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A Review of Respiratory Medicines Expenditure in the Primary Care Reimbursement Services. 2005-2015.

Jackie O'Dwyer

CARL Research Project
in collaboration with
Irish Asthma Society

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RESEARCH LINKS
University College Cork, Ireland

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A Review of Respiratory Medicines Expenditure in the Primary Care Reimbursement Services. 2005-2015.

By

Jackie O'Dwyer

Report on the research presented in partial fulfilment of the requirements for the degree of

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Table of Contents

Acknowledgements		**ii**
Frequently Used Terms		**iii**
Executive Summary		**viii**
Section 1:	**Introduction**	**1**
Section 2:	**Background and Approach**	**3**
Section 3:	**Methodology**	**8**
Section 4:	**Findings and Recommendations**	**12**
Section 5:	**Conclusions**	**32**
References		**35**
Appendix (i) Tables		**38**
Appendix (ii) Graphs		**44**

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Frequently Used Terms

Adherence	In medicine, compliance (also adherence) describes the degree to which a patient correctly follows medical advice. Most commonly, it refers to medication or drug compliance, but it can also apply to other situations such as medical device use, self-care, self-directed exercises, or therapy sessions.
PCRS	Primary Care Reimbursement Service
GMS	General Medical Service
DPS	Drug Payment Scheme
LTI	Long Term Illness Scheme
HT	High Tech distribution
OPD	Obstructive Pulmonary Disorder

Respiratory Drugs	**Indication**
Salbutamol	Indicated for the treatment or prevention of bronchospasm. It provides short acting bronchodilation in reversible airways obstruction due to asthma and chronic obstructive pulmonary disease (COPD) such as chronic bronchitis and emphysema.
Beclometasone	Indicated for the Prophylactic management in: Mild asthma (PEF values greater than 80% predicted at baseline with less than 20% variability): Patients requiring intermittent symptomatic bronchodilator asthma medication on more than an occasional basis. Moderate asthma (PEF values 60 - 80% predicted at baseline with 20 - 30% variability): Patients requiring regular asthma medication and patients with unstable or worsening asthma on other prophylactic therapy or

	bronchodilator alone. Severe asthma (PEF values less than 60% predicted at baseline with greater than 30% variability): Patients with severe chronic asthma.
Salmerterol & other drugs	Asthma: The regular treatment of asthma where use of a combination product (long-acting β2 agonist and inhaled corticosteroid) is appropriate Chronic Obstructive Pulmonary Disease (COPD): indicated for the symptomatic treatment of patients with COPD, with a FEV1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.
Salbutamol & other drugs	As above in combination.
Carbocisteine	Indicated for the adjunctive therapy of respiratory tract disorders characterised by excessive or viscous mucus.
Tiotropium bromide	Indicated as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD).
Formoterol & other drugs	Indicated for Prophylaxis and treatment of bronchoconstriction in patients with asthma as an add-on to inhaled corticosteroid (ICS) treatment. Prophylaxis of bronchospasm induced by inhaled allergens, cold air or exercise. Prophylaxis and treatment of bronchoconstriction in patients with reversible or irreversible chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.
Montelukast	Indicated in the treatment of asthma as add-on therapy in those patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom “as-needed” short acting beta-agonists

	provide inadequate clinical control of asthma. In those asthmatic patients in whom Montelukast is indicated in asthma, it can also provide symptomatic relief of seasonal allergic rhinitis. Montelukast is also indicated in the prophylaxis of asthma in which the predominant component is exercise-induced bronchoconstriction.
Fluticasone nasal	Indicated in adults, adolescents and children (6 years and over) for the treatment of the symptoms of allergic rhinitis.
Mometasone	Indicated in adults and adolescents 12 years of age and older for regular treatment to control persistent asthma.
Fluticasone inhaled	Asthma: Fluticasone propionate has a marked anti-inflammatory effect in the lungs. It reduces symptoms and exacerbations of asthma in patients previously treated with bronchodilator alone or with other prophylactic therapy. In the majority of patients it has no effect on adrenal function or reserve at the recommended doses. Severe asthma requires regular medical assessment as death may occur. Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60% predicted at baseline with greater than 30% variability, usually not returning entirely to normal after a bronchodilator. These patients will require high dose inhaled (see dosage instructions) or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

Sildenafil	Indicated for the treatment of adult patients (≥ 18 years) with pulmonary arterial hypertension who are currently prescribed oral Revatio and who are temporarily unable to take oral therapy, but are otherwise clinically and haemodynamically stable. The oral formulation is indicated for treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease.
Tadalafil	Indicated in adults for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity.
Bosentan	Indicated for treatment of pulmonary arterial hypertension (PAH) to improve exercise capacity and symptoms in patients with WHO functional class III. Efficacy has been shown in: Primary (idiopathic and heritable) pulmonary arterial hypertension. Pulmonary arterial hypertension secondary to scleroderma without significant interstitial pulmonary disease. Pulmonary arterial hypertension associated with congenital systemic-to-pulmonary shunts and Eisenmenger's physiology.
Iloprost	Indicated for Treatment of adult patients with primary pulmonary hypertension, classified as NYHA functional class III, to improve exercise capacity and symptoms.

Tobramycin	Indicated for management of chronic pulmonary infection due to Pseudomonas aeruginosa in patients with cystic fibrosis aged 6 years and older.
Palivizumab	Indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease: Children born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season. Children less than 2 years of age and requiring treatment for bronchopulmonary dysplasia within the last 6 months. Children less than 2 years of age and with haemodynamically significant congenital heart disease.
Ambrisentan	Indicated for treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment. Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease
Ivacaftor	Indicated for the treatment of patients with cystic fibrosis (CF) aged 18 years and older who have an R117H mutation in the CFTR gene
Pirfenidone	Indicated in adults for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF).
Aztreonam	Indicated for Lower respiratory tract infections: including pneumonia, bronchitis and lung infections in patients with cystic fibrosis.

Executive Summary

Respiratory disease, is part of the Governments chronic disease management policy. The aim is to manage chronic disease patients as close to their home for as long as possible. The economic benefit of this is to improve medicine adherence and avoid the cost of emergency hospital admissions. One adherence barrier is cost of medicines.

The aim of this report was to gain clarity on respiratory medicines expenditure for an eleven year period from 2005-2015. Findings showed that expenditure on all medicines have been decreasing in recent years, with 2015 figures being less than expenditure in 2006. Respiratory medicines have been less than 10% of total medicines expenditure in the PCRS during this time. Drugs for OPD are the most frequently prescribed and highest expenditure medicine class. B2 stimulants are the most frequently prescribed drug group and B2 stimulants and corticoids have the highest expenditure.87% of drugs to treat OPD are dispensed publicly and 13% privately. A scenario analysis estimated that the extra cost to the State ranged between €20.2m to €33.8m, to provide respiratory medicines through public schemes, thus removing a barrier to adherence. By improving adherence rates the department is providing best outcomes and use of its finite resources

Section 1. Introduction

In 2016, total Government expenditure was €55 billion of which €18 billion (24% of total expenditure) was spent in health[1]. There is a finite financial resource that can be allocated to the provision of healthcare. However, there is an increasing need to access this derived demand. People want to be healthy and in order to achieve it they have to access the health care system at different stages, whether for services of a health care professional or medicines. One factor that contributes to this demand is a rapidly aging population. Currently there are 540,000 people aged 65+ in Ireland, 12% of the total population. This is set to rise to 22%, by 2041 [2]. When one gets older, there is often more need to access health care due to the fact that inevitably there can be a higher frequency of ill health. Society wants to live longer, but it also wants that those years gained are lived in as much good health as possible. Considering aging as just one contributing factor, one can see that societies demand for health care can be unlimited.

Health care as a resource is therefore finite and has to be managed effectively, even more so in recent years with the effect the bailout and recession has had on reducing budgets. The reality of this has resulted in tighter regulation on funding and monitoring of expenditure in all sectors including health. From an economic perspective, the more clarity there is on expenditure of public and private funds, the better informed the State is on deciding which initiatives or medicines to invest in now so as to offset the future costs to the health service.

This report examines expenditure of medicines to treat respiratory disease. Respiratory disease is made up of a large number of smaller diseases that can affect a person. One of them is asthma, another is chronic obstructive pulmonary disease, and the State has implemented programmes to enable the management of these diseases outside the hospital. An example of one initiative they have introduced, in order to alleviate pressure (both financial and capacity) on the health care system in hospitals, are chronic disease management programmes [3]. This is where patients who have certain chronic diseases, are managed in the community. This satisfies the patients demand for health care and ultimately offsets the financial pressure on the State by aiming to

improve adherence to medicines to avoid future events including admissions to hospital. Cost of medicines is one barrier to adherence.

The aim of this report is to conduct an eleven year review of respiratory medicine expenditure in Ireland from 2005-2015 and to calculate an estimated cost for the State to cover the total cost of respiratory medicines through public schemes such as the LTI. Thus the State would be removing another barrier to adherence. By improving adherence rates the Government is aligning with its policy of chronic disease management programme, providing best outcomes for patients and best use of its finite resources.

Section 2. Background and Approach

The effects of the economic crisis that hit Ireland in 2008 are now abating and nearly ten years later the people of Ireland are beginning to feel confidence of coming out of a severe crisis and ongoing recession. Tight monitoring and control of expenditure on a national level has to remain in order to be able to manage the public finances well. In 2016, total Government expenditure was €55 billion of which €18 billion was spent in health. This was approximately 24% of total expenditure, second only to social protection which spent 36% of the budget[1]. Due to the fact that health is such a large proportion of total Government expenditure it is critical for the nation that this department controls its expenditure and manages the budget it receives most cost effectively. The Health budget of €18 billion contains all expenditure, including capital and pay and pensions etc. it also includes expenditure on medicines. The focus of this report is on expenditure of medicines (respiratory in particular) through the public schemes over an eleven year review period.

Healthcare in Ireland is managed under a two tier system of funding. 78.3% is funded by the Government through general taxation and the remainder is funded privately. Approximately half the population use the public system and half also purchase health insurance [4]. The Health Services Executive (HSE) controls both budget and services for the public funded sector. The HSE pays the primary care or community setting services via the Primary Care Reimbursement Service (PCRS). There are over 7,100 primary care contractors and a range of community health schemes[22].The schemes form the infrastructure through which the Irish Health System delivers a significant proportion of Primary Care to the public. The community health schemes that are the focus of this report are the General Medical Services (GMS), the Drug Payments Scheme (DPS) the Long Term Illness Scheme (LTI) and the High Tech Arrangement (HT). These are described in more detail in the appendices, table 1. If a patient does not fulfil the criteria for public reimbursement discussed above they pay themselves privately.

Though there is a finite resource allocated to health care, there is an unlimited demand for it. One factor that contributes to this unlimited demand is a rapidly aging population. In Ireland by 2041, there will be 1.4 million aged 65 and over (22% of the population) [2]. Part of the aging process is the development of chronic diseases. Chronic

diseases are long-term, life-limiting conditions which can be treated and controlled but not cured. 38% of the Irish population report that they have a chronic disease and over half of people over 50 have at least one chronic disease [5]. This rises to 62% in the over 65 category[5]. Chronic diseases are responsible for about 60% of deaths worldwide and 76% of deaths in Ireland [5]. 4 out of 10 hospitalisations in Ireland in 2011 were either directly or indirectly due to the four of the main chronic diseases - cancer, cardiovascular disease, respiratory disease and diabetes [5].40% of the adult population in Ireland will have one or more chronic diseases by 2020[5]. Having a chronic disease means that it has to be managed on an ongoing basis, thus one can see that both the increase in an aging population and an increase in chronic diseases will continue to contribute to the demand for healthcare. This (health care) is a derived demand. The demand is for people to have good health and this is brought about through accessing healthcare to maintain that good health.

Taking into account that there is an unlimited demand for health care it then follows that decisions have to be made on how to allocate finite resources, both budget and services, in order to provide the best outcomes for the nation for a healthy active old age. In order to be able to achieve this, the way chronic disease, is managed is an important contributing factor. One aspect of having a chronic disease is that adherence to medications can be low [6.] The State has considered this problem and has developed policies to overcome one of the adherence barriers which is access to medicines and treatments. They have initiated integrated care programmes for prevention and management of chronic disease. The aim of which is to provide care and support as close to home as is required, thereby facilitating the access to medications and treatments for the patients with the result that adherence will increase. If this occurs it will result in best health outcomes, enhanced clinical decision making and the most effective use of resources [7].

Irish research shows that there are several factors for a low adherence rate one of which is access to medications and treatments and another is cost of medications. It found that there were higher adherence rates in those who were on medical cards than those that had to pay or co-pay themselves[8]. This is following the economic law of demand which states that as the price of medicines increases the quantity of demand for medicines decreases ceteris paribus. Correspondingly, if the price of medicines

decreases (from the patients perspective) the demand for the medicine increases. If the law of demand were to be followed this could lead to removing another adherence barrier and increasing adherence rates. The State could remove the cost of medicines to the patient by paying for any not covered by an existing PCRS scheme on the LTI. From an economic perspective, the benefit of these programmes is that by closely managing patients in their community, this will lead to increased adherence to their medicines and improved compliance with disease management programmes [9]. This improvement in management of chronic disease can be offset against reduced admittance to hospital and reduced costs of more expensive crisis management of patients.

Respiratory disease, including asthma and pulmonary disease, are one of the main chronic diseases that the Government is aiming to shift from hospital to primary care management, through this programme and includes the national programme for asthma [9]. Respiratory medicine is concerned with the treatment of 30 respiratory and related conditions. At present lung disease causes one in five deaths in Ireland and is the third most common reason for emergency hospital admission [9] There are also upward trends in the prevalence of asthma, interstitial lung disease and sleep disorders. Respiratory diseases are therefore likely to remain a major burden on European societies for decades to come[9]. In Ireland there were 3,438 deaths from diseases of the respiratory system in 2011 of which 1,625 were males and 1,813 were females. Diseases of the respiratory system accounted for 12.1% of all deaths (0.75 per 1,000 of population), affecting, in particular, the older age groups, with 79.3% of these occurring in persons aged 75 and over. These were largely made up of 1,504 deaths from chronic lower respiratory diseases and 1,062 deaths due to pneumonia (which often accompanies COPD), which combined accounted for 75% of respiratory deaths [9]. Asthma in particular is a respiratory disease that is characterised, in Ireland, by high disease prevalence, suboptimal control in the majority of patients, low uptake of objective lung function tests for diagnosis and management, infrequent use of asthma management plans and poor patient education[10]. Ireland has the fourth highest prevalence of asthma world-wide, affecting an estimated 450,000 people. At least one person dies from asthma every week in Ireland[10]. The Global Initiative for Asthma (GINA) guidelines provides recommendations for the diagnosis and management of

asthma in patients aged 5 years and older, in the primary care setting and is a core component of the national asthma programme. The scope of the national asthma programme is to ensure the management of asthma is based on current international evidence-based care in all care settings including primary care. The aim of the programme is to reduce morbidity and mortality associated with asthma in Ireland and to improve the quality of life for all patients with asthma [10].

The impact of old age and chronic disease, in particular respiratory disease, in Ireland is large and has major implications to where the health care budget has had to have been spent. Thus we can see the importance from an economic perspective, of implementing Government policy and instigating an integrated chronic disease management programme for respiratory diseases such as asthma and COPD. The financial benefits of improved adherence with medicines and compliance with management of the chronic disease coupled with the discounted costs of reduced admittance to hospital and emergency medicine management are compelling for a department that have to manage this finite resource.

The focus of this report is to review respiratory medicines expenditure from 2005-2015 in order to be able to provide information on the cost of medicines in respiratory disease. In particular, to gain clarity on public and private spend in respiratory medicines, in order to calculate how much it would cost the State to cover all costs on respiratory medicines. If this was the case another adherence barrier, the cost of medicines to the patient, would be removed. This could result in increasing adherence and improving outcomes.

The idea for this report originated from Irish research on respiratory disease in Ireland (2003 and 2008). The INHALE report describes in depth the management of respiratory disease in Ireland. Brennan et al stated that they have "provided a benchmark for tracking changes and assessing trends in the mortality, morbidity and treatment of respiratory disease" [11].The second edition had amongst its report the following updates from the first edition: Comparisons with other countries and other diseases reveal that Ireland's record in tackling lung disease, rather than improving, has in fact fallen behind. Respiratory disease still causes one in five deaths in Ireland. Death rates from respiratory disease are almost twice the EU average. Lung cancer is

still the biggest cancer killer in Ireland. Statistics on the prevalence and cost of respiratory disease show a similarly bleak picture: Respiratory disease is still among the most commonly reported long-term illnesses in young adults. Respiratory diseases are still the most common reason to visit a GP and the third most common reason for acute admission to hospital. Drug prescriptions for respiratory disease are amongst the highest for any organ system. Prevalence of asthma, the most common chronic childhood disease, is rising. The authors commented that, "Increased resources to better manage the disease are required if this trend is to be reversed" [11]. The second edition of INHALE was published in 2008 and from this we can see that respiratory disease affects a large number of people in Ireland and how it is managed is important to provide the best outcomes for these patients in a setting as close to their home as possible. The purposes of the research undertaken here is to aid the information in this area. It follows on in part from INHALE by re-examining subsections of the INHALE report, such as expenditure on vaccinations for prevention of respiratory disease and expenditure in the PCRS on respiratory medicines. The aim of this report is to provide clarity on how much has been spent on medicines to treat respiratory disease in the primary care setting for the period that has been reviewed, 2005-2015. From this information trends will enable predictions and assumptions to be made on future expenditure on respiratory medicines in the primary care setting. It will also ascertain what proportion and how much has been spent on respiratory through the PCRS and privately. Finally, this report goes on to estimate the cost to the State if all respiratory medicines were included in LTI public scheme. If all respiratory medicines were paid via public schemes one more barrier to adherence of medications would be removed. This could increase adherence to medicines and align with Government policy of management of integrated care, chronic disease programmes for respiratory disease. The result of this could be to provide best outcomes for patients and best use of the departments finite resources.

Section 3. Methodology

Government policy is to implement integrated chronic disease management programmes. Resulting in best health outcomes, enhanced clinical decision making and the most effective use of resources[7]. From an economist perspective, the theory behind these programmes is that by increasing adherence to medicines and compliance to management of the chronic disease in the community will result in less expenditure in admittance to hospital and crisis management. Thus making most effective use of finite resources. Respiratory disease is part of the chronic disease management programme. One barrier to adherence is the cost of medicines. The aim of this report is to providing clarity on respiratory medicines expenditure by firstly conducting an eleven year review of respiratory medicine expenditure in Ireland from 2005-2015 and secondly to estimate the cost for the Government to pay for all respiratory medicines through PCRS. Thus removing an adherence barrier. Two data sets were used to conduct this univariate analysis. The first was the data from the published Primary Care Reimbursement Services (PCRS) statistical analysis reports and the second was data supplied by QuintilesIMS Ltd.

3.1. Data.

3.1.1. Primary Care Reimbursement Services (PCRS).

For the purposes of this research, the PCRS Schemes that are involved in patients that use respiratory medicines have been analysed over an eleven year period from 2005 to 2015. These schemes include the General Medical Card Scheme (GMS), The Drug Payments Scheme (DPS) the Long term Illness Scheme (LTI) and the Hi Tech Reimbursement Process (HTD). The HSE publishes a report detailing what has been spent in each scheme annually. It also publishes how frequently each preparation has been prescribed within each scheme. A detailed statistical analysis on the schemes involved in the PCRS is also published in this annual report.

The data for this analysis has been extracted from the following sections in the PCRS report for each year from 2005 to 2015 [12-22].

i) Total Spend of Major Therapeutic Classification of Drugs, Medicines and Appliances for:

-The General Medical Services Scheme (GMS)

-The Drug Payments Scheme (DPS) and

-The Long Term illness Scheme (LTI)

ii) Summary Statement of Activity during Year: Total Payments to Wholesalers under the Hi Tech Drugs Reimbursement Process (HTD).

Once the data was identified, for the eleven year review period, this was tabulated into both tables and graphs in order to be able to describe the data and draw conclusions from it.

3.1.2. QuintilesIMS Ltd Drugs for obstructive pulmonary disorder medicines data.

QuintilesIMS Ltd is a company that provides insights and data on different therapeutic areas to its client base. For the purposes of this research QuintilesIMS Ltd has made available the respiratory medicines data section, for the eleven year period that is being reviewed in this research. It comprises of two data sets, the first is the sell-in data for respiratory medicines[23]. This comprises of data on drugs that are used to treat obstructive pulmonary disease (OPD). It encompasses all pharmacies, either hospital or community. The data range is from 2005 to 2015. It supports the PCRS data and allows for in depth analysis to be carried out that enables the objectives of this research to be met. This data was extracted, tabulated and graphed in order to be able to compare and draw conclusions from it.

The second set of data that has been provided from QuintilesIMS Ltd is the sell-out data for respiratory medicines[23]. This is information identifying which scheme the medicine that is being dispensed from the pharmacy has been allocated to. The scheme will either be a Government scheme that comes under the PCRS review and will be either GMS, DPS, or LTI. The other option will be a private allocation which is funded by the individual patient. This data has been available since July 2014 and the review for this data set takes place from then until June 2016. The data set that has been provided is for respiratory medicines, in particular drugs for OPD. Using this data enables the final two objectives of this research to be able to be met by calculating the percentage allocation per scheme, and how much extra the Government would need to spend in order to cover the total cost of respiratory medicines to the public.

3.2. Data analysis methods.

From these two sets of data a univariate analysis was conducted to meet the aim of this research. The data analysis is structured in accordance to the four objectives of

the research. The first objective was to review expenditure on all PCRS medicines from 2005-2015. The PCRS data was used to achieve this objective. The statistical analysis reports from 2005-2015 were reviewed and the data extracted to tabulate this information. Graphs then illustrate the eleven year trend.

The second objective was to review expenditure on all respiratory medicine in the PCRS from 2005-2015. The statistical analysis reports and QuintilesIMS Ltd data were used. This is a large objective which is multi layered. Therefore this objective was subdivided further and an in-depth analysis was undertaken to review the following:

1) Compare PCRS expenditure on respiratory medicine to total expenditure.

2) Identify most frequently prescribed and highest expenditure respiratory medicine class.

3) Identify most frequently prescribed and highest expenditure drug class.

4) Review spend on prevention of respiratory disease.

The third objective used QuintilesIMS Ltd data to estimate what percentage of expenditure on respiratory medicines is privately funded.

The fourth objective is to calculate how much the Government would have to spend in order to cover the costs of respiratory medicines for all patients. This was determined by using the percentage calculated in objective three with the total public expenditure for respiratory medicines identified in the PCRS data. The private expenditure will also be identified in actual and percentage terms. This private amount is not currently covered by the Government and is the amount the Government would have to spend in order to cover the costs of respiratory medicines for all patients.

By completing these four objectives the aim of the research paper will have been achieved.

Section 4. Findings and Recommendations

4.1. Objective 1: Expenditure on all PCRS medicines from 2005 – 2015.

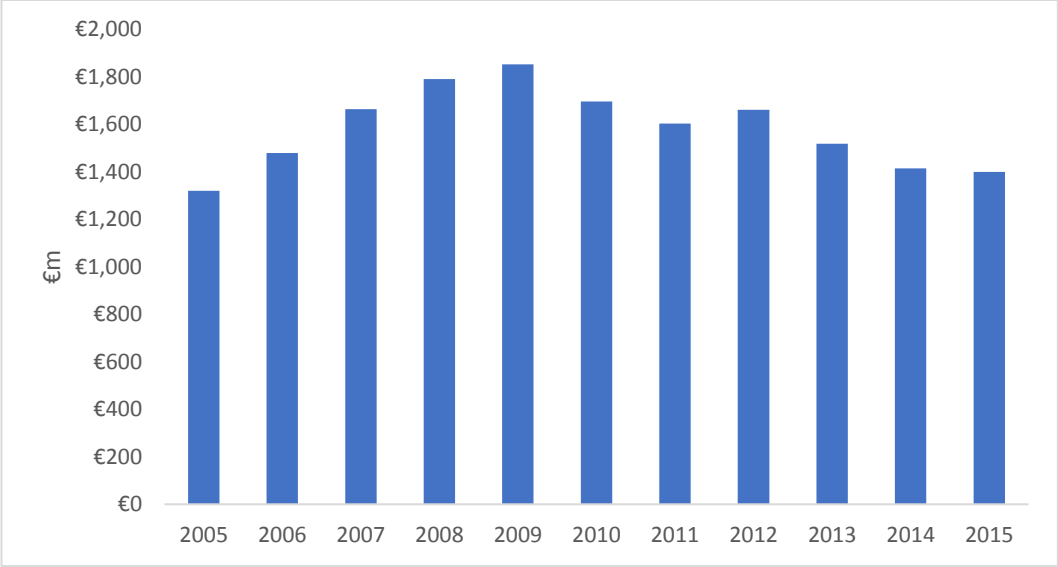
Table 2 and Graph 1 documents the total spend in the PCRS from the years 2005-2015. The total cost has increased from €1,320 million in 2005 to €1,399.65 million in 2015. The highest spend occurred in 2009 with a total spend on €1,851.72 million. Since 2009, there have been reductions in values to the extent that the 2015 amount is lower than 2006 expenditure.

Table 2: Total Spend of Major Therapeutic Classification of Drugs Medicines and Appliances. 2005-2014 PCRS schemes.

YEAR	GMS €M	DPS €M	LTI €M	TOTAL €M	HTD €M*
2005	831.44	388.02	100.54	1,320.00	168.76
2006	940.22	422.92	115.46	1,478.60	207.25
2007	1,048.40	491.19	124.46	1,664.05	238.51
2008	1,145.29	506.81	137.90	1,790.00	275.39
2009	1,260.25	451.71	139.76	1,851.72	315.36
2010	1,233.27	336.02	126.92	1,696.21	345.76
2011	1,207.34	277.50	118.10	1,602.94	350.18
2012	1,288.82	254.51	117.10	1,660.43	385.04
2013	1,222.21	189.43	106.51	1,518.15	442.27
2014	1,118.94	156.27	139.19	1,414.40	484.71
2015	1,054.30	155.87	189.48	1,399.65	544.19

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2005-2015.GMS = General Medical Service; DPS=Drug Payment Scheme; LTI=Long Term Illness Scheme; HTD= Hi Tech Drugs Scheme *Data from Summary Statement Payments to Wholesalers under the HTD Scheme.

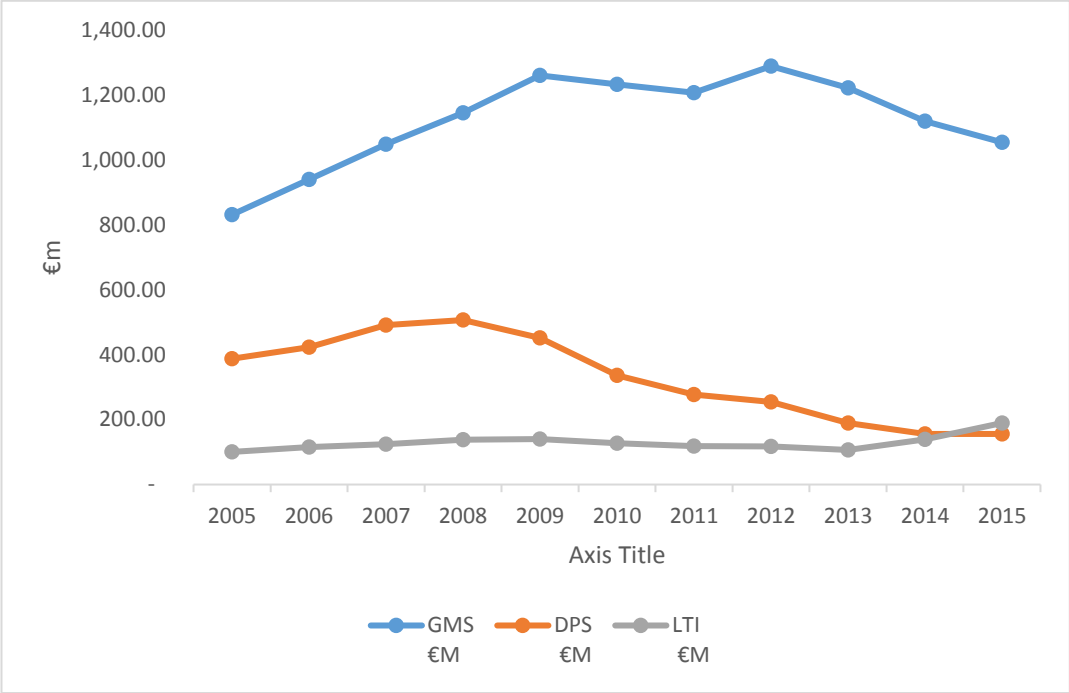
Graph 1. Total PCRS spend.



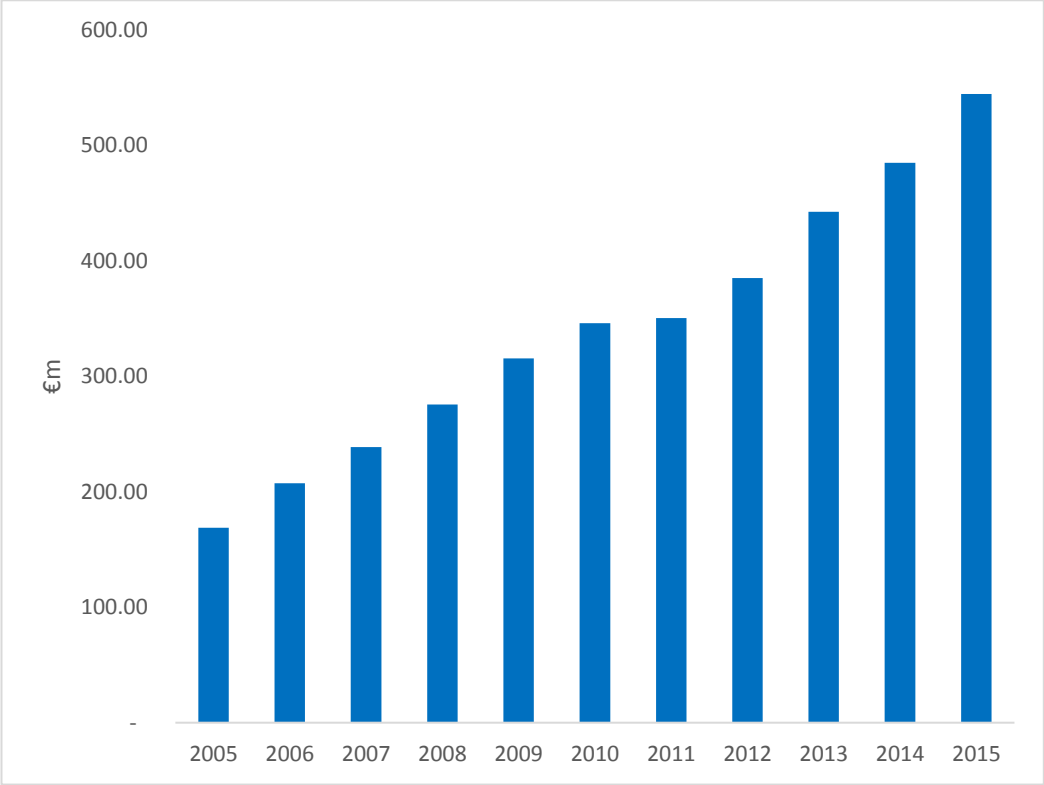
Graph 2 depicts the individual PCRS scheme, GMS [12-22], DPS [12-22] and LTI [12-22] from 2005-2015 which is documented in table 2. This graphs illustrates that there have been some fluctuations on a yearly basis between schemes. The largest allocation of budget has been to the GMS. The allocation on this scheme had been increasing on a continual basis from 2005 to 2009. However, in 2010 onwards it reduced to €1054.3m in 2015, which is less than 2008 values. The next largest scheme is the DPS scheme. Graph 2 also illustrates that the DPS scheme has reduced in spend consistently since 2008. The LTI scheme, has had the least amount of budget allocated to it out of all of these PCRS schemes. Spend on the LTI has consistently been below €140m until 2015 where it increased to €189.48m. Expenditure on the Hi Tech (HTD) scheme [12-22], has risen consistently from €168.76m in 2005, to a total spend of €544.19m in 2015, as shown in graph 3.

In summary, total PCRS expenditure on all medicines have been decreasing in recent years with 2015 figures being less than expenditure in 2006. Most expenditure is on the GMS scheme followed by the DPS and LTI. The HTD has risen in expenditure to €544.19m in 2015.

Graph 2. Total spend by PCRS scheme.



Graph 3. Payments to Wholesalers under the HTD. 2005-2015.

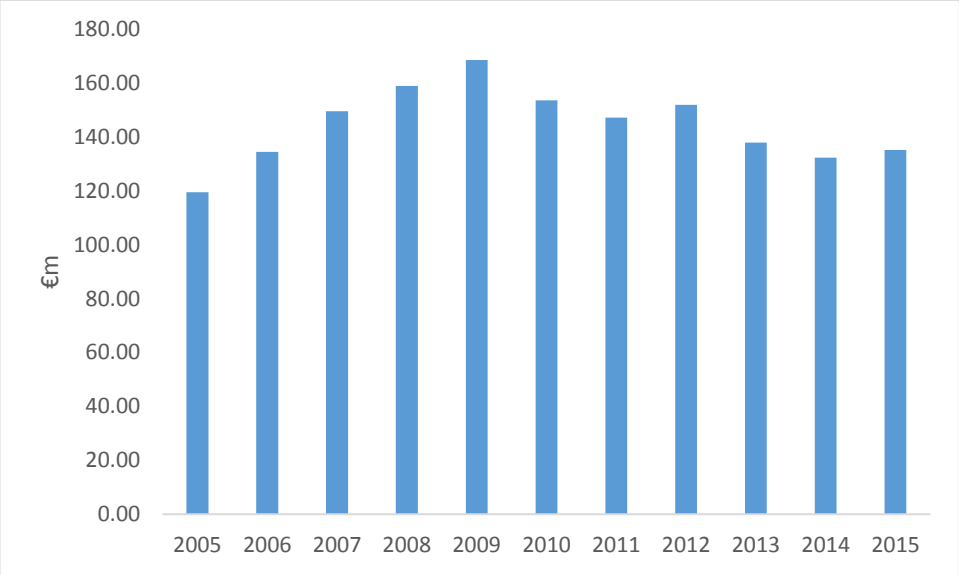


4.2. Objective 2: To review expenditure on all respiratory medicine in the PCRS from 2005 – 2015.

4.2.1. PCRS expenditure on respiratory medicine in comparison to total expenditure.

Table 3 and graph 4 illustrates that, similar to the PCRS total medicines expenditure, the combined PCRS expenditure on respiratory drugs had consistently risen on a yearly basis from 2005 to 2009. Expenditure then decreased to €135.25m in 2015 this is approximately 2006 respiratory medicine expenditure.

Graph 4. Total PCRS Respiratory Spend 2005 - 2015.



Total respiratory medicines expenditure has always been below 10% of total PCRS spend (graph 5). However, in 2015 there has been an increase from the 2009 (the highest year of respiratory medicine expenditure) 9.1% up to 9.66%. Thus reflecting that though the total respiratory medicine actual expenditure has decreased over the review period, it has not decreased as much as the total medicines expenditure in the PCRS.

Graph 5. Total PCRS Scheme spend v Total Respiratory PCRS scheme spend. 2005-2015.

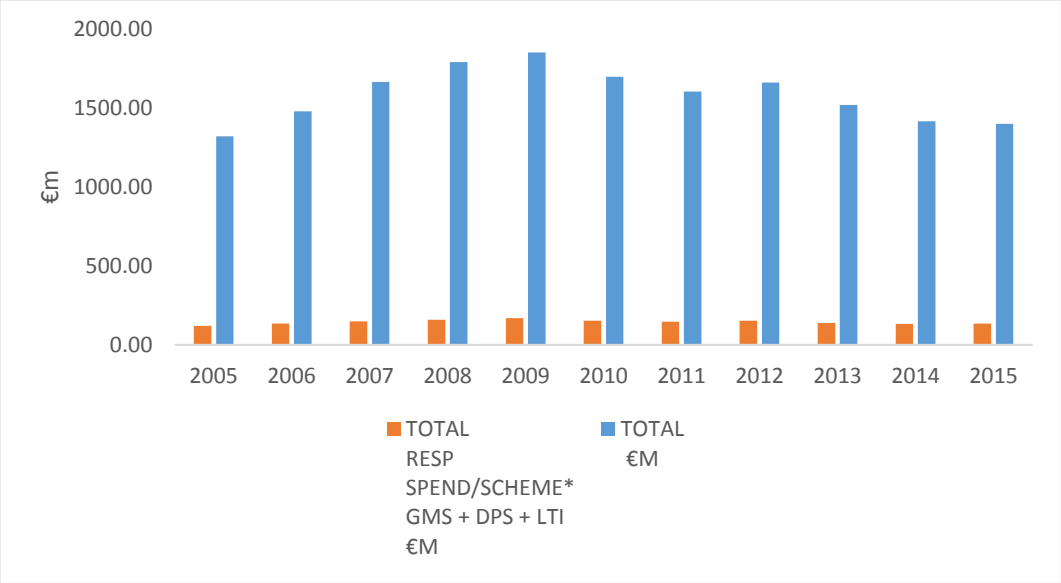


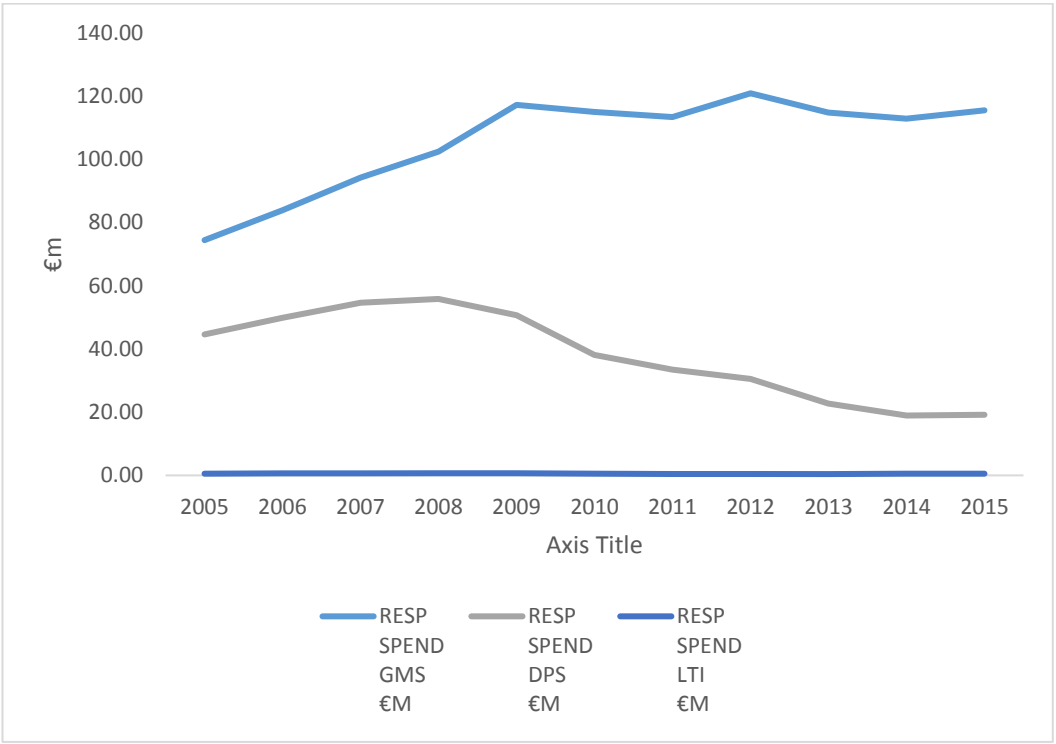
Table 3: 2005-2015 PCRS Schemes: Total Spend of Major Therapeutic Classification of Drugs, Medicines and Appliances. Respiratory.

YEAR	RESP SPEND GMS €M	RESP SPEND AS % OF TOTAL GMS SPEND	RESP SPEND DPS €M	RESP SPEND AS % OF TOTAL DPS SPEND	RESP SPEND LTI €M	RESP SPEND AS % OF TOTAL LTI SPEND	TOTAL RESP SPEND/ SCHEME* GMS + DPS + LTI €M	TOTAL RESP SPEND/ SCHEME AS % OF TOTAL SPEND/ SCHEME
2005	74.44	8.95	44.58	11.49	0.53	0.53	119.55	9.06
2006	83.93	8.93	49.90	11.27	0.59	0.51	134.42	9.09
2007	94.29	8.99	54.64	11.13	0.63	0.51	149.56	8.99
2008	102.45	8.95	55.83	11.02	0.67	0.49	158.95	8.88
2009	117.19	9.30	50.67	11.22	0.67	0.48	168.53	9.10
2010	115.01	9.33	38.12	11.35	0.49	0.39	153.62	9.06
2011	113.35	9.39	33.44	12.05	0.43	0.37	147.22	9.18
2012	120.91	9.38	30.57	12.01	0.44	0.38	151.92	9.15
2013	114.81	9.39	22.69	11.98	0.41	0.39	137.91	9.08
2014	112.85	10.09	18.94	12.12	0.51	0.37	132.30	9.35
2015	115.47	10.95	19.20	12.32	0.58	0.31	135.25	9.66

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2005-2015.GMS =General Medical Service; DPS=Drug Payment Scheme; LTI=Long Term Illness Scheme; RESP = Respiratory

To understand how this increase in 2015 has come about, further analysis was conducted to examine how the total respiratory spend was allocated into the different PCRS schemes. In table 3 and graph 6 GMS allocated respiratory medicines show a consistent increase from 2005-2009, thereafter the values decreased with the exception of 2012 onwards. This data was then analysed in percentage terms and despite the reduction of actual spend on respiratory drugs in recent years, expenditure has increased in percentage terms from 8.95% in 2005 to 10.95% in 2015. In the DPS, from 2009 onwards there is a decrease in actual spend on respiratory medicines but in percentage terms the expenditure has increased from 11.49% in 2005 to 12.32% in 2015. The only scheme that has decreased in percentage terms is the LTI scheme. This has decreased from 0.53% 2005 to 0.31% in 2015. Illustrating how few respiratory drugs on this scheme. The GMS is the largest public scheme in primary care and this is followed by the DPS, therefore any fluctuations seen in either of these schemes, but in particular the GMS, will have an impact on the total value. Which has been the case for respiratory medicine in 2015.

Graph 6: Respiratory spend per PCRS scheme. 2005-2015.



In summary, in this review, total respiratory medicines expenditure has always been below 10% of total PCRS spend. Though the total respiratory medicine spend has

decreased in expenditure it has not decreased as much as the expenditure on total medicines. What this means is that the proportion of expenditure has increased on respiratory medicines in this time frame. From a percentage aspect, the GMS and DPS has increased expenditure in respiratory medicines in 2015. As the GMS and DPS are the largest schemes in the PCRS this impacts on the total respiratory medicine expenditure in the PCRS.

4.2.2. Most frequently prescribed and highest expenditure respiratory medicine class.

All medicines including respiratory medicines are classified into a number of different Anatomical Therapeutic Classification (ATC) groups, by the World Health Organisation (WHO) [24]. There are 7 ATC classification for respiratory medicines. They are:

a) Drugs for obstructive pulmonary disorder(OPD)
b) Nasal Preparations
c) Antihistamines systemic use
d) Inhaled mucolytics
e) Cough and cold preparations
f) Throat preparations
g) Other Respiratory preparations

Using the data from the PCRS reports [12-22], Graph 7 and table 4 a and b in appendix i) presents the ten year ingredient cost per scheme of respiratory medicines according to ATC group. It shows that the most spend by far was in the drugs for obstructive pulmonary disorder (OPD) drugs. This group contributed to the highest ingredient cost from all schemes for all years (2005-2015). The ingredient cost for OPD drugs for all schemes, consistently rose from €82m in 2005 to €120m in 2009 than decreased to €97.8m in 2015. This 2015 value is less than 2007 expenditure on drugs for OPD on all schemes. There was much less expenditure for most of the other ATC classification groups. However, the same trend for expenditure was followed for most of these groups. Graph 7 illustrates the increase in expenditure from 2005-2009 for most groups then the subsequent decreases in expenditure to the 2015 value. The exception was the 'other respiratory systems' classification. This group has shown a sharp increase in cost since 2012. This sharp increase was only allocated to the HTD scheme and reflects the use of newly approved respiratory drugs that are only available on this scheme. The expenditure on the HTD in 2015 is €33m and contributes largely to the increase in expenditure for the total respiratory medicines value of €142.36m in 2015. To further support this, table 4 is an analysis of the respiratory ATC groups by scheme. The GMS (the largest scheme) 2015 value is less than 2009 expenditure. Whilst the

DPS 2015 value is less than the 2005 expenditure. HTD on the other hand has increased from 0 expenditure in 2005, when it was introduced, to €25.5m in 2013 and €34.13m in 2015 in the respiratory medicines category.

Graph 7. ATC Respiratory Ingredient cost per scheme. 2005-2015.

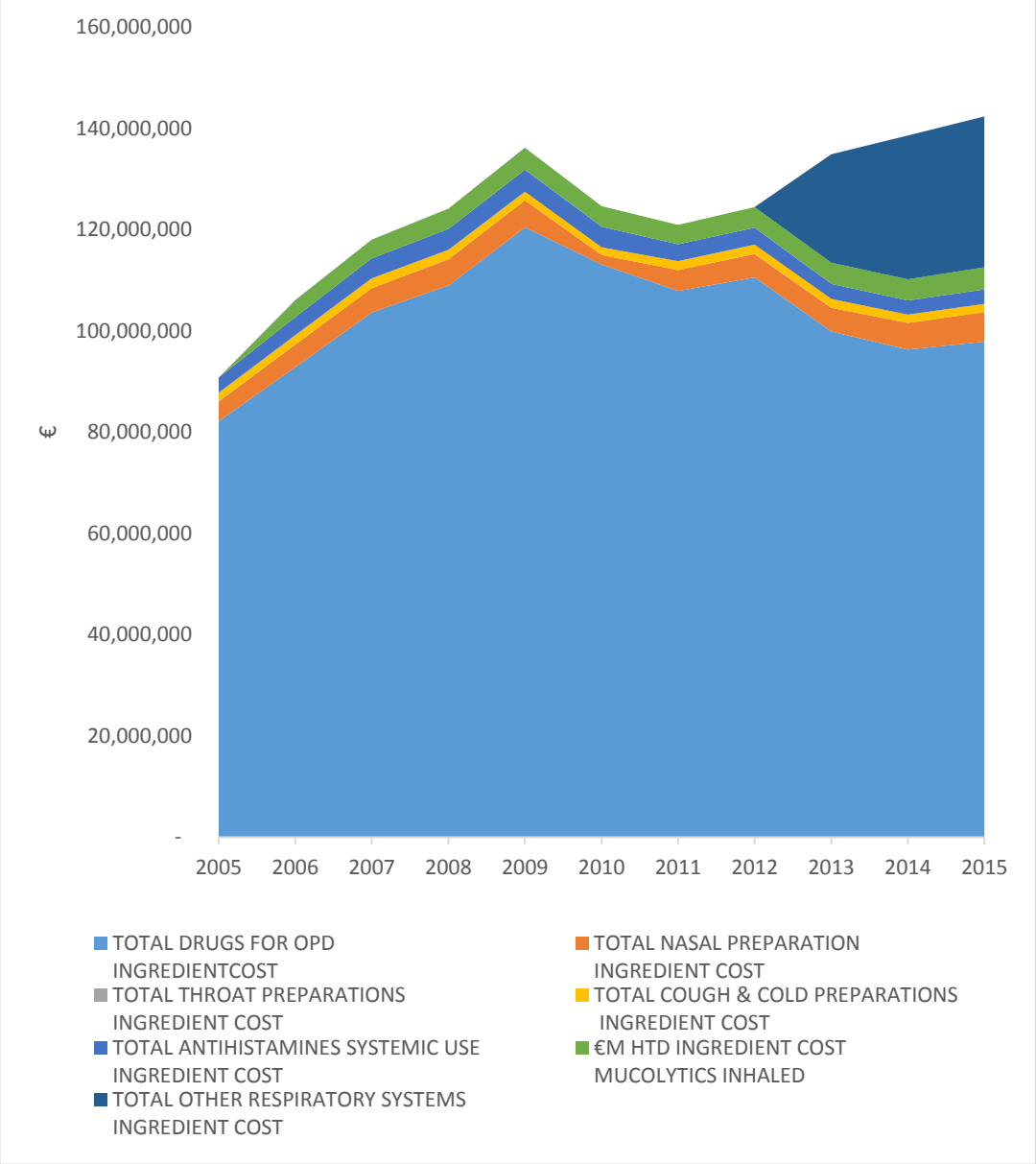


Table 5 (appendix (i)) examines the prescribing frequency per scheme of the respiratory products according to ATC group. Prescribing frequency tracks, how often a drug is being prescribed by a healthcare professional. If a medicine class is being

prescribed more, it is being used more to treat conditions and it will have an impact on expenditure allocated to the class. Drugs for OPD were prescribed most frequently in comparison to other preparations for treating respiratory disease. It can also be seen in graph 7 and tables 4 and 5 that the HTD, for respiratory medicines prescribing frequency and ingredient cost, have increased from 0, when it was introduced in 2005 to €34.13m (7972 prescriptions) in 2015. A relatively small number of prescriptions have been dispensed but there is a large ingredient cost associated with this scheme, indicating a large individual cost per item.

In summary, drugs for OPD, for this time range were the most frequently prescribed class and also the highest expenditure was allocated to this group of respiratory drugs. This indicates that on reviewing the respiratory ATC groups of medicines, drugs for OPD are the most commonly used to treat respiratory disease.

4.2.3. Highest expenditure and most frequently prescribed drug class.

QuintilesIms Ltd sell-in data[23] was used in this analysis of highest expenditure and most frequently prescribed drug class. The sell in data is data that is received on orders of medicines from pharmacies. The pharmacists place orders from prescriptions that have been written by healthcare professional prescribers. The orders are forwarded to drug wholesalers and when they receive the order they can then distribute the required medicine to the pharmacy that has requested it[23]. This sell-in data informs only on what has been ordered by pharmacies and not what happens to it after it has been dispensed from pharmacies to the patient. The most frequently used respiratory medicine ATC group is the drugs for OPD. A further analysis of the drugs to treat OPD was conducted to ascertain which was the most frequently prescribed and which had the highest expenditure. The drug classes that are used to treat OPD are:

a. B2 stimulants and corticoids
b. Anticholinergic and B2 stimulants
c. Corticoids
d. B2 Stimulants
e. Antileuk, anti-asthmatics
f. Xanthines

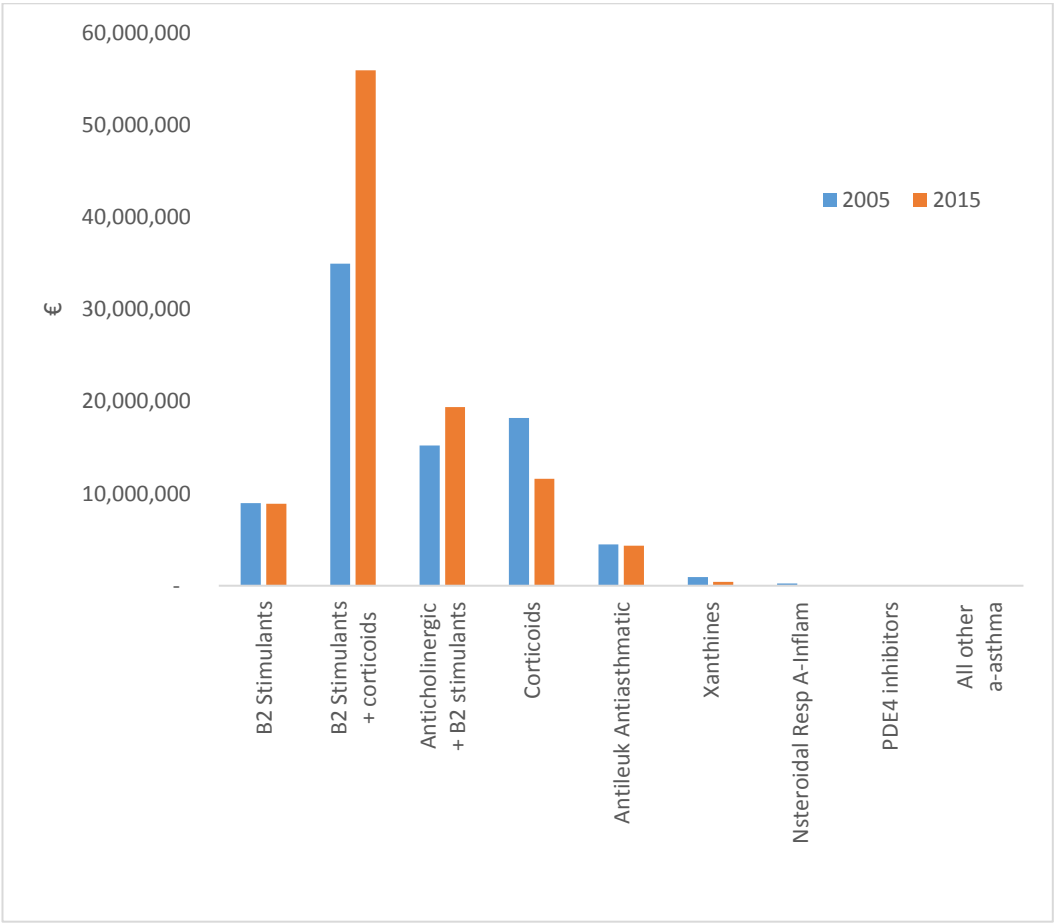
g. Nonsteroidal anti-inflammatories

h. PDE4 inhibitors

i. All other anti-asthmatics.

Graph 8 shows the expenditure of each drug for OPD class for 2005 and contrasts with 2014. B2 stimulants and corticoids have the highest expenditure. They have increased from €34.9m in 2005 to €55.9m in 2015 .This is followed by anticholinergic B2 stimulants and then by corticoids alone.

Graph 8: Respiratory medicine class comparison 2005 v 2015.



In table 6, B2 stimulants and corticoids group had consistently the highest expenditure in the period. The highest was in 2012 at €61.5m that had reduced in 2015 to €55.9m. The next highest expenditure was the anticholinergic and B2 stimulants. Since 2008 approximately €20m per year has been spent by community pharmacies for this group of medicines. Corticoids have the third highest expenditure. There has been a decline

in this class since 2005 when €18 million was spent in comparison to 2015,when this had reduced to €11million. B2 stimulants reflect a variable but still consistent buying pattern, where the community pharmacy spent between €8-9m a year throughout the review period . The other drug classes have variable and small expenditure as seen in Table6.

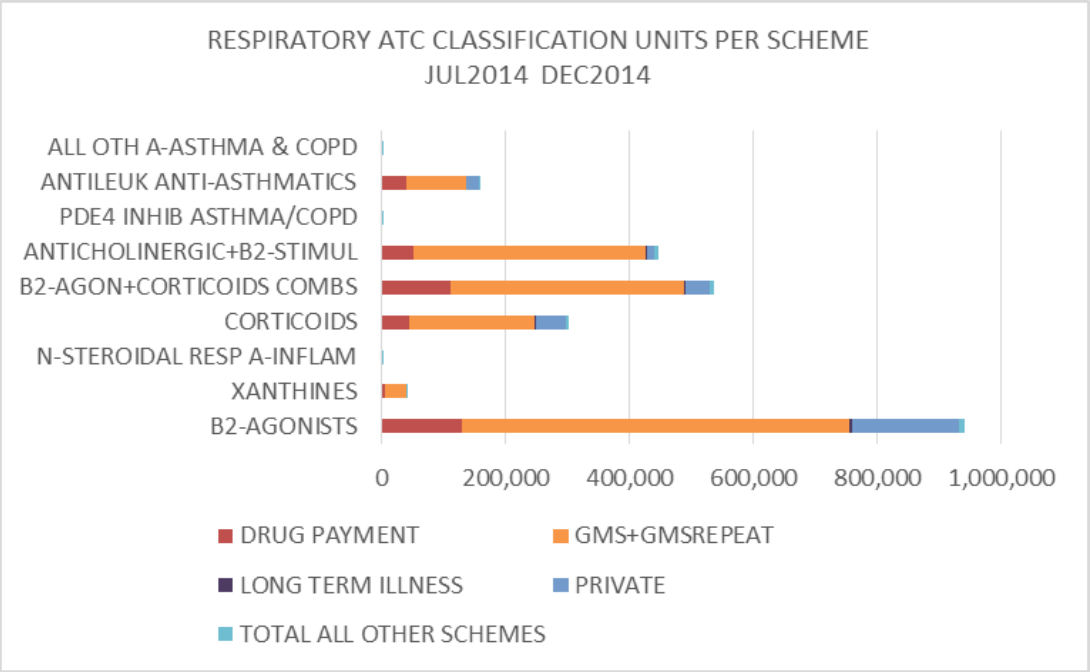
Table 6: Respiratory drug class from drugs that treat OPD. 2005-2014. Expenditure in retail pharmacies. Euros.

Drugs for OPD Class €	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
B2-STIMULANTS	8,954,521	8,704,204	8,897,762	8,713,832	9,343,429	8,708,990	8,789,502	9,629,269	8,914,776	8,830,082	8,899,047
B2-STIMULANTS+CORTICOIDS	34,939,525	40,788,273	46,833,508	52,516,060	58,977,610	60,025,903	59,400,367	61,467,965	56,677,502	55,776,955	55,905,811
ANTICHOLINERGIC+B2-STIMUL	15,226,846	17,618,171	19,963,189	21,819,383	22,435,171	21,236,599	20,927,340	21,004,476	20,608,822	22,117,861	19,383,348
CORTICOIDS	18,183,174	17,975,646	17,835,211	17,220,734	16,881,228	15,542,203	14,131,818	14,041,053	12,167,642	11,304,611	11,614,440
ANTILEUK ANTI-ASTHMATICS	4,494,543	5,868,190	7,438,045	8,552,449	9,168,111	9,874,542	11,421,522	12,257,165	8,095,542	5,279,169	4,336,822
XANTHINES	945,453	903,685	831,872	757,010	718,113	660,638	612,044	583,436	468,116	428,269	406,433
N-STEROIDAL RESP A-INFLAM	235,431	152,742	89,261	78,674	75,921	66,436	58,928	57,772	52,543	35,449	39,145
PDE4 INHIB ASTHMA/COPD	0	0	0	0	0	0	0	0	0	32,972	45,418
ALL OTH A-ASTHMA & COPD	1,192	4,547	6,726	6,857	1,049	1,713	1,263	5,297	3,253	2,017	3,801
Total Drugs for OPD	**82,980,686**	**92,015,458**	**101,895,575**	**109,665,000**	**117,600,633**	**116,117,024**	**115,342,783**	**119,046,433**	**106,988,196**	**103,807,386**	**100,634,264**

Source: QuintilesIMS data. Respiratory medicines distributed from wholesalers to pharmacies. 2005-2015. Euros.

The sell-out data [23] provided by QuintilesIMS Ltd provides the information on how frequently a drug class is prescribed. The sell-out data is collated by how it is dispensed from the community pharmacy to the scheme the patient is with [23]. This scheme could be a Government run or public scheme such as the GMS, DPS or LTI schemes or the patient may be buying the medicine privately. This data is analysed by the drug groups that treat OPD. This data has been available from July 2014 onwards. Graph 9 depicts how the respiratory drug class is dispensed into a particular scheme. The schemes have been categorised into five groups. They are; general medical and general medical scheme repeat, drug payment scheme, the long term illness scheme, other schemes and finally private prescriptions. This data is represented by units dispensed.

Graph 9. Respiratory ATC Classification units per scheme. Jul 2014- Dec 2014.



Graph 9, the B2 agonists are the most commonly dispensed units in all the schemes. It should be noted here that though the B2 agonists are the most frequently dispensed drug class, they do not have the highest expenditure as per table 6. This indicates that they are a low cost item on a per pack basis. This is followed by the B2 agonists and corticoid combinations, here the second highest dispensed but first in expenditure indicating a higher cost per pack than the B2 agonists, though this drug class is a combination of two active medications and not one. The next highest dispensed are the anticholinergic and B2 stimulants. The same trend can be seen (appendix ii) graphs 10 and 11) for all time periods available.

In summary, the highest expenditure of drug groups that treat OPD by community pharmacies are the B2 stimulants and corticoids where in 2015 €55.9m had been spent. This group is the second highest most dispensed group. The second largest expenditure was in the drug group, anticholinergic and B2 stimulants, where €19.3m was spent in 2015. The next largest class were the corticoids where €11m was spent in 2015. However, the highest dispensed drug class to treat OPD are the B2 stimulants, which have a lower expenditure (€8.8m in 2015) indicating a lower cost per item.

4.2.4. **Trends in prevention of respiratory disease**.

Prevention of respiratory disease can be undertaken by a person getting vaccinations such as the influenza and pneumococcal vaccinations and also by taking a nebuliser to prevent an incident from getting worse. Using data published In the PCRS reports [12-22], analysis of certain respiratory disease prevention drugs can be conducted. These include nebuliser use, and vaccinations, in particular, the pneumococcal, influenza and the combination of pneumococcal/influenza vaccinations. These have been documented by number of claims and cost of claims in each annual report. Table 7 documents that nebuliser use has increased on nearly an annual basis from 47,775 claims in 2005 to 88,031 claims in 2015. The cost per nebuliser use was €36 in 2005 and this steadily rose to €45 in 2008 and 2009 but since then has steadily decreased in cost from 2010 (€43) onwards. In 2015 it cost €37 for nebuliser use in the PCRS scheme. This is approximately the same as the 2005 value. A similar trend has been seen in the cost of the pneumococcal vaccination. In 2005, the price per vaccination was €34 this rose each year to €42 in 2010 then steadily declined to €28 in 2015. Again less than 2005 values. This same trend has been replicated in both the influenza vaccination and the combination of the pneumococcal /influenza vaccination. The cost per vaccination was €33 and €50 respectively in 2005 rising to €42 and decreasing to €15 and €42 in 2015 respectively, less than 2005 values. Management of respiratory drugs and prevention interventions have decreased in cost from 2009 onwards, with an exception in 2012, which did not exceed 2009 levels.

Table 7: 2005-2015 PCRS Schemes: Analysis of Special Items of Service. – Related to Respiratory Disease

NUMBER OF CLAIMS	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
NEBULISER	47,775	50,496	49,863	53,715	50,945	57,691	65,669	74,203	74,346	80,542	88,031
PNEUMONOCOCCAL VACCINATION	20,337	12,339	12,264	16,307	14,588	14,332	17,201	16,711	16,195	14,353	14,950
INFLUENZA VACCINATION	299,094	299,769	320,634	329,030	349,890	371,659	401,614	366,166	372,694	375,660	386,716
PNEUMONOCOCCAL/ INFLUENZA VACCINATION	23,885	16,286	14,829	17,021	13,482	14,123	15,168	13,119	12,142	10,324	9,354
COST OF CLAIMS €											
NEBULISER	1,726,807	2,139,503	2,215,589	2,454,626	2,334,488	2,493,436	2,631,021	2,973,263	2,866,126	2,985,832	3,275,709
PNEUMONOCOCCAL VACCINATION	699,646	474,463	494,740	671,109	625,251	612,650	637,802	477,029	461,619	409,133	426,075
INFLUENZA VACCINATION	9,989,318	11,582,655	13,006,903	13,481,357	14,961,300	15,887,673	15,940,542	10,458,833	5,780,058	5,642,331	5,800,864
PNEUMONOCOCCAL/ INFLUENZA VACCINATION	1,204,778	942,133	901,338	1,047,577	863,658	905,535	885,028	562,183	519,158	441,374	399,884
COST PER ITEM €											
NEBULISER	36.14	42.37	44.43	45.70	45.82	43.22	40.06	40.07	38.55	37.07	37.21
PNEUMONOCOCCAL VACCINATION	34.40	38.45	40.34	41.15	42.86	42.75	37.08	28.55	28.50	28.51	28.50
INFLUENZA VACCINATION	33.40	38.64	40.57	40.97	42.76	42.75	39.69	28.56	15.51	15.02	15.00
PNEUMONOCOCCAL/ INFLUENZA VACCINATION	50.44	57.85	60.78	61.55	64.06	64.12	58.35	42.85	42.76	42.75	42.75

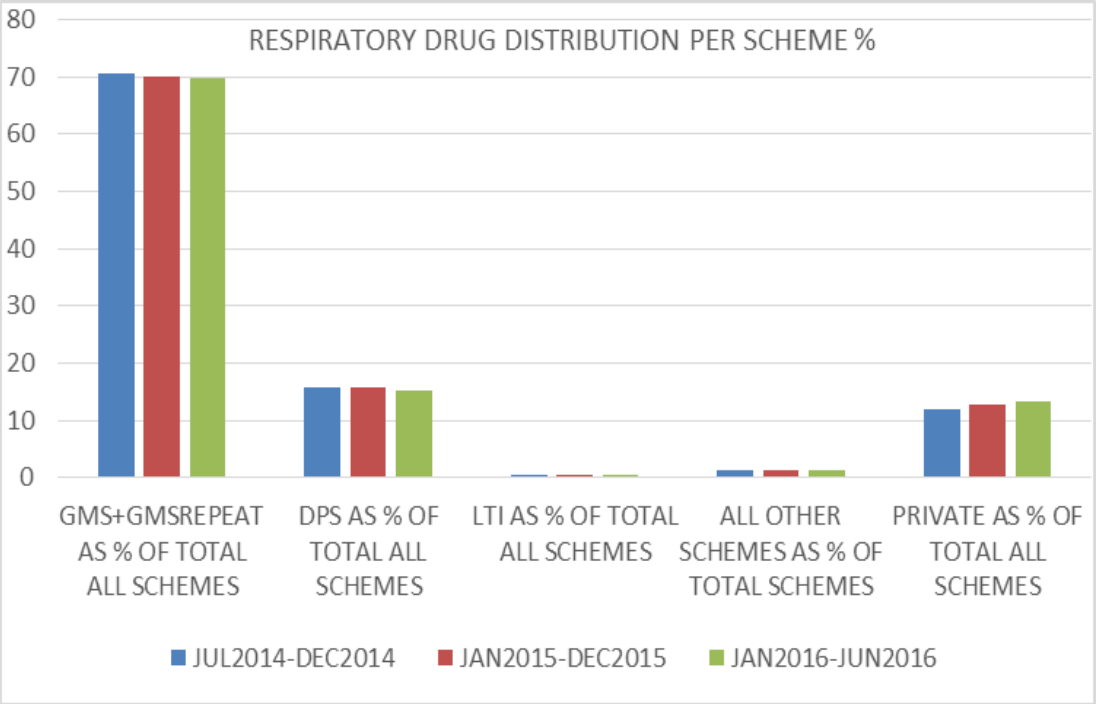
Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2005-2015.

In summary, firstly, during the period that was under review, respiratory medicine expenditure has been less than ten percent of all PCRS expenditure. Secondly, the highest expenditure were drugs for obstructive pulmonary disorder and they are the most frequently prescribed respiratory medicine ATC Class. Thirdly, that the B2 stimulants and corticoids combination group have the highest expenditure out of the drugs for OPD, and the B2 stimulants group are the most frequently dispensed. Finally, preventative measures are taken to combat respiratory disease such as vaccinations and nebuliser use. The cost of these items have decreased over the review period. Nebuliser and the influenza vaccination use has increased over this time and the pneumococcal and influenza/ pneumococcal combination vaccinations has decreased.

4.3. Objective 3: Estimation of percentage of private respiratory medicines expenditure.

To set the percentage the sell-out data[23] (described previously) provided by QuintilesIMS Ltd was used. In this section the total drugs for OPD dispensed per scheme are reviewed as a percentage. Each year or part thereof has been reviewed to analyse any trends that may occur. Graph 12 below shows that the sell-out data is consistently dispensed through each time bracket.

Graph 12. Respiratory drug distribution per scheme. Percentage.



The GMS and GMS repeat scheme (the GMS repeat scheme is where a doctor may prescribe a maximum of three months' treatment for a medical card patient on a separate repeat GMS prescription form. The prescriber must write 'repeat x 2' on the top copy. The repeat GMS prescription form is a six-part form, two parts to each dispensing. Each of the instalments can be dispensed at any pharmacy. When a pharmacist had dispensed the first month's instalment they keep the bottom two copies, stamp the top copy and write the date of dispensing on it and return the remaining copies to the patient. The same procedure applies on the second and third dispensing[25]) accounted for 70-71% since July 2014 to June 2016.The DPS

accounted for 15-16%, the LTI accounted for 0%, and all other schemes accounted for 1% during the same time period. The dispensing of respiratory drugs to the private group are between 12-13% for the time period July 2014 to June 2016.

Since this sell out data became available there is a consistent trend in the percentage of units dispensed that are allocated to the relevant PCRS and private schemes. Most drugs for OPD are dispensed to patients in the GMS and GMS repeat scheme, followed by the DPS and private schemes. Graph 12 illustrates that in total 87% of drugs to treat OPD in the community are dispensed through a Government funded scheme and 13% are paid for privately. Though this data is demonstrated for the medicines in ATC class – drugs for OPD, which has by far the largest expenditure, Graph 7 illustrates that the same trends have been followed for the other respiratory medicines classes, apart from the Hi tech respiratory medicines. These medicines are not licenced to treat the respiratory diseases that are involved in the chronic disease management programmes. The assumption is therefore made that 87% of respiratory medicines that are dispensed in the retail pharmacy are funded by a public Government scheme.

In summary, 87% of respiratory medicines that are dispensed in retail pharmacy are funded by a public Government scheme and 13% are funded privately.

4.4. Objective 4: Calculation to determine the cost of funding respiratory medicines through public schemes.

To estimate cost a scenario analysis (table 8) using two different approaches was used.

Scenario 1. In objective three, section 4.3, an analysis was conducted and determined that 87% of respiratory medicines in the primary setting are funded by the Government through its public schemes. Thus 13% of respiratory medicines are funded privately. Scenario 1 in Table 8, demonstrates how much it would cost the State to pay for respiratory medicines in 2015 if 87% was used as the proportion of public expenditure on respiratory medicine. A calculation was then conducted to determine the private expenditure on respiratory medicines. In 2015, the private spend equates to €20.2m. Using these assumptions, if the Government were to undertake to cover the cost of publically funding all respiratory medicines, the total

cost in 2015 would be €155m of which €135.25m is already funded by the Government.

Scenario 1. 87%:	**€m**	**Scenario 2. 80%:**	**€m**
87% Public Total Resp Spend	135.25	80% Public Total Resp Spend	135.25
13% Private Total Resp Spend	20.20	20% Private Total Resp Spend	33.80
Total Cost of Publically funding Resp Spend	155	Total cost of Publically funding Resp Spend	169

Scenario 2 In this scenario a literature review was undertaken to ascertain if there was any published information informing on what percentage of expenditure on medicines are paid for publicly and privately. The Irish Pharmaceutical Health care Association published on their website that 80% of medicines are paid for by the State in Ireland [26]. Using this data, Scenario two in table 8 demonstrates how much it would cost for the State to pay for respiratory medicines in 2015, if this percentage ratio was used. The public cost was €135.25m in 2015 and if that equates to 80% of all expenditure in the public schemes on respiratory medicines, then 20% equates to private spend which is €33.8m. Adding the private cost to the public expenditure would result in a value of €169m for the Government to cover the costs of all respiratory medicines in 2015, of which they already provided €135.25m.

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Table 8. Scenario Analysis. Calculation of cost to Government to fund all respiratory medicine expenditure. 2015. €m.

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements2015. GMS =General Medical Service; DPS=Drug Payment Scheme; LTI=Long Term Illness Scheme; RESP = Respiratory.

In conclusion, using these two scenarios, the total cost to the State to provide all respiratory medicines through public schemes could range from €155m to €169m of which they are already financing €135.25m (2015 figures). The extra cost in order to provide all respiratory medicines through public schemes could range from between €20.2m to €33.8m. As respiratory disease are chronic diseases and some are part of the chronic disease management programmes this extra cost could be paid through the LTI scheme. This could result in the removal of an adherence barrier, i.e. cost of medications. This aligns with the Governments policy on chronic disease management, which endeavours to increase adherence of chronic disease medicines (amongst other initiatives) to provide best outcomes for patients and most effective use of finite resources.

Section 5. Conclusions

The aim of this research paper was to conduct a review of respiratory medicine expenditure in Ireland from 2005-2015. Four objectives were set.

Objective 1. To review expenditure on all PCRS medicines from 2005-2015.

Objective 2. To review expenditure on all respiratory medicine in the PCRS from 2005-2015.

Objective 3. To estimate what percentage of expenditure on respiratory medicines is allocated to private funding.

Objective 4. To calculate how much the Government would have to spend in order to cover the costs of respiratory medicines for all patients.

This research showed that total PCRS expenditure on all medicines have been decreasing in recent years with 2015 figures being less than expenditure in 2006. Most expenditure is on the GMS scheme.

Respiratory medicines expenditure has always been below 10% of total PCRS spend. Though the actual respiratory medicine spend has decreased in expenditure over the eleven year period, it has not decreased as much as the total medicines expenditure in the PCRS, thereby increasing in percentage terms.

The most frequently prescribed class and also the highest expenditure was allocated to Drugs to treat OPD, these are the most commonly used class to treat respiratory disease.

B2 stimulants and corticoids combination class have the highest expenditure out of the drugs for OPD, and the B2 stimulants class are the most frequently dispensed.

Preventative measures are taken to combat respiratory disease such as vaccinations and nebuliser use. The cost of these items have decreased, nebuliser and influenza vaccination use has increased over this period whilst the pneumococcal and influenza/pneumococcal combination vaccinations have decreased.

87% of drugs to treat OPD are dispensed publicly and 13% privately. Though this data demonstrated using the drugs for OPD class, the assumption was made that this equates to the same for all respiratory medicines.

A scenario analysis was conducted, in which in scenario 1 an 87% public spend was assumed. The private spend equates to €20.2m. The total cost in 2015 would be €155m of which €135.25m is already funded by the Government. Scenario 2 assumed

an 80% public spend equating to €135.25m in 2015 and 20% private spend of €33.8m. Total State cost of €169m. The extra cost to the State could range from between €20.2m to €33.8m, in order to provide all respiratory medicines through public schemes. This extra cost could be paid through the LTI scheme.

To effectively manage resources, the State has introduced a policy to implement chronic disease management programmes. Some respiratory diseases are part of this programme. By managing patients in the community the aim is to increase adherence to medicines and offset the costs of emergency hospital admissions amongst other cost effective measures. If the State paid for the total cost of respiratory medicines, which from this research could range from an extra €20.2m to €33.8m on the LTI scheme, then they would be removing an adherence barrier and be supporting their overall strategy of effectively managing a chronic disease programme with the advantage of the long term financial benefits.

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Appendix.

Appendix i) Supplementary Tables.

Table 1: Description of Community Health Schemes.

General Medical Services. GMS.	Persons who are unable without undue hardship to arrange general practitioner medical and surgical services for themselves and their dependants are eligible for the GMS Scheme. Drugs, medicines and appliances approved under the Scheme are provided through Community Pharmacists. In most cases the GP gives a completed prescription form to an eligible person, who takes it to any Pharmacy that has an agreement

	with the Health Service Executive to dispense drugs, medicines and appliances on presentation of GMS prescription forms. In rural areas a small number of GPs hold contracts to dispense drugs and medications to GMS cardholders who opt to have their medicines dispensed by him/her directly. All GMS claims are processed and paid by the Primary Care Reimbursement Service. Since the 1st October 2010, an eligible person who is supplied a drug, medicine or medical or surgical appliance on the prescription of a Registered Medical Practitioner, Registered Dentist or Registered Nurse Prescriber, is charged a prescription charge by the Community Pharmacy Contractor, currently €2.50 per item subject to a limit of €25 per family per month (effective 1st December 2013). The prescription charge is recouped by the HSE from the Pharmacist [5].
Drugs Payment Scheme. DPS.	The Drugs Payment Scheme (DPS) provides for payment to the Pharmacist for the supply of medicines to individuals and families where the threshold of €144, effective from 1st January 2013, has been exceeded in a calendar month. In order to avail of the Drugs Payment Scheme a person or family must register for the Scheme with the HSE PCRS. Drugs, medicines and appliances currently reimbursable under the Scheme are listed on the HSE website. Other items which were reimbursable under the Drug Cost Subsidisation Scheme and Refund of Drugs Scheme continue, in certain circumstances, to be reimbursable under the Drugs Payment Scheme [5]
Long Term Illness Scheme. LTI.	on approval by the Health Service Executive, persons who suffer from one or more of a schedule of illnesses are entitled to obtain, without charge, irrespective of income, necessary drugs/medicines and/or appliances under the LTI Scheme [5]
High Tech Arrangements. HTD.	Arrangements are in place for the supply and dispensing of High Tech medicines through Community Pharmacists. Such medicines are generally only prescribed or initiated in hospital and would include items such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy or hormonal therapy. The medicines are purchased by the Health Service Executive and supplied through Community Pharmacists for which Pharmacists are paid a patient care fee. The cost of the medicines and patient care fees are paid by the Primary Care Reimbursement Service.

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2015.

Table 4a:2005-2015 PCRS Schemes: Respiratory System: Distribution of Medicines and Appliances by Anatomical Therapeutic Chemical Classification. Ingredient Cost.

YEAR	€M GMS RESPIRATORY SYSTEM INGREDIENT COST	€M DPS RESPIRATORY SYSTEM INGREDIENT COST	€M LTI RESPIRATORY SYSTEM INGREDIENT COST	€M HTD RESPIRATORY SYSTEM INGREDIENT COST	€M TOTAL RESPIRATORY SYSTEM INGREDIENT COST ALL SCHEMES GMS+DPS+LTI+HTD	€M GMS INGREDIENT COST NASAL PREPARATIONS	€M DPS INGREDIENT COST NASAL PREPARATIONS	€M LTI INGREDIENT COST NASAL PREPARATIONS	TOTAL NASAL PREPARATION INGREDIENT COST ALL SCHEMES GMS+DPS+LTI	€M GMS INGREDIENT COST THROAT PREPARATIONS	€M DPS INGREDIENT COST THROAT PREPARATIONS	€M LTI INGREDIENT COST THROAT PREPARATIONS	TOTAL THROAT PREPARATIONS INGREDIENT COST ALL SCHEMES GMS+DPS+LTI	€M GMS INGREDIENT COST DRUGS FOR OPD	€M DPS INGREDIENT COST DRUGS FOR OPD	€M LTI INGREDIENT COST DRUGS FOR OPD	TOTAL DRUGS FOR OPD INGREDIENTCOST ALL SCHEMES GMS+DPS+LTI
2005	63,292,283	27,206,227	324,411	-	90,822,921	2,118,399	1,751,043	21,003	3,890,445	19,931	5,792	157	25,880	57,823,822	24,080,005	284,282	82,188,109
2006	71,957,313	30,452,666	357,439	3,310,475	106,077,893	2,439,052	1,975,379	22,166	4,436,597	19,368	6,382	76	25,826	65,714,346	26,847,211	313,826	92,875,383
2007	80,591,553	33,368,619	386,751	3,683,511	118,030,434	2,671,242	2,120,224	20,271	4,811,737	21,778	7,837	89	29,704	73,822,405	29,462,482	344,563	103,629,450
2008	86,217,131	33,552,453	404,830	3,983,645	124,158,059	2,965,692	2,151,701	21,444	5,138,837	22,476	7,166	122	29,764	78,998,344	29,675,007	349,708	109,023,059
2009	98,264,490	33,158,341	443,749	4,286,257	136,152,837	3,340,128	1,979,040	19,107	5,338,275	26,803	6,109	273	33,185	90,480,098	29,618,540	363,755	120,462,393
2010	95,767,539	27,440,182	356,716	4,072,793	127,637,230	332,698	1,505,733	13,388	1,851,819	24,057	3,770	92	27,919	88,123,366	24,749,324	256,210	113,128,900
2011	92,979,263	23,840,546	311,561	3,823,383	120,954,753	2,981,353	1,136,667	9,703	4,127,723	26,083	3,119	96	29,298	85,908,631	21,796,022	197,540	107,902,193
2012	98,412,774	21,705,902	315,295	4,047,173	124,481,144	3,522,629	1,074,249	9,815	4,606,693	27,741	2,742	63	30,546	90,594,829	19,827,948	181,310	110,604,087
2013	92,032,133	16,954,462	309,951	25,579,372	134,875,918	3,750,217	909,824	10,422	4,670,463	27,437	2,346	63	29,846	84,268,287	15,436,820	163,703	99,868,810
2014	90,121,510	15,482,059	414,422	32,616,923	138,634,914	4,283,524	962,973	16,722	5,263,219	23,641	1,766	38	25,445	82,097,475	13,976,503	233,100	96,307,078
2015	92,107,418	15,655,216	474,533	34,136,127	142,373,294	4,774,176	1,050,201	17,364	5,841,741	20,700	1,707	33	22,440	83,545,262	14,044,655	272,546	97,862,463

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2005-2015. GMS = General Medical Service; DPS=Drug Payment Scheme; LTI=Long Term Illness Scheme; HTD= Hi Tech Drugs Scheme.

Table 4b:2005-2015 PCRS Schemes: Respiratory System: Distribution of Medicines and Appliances by Anatomical Therapeutic Chemical Classification. Ingredient Cost. Continued.

YEAR	€M GMS INGREDIENT COST COUGH & COLD PREPARATIONS	€M DPS INGREDIENT COST COUGH & COLD PREPARATIONS	€M LTI INGREDIENT COST COUGH & COLD PREPARATIONS	TOTAL COUGH & COLD PREPARATIONS INGREDIENT COST ALL SCHEMES GMS+DPS+LTI	€M GMS INGREDIENT COST ANTIHISTAMINES SYSTEMIC USE	€M DPS INGREDIENT COST ANTIHISTAMINES SYSTEMIC USE	€M LYI INGREDIENT COST ANTIHISTAMINES SYSTEMIC USE	TOTAL ANTITHISTAMINES SYSTEMIC USE INGREDIENT COST ALL SCHEMES GMS+DPS+LTI	€M GMS INGREDIENT COST OTHER RESPIRATORY SYSTEM PRODUCTS	€M DPS INGREDIENT COST OTHER RESPIRATORY SYSTEM PRODUCTS	€M LTI INGREDIENT COST OTHER RESPIRATORY SYSTEM PRODUCTS	€M HTD INGREDIENT COST OTHER RESP SYSTEM PRODUCTS	TOTAL OTHER RESPIRATORY SYSTEMS INGREDIENT COST ALL SCHEMES GMS+DPS+LTI+HTD	€M HTD INGREDIENT COST MUCOLYTICS INHALED
2005	1,404,147	295,327	5,813	1,705,287	1,902,221	1,072,590	13,156	2,987,967	23,763	1,470	0	0	25,233	0
2006	1,516,352	331,405	5,443	1,853,200	2,245,256	1,290,777	15,928	3,551,961	22,759	1,512	0	0	24,271	3,310,475
2007	1,566,293	338,785	4,579	1,909,657	2,491,471	1,438,019	17,249	3,946,739	18,364	1,272	0	0	19,636	3,683,511
2008	1,539,813	303,592	12,556	1,855,961	2,676,784	1,413,979	21,000	4,111,763	14,022	1,008	0	0	15,030	3,983,645
2009	1,396,577	224,557	41,588	1,662,722	3,009,095	1,329,459	19,026	4,357,580	11,789	636	0	0	12,425	4,286,257
2010	1,250,716	161,925	72,856	1,485,497	3,031,589	1,019,087	14,260	4,064,936	5,113	343	0	0	5,456	4,072,793
2011	1,485,851	168,430	93,860	1,748,141	2,573,906	736,182	10,452	3,320,540	3,439	126	0	0	3,565	3,823,383
2012	1,574,653	150,858	112,542	1,838,053	2,692,518	650,070	11,565	3,354,153	404	35	0	0	439	4,047,173
2013	1,492,670	127,360	122,118	1,742,148	2,493,504	478,112	13,645	2,985,261	18	0	0	21,362,464	21,362,482	4,216,908
2014	1,368,040	125,113	146,589	1,639,742	2,348,830	415,704	17,973	2,782,507	0	0	0	28,405,929	28,405,929	4,210,994
2015	1,339,161	131,612	165,135	1,635,908	2,428,119	427,041	19,455	2,874,615	0	0	0	29,806,775	29,806,775	4,329,352

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2005-2015. GMS = General Medical Service; DPS=Drug Payment Scheme; LTI=Long Term Illness Scheme; HTD= Hi Tech Drugs Schem

Table 5a:2005-2015 PCRS Schemes: Respiratory System: Distribution of Medicines and Appliances by Anatomical Therapeutic Chemical Classification. Prescribing Frequency.

YEAR	GMS RESPIRATORY SYSTEM PRESCRIBING FREQUENCY	DPS RESPIRATORY SYSTEM PRESCRIBING FREQUENCY	LTI RESPIRATORY SYSTEM PRESCRIBING FREQUENCY	HTD RESPIRATORY SYSTEM PRESCRIBING FREQUENCY	TOTAL RESPIRATORY SYSTEM PRESCRIBING FREQUENCY ALL SCHEMES GMS+DPS+LTI+HTD	GMS NASAL PREPARATIONS PRESCRIBING FREQUENCY	DPS NASAL PREPARATIONS PRESCRIBING FREQUENCY	LTI NASAL PREPARATIONS PRESCRIBING FREQUENCY	TOTAL NASAL PREPARATIONS PRESCRIBING FREQUENCY ALL SCHEMES GMS+DPS+LTI	GMS THROAT PREPARATIONS PRESCRIBING FREQUENCY	DPS THROAT PREPARATIONS PRESCRIBING FREQUENCY	LTI THROAT PREPARATIONS PRESCRIBING FREQUENCY	TOTAL THROAT PREPARATIONS PRESCRIBING FREQUENCY ALL SCHEMES GMS+DPS+LTI	GMS DRUGS FOR OPD PRESCRIBING FREQUENCY	DPS DRUGS FOR OPD PRESCRIBING FREQUENCY	LTI DRUGS FOR OPD PRESCRIBING FREQUENCY	TOTAL DRUGS FOR OPD PRESCRIBING FREQUENCY ALL SCHEMES GMS+DPS+LTI
2005	2,745,138	1,086,842	13,686	-	3,845,666	183,748	131,181	1,517	316,446	8,757	2,575	27	11,359	2,060,368	795,004	9,775	2,865,147
2006	2,975,130	1,208,575	14,464	3,658	4,201,827	207,516	147,289	1,644	356,449	8,503	2,797	29	11,329	2,211,224	871,350	10,253	3,092,827
2007	3,239,879	1,335,221	14,771	3,849	4,593,720	232,317	163,744	1,600	397,661	9,564	3,509	37	13,110	2,386,606	954,072	10,668	3,351,346
2008	3,524,959	1,366,662	16,199	4,170	4,911,990	266,010	173,809	1,729	441,548	10,376	3,352	48	13,776	2,577,213	973,503	11,429	3,562,145
2009	3,750,446	1,281,721	16,074	4,437	5,052,678	298,437	166,948	1,569	466,954	11,595	2,825	40	14,460	2,733,416	914,645	11,583	3,659,644
2010	4,067,914	1,057,441	13,262	4,359	5,142,976	352,159	143,473	1,277	496,909	11,303	1,783	33	13,119	2,939,392	750,823	9,039	3,699,254
2011	4,337,703	979,953	11,916	4,595	5,334,167	393,155	135,284	1,123	529,562	12,256	1,499	29	13,784	3,084,042	690,690	7,604	3,782,336
2012	4,785,070	910,661	11,968	4,918	5,712,617	444,843	123,806	1,152	569,801	13,381	1,340	23	14,744	3,384,351	641,161	7,439	4,032,951
2013	4,780,296	757,892	12,353	6,264	5,556,805	472,301	105,625	1,258	579,184	13,215	1,144	19	14,378	3,344,201	527,514	7,526	3,879,241
2014	4,717,035	698,842	17,058	6,584	5,439,519	478,737	97,171	1,767	577,675	11,458	855	13	12,326	3,309,962	485,498	11,071	3,806,531
2015	4,807,848	713,622	20,471	7,972	5,549,913	495,103	100,051	1,777	596,931	9,963	829	9	10,801	3,373,497	494,797	13,358	3,881,652

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2005-2015. GMS = General Medical Service; DPS=Drug Payment Scheme; LTI=Long Term Illness Scheme; HTD= Hi Tech Drugs Scheme

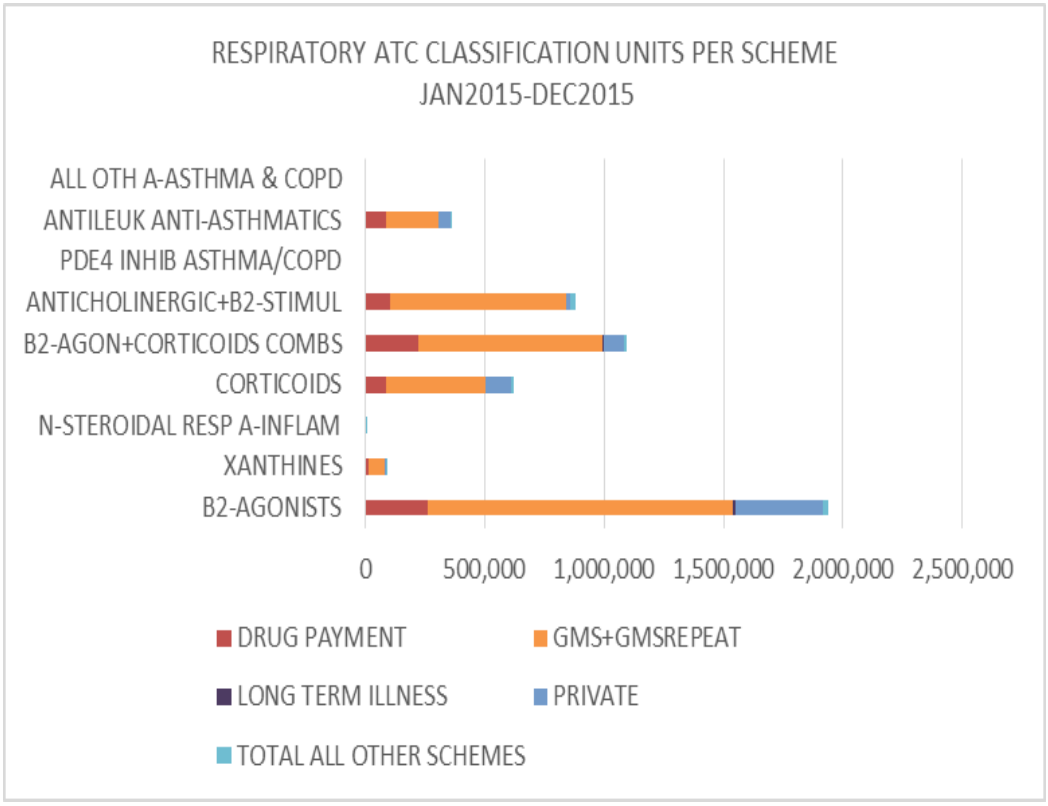
Table 5b: 2005-2015 PCRS Schemes: Respiratory System: Distribution of Medicines and Appliances by Anatomical Therapeutic Chemical Classification. Prescribing Frequency. Continued.

YEAR	GMS COUGH & COLD PREPARATIONS PRESCRIBING FREQUENCY	DPS COUGH & COLD PREPARATIONS PRESCRIBING FREQUENCY	LTI COUGH & COLD PREPARATIONS PRESCRIBING FREQUENCY	TOTAL COUGH & COLD PREPARATIONS PRESCRIBING FREQUENCY ALL SCHEMES GMS+DPS+LTI	GMS ANTIHISTAMINES SYSTEMIC USE PRESCRIBING FREQUENCY	DPS ANTIHISTAMINES SYSTEMIC USE PRESCRIBING FREQUENCY	LTI ANTIHISTAMINES SYSTEMIC USE PRESCRIBING FREQUENCY	TOTAL ANTIHISTAMINES SYSTEMIC USE PRESCRIBING FREQUENCY ALL SCHEMES GMS+DPS+LTI	GMS OTHER RESPIRATORY SYSTEM PRODUCTS PRESCRIBING FREQUENCY	DPS OTHER RESPIRATORY SYSTEM PRODUCTS PRESCRIBING FREQUENCY	LTI OTHER RESPIRATORY SYSTEM PRODUCTS PRESCRIBING FREQUENCY	HTD OTHER RESPIRATORY SYSTEM PRODUCTS PRESCRIBING FREQUENCY	TOTAL OTHER RESPIRATORY SYSTEMS PRESCRIBING FREQUENCY ALL SCHEMES	HTD MUCOLYTICS INHALED PRESCRIBING FREQUENCY
2005	273,563	53,210	873	327,646	217,649	104,804	1,494	323,947	1,053	68	0	0	1,121	-
2006	291,462	60,258	826	352,546	255,476	126,809	1,712	383,997	949	72	0	0	1,021	3,658
2007	326,126	67,233	693	394,052	284,523	146,605	1,773	432,901	743	58	0	0	801	3,849
2008	351,277	64,238	876	416,391	319,518	151,715	2,117	473,350	565	45	0	0	610	4,170
2009	352,058	51,593	1,088	404,739	354,500	145,683	1,794	501,977	440	27	0	0	467	4,437
2010	355,115	38,174	1,457	394,746	409,760	123,176	1,456	534,392	185	12	0	0	197	4,359
2011	392,586	36,901	1,788	431,275	455,570	115,572	1,372	572,514	94	7	0	0	101	4,595
2012	415,711	32,781	2,078	450,570	526,772	111,571	1,276	639,619	12	2	0	0	14	4,918
2013	380,431	26,051	2,385	408,867	570,147	97,558	1,165	668,870	1	-	0	1,192	1,193	5,072
2014	335,676	23,197	3,070	361,943	581,202	92,121	1,587	674,910	0	0	0	1,576	1,576	5,008
2015	327,459	23,140	3,629	354,228	601,826	94,805	1,698	698,329	0	0	0	1,976	1,976	5,996

Source: Primary Care Reimbursement Service (PCRS): Statistical Analysis of Claims and Reimbursements 2005-2015.GMS = General Medical Service; DPS=Drug Payment Scheme; LTI=Long Term Illness Scheme; HTD= Hi Tech Drugs Scheme

Appendix ii) Supplemental Graphs.

Graph 10 Respiratory ATC Classification units per scheme. Jan 2015-Dec2015.



Graph 11. Respiratory ATC Classification units per scheme. Jan 2016-Jun2016.

