IRISH PHARMACY UNION
The voice of community pharmacy

Submission under the Financial Emergency Measures in the Public Interest Act 2009

Irish Pharmacy Union

June 2018

Executive Summary

1. The Financial Emergency Measures in the Public Interest Act 2009 (FEMPI Act) and the regulations made under it were used to cut payment rates to pharmacists and other professionals, which, if it were not for the emergency in the State's finances, would have been unlawful.

2. The community pharmacy sector is experiencing a decade-long decline. Between 2009 and 2017, the State, through both FEMPI and non-FEMPI related measures, extracted a total of approximately €3.1 billion from the community pharmacy sector in reduced medicine reimbursements and cuts to pharmacy fees.

3. HSE PCRS statistics for 2009 to 2016 (2017 not yet published) show that the cost of medicines to the State has reduced by 33%. There has been a 15.8% decrease in the fee per item paid to pharmacies, and pharmacy output and efficiency have increased as the average fee payments to each pharmacy have fallen by nearly 17%. In addition to the cut in the fees paid per item dispensed, the HSE systematically reimburses pharmacies for many medicines at or below the prices pharmacies pay, with all refrigerated medicines currently systematically under-reimbursed by 4.8%.

4. Having come through a very difficult period, the economy has now recovered strongly, which is having a very positive impact on all fiscal indicators. The CSO estimates that *'modified domestic demand'* expanded by 3.9% in 2017. Ireland's government debt to GDP ratio declined to 68.5% last year, down from 120% in 2013. The Health Service has been allocated an extra €685 million in current and capital funding for 2018.

5. The costs of doing business in Ireland are much higher than in most other states in Europe. The cost of labour is the most significant driver of business costs, in addition to increasing rents (31.5% increase from 2014 – 2016), very high insurance costs (professional indemnity costs alone have increased by 70% in two years), and high regulatory, registration and waste disposal costs. Upward pressure on staff costs is increasing in line with wage growth in the economy and increases in both the minimum wage and in State salaries, but without a commensurate increase in pharmacy income.

6. There have been other significant changes in circumstances, making it no longer justifiable for there not to be a substantial reversal of the cuts in payments to pharmacists under FEMPI. Since 2009, €3.1 billion has been extracted from the community pharmacy sector, €1.73 billion of which was not under FEMPI. For example, the savings achieved under reference pricing alone amounted to an extraordinary €837 million by the end of May 2018.

7. The cost of the restoration of public pay under the Public Service Pay and Pension Act 2017 will be €844 million up to September 2018, which is equivalent to 38% of the €2.2 billion savings made in the public pay bill under FEMPI. By comparison, the amount promised in 2016 to be restored to community pharmacists was miniscule and, even so, was inexcusably not delivered.

8. The State's spend on High Tech drugs is a key factor in the HSE's medicines budget – it accounted for €612 million or 39% of the HSE's spend on medicines in 2016, up from €315 million or 19.8% in 2009. No margin on drug cost is made on these High Tech items by pharmacists, nor do they add to pharmacy revenues, as they are procured and paid for separately by the State.

9. Pharmacists expect a significant and immediate unwinding of FEMPI. There have been consistent and repeated statements from various Ministers, including the Minister for Health, Simon Harris TD, regarding this. Following the publication of the then Public Service Pay and Pensions Bill in 2017, Minister Harris, along with the Minister for Public Expenditure and Reform, made it clear in a number of statements that they are committed to engaging with health contractors on the revision of fees, as allowed under the new Act in 2018. Despite this commitment, there has been no engagement as yet with the IPU on behalf of community pharmacy contractors.

10. In May 2017, the Sláintecare report outlined the severe pressures on the Irish health service, and the requirement for health services to be reoriented towards primary care. There are simply not enough GPs to deliver this shift to primary care. The solution lies in the underutilised network of 1,830 Irish community pharmacies and the highly trained, strictly regulated pharmacy professionals around the country who are trusted by the public, and have demonstrated success in providing new services. The IPU has consistently argued for expansion of the services that pharmacists offer and has put forward costed proposals in this

regard, as well as quantifying the benefits that community pharmacy can deliver to the patient and to the wider health system.

11. Pharmacies have delivered excellent value for money to the State in the face of massive cuts to fees. A recent analysis by accountants Smith & Williamson concluded that the current fee is set at an uneconomic level for the service provided, given the time taken by a qualified professional with regulatory obligations and reporting requirements to deliver the service.

Immediate Requirements

1. **Implementation of Dorgan Report:** The process for the complete unwinding of FEMPI should see the implementation of the recommendations of the Independent Body on Pharmacy Contract Pricing, established by the Minister for Health and Children in 2008, and chaired by Sean Dorgan. Pharmacies have delivered excellent value for money to the State in the face of massive cuts to fees. The Dorgan report recommended a tiered fee of €7.00 per item dispensed for the first 20,000 items, €6.50 for the next 10,000 items and €6.00 for each other item dispensed per month.

2. **Agree a new contract to deliver modernity and change:** Community pharmacists have cooperated with significant work changes including the introduction of new validation and accountability measures for the HSE. This increased administrative workload in pharmacies has come at significant cost to community pharmacy contractors in terms of time and resources, while being of no direct material benefit to pharmacists or their patients.

   The State needs to reciprocate by implementing system improvements that will benefit pharmacies and patients while reducing unnecessary bureaucracy. The State schemes are themselves unnecessarily complex and inefficient. In order to bring about improvements in this regard, the IPU repeats its calls for the following:

   (i) a framework agreement to govern relations between the HSE and the Department and the IPU; and

   (ii) a new contract to replace the outdated and malfunctioning contract between the HSE and pharmacy contractors.

3. **Develop pharmacy services as a solution to health sector constraints:**

   EY-DKM has analysed the Irish community pharmacy sector and has concluded that there is an under-provision of certain services in pharmacies in rural and disadvantaged areas, where demand for these services is higher. There is less opportunity in these areas for pharmacies to develop the retail business which is necessary to subsidise the income from State schemes, upon which rural pharmacies are utterly reliant. It is clear that the State urgently needs to invest in enhanced pharmacy-based services which, internationally and domestically, have demonstrated real benefits in terms of patient outcomes, reduced total care costs and, crucially, the additional capacity which can be released in more complex healthcare settings such as General Practice and Emergency Departments.

Conclusion

Any fee payment model and reversal of FEMPI must be viable and realistic, providing a sustainable dispensing fee across all schemes, with appropriate professional and administrative allowances to cover State-imposed costs, and supports for marginal pharmacies in disadvantaged, rural or isolated communities. Unless dispensing fees are increased to the levels recommended in the Dorgan Report of 2008, a significant number of non-urban pharmacies will ultimately close.

The Dorgan Report recommended a tiered fee, as set out below:

Figure 1: Dispensing Fees recommended by Dorgan Report 2008

Number of items dispensed per annum	Fee per Item
Up to 20,000 items	**€7.00**
20,001 to 30,000 items	**€6.50**
Over 30,000 items	**€6.00**

Recent independent analysis by EY-DKM Economic Consultants and Smith & Williamson Accountants indicates that fees at this level, index linked to today and into the future, are imperative for a sustainable pharmacy sector across the country. The Dorgan Report also noted their "strong view that a new contract is required urgently and that the parties should move to achieve that". Ten years on, it is past time that the Minister and the HSE engaged with the IPU in such discussions.

1. Introduction

The FEMPI Act and the regulations made under it were used to cut payment rates to pharmacists and other professionals, which, if it were not for the emergency in the State's finances, would have been unlawful.

Under the FEMPI Act, the Minister "may from time to time", and shall "every year after 2010 carry out a review". We anticipate, given the correspondence between the IPU and the DoH and following on from previous commitments, that the IPU will be consulted prior to the Minister making regulations, having not made any variance to regulations following the formal consultation process in 2016 despite commitments to do so. Furthermore, in June 2017, the IPU was requested to make a submission, which we duly did, but there was no formal engagement process, despite our request for one, nor were fees increased as they should have been in light of the unwinding of FEMPI-related cuts for all public servants.

We expect that, in accordance with the FEMPI Act, and the new Public Service Pay and Pension Act 2017, there will be a review in 2018, through which the Minister for Health, in exercise of his powers under the Acts, will make regulations varying the payments to community pharmacy contractors.

2. Background

Section 9 of the Financial Emergency Measures in the Public Interest Act 2009 (as amended) (FEMPI Act) provided for the introduction of regulations to permit the Minister to make reductions[1] to the fees payable to community pharmacy contractors, "notwithstanding any other

[1] The FEMPI Act was amended in 2015 to allow the Minister to "*vary*" payments to health professionals (and not just reduce them).

enactment, contract, arrangement, understanding, expectation, circular or instrument or other document".

The justification for this is set out in the recitals to the FEMPI Act, which include the following:

> "WHEREAS a serious disturbance in the economy and a decline in the economic circumstances of the State have occurred, which threaten the wellbeing of the community."
>
> "AND WHEREAS it is necessary to cut current Exchequer spending substantially to demonstrate to the international financial markets that public expenditure is being significantly controlled so as to ensure continued access to international funding, and to protect the State's credit rating and reverse the erosion of the State's international competitiveness."

The regulations made under the FEMPI Act, which affect community pharmacy contractors are S.I. No. 246/2009 – Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2009, S.I. No. 300/2011 – Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2011 and S.I. No. 279/2013 – Health Professionals (Reductions of Payments to Community Pharmacy Contractors) Regulations 2013.

These regulations introduced wide-ranging reductions to the payments to community pharmacy contractors, and the effect of these reductions is set out below:

- The 2009 Regulations resulted in the reduction of payments in respect of the wholesale mark-up on medicines from 17.66% to 10%, the introduction of a common sliding dispensing fee (€5.00 for the first 1,667 items, €4.50 for the next 833 items and €3.50 for any additional items) for all schemes, and a reduction in the retail mark-up on drug items paid in a number of schemes from 50% to 20%;
- The 2011 Regulations introduced further reductions – a reduction in the payments in respect of the wholesale mark-up/ingredient cost from 10% to 8%, a reduction in the wholesale mark-up/ingredient cost on controlled drugs from 17.66% to 8%, a reduction in the wholesale mark-up/ingredient cost on fridge items from 17.66% to 12%, a reduction in the retail mark-up on non-drug items from 50% to 20%, a reduction in the High Tech non-dispensing fee from €62.03 to €31.02, and a reduction in the allowance on stock-orders from 25% to 20%; and

- The 2013 Regulations introduced even further reductions, by the removal of the 20% retail mark-up for drug and non-drug items under DPS/LTI Scheme payment entirely.

As part of his review the Minister is required to:

1. Review the operation, effectiveness and impact of the amounts and rates fixed by regulation; and
2. Consider the appropriateness of those amounts and rates, having regard to any change of circumstances and, in particular, any alteration of any of the matters in Section 9(5)(a)-(g)[2].

In light of all the circumstances, we must assume that, despite the absence of an invitation to make a submission, the Minister will consider that it is now appropriate to adjust the amount or rate of payment to community pharmacy contractors, and will therefore wish to consult with the IPU before then fixing the amounts or rate he considers to be fair and reasonable in light of the purposes of the Act, including the matters listed at Section 9(5)(a) – (g)[3].

3. The Operation, Effectiveness and Impact of the Amounts and Rates Fixed

At the outset of this section, we wish to make two important points before discussing the effectiveness and impact of the amounts and rates fixed under FEMPI:

[2]

a. The terms of any existing contractual arrangements or understandings with community pharmacy contractors or any expectation on their part;
b. The terms of any circular, instrument, or document which apply to community pharmacy contractors;
c. Any submissions made and views expressed during the consultations;
d. The nature of the services rendered by different classes of health professionals and the general nature of expenses and commitments of the health professionals providing those services;
e. The impact, if any, on the State's ability to continue to provide health services at existing levels;
f. The fairness and efficiency of any method of effecting any amendment to payments having regard to the requirements of good and effective administration; and
g. The need to retain firm control of current Exchequer expenditure so as to ensure ongoing access to international funding and improve competitiveness, while taking into account the continuing risks to the public finances which remain, and the need to meet the State's commitments to have a prudent fiscal policy under the Stability and Growth Pact and the Fiscal Compact.

[3] We note that under Section 9(5) of the FEMPI Act, when making regulations to fix amounts or rates the Minister believes to be fair and reasonable, he may have regard to the matters listed at Section 9(5)(a) – (g), whereas in the review to be carried out by the Minister under Section 9(13), he is required to have regard to any alteration of the matters listed in Section 9(5)(a) – (g).

1. The FEMPI Act requires the Minister to review the operation, effectiveness and impact of the amounts and rates fixed under the regulations (e.g. the reduced dispensing fees per item of €5.00, €4.50 and €3.50). The cumulative figure of fees paid to pharmacists by the PCRS under the State schemes depends on a variety of factors, primarily the number of medical cards in issue, and the figure is not relevant when considering the amounts and rates fixed under the regulations.

2. In recent years, the DoH has argued that cuts to the wholesale margin (defined as the ingredient cost in the regulations) are not cuts to the income of pharmacists, and it has not considered these cuts as part of its analysis. However, under the review process in the FEMPI Act, the Minister is required to "review the operation, effectiveness and impact of the amounts and rates fixed by regulation" and "consider the appropriateness of those amounts and rates".

   The cuts to the wholesale margin/ingredient cost were cuts made under the FEMPI regulations. Furthermore, Section 9(19) of the FEMPI Act specifically provides that payment in respect of a service rendered includes payment in respect of goods provided as part of that service. As such, there is a legal obligation to review the effectiveness and impact of the cuts to the wholesale margin/ingredient cost, in addition to reductions in dispensing fees and mark-up payments.

It is calculated that, since 2009, there has been a minimum of €1.386 billion[4] in cuts to payments to pharmacies under FEMPI. This comprises €527 million in cuts to dispensing fees and mark-up and €859.5 million in cuts to the wholesale margin/ingredient cost. By any measure, the cuts in the amounts and rates paid to community pharmacy contractors under the 2009, 2011 and 2013 regulations have been exceptionally effective in achieving savings for the State.

The average value of State fee and mark-up payments has fallen from €6.21 per item in 2009 to €5.29 per item in 2017. Figure 2 applies these average annual reductions to total State scheme dispensing during the same period.

[4] These figures have been prepared by Chartered Accountants Fitzgerald Power based on published PCRS data and an in-depth two-year study of the sector. As published PCRS information only runs to 2016, State savings for 2017 are estimated based on historical results.

Figure 2: Reductions in Fees and Mark-ups Paid to Pharmacists by the State

Year	Pharmacy fees & mark-ups	No. of items dispensed under State schemes	Mark-up & fees per item	Reduction per item since 2009	State savings
2017 (estimate)		76,312,934	€5.29	€0.92	€70,182,372
2016	€397,440,000	75,175,841	€5.29	€0.92	€69,136,626
2015	€389,740,000	73,542,223	€5.30	€0.91	€66,697,624
2014	€381,070,000	72,715,536	€5.24	€0.97	€70,236,816
2013	€393,930,000	74,378,504	€5.30	€0.91	€67,697,977
2012	€403,860,000	75,724,736	€5.33	€0.88	€66,123,326
2011	€386,630,000	72,023,261	€5.37	€0.84	€60,380,232
2010	€372,990,000	69,251,377	€5.39	€0.82	€56,816,616
2009	€420,960,000	67,825,991	€6.21		
Total					**€527,271,589**

4. Appropriateness of Amounts and Rates having regard to any Change of Circumstances

4.1 Reference Pricing and Other Non-FEMPI Cuts to Medicine Prices

As detailed in Section 3, the cuts to payments to pharmacies under FEMPI have amounted to €1.3 billion. This means that, in the period from 2009 – 2017, an additional €1.8 billion in savings has been realised by the State in reduced payment for medicines, as well as cuts already imposed under FEMPI. These further reductions are undoubtedly a very significant change in circumstances and must therefore be taken into consideration by the Minister.

Figure 3: Reductions in Medicine Reimbursements Paid to Pharmacists by the State

Year	PCRS payments for medicines	Items dispensed under State schemes	Cost per item	Reduction per item since 2009	FEMPI reductions	State savings
2017*		75,579,617*			€84,500,000*	
2016	€945,900,000	74,494,210	€12.70	€6.18	€84,492,157	€460,509,104
2015	€956,750,000	72,911,181	€13.12	€5.76	€85,461,329	€419,772,401
2014	€979,010,000	72,132,792	€13.57	€5.31	€87,449,695	€382,816,851
2013	€1,053,290,000	73,823,818	€14.27	€4.61	€94,084,728	€340,462,478
2012	€1,161,460,000	75,202,381	€15.44	€3.43	€103,746,972	€258,318,978
2011	€1,114,610,000	71,590,122	€15.57	€3.31	€99,562,113	€236,971,544
2010	€1,191,880,000	68,860539	€17.31	€1.57	€106,464,227	€108,168,541
2009	€1,273,770,000	67,468626	€18.88		€113,779,020	
Total					**€859,540,240**	**€2,207,019,896**

(*estimate)

Since reference pricing was introduced in November 2013, it has had an egregious effect on pharmacies. On average from December 2013 to May 2017, the revenue lost to an average individual pharmacy was €463,000. By July 2018, 52 molecules will have been reference priced. In 2016 that number stood at 38. Since 2013, hmR Ireland data estimates that **close to €837 million of savings have been generated for the State, largely at the expense of pharmacy margins**.

4.2 Economic Improvement

In 2009, the Irish economy and its financial system were in a very difficult place. That year, gross domestic product (GDP) contracted by 5.6% and gross national product (GNP) contracted by 8%[5]. Ireland's international reputation and, consequently, the ability of the Government to borrow at realistic borrowing costs were under serious pressure.

[5] The figures and analysis in this section have been provided by economist Jim Power.

The first estimate of growth in the Irish economy for 2017 from the Central Statistics Office suggests that there was growth in real terms in the Irish economy of 3.9% last year. In 2017, Ireland's government debt to GDP ratio declined to 68.5% from 120% in 2013. Consumer spending on goods and services increased by 1.9%, net government expenditure expanded by 1.8%, and net exports expanded by €40.7 billion. Having come through a very difficult period, the economy is now recovering strongly, which is having a very positive impact on all fiscal indicators and the international reputation of Ireland.

As we approach the mid-point of 2018, the economic growth background remains positive. The Department of Finance[6] is now forecasting GDP growth of 5.6% this year followed by an expansion of 4.0% next year, and also GNP growth of 5.6% in 2018. The medium-term forecasts for the economy are also projected to be strong. Between 2017 and 2021, real GDP growth is forecast to average 4.7% per annum and real GNP growth is forecast to average 4.3%. Employment is projected to reach 2.389 million by 2021 and the unemployment rate is projected to average 5.4% in 2021. The GGB is forecast to move into modest surplus in 2020, with a surplus equivalent to 0.4% of GDP projected by 2021.

It is clear that the 'crisis' situation that lead to the introduction of the FEMPI legislation has passed, and the future now looks considerably better. There has been a monumental change in the finances of the State and the state of the economy, the disastrous state of which were of course the underlying rationale and justification for the cuts in the first instance. **The justifications set out in the recitals of the FEMPI Act** (see Section 2 of this submission) **no longer apply**.

4.3 Restoration of Public Sector Pay

According to analysis by economist Jim Power, FEMPI measures are estimated, in total, to have resulted in over €2.2 billion in direct reductions in public service remuneration and pensions[7].

[6] Stability Programme Update, Department of Finance, April 2018.

[7] Under the FEMPI Act 2009, a comprehensive pay cut for public sector workers was introduced at the beginning of 2010. That graduated pay cut yielded savings of €1.2 billion in the pay bill in 2010. A further reduction in pay, ranging from 5.5% to 10%, for those earning more than €65,000 was introduced in July 2013 under the FEMPI Act 2013.

The FEMPI 2010 Act introduced the Public Service Pension Reduction (PSPR), which came into effect on 1 January 2011. The 2010 Act introduced an income-graduated reduction applied to each gross annual public

Under the FEMPI Act 2015, the process of reversing the cuts to public sector pay and pensions has been put in train. The cost of the measures under FEMPI 2015 will be €844 million in the period to September 2018, which is equivalent to 38% of the €2.2 billion savings made in the public pay bill under FEMPI. It is clear that the €844 million contained under FEMPI 2015 represents the first phase of pay restoration; eventually most, if not all, of the cuts to public service pay will be reversed. From 1 January 2018 the Public Service stability agreement 2013 – 2018 will be extended until December 2020 which the Government estimate will cost €887 million over the three years.

Not only has the economy improved markedly and public sector pay under FEMPI been restored to a far greater degree than is proposed in respect of pharmacists, there have been other significant changes in circumstances which mean **it is no longer justifiable for there not to be a substantial reversal of the cuts in payments to pharmacists implemented under FEMPI**.

5. Matters to be considered in Decision on Fair and Reasonable Amounts or Rates

In addition to considering the submissions of the IPU when making the regulations, the Minister is required to consider the following points.

5.1 Terms of Existing Contractual Arrangements and Understandings and Expectations

The expectation of pharmacists is that there will be a significant immediate unwinding of FEMPI. This expectation arises from consistent and repeated statements from Ministers, including the following:

1. The Minister for Finance and Public Expenditure and Reform, Pascal Donohoe TD, in a statement to the Oireachtas on Thursday 29 June 2017, said, "*The legislation [FEMPI] that is*

service pension in excess of €12,000, amounting to an average reduction of 4% to pensions in payment before 29 February 2012. Further reductions were applied to pensions of €32,500 and over from 1 July 2013, under the 2013 FEMPI Act. Both these measures were together expected to yield full-year savings of around €125 million.

the subject of this debate was necessary to restore order at a time of unprecedented economic crisis. That said, the Government is committed to the affordable and orderly unwinding of the legislation". In an address to the Oireachtas during the second stage of the Public Service Pay and Pension Bill in November 2017, Minister Donohoe further committed to engaging with health contractors "*As part of these transitional arrangements and in the context of exiting the FEMPI legislative framework, the Minister for Health has announced that he intends to initiate a process of engagement in 2018, in consultation with my Department, with relevant representative bodies on service delivery, contractual reform and associated fees. This process will aim to conclude a multiannual approach to fees, commencing in 2019, in return for service improvement and contractual reform, and in line with Government priorities for the health service*."

2. The Minister for Health Simon Harris TD, when addressing the IPU conference in April 2017, stated "*there are undoubted opportunities for community pharmacy contractors in the shift to primary care. There will be significant state investment in this process. With our changed economic circumstances and the future of FEMPI, we are considering our options for moving forward. I am equally clear that expanded remuneration must be tied to improved and extended services.*"

3. A letter from the Chief State Solicitor dated 8 January 2016 (following agreement to settle the case of J & J Haire Company Ltd v Minister for Health and Children) stated, "*It is the intention of the Minister for Health to initiate a formal consultation process under section 9 of the FEMPI Act 2009 before the end of January 2016 in relation to the regulations made pursuant to section 9 in relation to payments to community pharmacy contractors. It is the Minister's intention to consider, determine and implement, as soon as possible following the consultation process, regulations which, with the consent of the Minister for Public Expenditure and Reform, will have the effect of varying, whether by formula or otherwise, the amount or rate of payment to contracted community pharmacies under the powers conferred on him by section 9(1) of the Act as amended in 2015.*"

Pharmacists, therefore, have a very clear understanding from the Government that FEMPI will be unwound. It is understood by pharmacists that in unwinding FEMPI in its application to public servants, or to a specific class of health professionals, both the negotiation process and any

actions taken in this regard must be applied equally to all others impacted by the legislation. There must be parity of application and of process, and the unwinding must of course be fair, equitable and proportionate to each profession in terms of the cuts suffered by each. This understanding was expressed in correspondence from the IPU to the Minister for Health and the Minister for Public Expenditure and Reform over recent years, and again in November 2017 following the publication of the Public Service Pay and Pension Bill.

5.2 Value for Money

The cumulative amount of money paid to pharmacists by the PCRS under the State schemes depends on a variety of factors, primarily the number of medical cards in issue, the mix of medicines prescribed, and the cost of those medicines. Other factors also have a sizeable impact upon the State's medicines bill, but are not pertinent in terms of the fees paid to pharmacies, in particular, the cost of High Tech medicines, which are initiated and prescribed in the hospital setting rather than in primary care. The number of High Tech items dispensed has increased from 357,365 in 2009 to 681,631 in 2016. The cost of these High Tech medicines in 2009 was €315.3 million; by 2016 it had increased to €611.7 million. No margin on drug cost is made on these High Tech items by pharmacists, nor do they add to pharmacy revenues as they are procured and paid for separately by the State.

Figure 4: High Tech Medicines Expenditure: (Ref PCRS Annual Reports)

Year	No. of High Tech items	HT fees to pharmacies €m	No. of pharmacies	Avg. HT fees per pharmacy €	Change on 2009	Avg. HT fees per item €	Change on 2009
2009	357,365	15.94	1,630	9,779.14		44.60	
2010	390,838	15.48	1,671	9,263.91	-5.3%	39.61	-11.2%
2011	433,139	18.00	1,690	10,650.89	8.9%	41.56	-6.8%
2012	522,355	17.10	1,713	9,982.49	2.1%	32.74	-26.6%
2013	554,686	17.50	1,744	10,034.40	2.6%	31.55	-29.3%
2014	582,744	17.30	1,778	9,730.03	-0.5%	29.69	-33.4%
2015	631,042	18.10	1,801	10,049.97	2.8%	28.68	-35.7%
2016	681,631	19.49	1,830	10,650.27	8.9%	28.59	-35.9%

Following an analysis of published PCRS data, Smith & Williamson calculated that, between 2009 and 2016, the State, using both FEMPI and non-FEMPI related measures, had extracted a total of approximately €2.686 billion in savings from the community pharmacy sector through a combination of reduced medicine reimbursements and cuts to pharmacy fees and mark-ups.

Figure 5: Average Pharmacy Payments 2009 – 2016

Year	No of pharmacies	Change on 2010	No of items per pharmacy	Change on 2009	Drug costs per pharmacy	Change on 2009	Fees/mark-ups per pharmacy	Change on 2009
2009	1,630		41,611		€781,454		€248,479	
2010	1,671	2.5%	41,443	-0.4%	€713,273	-8.7%	€213,950	-13.9%
2011	1,690	3.7%	42,617	2.4%	€659,533	-15.6%	€218,124	-12.2%
2012	1,713	5.1%	44,202	6.2%	€678,027	-13.2%	€225,779	-9.1%
2013	1,744	7.0%	42,648	2.5%	€603,951	-22.7%	€215,843	-13.1%
2014	1,778	9.1%	40,897	-1.7%	€550,624	-29.5%	€204,595	-17.7%
2015	1,801	10.5%	40,834	-1.9%	€531,233	-32.0%	€206,352	-17.0%
2016	1,830	12.3%	41,080	-1.3%	€516,885	-33.9%	€206,530	-16.9%

HSE PCRS statistics for 2009 to 2016 show that:

1. ***Pharmacy efficiency*** ↑: In 2009, 67,825,991 items were dispensed by 1,630 pharmacies, i.e. an average of 41,611 items dispensed per pharmacy. In 2016, 75,175,841 items were dispensed by 1,830 pharmacies i.e. an average of 41,080 items dispensed per pharmacy. Output per pharmacy dropped by only 1%, while the average pharmacy suffered a fall in payments of 16.9%**.**

2. ***Cost of medicines to State*** ↓: The cost of medicines reimbursed in 2009 was €1,273.77 million for 67.8 million items; this equates to an average cost per item of €18.78. For 2016, PCRS paid €945.9 million for 75.2 million items; this equates to an average cost per item of €12.58, which is a 33% reduction.

3. ***Fees and mark-ups to pharmacies*** ↓: In 2009, pharmacies were paid €405.02 million to dispense 67.8 million items, giving an average fee of €5.97 per item. In 2016 the figure was €377.95 million to dispense 75.2 million items, or an average of €5.03 per item. This is a 15.8% decrease in fees per item.

4. ***Average amount paid to each pharmacy*** ↓: The average amount paid to each pharmacy has reduced. In 2009, fee and mark-up payments totalling €405.02 million were paid to 1,630 pharmacies, an average of €248,479 per pharmacy. In 2016, €377.95 million was paid to 1,830 pharmacies, an average of €206,530 per pharmacy, which is a reduction of 16.9%.

5. ***Index linked fee would be €6.27***: If the average fees and mark-up per item paid to pharmacies in 2009, i.e. €5.97, were index linked using the Consumer Price Index (CPI) 2009 – 2016, the average fee per item in 2016 would have been €6.27, 25% higher than the €5.03 actually paid. Excluding fees for phased dispensing, which is a discrete service, the average fee payment per item in 2016 was only €4.15.

Any growth in medicines spending which has occurred in the last decade is due to increased spending on High Tech medicines, which are generally hospital-initiated and prescribed, and are funded separately to other medicines. Use of these medicines increased from 357,365 items costing €315 million in 2009, to 681,631 items costing €612 million in 2016 – an overall increase of 90.1% in volume and 94% in value. This has inflated the primary care drugs bill, but has not added to pharmacy turnover. In the meantime, all pharmacy business costs, including staff, property, regulatory and administrative costs, have increased.

5.3 Reimbursement

The HSE reimburses pharmacies for medicines at or below the cost pharmacies pay: currently, the reimbursement rate is at 91.8% of invoice cost for most medicines, and 95.2% on fridge medicines. There are now only two full-line medicines wholesalers remaining in Ireland. Typically, a pharmacy will have a preferred wholesaler and a secondary wholesaler, where the former generally offers a discount on the invoice price, bringing it to the level of the reimbursement price, while the latter does not. However, neither wholesaler carries all medicines, nor provides a discount on fridge medicines. This calls into question the sustainability of pharmacies supplying fridge medicines (e.g. insulin). In addition, due to the implementation a number of years ago of a stringent pricing policy by one of the two remaining full-line wholesalers, which now offers no discount on the first €2,000 of monthly purchases and charges pharmacists 9% above the reimbursement price on at least €24,000 of purchases per year, each pharmacy is effectively subsidising the HSE to the tune of thousands of euro annually.

5.4 Other Costs

The costs of doing business in Ireland are much higher than in most other states in Europe and therefore a higher gross profit is required to meet these costs.

The cost of labour is the most significant driver of business costs, particularly for service providers. With payments under the State schemes in steady decline, the scope for wage rate increases is narrow. With rates of pay creeping up across all staff categories, it is becoming increasingly difficult for pharmacy operators to balance staff retention considerations and commensurate rates of pay.

The State has commenced the reversal of FEMPI-related cuts to public sector pay, thereby improving the attractiveness to pharmacists and other staff of working in the public sector. The community pharmacy sector has to compete with public salaries and other terms of employment, such as hours of work, weekend cover, and other benefits. As the labour market tightens further and the national minimum wage is also increased, upward pressures on labour costs will be exacerbated.

Staff costs increased by 4.23% over a twelve-month period from €269,395 in 2016 to €280,807 in 2017. With revenues more or less flat, the proportional spend on wages and salaries increased. The average pharmacy spent 16.9% of turnover on wages and salaries; by 2016, this had increased to 19.6%. Community pharmacy must compete with HSE pay rates and conditions, which are improving as a result of FEMPI unwinding; this, combined with the attractiveness of permanent and pensionable posts allied with shorter and less anti-social working hours, means there is a difficulty attracting full-time and locum pharmacists and technicians into community practice.

After labour costs, property costs represent the next most significant cost factor in the profile of business costs. By 2016, prime retail rents in Ireland had increased by 31.5% on average since 2014, and Ireland was the fifth most expensive location in the Euro area (National Competitiveness Council 2017). In addition, rates and service charges imposed by local authorities also rank among the highest in the EU.

Insurance costs in Ireland rank among the highest in Europe. According to the IMF Country Report 2016 (no.16/311) insurance penetration in Ireland is almost three times the EU average and four times more premium per capita is spent than the EU average. Irish insurance costs have increased significantly above the UK rate and the Euro area average from early 2014, with pharmacists' professional indemnity premiums having increased by 70% since 2014.

Waste charges for disposal of medicines, which require special collection and disposal services, are expensive. General waste costs are also increasing with Irish landfill costs amongst the most expensive in the benchmarked countries/regions, at €113 per tonne. The importance of thermal treatment (incineration) is growing in Ireland. Thermal treatment costs (gate fees) in Ireland are also amongst the most expensive (c. €100 per tonne) in the benchmarked countries/regions.

Pharmacies have had to become extremely efficient over the last number of years, as a result of revenue and fee reductions. Additional overhead savings are now impossible, particularly in the principal overhead categories of employment and property costs.

5.5 Compliance Costs

The IPU recognises the importance of effective and transparent regulation; however, the cost of complying with new regulations and guidelines has increased significantly in recent years. This includes, for example, ongoing regulation costs, the cost of providing and maintaining consultation areas and, in general, compliance with the Pharmacy Act 2007.

The cost of registration with the PSI remains far out of line with international comparisons. The annual pharmacist registration fee is €380 (€540 on first registration), and each pharmacy must pay €2,135 per year to register (€3,325 on first registration).

6. Cooperating with Change and Modernity

6.1 Develop Pharmacy Services

The IPU notes the commitment in the Programme for Government to expand the role of the community pharmacist. By expanding the services that pharmacists provide, many of the healthcare needs of patients can be addressed in the existing facilities and infrastructure already in place in pharmacies across the country. Modest investment in pharmacy-based services would

free up crucial capacity in GP surgeries and achieve cost-efficient treatment across the continuum of care.

In Ireland, potential enhancements of the pharmacy service would include:

1. Improving equality of access to care;
2. Provision of oral contraception services and contraception advice;
3. Treating GMS patients for common ailments with Over the Counter medication;
4. Supporting better use of medicines for those newly starting a medicine for a long-term condition;
5. Supporting people with long-term conditions such as cardiovascular disease or asthma;
6. Improving the public's health through helping to deliver screening programmes as part of a national health promotion strategy; and
7. Provision of smoking cessation services.

The report, *Future Pharmacy Practice in Ireland – Meeting Patients' Needs*, published by the PSI in November 2016, outlined the potential role of pharmacy practice in patient care. The Minister for Health at the IPU conference in May 2017 stated that the Future Pharmacy Practice report was "*a key document for yourselves and for State policy. We are very keen, as I have said on more than one occasion, to expand community pharmacy services to our patients, particularly with the challenges we are facing, such as an aging population, the need for earlier hospital discharge and the increasing range of community-delivered treatment*".

Following the publication of the report, the IPU commissioned PwC to investigate and quantify the benefits that community pharmacy can deliver to the patient and to the wider health system in Ireland, and subsequently provided the Minister and Department of Health with costed proposals in this regard.

There is a very clear rationale for funding enhanced pharmacy-based services, based on successful international and domestic implementation of these services, which have demonstrated benefits in terms of patient outcomes, reduced total care costs and, crucially, the additional capacity which can be released in more complex healthcare settings such as General Practice and Emergency Departments.

The 2016 FEMPI review, carried out by the DoH, concluded with a recommendation to the Minister that changes to remuneration structures for community pharmacy contractors must be linked to Government priorities for the health service which, in the case of community pharmacy, included areas such as probity, piloting of a minor ailment service, vaccination, expansion of interchangeable medicine use and reference pricing, and electronic interface with the HSE PCRS. The IPU and community pharmacists have delivered on almost all of these, but no reversal of cuts to pharmacies' payments has yet been implemented or even committed to.

6.2 Probity

In 2016, the IPU signed a *Relationship Values Charter* with the HSE. As signatories to the charter, the parties agree to work together to maintain stable contractual relationships between the HSE and the community pharmacy contractors participating in the Community Drugs Schemes. The IPU has engaged constructively with the HSE and pharmacists have cooperated with new obligations to provide assurance that public funds and resources are managed to good effect, are properly accounted for, and are contributing to an improvement in public administration. Community pharmacists have, for example, cooperated with the introduction of new validation arrangements for the phased dispensing of medicines which provide greater financial transparency to account for State spending.

New procedures and directives from the HSE have dramatically increased the administrative workload in pharmacies and have come at significant cost to community pharmacy contractors in terms of time and resources, while being of no direct material benefit to pharmacists or their patients. However, they meet the requirements of the HSE to administer its resources economically and efficiently, and ultimately aim to satisfy the audit and validation requirements of the Comptroller and Auditor General.

7. Recognising the National Contribution made by Community Pharmacies

EY-DKM conducted an analysis of the contribution of the community pharmacy sector to the national economy. The community pharmacy sector employed approximately 9,140 full time and 7,300 part-time pharmacy level staff members in 2016, equivalent to 11,600 whole time

equivalents (WTE). This analysis excludes support or head office staff. The pharmacy profession in Ireland is young, with more than 70% being under 45 years of age.

Contribution to National GDP:

- Direct impacts, i.e. those that arise through the pharmacy sector's activity, are significant: total turnover in the sector is €1.915 billion, and in total the sector contributed €624 million to national GDP in 2016;
- Indirect impacts comprise €1.02 billion GDP, generated through the pharmacy sector's Irish supply chain;
- Induced impacts, as the direct and indirect wages are spent in the wider economy, are estimated to add a further €403 million to national GDP in 2016; and
- In total, the direct, indirect and induced contribution of the sector to national GDP was €2.046 billion in 2016.

Employment Impacts:

- Direct employment in the pharmacy sector is comprised of pharmacists, pharmaceutical assistants, technicians, and other retail and administrative staff. As of 2016, the total number of persons employed in the sector is 11,600 (WTE);
- Further indirect employment of 11,700 is generated in Irish firms that supply goods and services to the pharmacy sector, e.g. wholesalers and manufacturers and various business service providers;
- Induced employment impacts, i.e. additional employment as direct and indirect payroll is spent in the wider economy, is estimated at over 3,400; and
- Thus the total direct, indirect and induced employment impact of the community pharmacy sector in 2016 is estimated at approximately 26,700 (WTE).

Exchequer Impacts:

- The total tax benefit to the Exchequer from the above economic impacts is very substantial. The payroll, income and corporation taxes in 2016 are estimated to amount to €146 million, taking into account the direct impacts of the pharmacy sector itself;
- The Exchequer revenue from the indirect impact, back through the sector's Irish supply chain, is estimated at €196 million in 2016;
- The estimated Exchequer revenue from the induced impact is €124 million in 2016; and

- Thus the total Exchequer revenues in 2016 are estimated at €466 million.

It should be noted that the Exchequer revenue generated (€466 million) exceeds the total fees paid to pharmacies by the State in the year (€397 million).

7.1 Sustainability

The dispensing fee should be viewed from more than solely a financial perspective. The interaction between the pharmacist and the patient requires awareness and empathy, and an understanding of medicine, pharmacology, law, and public policy.

Given the dependence of many pharmacies on the dispensing fee as a source of income, and the needs of the State to provide services cost-effectively, it is natural that the State would seek to determine value for money. However, considering the level of expertise required to dispense medication safely, and the legal obligations that must be adhered to, the costs associated with maintaining a pharmacy business are significant, as has been outlined. It should also be noted that the additional services which are provided by the profession and the sector are often offered to the public voluntarily, without State remuneration, which suggests there is a substantial social value that must be accounted for in policy-making.

7.2 Present Challenges

As outlined herein, pharmacies face excessive and increasing State-imposed legislative and regulatory costs.

Pharmacies are required to install and maintain computerised patient medication record systems, at a minimum cost of €3,000 per terminal per year. IT changes which are required to facilitate State initiatives, such as collecting and accounting for the GMS prescription levy, or implementing generic substitution and reference pricing, have been funded entirely by the pharmacy sector. The Falsified Medicines Directive (2011/62/EU) mandates a medicines authentication process commencing in February 2019. This will necessitate the installation of additional software and scanners in pharmacies, at a likely cost of €300 – €500 per pharmacy per year, and will oblige pharmacies to scan a unique two dimensional barcode on every pack of medicine as it is dispensed to a patient to verify its authenticity. With approximately 90 million packs of medicine dispensed to Irish patients each year, and assuming 5 – 10 seconds per scan, this will consume

approximately 70 – 140 hours of staff time per pharmacy per year. Given an average hourly cost of €13.50 for a pharmacy technician, this implies an additional annual personnel cost of €945 – €1,890 per pharmacy. The Directive will cost each pharmacy between €1,245 and €2,390 per year, or an average of approximately €1,800.

There are mandatory CPD requirements, ePortfolio reviews, pharmacy practice reviews, significant medicine waste charges and the recent increase in the minimum wage. All of this involves further increased costs on pharmacists. Tonic Consultancy estimated that pharmacies already spend an average of €4,250 on pharmacy-specific training each year. Pharmacists have now had a model of CPD and practice assessment imposed, which is supposedly modelled on the system which applies in Ontario, Canada. One key difference is that in Ontario the regulator carries the full cost of participation in the practice assessments, whereas in Ireland the pharmacist must pay the cost of travel to the assessment venue in Dublin, and pharmacy owners carry the cost of having to provide alternative pharmacist cover to facilitate the process.

Figure 6: State-Imposed costs on pharmacy (Ref. Tonic Consultancy)

	Amount €
Falsified Medicines Directive	1,800
Patient Medication Record IT System	3,000
PSI requirements inc. Pharmacy Self-Assessment	20,088
Pharmacy-specific staff training	4,250
Pharmacy Registration fees	2,135
Pharmacist Registration fee (x 2 per pharmacy)	760
Audit and reconciliation of PCRS payments	3,368
Total State-imposed costs	**35,401**

The perception of a career in community pharmacy among young pharmacists is deteriorating rapidly. This arises from the standard of HSE administration, and the increased levels of regulation, inspection, audit, validation and administration, as well as the constant rule changes and the impact on patients of increasing restrictions on reimbursement. When combined with regular evening and weekend working, it is no surprise that there is now a shortage of pharmacy professionals (in addition to the shortage of GPs, nurses, occupational therapists and other health professionals).

7.3 Financial Sustainability

The international medicine market is going through a period of substantial change. The use of generics is now widespread and this has radically altered the dispensing profile of the pharmacy sector in Ireland. Continued downward pressure on State scheme medicine payments continues to depress pharmacy earnings. After a sustained period of turnover reductions, labour and property market pressures are the current challenges.

Annual fee income per pharmacy declined again in 2016, which is evidenced in the 2016 PCRS Annual Report. With an increasing patient population served by a larger number of pharmacies, there is less revenue per pharmacy, despite transaction volumes continuing to increase year on year. Much of the volume growth comes from generic prescribing and dispensing, although the increase in the number of medicine items dispensed is not sufficient to offset the decrease in the value of those medicines. PCRS statistics indicate that, in 2015, 700 pharmacies received less than €120,000 in fees and 435 received less than €80,000. Accountants Fitzgerald Power have found that there are approximately 250 to 300 pharmacies in the country with a turnover of €650,000 or less, and which are therefore 'at-risk'. €650,000 is a significant watershed as it is the point below which a pharmacy business is loss-making if average gross profit margins and overhead expenditure levels are applied.

EY-DKM analysis established that the pharmacies with the lowest average turnovers and the weakest profitability are those located in areas of greatest social need, particularly in rural, outlying and disadvantaged areas. This may well lead to future difficulties with patient access to medicines in those locations. Analysis by Smith & Williamson found that pharmacy sales started to decline in the fourth quarter of 2007 and that the value of dispensary sales in pharmacy has reduced every year since then, causing a decade of decline, as the HSE has brought in a series of drug price and fee reductions over the years.

There is clear evidence that the current dispensing fees are inadequate. Pharmacies with higher reliance on dispensing fees are the least profitable, whereas those which can subsidise their core patient care function with retail activities are strongest. The State should not expect pharmacists to cross-subsidise their medicines dispensing function and associated healthcare role using income from unrelated activity.

8. Conclusion

There are any number of ways of varying the rates and amounts payable to pharmacists under FEMPI. The IPU is of the view that the most appropriate fee to be varied is the dispensing fee in Schedule 1 of the regulations. Schedule 1 from the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2013 is set out below:

Figure 7: Current Dispensing Fee Schedule

SCHEDULE 1	
Amounts payable for dispensing drug items and non-drug items (excluding drug items which are subject to extemporaneous preparation and compounding) under the General Medical Services Scheme, the Drugs Payment Scheme, the Long-Term Illness Scheme, the European Economic Area Scheme and the Health (Amendment) Act 1996 Scheme	
Description (1)	Amount (2)
Standard dispensing fee payable to a community pharmacy contractor under the General Medical Services Scheme, the Drugs Payment Scheme, the Long-Term Illness Scheme, the European Economic Area Scheme and the Health (Amendment) Act 1996 Scheme per item dispensed under those schemes:	
— for each of the first 1,667 items dispensed by the community pharmacy contractor in a month	€5.00
— for each of the next 833 items dispensed by the community pharmacy contractor in that month	€4.50
— for each other item dispensed by the community pharmacy contractor in that month	€3.50

The State has extracted disproportionate savings from pharmacies over many years, leading to a decade of decline for the sector. Pharmacies have delivered substantial productivity and efficiency gains, under a growing regulatory and administrative burden and in the face of increased demand and greatly reduced fees.

Since 2009, average per item dispensing fees have fallen 15.8% and average annual fees paid per pharmacy have fallen by 16.9%. Average pharmacy medicine prices have fallen by 33% and the overall pharmacy medicines bill has fallen 25.7%, despite an increase of 10.8% in items dispensed. At the same time, the High Tech medicines bill, over which pharmacists have no control and from which pharmacies do not benefit, has ballooned by 94%, consuming all of the savings delivered by the pharmacy sector.

Behaviours & Attitudes research found that public trust in pharmacists is at 96%, that 86% rate value for money in the pharmacy sector as good or very good, and that there is a strong public appetite for a more extensive range of healthcare services to be provided through pharmacies.

Pharmaceutical Society of Ireland research found that the public wants services such as health screening, minor ailments scheme, new medicine service, medicine usage review and warfarin monitoring clinics, provided in pharmacies. In their *Future Pharmacy Practice* report, the PSI identified additional services which, if provided by pharmacies, would improve patients' health outcomes and save on long-term healthcare costs.

Further to the PSI report, the IPU has set out costed proposals for a number of services, aligned with public demand, which if implemented would help the State deliver on its commitment to make a decisive shift to primary care, free up capacity in general practice, and improve the accessibility of healthcare.

Tonic Consultancy has quantified the costs imposed by the State and its agencies, the HSE and the PSI, at over €35,000 per pharmacy per year.

EY-DKM analysis found that pharmacies in areas of greatest social and healthcare need have lower revenues and operate on the thinnest margins; these pharmacies have the least resources to subsidise healthcare services and are the most vulnerable, and therefore need additional supports – supports which are a feature of reimbursement systems in both Australia and Canada.

Any reimbursement model must be viable and realistic, providing a sustainable dispensing fee across all schemes, with appropriate professional and administrative allowances to cover State-imposed costs and supports for marginal pharmacies in disadvantaged, rural or isolated communities. Where a pharmacy is located impacts its profitability and, unless dispensing fees are increased, a significant number of non-urban pharmacies will ultimately close. Smith & Williamson calculated that, in order to recover costs adequately, and provide a sustainable service, pharmacies require a dispensing fee in the region of €8.

The Dorgan Report, prepared independently for the Minister for Health in June 2008 to advise on the appropriate level of dispensing fee to be paid to community pharmacists for existing services

provided under the GMS and community drug schemes, recognised "the dichotomy between a remuneration model built around drug dispensing and a service provision model that is, or needs to be, built around wider professional, retail and advice services in the community pharmacy. Community pharmacists today provide extensive and valuable services, but there is an apparent disconnect with the remuneration model."

The Dorgan Report recommended a tiered fee, as set out below.

Figure 8: Dispensing Fees recommended by Dorgan Report 2008

Number of items dispensed per annum	Fee per Item
Up to 20,000 items	**€7.00**
20,001 to 30,000 items	**€6.50**
Over 30,000 items	**€6.00**

Analysis by both EY-DKM and Smith & Williamson concluded that these fees, index linked to the present and into the future, are imperative for a sustainable pharmacy sector across the country. The Dorgan report also notes "our strong view that a new contract is required urgently and that the parties should move to achieve that".

In circumstances where the previous Minister for Health, Leo Varadkar TD, committed to commencing the unwinding of FEMPI, (but no unwinding ever occurred) where legislation is now in place and public sector pay is now being restored to pre-economic crisis levels and GPs are in contract negotiations with the Government, it is only fair and equitable that the Minister now begins to reverse the savage cuts that were imposed upon community pharmacy contractors.

The IPU has participated fully and constructively in all statutory consultation processes and has worked collaboratively with the DoH and the HSE in developing patient services, and in improving financial accountability and probity.

The IPU expects that the Government will now honour its commitments and commence the unwinding of FEMPI for community pharmacy contractors, in recognition of the contribution they have made to achieving significant savings for the State during the recent financial crisis.