket. If the drug is not available in those nine European countries, is it correct that it is to a minimum of three countries? ...if there are nine countries, there is a better chance that there will be an average, but if a company is going to make its drug available and

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knows that the price is going to be based on three countries, it will obviously make it available to the dear ones first and work out from that. Is there not a huge flaw in the system there in terms of pricing? The average will always come from the highest down as opposed to from the other way up or from the middle. There is quite a weak area in the mechanism of adjudication of the price.”

During the Committee hearings, the HSE stated that a Health Technology Assessment (HTA) is also taken into account when considering price. The HSE clarified that the basket of goods method should be seen as “not the setting point, rather it is the starting point”. As such, the revised pricing system introduced in 2013 makes some effort to ensure that manufacturers must justify the price.

Recommendation 1: The Pricing Mechanism

1.1 Consideration should be given as to whether the ‘average price’ methodology is the most cost effective option, given that it is the acknowledged ‘starting point’ for negotiations on pricing.

1.2 The Committee notes that the ESRI’s 2012 recommendations in relation to a “lowest price” model, and a mid-point review of the Agreement, were not implemented.

1.3 With regard to the basket of countries used in average-price calculations, the Committee recommends that the Minister should consider expanding to 15 the number of countries used for calculating the average, to ensure that lower cost countries are included.

1.4 In cases where average prices are based on a small sample size, the Minister should consider ensuring that any new model includes an automatic annual review mechanism to ensure value for money.

2.2 Continuity of Supply

In drug pricing, a major challenge is to balance the twin aims of achieving cost reductions and also ensuring secure access to medicines. Maintaining supply is also a statutory obligation, following the enactment of the Health (Pricing and Supply of Medical Goods) Act 2013.17

The introductory section to this Report highlighted the fact that by 2021 the population over the age of 65 in Ireland will increase by 40% from 2011 levels, representing an additional 200,000 people. In its opening statement on 12 March, the HSE also stated that life expectancy has increased notably over a ten-year period (2002-2012), with male life expectancy increasing by 3.7 years and female life expectancy by 2.8 years.

In the context of an ageing population and forecast population growth, long-term demands for medical treatments will increase18. As a result of such trends, there is likely to be additional pressure on the future supply of medicine for Irish patients.

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17 Section 20 (2) and Part 3 (c).
18 By between 25-33% according to Teva Pharmaceuticals.
During Committee hearings, a number of stakeholders cautioned about the possibility of future medicine shortages, as the prices of certain medicines begin to reduce in Ireland. The IPU highlighted research, conducted in August 2014, which stated that 99% of the pharmacists who took part in the study could confirm medicine shortages in the preceding year and over half (52%) believed that the health of their patients has been adversely affected or put at risk as a result. However, the Committee did not identify any verified evidence demonstrating a link between cost reduction measures and drug shortages in other European countries.

Under the current Agreement, product price adjustments are only permitted on an **exceptional basis** and on condition that any such modulation is demonstrably cost neutral for the State.

The APMI describes this modulation method as “cumbersome” and proposes the introduction of concessionary pricing. Similarly, the IPU recommends a new mechanism to provide enough flexibility to maintain continuity of supply.

According to the IPHA, Ireland is now the largest net exporter of pharmaceuticals in the EU. Furthermore, the IPU stated that Spain,\(^{19}\) as an EU Member State with comparatively low pharmaceutical prices, has introduced export bans on some products to address supply shortages. This ban specifically applies to medicines which are the only ones registered in Spain for a certain ailment (due to their active ingredient or dosage), or for which there is no alternative to dispense.\(^{20}\)

These actions were in response to the increasing prevalence of **parallel trading** whereby a pharmaceutical sold for a low price in one EU Member State is bought by a wholesaler and transported to a second country in which the same product sells for a profit.

At European level, the issue of supply was recently recognised by the EU Health Commissioner, Vytenis Andriukaitis. With regard to parallel pricing, the Commissioner advised that EU countries have a clear right to prevent wholesalers from selling drugs outside one country at cheaper prices in another country, if it impacts on patients’ access to treatment. He stated that such regulation is an “**absolutely legal instrument**” that EU countries have, and pointed out that Slovakia and Poland took action to regulate the parallel drugs trade.\(^{21}\)

### Recommendation 2: Parallel Trade and Export controls

Considering the challenges the State faces in relation to pricing, demand and supply of pharmaceuticals,

2.1 **The HSE and the Department of Health need to maintain strong surveillance on the impact of national drug price policy on the drug supply.**

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2.2 The HSE should clarify whether a contingency plan has been prepared should drug shortages arise, and if so, whether this includes consideration of certain export controls (similar to those adopted by Spain and other countries).

2.3 The Department and the HSE should examine the feasibility of introducing concessionary pricing, as a more flexible way of adjusting prices of individual products, where supply is an issue.

Many European countries face similar challenges in this regard. Greater co-ordination on drug procurement and supply may be desirable in future. For example, EU Commissioner Vytenis Andriukaitis wrote to all 28 EU countries to highlight action by Belgium, the Netherlands, Romania and Bulgaria on joint drug procurement, and to encourage other countries to explore options for joint approaches.\[22\]

At a more strategic level, the Irish State may need to adopt a longer-term plan, based on analysis of future challenges, such as demographic trends and changes in demand and supply of medicines.

**Recommendation 3: Study on maintaining supply of medicines**

The Joint Committee recommends that the Government commission a future-focused assessment of the challenges posed by pricing, supply and demand for pharmaceuticals in Ireland.

The proposed study would take account of progress achieved under the Health (Pricing and Supply of Medical Goods) Act 2013, and map out possible future options including the potential for co-ordinated action with EU partners on joint procurement and parallel trading.

**2.3 Transparency in negotiations**

The European Commission, in a Working Paper, highlighted the fact that delays in reaching a new drug pricing Agreement in Ireland would place further savings at “significant risk”.\[23\]

A number of stakeholders stated that re-alignment of pharmaceutical prices does occur at intervals during the period in which State/Industry agreements are in place (November 2012 and November 2013 were explicitly mentioned).

However, there is significant confusion over certain terms in the current Agreement, and the price review mechanism, as reflected in public comment on the matter.\[24\] For example, a mid-term review is a component of the 2012 – 2015 State / IPHA agreement, but a formal review of pricing does not appear to have taken place, nor is it explicitly specified as part of the Agreement.

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\[23\] cannot identify this Working Paper

Recommendation 4: Clarity over review of pricing mechanism

4.1 The Committee recognises the need for private negotiations between stakeholders in line with standard industry practice. However, having regard to the successor Agreement to the 2012-2015 negotiations, the Committee recommends that greater clarity and transparency are needed in relation to the Terms of any new Agreement.

4.2 Consideration should be given to publishing the drug reference pricing model which underpins any new Agreement, including justification for the chosen model.

4.3 The Committee recommends the publication of baseline price comparisons for all EU member states on an annual basis.

2.4 The State ‘cumulative savings/cost reduction’ figures

Earlier correspondence supplied to the Committee (January 2015) detailed a saving of (approximately) €768m\(^{25}\) under the State/IPHA/APMI agreements over the period 2006-2014.

However, the HSE subsequently stated (12 March) that cumulative ‘gross’ savings (and ‘cost avoidance’ measures) achieved under these agreements amounted to €1.5bn\(^{26}\) over that same period. The IPHA stated to the Joint Committee (5 March) that savings of at least €1.2bn\(^{27}\) were delivered from 2006 to October 2015 under successive agreements. The IPU stated that since 2009 a minimum of €314m in pharmacy payments has been saved by the State, with an additional €1.42bn realised in reduced payments for medicines in general.\(^{28}\)

The Committee hearings revealed a need to provide an accurate, and verified set of cost savings/reductions in relation to overall State expenditure on pharmaceuticals. Currently, the only publically available data is the PCRS Financial and Statistical Analyses publications, which may not reflect all verified and available data.

\(^{26}\) HSE (2015) Opening Statement by Mr. John Hennessy, National Director – Primary Care Division, HSE. 12 March 2015.
\(^{28}\) IPU (2015) Presentation to the Joint Oireachtas Committee on Health & Children by the IPU. 5 March 2015.
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Recommendation 5: State/Industry agreement ‘savings / cost reduction’ figures

5.1. There is a need for the HSE to reconcile the various figures to provide a firm, measurable figure for overall savings and/or cost reductions achieved from 2006 to October 2015.

5.2 A more frequent publication of data on cost savings merits consideration. This would allow appropriate scrutiny by all stakeholders, including the Select Committee on Health and Children as part of its financial scrutiny of the Department of Health’s Estimates of Expenditure.

5.3 The Committee recommends that consideration be given to the inclusion of key performance indicators for drug price savings under a new Agreement.

In its opening statement to the Joint Committee on 5 March, Teva Pharmaceuticals suggested that €113m per annum in additional savings could be achieved in four specific areas set out as follows:

a. €60m by opening up generic competition in the low value / volume sector of the medicines market which currently costs €200m annually;

b. €25m by instructing prescribers in hospitals to switch from expensive biological medicines to more affordable, bio-similar alternatives;

c. €15m by allowing pharmacists to dispense more affordable generic alternatives to first time patients on a particular course of medication (where their medication is included on the non-interchangeable list);

d. €18m by incentivising cost-effective prescribing for non-interchangeable medicines such as inhaler devices.

Teva Pharmaceuticals indicated that it has presented these recommendations to the HSE, Department of Health and the Department of Public Expenditure and Reform.

Recommendation 6: Potential additional cost savings

The HSE and the Department of Health should consider providing a response on the suggested €113m cost savings as detailed by Teva Pharmaceuticals, incorporating measures such as generic alternatives and cost-effective prescribing.

2.5 An Irish Medicines Service and Medicine Use Reviews (MURs)

Committee hearings also considered the potential for community pharmacists to play a more pro-active role in reviewing prescription use. In this regard, the IPU highlighted the UK New Medicines Service (NMS) model as an example of best practice. Under Medicines Use Reviews (MURs), community pharmacists meet with patients with long-term illnesses to carry out joint reviews of their prescriptions on an annual basis.
The findings from the NMS suggest that such reviews have the potential to enhance patients' lives, reduce the number of hospital stays, and result in more effective use of prescription drugs.

MURs are used in the UK and were previously recommended by the Joint Committee in 2007. A MUR pilot project prepared for the HSE’s Primary Care Group in 2012 recommended that they should be implemented as a practice-based service supported by the HSE. The IPU has also previously made this recommendation to the Committee (July 2014) where it highlighted the finding that, in Scotland, such reviews have reduced hospital re-admission rates by more than 30% for elderly patients suffering chronic illnesses and taking multiple medications.

### Recommendation 7: Feasibility of an Irish Medicines Service and Medicine Use Reviews

7.1 The Committee recommends that the feasibility of establishing an Irish Medicines Service. The introduction of Medicine Use Reviews (MURs), where patients with long-term illness, jointly review their prescriptions with pharmacists on a regular basis, also merits examination.

7.2 The Minister should also consider what other steps can be taken to support and enhance the role of the pharmacist in the provision of primary care to patients.

### 2.6 Bio-similar and High Tech molecule products

According to the HSE’s opening statement to the Committee on 12 March, the High Tech Drug (HTD) scheme is the only PCRS scheme which has seen an increase in expenditure from €315m (in 2009) to €485m (in 2014), or 54%. According to the HSE, “in the future, the expectation is that new medicines will in the main be in the High Tech area”. As such, action in this area is viewed as necessary.

One option, proposed by some stakeholders, is for the State to enact legislation to facilitate the listing of bio-similar or High Tech molecule medicines as “interchangeable”, something which is currently prohibited.

The APMI recommended legislation to facilitate the prescribing of bio-similar and High Tech molecule medicines. In Committee hearings, it was stated that this could reduce the State’s pharmaceutical bill, treat more patients within existing budgets, and allow improved access for patients to newer, innovative medicines. An enhanced use of biosimilars was also endorsed by Teva Pharmaceuticals as a means of achieving an additional €25m in cost savings. Such a measure would impact on prescriber behaviour / procurement processes in hospitals and facilitate switching to a bio-similar alternative.

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31 Joint Committee on Health and Children *Expanding the Role of the Pharmacy*, 1 July 2014.
Recommendation 8: Bio-similars and the High Tech molecules

8.1 It is necessary to clarify if the Government expects to introduce legislation to enable the interchangeable prescription of biosimilar pharmaceuticals to Irish patients, or whether any consultations have been held to assess any likely regulatory impacts of such measures.

8.2 The potential application of a financial incentive mechanism for pharmacists to supply generic versions of products on the HTD scheme should be assessed.

2.7 Prescriber behaviour

A number of issues related to prescriber behaviour were raised by stakeholders at the Committee hearings. The following represents brief overviews of the main topics.

2.7.1 Single, accessible, patient website (drug information)

The need to provide accessible and understandable information on prescription pharmaceuticals to patients is a significant issue. Referring to patient preferences, Professor Colum Dunne of the University of Limerick indicated in his opening statement that “the information available on the internet may influence the understanding of generic medicines…very similar to other jurisdictions, in Ireland none of the websites most likely to be seen by a searcher demonstrated the desired combination of providing high quality information in a readily accessible fashion”[32].

Research found that unverified sources such as Wikipedia were identified as “far and away” the primary source of information for Irish patients on prescription drugs. In response, a new web tool, ‘Understand Generics’ was developed and validated to remedy this deficit.

Recommendation 9: Development of a single web-based resource for patients and awareness campaign

Misinformation may potentially threaten patient safety and should be comprehensively addressed through a reliable and accessible patient-focused resource.

9.1 An accessible and comprehensive website and comparator tool should be developed and promoted to provide both prescribers and patients with information on all available pharmaceutical products in Ireland, similar to the role of the website ‘Understand Generics’.

9.2 A further awareness and educational campaign, to promote the use of generic pharmaceuticals, could also be actively promoted by the HSE in partnership with pharmaceutical representatives, the IPU and the Irish College of General Practitioners (ICGP).

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[32] Dunne, Colum. Opening Statement by Prof. Colum Dunne – Foundation Chair and Director of Research, Graduate Entry Medical School, University of Limerick, 5 March 2015.
2.7.2 Prescribing patterns

The prescribing behaviour of GPs, and discretion of community pharmacists is a prominent issue. Professor Dunne stated that a larger study of the prescribing behaviour of GPs, including a body such as the Irish College of General Practitioners, should be considered.

Recommendation 10: Prescribing Patterns

10.1 A detailed study is needed on prescribing patterns in Ireland. This could be conducted under the auspices of the HSE’s Medicine Management Programme which already enjoys a strong, collaborative working relationship with the ICGP.

10.2 In the interests of transparency and informing patients and prescribers alike, the HSE’s Medicines Management Programme could consider providing regular written updates to the Committee to ensure progress can be sustained.

Although pharmacists have no role in the setting of reimbursement prices for medicines, the role of the community pharmacist is recognised as integral to the provision of advice to patients on generic substitution. Under the Health (Pricing and Supply of Medicines) Act 2013, pharmacists have the discretion to supply a substitute generic product (via the designated Interchangeable List) if a proprietary branded drug is not explicitly written on the prescription by the GP.

The role of the pharmacist extends also to improving patient awareness including in relation to supporting patients to make healthier lifestyle choices. As stated by the IPU:

“Pharmacists spend many hours at the counter telling patients that the little white tablet that is round and flat is the same as the little blue tablet that may be oblong.”

The Committee previously held a hearing on ‘Expanding the Role of the Pharmacy’ (1 July 2014) with the IPU, which helped to inform the Committee’s recommendations.

Recommendation 11: Expanding the role of the community pharmacist

11.1 Considering the wide knowledge possessed by community pharmacists and their proximity to patients, a detailed analysis of the potential to expand their role with respect to the delegation of prescribing competencies merits further consideration.

11.2 The Committee supports the reclassification by the Health Products Regulatory Authority (HPRA) of a broader level of medicines from ‘prescription-only’ to over-the-counter (OTC) medicines, in line with best practice in other EU countries.
2.7.3 Pricing transparency of prescription medicines

As part of its discussion, the Committee considered the issue of price transparency and possible measures to enhance competition in the pharmacy sector.

In 2013, the then-National Consumer Agency (NCA) published research\textsuperscript{33} found a high level of variation in prices charged from pharmacy to pharmacy, arising from individual pharmacies’ dispensing fees. The NCA recommended measures to allow patients to more easily compare the costs of prescription medicines between pharmacies.

In its 2012 Report ‘Delivery of Pharmaceuticals in Ireland – Getting a Bigger Bang for the Buck’, the ESRI recommended that a standard template should be used in pharmacies to display the dispensing fee, and the level of mark-up\textsuperscript{34}.

In discussion with the Committee, the IPU stated that it does not gather data on private pricing from among its 1,700 member pharmacies, as this would contravene competition law. The IPU also highlighted the fact that advertising of prescription-only medicines to the general public is not permitted.

The Committee also heard evidence from Healthwave, which outlined a new business model for a subscription-based retail pharmacy based in Dublin. In its submission, it placed a strong emphasis on the fact that it publishes and displays its prescription medication prices to ensure that consumers are better informed.

Mr Shane O’Keeffe from Healthwave noted that initial complaints about this practice were made to the PSI by competitor pharmacies:

“The most basic change we made when launching Healthwave in 2013 was to publish our prescription prices for everyone to see…Thankfully, the pharmacy regulator moved to support this transparency, and in 2014 published guidance encouraging other pharmacies to follow suit.”

The Pharmaceutical Society of Ireland subsequently published guidance in 2014 on this matter, stating that the display of factual information, such as price lists, is permitted provided certain clarifications are given.

 Recommendation 12: Standard pricing templates

In the interests of ensuring a high-level of public transparency, and to enhance consumer choice, the display by community pharmacists of a standard template detailing fees merits consideration by the PSI.

\textsuperscript{34} Ibid, Recommendation 6.1.
2.7.4 Community Pharmacies and Alternative Business Models

The Committee examined the future role of Irish community pharmacies, and the emergence of alternative business models. Community pharmacists face a number of challenges including increased competition and reduced margins arising from government measures to reduce the cost of pharmaceuticals.

Healthwave is an example of a new model of discount-pharmacy. Such pharmacies generally operate in urban centres as providers of high volume discount services to its members, mainly providing generic products. This model is also notable for offering a delivery service on a regional basis in urban centres. The benefits of new pharmacy models were discussed in terms of affordability, and in terms of providing transparent pricing systems to members. The Department of Health acknowledged the valid role played by new business models in the health service.

However, differences were also highlighted between pharmacists who provide a whole-of-service approach, and discount pharmacy models. The likely emergence of a new range of online pharmaceutical services was also presented as a future issue for consideration by regulators and policy-makers:

“If one needs a prescription late at night and one is in Cork, west Clare where I am from or wherever, one will want a local pharmacy at which one can get a prescription for that child and get it quickly to avoid a hospital admission. If one is in the unfortunate position of having a family member who is coming home to spend his or her last few days with one and if one needs access to opiates of whatever, one will not be going to a pharmacy in south Dublin with a huge population around it. That model is built on chronic patients with no changes whatever and our pharmacy model delivers a great deal more than the other type of model.”

2.7.5 Packaging

Professor Dunne highlighted that patient behaviour may be impacted directly by addressing colour, shape and packaging differences between patented pharmaceuticals and their generic equivalents. This, according to Professor Dunne, is a matter for the manufacturers.

**Recommendation 13: Pharmaceutical packaging**

Generic manufacturers should take appropriate account of the packaging similarities between their products and the branded or off-patent equivalent in order to reduce confusion for patients.

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35 Mr Shaun Flanagan, HSE: Evidence to Joint Committee on Health and Children, 12 March 2015