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Northern Ireland Audit Office

Primary Care Prescribing

REPORT BY THE COMPTROLLER AND AUDITOR GENERAL
27 November 2014

Northern Ireland Audit Office

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K J Donnelly
Comptroller and Auditor General

Northern Ireland Audit Office
27 November 2014

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For further information about the Northern Ireland Audit Office please contact:

Northern Ireland Audit Office
106 University Street
BELFAST
BT7 1EU

Tel: 028 9025 1100
email: info@niauditoffice.gov.uk
website: **www.niauditoffice.gov.uk**

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Abbreviations

ABPI	Association of British Pharmaceutical Industry
APP	Annual Professional Practice Allowance
BNF	British National Formulary
BSO	Business Service Organisation
CoSI	Cost of Service Investigation
CPC	Community Pharmacy Contractor
CPNI	Community Pharmacy Northern Ireland
DHSSPS	Department of Health, Social Services and Public Safety
GMS	General Medical Services
GP	General Practitioner
HSC	Health and Social Care
HSCB	Health and Social Care Board
JR	Judicial Review
LDL	Low Density Lipoprotein
MMA	Medicines Management Adviser
NAO	National Audit Office
NHS	National Health Service
NI	Northern Ireland
NIAO	Northern Ireland Audit Office
NICE	National Institute of Health and Clinical Excellence
PCC	Pharmaceutical Contractors Committee
PCEP	Pharmaceutical Clinical Effectiveness Programme
PIS	Prescibing Incentive Scheme
PPI	Proton Pump Inhibitor
PPRS	Pharmaceutical Price Regulation Scheme
PU	Prescribing Unit
QOF	Quality and Outcomes Framework
RIA	Regulatory Impact Assessment
UK	United Kingdom
WTE	Whole Time Equivalent

Glossary of terms

Association of British Pharmaceutical Industry (ABPI)	Represents biopharmaceutical companies and is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.
British National Formulary (BNF)	A joint publication of the British Medical Association and the Royal Pharmaceutical Society. It aims to provide prescribers, pharmacists, and other healthcare professionals with sound, up-to-date information about the use of medicines.
Community Pharmacy Contractor (CPC)	Dispenses health service prescriptions after application and acceptance onto the Health and Social Care pharmaceutical list. Applications can be made by registered pharmacists or non-pharmacists, partnerships or bodies corporate, as long as a registered pharmacist is employed.
The Comprehensive Spending Review (CSR)	The Comprehensive Spending Review sets out the Government's objectives and priorities and allocates resources accordingly.
Cost of Service Inquiry (COSI)	Identifies and quantifies the various NHS costs involved in delivering community pharmacy services.
Generic drugs	A pharmaceutical product no longer protected by a patent which can be copied by other companies. It may be marketed either under its own brand or as an unbranded product. Generic drugs are frequently as effective as, but much cheaper than, brand-name drugs, because their manufacturers do not incur the risks and costs associated with the research and development of innovative medicines.
Generic Prescribing	Current policy is that generic medicines should be prescribed in all appropriate circumstances. It is considered that around 75 per cent of medicines can be dispensed generically.
Judicial Review	A process by which the courts review the lawfulness of a decision made (or sometimes lack of a decision made) or action taken (or sometimes failure to act) by a public body. A judge considers whether a public body has acted in accordance with its legal obligations and if not, can declare a decision taken by it invalid.
Local Commissioning Groups (LCGs)	There are five Local Commissioning Groups in Northern Ireland (Belfast, Northern, South Eastern, Southern and Western). LCGs are committees of the Health and Social Care Board and are responsible for commissioning health and social care for their local population. They also have responsibility for planning and delivering health and social care to meet assessed needs.

Medicines Management Advisers (MMAs)	Pharmacists employed by the Health and Social Care Board who work with GP surgeries in order to support the safe effective and efficient use of medicines in primary care.
Prescription Item	A medicine, appliance or device written by a practitioner onto an appropriate prescription form.
National Institute for Health and Care Excellence (NICE)	An executive non departmental public body of the Department of Health in the United Kingdom. NICE provides guidance on current best practice in health and social care, including public health, to the NHS in England and Wales. All NICE guidance published since 1 July 2006, is reviewed locally, for its applicability to Northern Ireland and, where applicable, is endorsed for implementation.
Community Pharmacy Northern Ireland (CPNI)	The local representative body for community pharmacist contractors provide services under the National Health Service in Northern Ireland. It negotiates on services, the pharmacy contract and remuneration and reimbursement with the Health and Social Care Board and the Department of Health, Social Services and Public Safety.
Pharmaceutical Clinical Effectiveness (PCE)	A systematic approach to rational product selection and use, consistently applied across secondary and primary care, taking account of clinical need, evidential product clinical performance, product presentation, safety characteristics and economic factors. The process can be applied to medicines, wound care and medical and surgical disposable products.
Pharmaceutical Price Regulation Scheme (PPRS)	A non-contractual, 5 year, voluntary scheme between UK Government and Industry covering all the relevant key issues that underpin the pricing of the majority of NHS branded medicines.
Northern Ireland Prescribing Units (NI-PU)	Weight individual General Practitioner (GP) practices or Local Commissioning Groups' populations for age, gender and need to enable comparison of prescribing patterns. The figures are based on cost of prescribing across all therapeutic areas. The cost based weightings are standardised (based on a female aged 5-15). Comparisons can therefore take account, for example, of the greater needs of elderly people and of people living in deprived areas or whose socio-economic circumstances mean they have higher than NI average need for prescribing resources.
Regulatory Impact Assessment (RIA)	A detailed and systematic appraisal of the potential impacts of a new regulation. New regulations should only be introduced when other alternatives have been considered and rejected and where the benefits justify the costs.

Executive Summary

Executive Summary

1. Most health service drug expenditure is incurred in primary care where General Practitioners (GPs) prescribe medicines or treatments to address the clinical needs of patients. The role of GPs in deciding how resources should be spent on these drugs is, therefore, key. Patient consultations with GPs have increased by almost 22 per cent over the six year period to 2013-14. The trend in rising patient consultations with GPs is likely to continue due to the following drivers:

    - Like all UK regions the population of older people is increasing[1];
    - Poor lifestyles are a threat to population health particularly in lower socioeconomic groups;
    - Overuse, sub optimal use and abuse of prescription medicines; and
    - Pharmaceutical innovation and medical advances.

2. Decisions on which medication or treatment is prescribed rests with the GP and these decisions are highly regulated and controlled. However, patients' requests and expectations (and prescribers' perceptions of these) can influence prescribing behaviour. Further, the decision on whether or not to consume prescribed medication rests with the patient.

3. Once in receipt of a prescription, the patient takes it to a Community Pharmacy Contractor (CPC)[2]. The CPC dispenses the drug in question, currently at no charge to the patient. CPCs are responsible for purchasing the drugs either directly from manufacturers or through wholesalers. They are subsequently reimbursed by the Health and Social Care (HSC) Board for the cost of these drugs.

4. In 2013 CPCs received almost £460 million for providing community pharmaceutical services, which included reimbursement[3] of £381 million for dispensing almost 39 million items prescribed by GPs.

5. This report demonstrates that demand for primary care medicines is characterised by a particularly complex and unique set of relationships, in which:

    - Patients neither decide nor directly pay (currently) for the medicines they consume;

1 Office of National Statistics, National Population Projections, 2012-based Statistical Bulletin

2 The Health and Social Care (HSC) Board is legislatively required to make arrangements for the provision of community pharmaceutical services in Northern Ireland. In practice, it contracts out these services to Community Pharmacy Contractors (CPCs). In 2014, the HSC Board had contracts with 225 CPCs who dispensed prescriptions from 535 pharmacies. According to Office of Fair Trading (Evaluating the Impact of the 2003 OFT Study on the Control of Entry Regulations in the Retail Pharmacies Market (March 2010)); NHS Information Centre, (General Pharmaceutical Services in England, 2001-2002 to 2010-2011 (November 2011)), the combined share of this market among the larger multiples and supermarkets is now estimated to be slightly over 50 per cent.

3 Traditionally arrangements for reimbursing NI CPCs followed those in place elsewhere in the UK. However, new contractual arrangements which were adopted in England, Wales and Scotland were rejected by NI CPCs and they subsequently legally challenged the continued reliance on the UK Drug Tariff in NI. The legal challenge was upheld. Subsequent negotiations failed to find a resolution and NI CPCs again took legal action. Again the legal challenge was upheld. No resolution has yet been found and negotiations continue.

- GPs decide which medicines should be used but are not responsible for the cost of what they prescribe; whereas

- the HSC Board pays for medicines by reimbursing pharmacies for dispensing them but is not responsible for deciding which medicines are to be prescribed.

6. Against the background of these relationships, the main thrust of this report is that more rational prescribing by GPs can achieve significant economies in drug expenditure and release money from within the drugs budget without compromising patient care. It is acknowledged that between 2006 and 2013, the cost of prescribing was reduced in real terms by 18 per cent.

7. As the drugs budget is spent predominantly by GPs, the HSC Board does not directly control prescribing behaviour. Moreover, the prescribing decisions GPs make can be affected by a range of factors, such as patient need, clinical guidance, access to good information and the marketing activities of the pharmaceutical industry [4]. A key challenge for the Board, therefore, is to effectively influence the prescribing behaviour of GPs.

8. We acknowledge the key role played by the Board's Medicine Management Advisers (MMAs) in instigating and facilitating change through the promotion of more rational, safe, economic and effective prescribing among GP practices. While MMAs have little power to compel doctors to prescribe in a particular way, they have had considerable success in working alongside GP practices to facilitate change and generate savings in the prescribing budget. For instance, while the volume of prescriptions increased by around 5 per cent between 2010 and 2012, the cost of prescribing these drugs has decreased by just over 7 per cent in the same period. Commendably, one of the reasons for the reduction in costs is that generic prescribing rates have improved considerably in NI over recent years and are now on a par with levels elsewhere in the UK. Also, the variations between practices have reduced significantly over the period 2010 to 2013.

9. The report draws particular attention to the continuing variations shown by data on prescribing activity and prescribing expenditure, both between GP practices locally and with their peers in other parts of the UK using national data. We found variations in the volumes and cost of prescribing which did not appear to match variations in indicators of clinical need, such as disease prevalence. The HSC Board regard Quality and Outcomes Framework (QOF) data on disease prevalence as extremely useful

4 House of Commons Health Committee, The Influence of the Pharmaceutical Industry, 5 April 2005.

Executive Summary

for assessing clinical need and planning service development. However, the Department considers that the use of QOF data in reaching any conclusion on relative need between populations is erroneous. It told us it had been advised by the Northern Ireland Statistics and Research Agency and the Health and Social Care Information Centre in England that QOF data is unsuitable as a measure of need in this context. Our report stresses the importance of the HSC Board and GPs using all available sources of relevant data to support the benchmarking of GP practices in identifying prescribing patterns which are significantly different between peers and which warrant further examination.

10. We acknowledge that high-level prescribing cost comparisons with the other UK regions have to be drawn with great caution. In the Department's view, such comparisons are deeply flawed given the differences in data definitions and prescribing practices within the jurisdictions. However, available national statistics would suggest that if prescribing expenditure here had been in line with that in Wales in 2013, costs would have been reduced by £73 million. The Department does not accept that these statistics are a measure of relative efficiency and would not support the view that costs could be reduced by £73 million, as in its view, the statistics do not compare jurisdictions on a like for like basis.

11. More pertinent are the large variations we found in prescribing costs between local GP practices after standardising their caseloads, meaning that there is scope for GP practices to improve efficiency, without affecting clinical outcomes. As a result, we estimated that, in 2013, potential savings of £19 million could have been realised if all GP practices had achieved at least the standard of the average practice. We recognise that it will be challenging for GPs to achieve all such potential savings given that the savings need to be made across a wide range of prescribed drugs. The department has commented that such estimates are crude and do not take into consideration the other factors associated with prescribing such as access to other services; the impact of cross-border workers; private healthcare. The Department considers that there will always be a degree of variability between GP practices and therefore the full quantum of such efficiencies will not be realisable.

12. We also examined three groups of drugs used to treat conditions for which there are several suitable drugs available at differing prices. We found large variations in the extent to which local GP practices prescribed lower cost drugs in comparison to GP practices in the rest of the UK. We also examined use of the drug which has incurred the highest cost in NI in the last number of years. We calculated that the opportunity cost to health and social care services here of

not meeting UK levels was £17 million in 2012 and £15 million in 2013.

13. Potential economies may also be achievable in other areas. For example, research published in England estimated that NHS primary and community care prescription medicines waste cost £300 million. This indicates that an estimated £18 million may be lost every year in Northern Ireland in wasted prescriptions. However, we have been advised by the Department that while there is potential waste, the interventions needed to address this issue would offset the potential savings. It is also important to note that this is not in addition to the monies referred to above. There may also be potential for generating further savings by reducing the number of prescriptions for drugs of limited clinical value or drugs which are not clinically necessary. In this report we looked at the potential for generating savings by moving from off-patent branded medicines to much cheaper generic equivalents.

Part One:
Background and Scope of Report

Part One:
Background and Scope of Report

In Northern Ireland, the Health and Social Care Board contracts external providers to supply pharmaceutical services to the public

1.1 The Health and Social Care (HSC) Board[5] is legislatively required to make arrangements for the provision of community pharmaceutical services in Northern Ireland. These services include dispensing those drugs prescribed by General Practitioners (GPs)[6]. In practice, it contracts out these services to independent, retail pharmacy-outlet owners (known as Community Pharmacy Contractors (CPCs)).

1.2 CPCs can be registered pharmacists, non-pharmacists, partnerships or bodies corporate (providing a registered pharmacist is employed in each pharmacy outlet). In 2014, the HSC Board had contracts with 225 CPCs to provide community pharmaceutical services from 535 pharmacies.

1.3 In 2014, 51 per cent of NI Pharmacies were small independent businesses, 30 per cent operated in local partnerships and the remainder, 19 per cent, formed part of UK or multi-national groups.

In 2013 community pharmaceutical services cost £460 million and CPCs dispensed almost 39 million prescription items

1.4 In Northern Ireland, in 2013, almost 39 million items prescribed by GPs, were dispensed by CPCs. That year, funding to CPCs for providing community pharmaceutical services amounted to £460 million. This represents approximately 10 per cent of the total spend on health and social care in Northern Ireland.

1.5 Research published by York Health Economics consortium in *An Evaluation of the Scale, Causes and Costs of Waste Medicines* reported that in England NHS primary and community care prescription medicines waste cost £300 million. This indicates that a level of £18 million may be lost every year in Northern Ireland in wasted prescriptions[7]. This estimate reflects patients' failure to take appropriate medicine which in turn impacts on:

- the patient – who may not see an improvement in their condition or whose health may deteriorate;

5 Under Article 63 of the Health and Social Services (NI) Order 1972.

6 GPs are medically-qualified doctors with responsibility for attending to the everyday medical needs of a community. They operate in the primary care sector. In Northern Ireland, the term 'primary care' refers to any of '*the many forms of health and social care and/or treatment accessed through a first point of contact provided outside hospitals*'. Treatment provided in a hospital setting is referred to as 'secondary care'.

7 NI Direct website – Health and Well-being.

- the HSC Budget – which could re-direct resources within the HSC sector; and

- the pharmaceutical industry – which may struggle to prove the effectiveness of new and innovative drugs through post-marketing surveillance.

1.6 Since 2010-11, the Department and the Health and Social Care (HSC) Board ran an annual '*Don't Use It, Don't Order it*' prescriptions medicines wastage advertising campaign. In 2013-14, the campaign included a new message '*Wasting Medicines Wastes Money*' with the aim of influencing patients' attitudes and behaviours to prevent over-ordering of repeat prescription medicines.

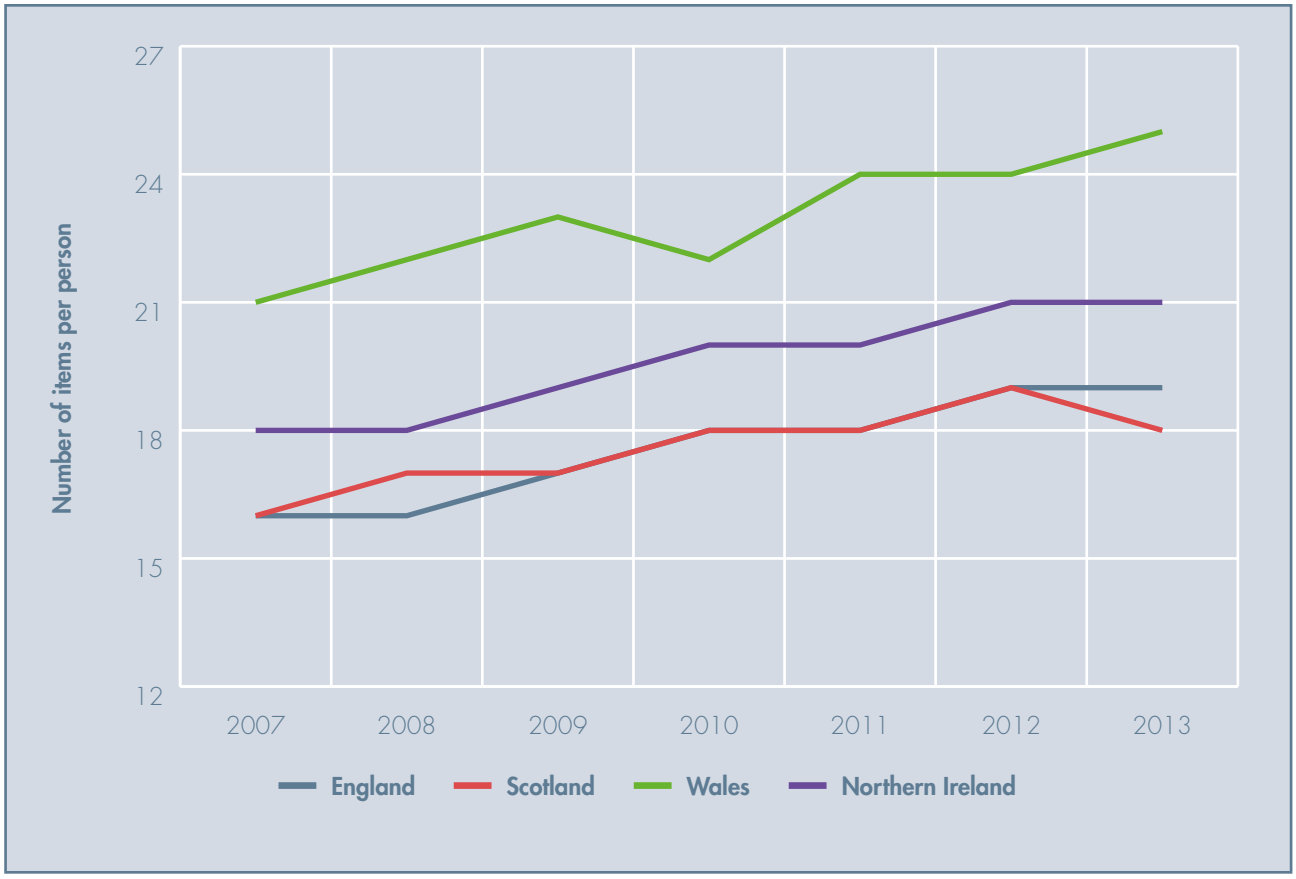
1.7 However, we have been advised by the Department that while there is potential waste, the interventions needed to address this issue could offset the potential savings. Since a proportion of medicines waste is therefore inevitable, complementary measures which improve the quality and safety of prescribing are required. We welcome the introduction of such initiatives which have the potential to reduce expenditure.

High level comparison of the number and cost of prescriptions elsewhere in the United Kingdom indicates that there is potential for improving cost effective prescribing in Northern Ireland

1.8 The number of items prescribed has increased in each region of the United Kingdom (UK) over the seven year period to 2013. **Figure 1** shows that Wales has consistently prescribed more items per head of population that any other UK region. Prescribing levels in NI, although lower than those in Wales have been higher than levels in England and Scotland in each of the last seven years. Levels in England and Scotland are very similar.

Part One:
Background and Scope of Report

Figure 1: Number of items prescribed per head of population in the UK over the period 2007-2013



Source: Business Services Organisation – Prescription Cost Analysis Reports[8]

1.9 **Figure 2** compares the cost of prescribing per head of population in England, Scotland, Wales and NI over the seven year period to 2013. Overall, England has consistently had the lowest cost per head of population in each year since 2007. There are, of course, regional variations across England. For example, the number of items prescribed per head of population in the North East of England is 50 per cent greater than the number in the South of England. Costs in Scotland and Wales are broadly similar, higher than those in England but less than those in NI. NI has had the highest cost per head of population since 2007 and is the only region in which costs per head of population are higher in 2013 than they were in 2007.

8 Mid year population figures for 2012 were used as the 2013 population statistics were not available at the time of publication.

Figure 2: Prescribing cost per head of population

Source: Business Services Organisation – Prescription Cost Analysis Reports

		2007	2010	2013
	NI	£221.09	£243.94	£223.54
	England	£162.95	£167.82	£160.12
	Scotland	£187.92	£192.25	£183.73
	Wales	£196.37	£193.05	£182.96

Part One:
Background and Scope of Report

1.10 It is important to remember that this form of high level analysis, while demonstrating trends over time, does not take account of definitional or organisational differences across regions. However, using these comparative statistics as a very basic measure of relative efficiency, the variation in prescribing costs here compared with other UK countries provides some evidence that it is possible for local GPs to prescribe less expensively. For example, if prescribing costs had been in line with those in Wales in 2013, overall prescribing costs could have been reduced by £73 million.

1.11 The Department does not accept that these statistics are a measure of relative efficiency across the UK and would not support the NIAO view that costs could be reduced by £73 million if prescribing costs here were in line with Wales. In its view, the statistics do not compare jurisdictions on a like for like basis: for example, the Department told us that they do not take account of variations in the ratio of community to hospital prescribing that exist across jurisdictions. In England in 2012, 63.5 per cent of total medicines expenditure took place in the primary care setting, the comparable figure here was 72.7 per cent.

1.12 We acknowledge that prescribing arrangements can differ between the four countries: for instance, outpatients who are prescribed drugs by consultants here will have that prescription filled out by their GP; in England, by contrast, such a prescription will be dispensed by the hospital and therefore will not be a charge on the primary care budget.

1.13 As a result, we recognise that it will be important to account for the precise differences in the prescribing patterns of GPs here when comparing them with elsewhere in the UK. This basic comparison, which is based on published data, points up the need for a comprehensive examination of the cost implications of prescribing in order to explore and implement specific measures to promote more cost-effective prescribing patterns among local GP practices. Our study looks in more detail at this in Part 4.

1.14 In addition to variations in prescribing arrangements, the higher cost of prescribed medicines in primary care in Northern Ireland is due to, for example:

- progress in achieving savings through generic, rather than branded, prescribing has been slower here than elsewhere in the UK (see paragraph 4.5);

- unlike the other UK regions, the introduction of new drugs was not as tightly controlled here, therefore the prescribing of newer, and usually more expensive drugs (including generics) can be more widespread in NI; and

- secondary care (hospital) prescribing practice has more impact on GP prescribing practices in NI than elsewhere in the UK .

The Department has advised us that it does not accept the final two bullet points.

1.15 The Department told us that prior to 2004, the approach taken to reducing medicines expenditure had been to focus on the costs and seek to deliver a range of cost cutting initiatives. However an exclusively financial focus can have far reaching consequences in respect of quality, safety and well being of patients. This has been borne out in recent times in the Francis Report into the Mid -Staffordshire Trust. A sole financial focus in the management of medicines has only limited success and does not address the challenge of optimising the outcomes for patients through the use of prescribed medicines. Since 2004, medicines optimisation policy in Northern Ireland has been predicated on quality and safety improvement delivering improved health outcomes and realised efficiencies. Such an approach addresses value for money requirements in addition to important medicines optimisation principles including:

- **Rationality** Attention to the evidence base for the prescribing of medicines;

- **Safety** Address avoidable medication related errors and adverse incidents;

- **Individuality** Optimise outcomes for individual patients;

- **Equity** Ensuring equality of provision across the population, therapeutic conditions and new medicine;

- **Consistency** Prescribing practice that conforms to acceptable standards;

- **Continuity** Optimised medicines outcomes across sectors and professional groups; and

- **Innovation** Removing barriers to continuous quality improvement.

Part One:
Background and Scope of Report

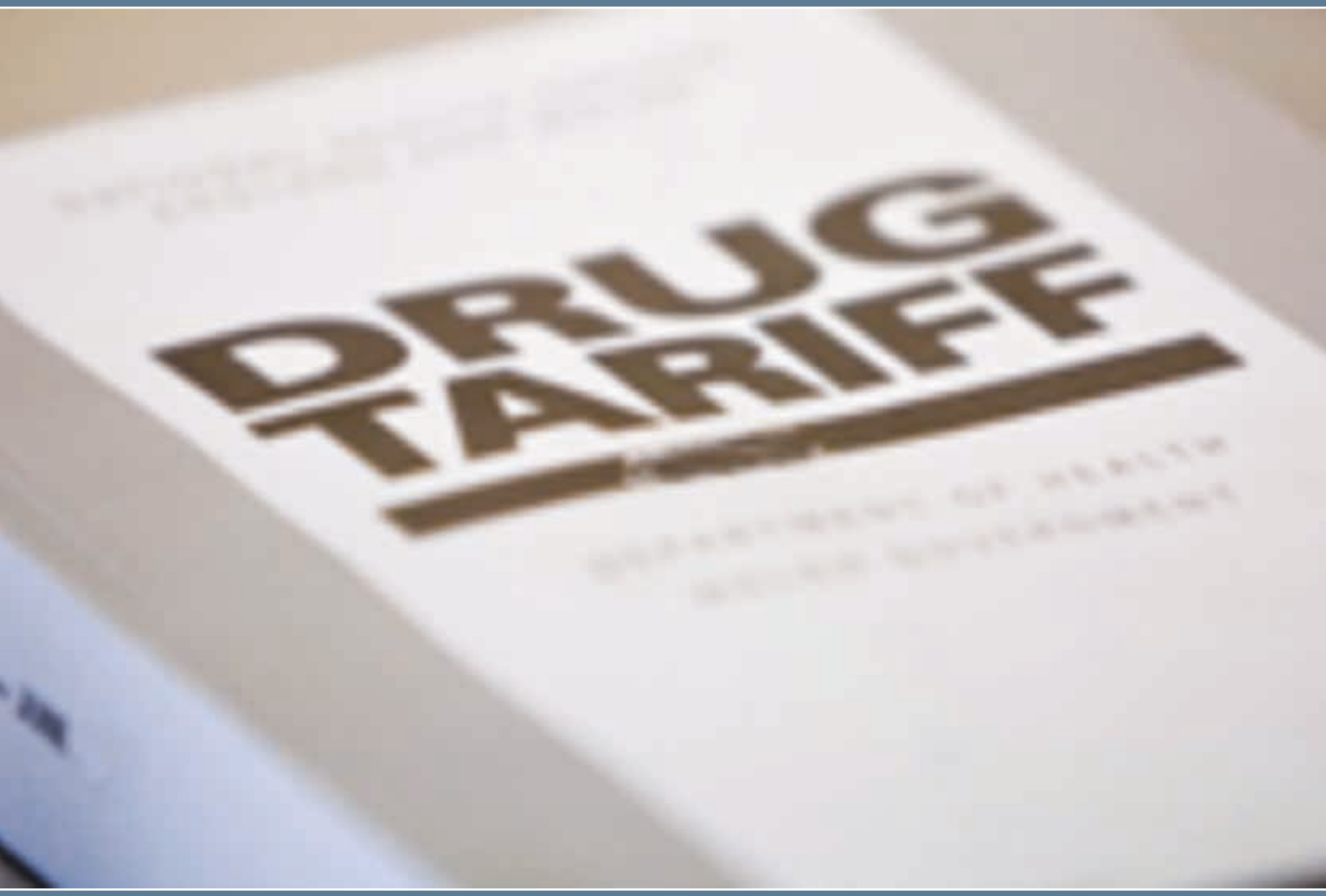
Purpose and Scope of our review

1.16 This report looks at the value for money of primary care drugs prescribing and dispensing:

- Part 2 considers the arrangements for reimbursing CPCs;
- Part 3 looks at trends in GP prescribing, the volume of prescriptions and the cost pressures on the prescribing budget; and
- Part 4 examines the potential for further cost savings.

1.17 The report does not examine secondary care (hospital) prescribing or quantify its impact on primary care prescribing. It is important to note, however, that secondary care prescribing decisions often impact on primary care prescribing decisions and costs (see paragraph 3.2). Further, this report does not consider in detail the potential for generating savings by reducing drug wastage.

Part Two:
Community Pharmacy Contractors' Reimbursement

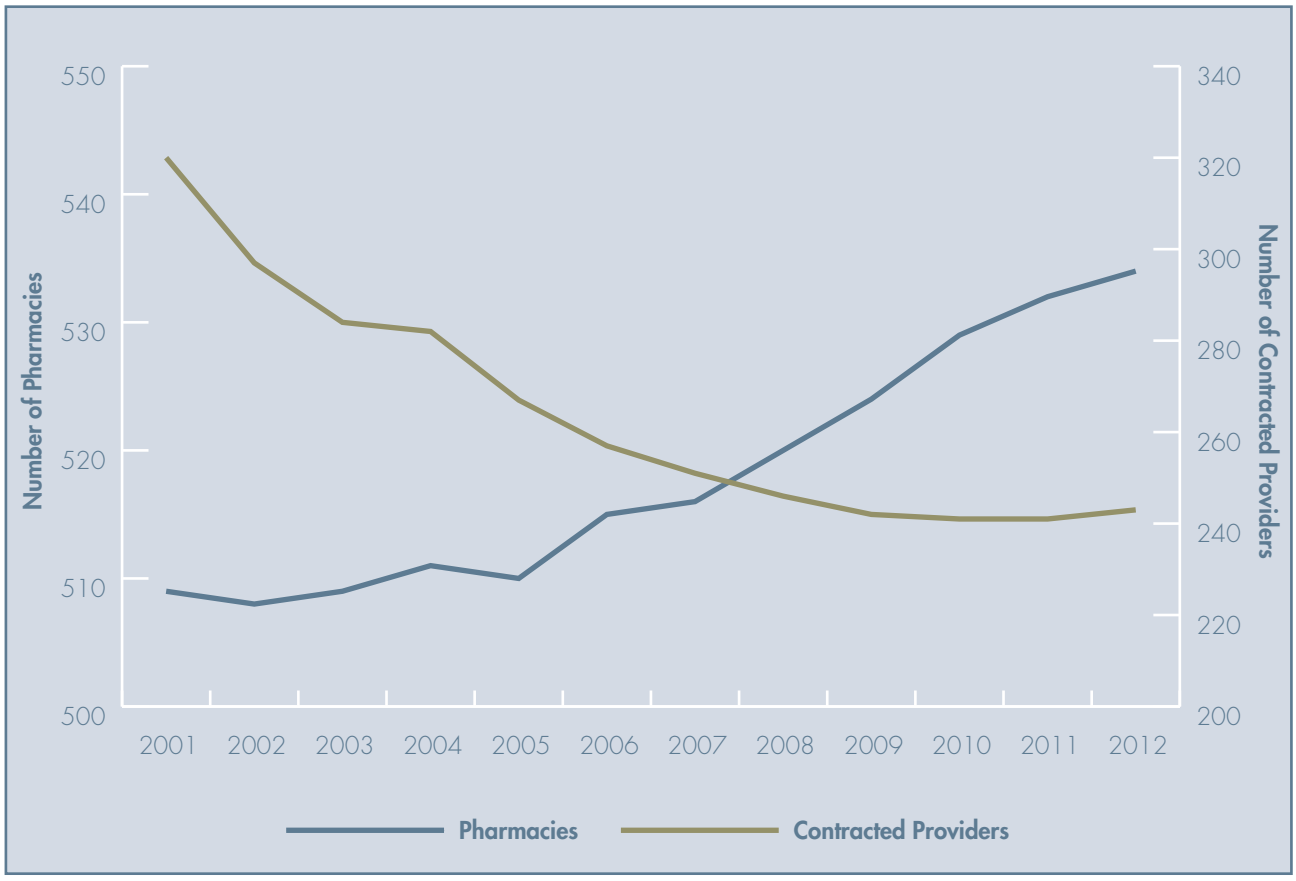


Part Two:
Community Pharmacy Contractors' Reimbursement

Over time, the number of pharmacy outlets in Northern Ireland has risen while the number of CPCs has fallen

2.1 In 2012, the HSC Board had contracts with 243 CPCs to provide community pharmaceutical services (including dispensing health service-prescribed medicines) from 547 pharmacies. Twelve years ago, 320 CPCs were contracted to provide services in 509 pharmacies in Northern Ireland (see **Figure 3**). Therefore, over time, while the number of pharmacy outlets increased, the number of CPCs decreased by almost 25 per cent. The Department told us that in 2014, the HSC Board had contracts with 225 CPCs to provide community pharmaceutical services from 535 pharmacies.

Figure 3: The number of providers contracted to provide pharmaceutical services and the total number of pharmacies over the period 2001 to 2012



Source: The Department of Health, Social Services and Public Safety

Northern Ireland CPCs dispense more prescriptions per head of population than those in England and Scotland.

2.2 Northern Ireland has a lower average population per service provider than England and Wales. The average number of prescriptions dispensed by service providers in Northern Ireland is higher than those in England and Scotland but lower than Wales. **Figure 4** provides comparative figures.

Figure 4: UK Comparative Pharmacy Information -2013

	Northern Ireland	England	Scotland	Wales
Population Estimate (millions)	1.8	53.9	5.3	3.1
Total Service Providers	547	17,823	1,580	1,067
Total Prescriptions (millions)	38.7	1,003.8	97.7	76.2
Number of Service Providers/1000 population	0.30	0.33	0.30	0.34
Average population per service provider	3,291	3,024	3,354	2,905
Average prescriptions per service provider	70,750	56,320	61,835	71,415
Prescriptions per head of population	21.50	18.62	18.43	24.58

Source: Business Services Organisation

Notes: Data is for calendar year 2013 with exception of England which is only available as financiaL year 2012-13

Total Prescription Items includes items dispensed by community pharmacies, appliance contractors and dispensing doctors

Service provider refers to Pharmacies, Appliance Contractors and Dispensing GPs (i.e. individual GPs not Dispensing Practice)

Part Two:
Community Pharmacy Contractors' Reimbursement

2.3 In looking at the numbers of pharmacies for each population it is worth considering the issue of access to services for service users. Pharmacies in NI offer some, or all, of the following examples of services:

- minor ailments scheme;
- smoking cessation scheme;
- medicines management services;
- medicines use reviews;
- repeat dispensing services;
- oxygen supply;
- emergency hormonal contraception;
- Helicobacter Pylori testing;
- supply of palliative medicine (out of hours);
- measuring and fitting of hosiery garments;
- supply of substitution medicines to addicted persons;
- needle exchange schemes; and
- receipt and disposal of unwanted medicines.

2.4 Pharmacists are often the first port of call for sick persons seeking advice or treatment of minor ailments and are able to refer patients with more serious injuries to the appropriate treatment channels. Some pharmacies also offer services such as blood sugar testing, cholesterol testing, blood pressure measurement, body mass index measurements and weight management schemes which do not form part of contractual arrangements.

2.5 Contracts are regulated by the Control of Entry Regulations which set out the criteria which must be met before the HSC Board can commission a CPC to provide pharmaceutical services. There are currently no established legislative mechanisms or processes in place to either remove commissioned CPCs who continue to meet the relevant criteria from the pharmaceutical list or to reduce the overall number of contracts. However, the Department and the HSC Board are currently undertaking a Needs Assessment to identify areas of under or over provision of pharmaceutical services in Northern Ireland.

In 2012-13 CPCs received £460 million for providing community pharmaceutical services

2.6 CPCs attract a range of funding for the services they provide on behalf of the HSC Board. In 2012-13, just under £460 million was paid to CPCs. **Figure 5** provides a breakdown of the various elements of the 2012-13 funding envelope.

Reimbursement costs are the most significant element of the funding package

2.7 The most significant element of CPC funding relates to reimbursement for purchasing and dispensing drugs. During 2012-13, reimbursement fees to pharmacists amounted to £381 million (see **Figure 5**).

The majority of reimbursement costs each year relate to 'branded' drugs

2.8 About 70 per cent of the reimbursement cost in 2012-13 related to the supply of 'branded' drugs – drugs still protected by patent and known by the trade name given by the manufacturer. While branded drugs account for nearly 70 per cent of reimbursement costs, they only account for about 30 per cent of the total volume of items dispensed each year.

2.9 Reimbursement levels for branded drugs are determined by the published list price[9] which balances the need to ensure that safe and effective medicines are provided on terms acceptable to the health service against the need to support a profitable pharmaceutical industry in the UK.

2.10 The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement between government[10] and the UK pharmaceutical industry covering the supply of most branded medicines. The latest PPRS runs for five years from 1 January 2014. Under the terms of the current PPRS, the pharmaceutical industry has guaranteed that it will underwrite any additional cost of supplying branded medicines in the next two years. The industry has also agreed to absorb an element of any additional costs incurred in the final three years of the PPRS.

2.11 The latest PPRS offers predictability (for government and the pharmaceutical industry) in the cost of branded medicines for the next five years. As a result of the increased certainty over cost, the NHS hopes to move more rapidly in adopting innovative medicines and treatments where these will improve patient outcomes. As PPRS is a UK wide scheme further work is underway to determine how its financial receipt for NI is calculated.

NI reimbursement rates for dispensing certain 'generic' drugs were based on the Scottish Drug Tariff but this led to legal challenge

2.12 The majority of items dispensed by CPCs are generic drugs – that is, drugs comparable to branded drugs in dosage, strength, route of administration, intended use, quality and performance characteristics but created after expiry of a patent. The Department has a statutory obligation to compile and

9 The Pharmaceutical Price Regulation Scheme (PPRS) determines the prices drug manufacturers can charge for branded drugs. Agreed prices follow negotiations between Association of the British Pharmaceutical Industry and the Department of Health (acting on behalf of England, Scotland, Wales and Northern Ireland). In November 2013, a new PPRS was announced which took effect from January 2014 and will last for five years.

10 Although the agreement is made by the Department of Health, the arrangements apply to England, Scotland, Wales and Northern Ireland. The Association of the British Pharmaceutical Industry (ABPI) negotiates on behalf of the entire UK pharmaceutical industry.

Part Two:
Community Pharmacy Contractors' Reimbursement

Figure 5: Breakdown of the funding provided to CPCs in 2012-13

Element	Definition	Amount Paid in 2012-13
Reimbursement costs	Contractors receive reimbursement for purchasing and dispensing drugs on behalf of the HSC Board. The actual price reimbursed to contractors for individual items dispensed is set out in the Northern Ireland Drug Tariff. The payments made are net of discounts to list prices, in line with the process set out in the Drug Tariff. (£409 million - £28.1 million discount) Contractors achieve a level of 'retained profit' through their purchase of medicines. Retained profit is the difference between the price a contractor pays for a drug and the price at which the contractor is reimbursed (as set out in the Drug Tariff). The 2011-12 Margin Survey demonstrated that contractors were generating an estimated profit of £28 million through their procurement activities. The estimated rate of the margin for branded and generic medicines is similar to those identified in the rest of the UK. Propriety mitigation payments (amounting to £3.6 million in 2012-13) were paid to contractors prior to completion of the Margins Survey. Depending on the results of the Margins Survey for 2012-13, propriety mitigation payments may be subject to clawback. The Department has commenced a Cost of Service Investigation. The outcome of this investigation will be used to inform future negotiations with community pharmacy contractors and will inform the allowed level of retained profit.	**£380.9 million**

Global Sum	**Consists of two components:** **(i) Annual Professional Practice Allowance (APP Allowance)** Each year, a payment of £18,000 is paid for each pharmacy in recognition that contractors contribute to the provision of public health services. **(ii) Dispensing Fee** Contractors receive a fixed fee for dispensing an approved drug or appliance to a public health service patient. In 2012-13, the basic dispensing fees were: Ordinary Fees: £1.03 Multiple Dispensing Fee: £0.49 Since 2009-10, a cap has been introduced on the total Global Sum payable. In 2012-13, the number of ordinary items dispensed was higher than anticipated. An amount of £0.5 million was adjusted in 2013-14 to realign the payments to the Global Sum, in line with the standard operating process.	**£51.4 million** £9.6 million. £41.8 million
Additional Non-Recurrent Funding	The HSC Board also paid £7 million to contractors in 2012-13. This figure relates to a negotiated settlement with CPCs following the outcome of a judicial review of the Northern Ireland funding arrangements.	**£7 million**
Ancillary Services and Other Fees	Pharmacists can attract additional payments where they provide supplementary services to patients. These services may include availability of out of hours, the provision of pharmacy advice to nursing and residential homes, or the provision of training to non-qualified pharmacists. Remuneration rates for supplementary services are set out in the Drug Tariff.	**£19.8 million**
TOTAL FUNDING 2012-13		**£459.1 million**

Source: HSC Board

Part Two:
Community Pharmacy Contractors' Reimbursement

publish a statement known as the Northern Ireland Drug Tariff. The Tariff sets out pricing models for generic drug categories (Appendix 1). In July 1994, the Department and the Pharmaceutical Contractors Committee (PCC) [11] agreed that it was appropriate to adopt the Scottish Drug Tariff model in Northern Ireland. Prices listed in the Scottish Drug Tariff reflect prices set by the Department of Health (England) since the UK operates as one medicines market.

2.13 In 1999, following turbulence in the pharmaceutical market, the Department of Health (England) sought to rationalise the prices of medicines to the NHS. Research[12] published by the Department of Health in England in 2003 estimated that CPCs were typically able to make 30 per cent or more retained profit on generic drugs. Research undertaken to establish profit margins on 'branded' drugs in NI revealed similar trends to other parts of the UK.

2.14 The research was not extended in Northern Ireland to cover generic drugs because local CPCs refused to provide the required information. Later research[13/14] has supported the view that Northern Ireland CPCs, as part of the UK-wide medicines market, enjoy similar levels of profit to those generated elsewhere in the UK. The on-going Margins Survey estimates that CPCs typically generated profit levels of 40 per cent in 2011-12.

2.15 On foot of the UK research, the Department of Health (England) launched a revised community pharmacy contract in England and Wales in April 2005. In Scotland the contract was phased in during 2006. An integral part of that contract was the introduction of a significant new category within the UK Drug Tariff - Category M. The Drug Tariff provides a funding mechanism for pharmacists as well as stimulating competition in the supply chain. Financially, the Drug Tariff is set to deliver a target level of retained profit for CPCs and in Northern Ireland this is set at £16.5m. Funding released from the new Category M arrangements are available to fund additional patient focussed pharmaceutical services in the community setting.

2.16 The revised contract was not introduced in NI because pharmaceutical representatives here contended that, because the supporting information-gathering exercise had not been extended to NI, it could not be assured that the new Category M would fairly remunerate NI CPCs.

2.17 Despite the absence of agreement with the local representatives, the Department continued to apply the Scottish Drug Tariff in Northern Ireland [15]. On the basis that Northern Ireland was recognised as part of a UK wide Drugs Market and had been since 1998. In effect, Category M was introduced in

11 The Pharmaceutical Contractors Committee (PCC) is the local representative body for community pharmacists providing services under the National Health Service in Northern Ireland.

12 A pharmacy Cost of Service Inquiry (CoSI) report 2003.

13 NI - True Costs of NHS Pharmacy, The Tribal Report, 13 January 2011.

14 The on-going Margins Survey commenced in April 2011.

15 The drugs market operates on a UK-basis. All generic prices are set by the Department of Health (England) and included in an English Drug Tariff. That Tariff covers England and Wales and is applied in NI. Scotland applies the English Drug Tariff (after amendment to reflect variations in discount rates).

Northern Ireland and CPCs in Northern Ireland (as in other regions) saw their reimbursement levels reduced.

2.18 Category M covers over 500 of the most common generic medicines dispensed. In NI, category M covers about 55 per cent of all items reimbursed and about 86 per cent of all generic items reimbursed.

2.19 Given the concerns of CPCs, the Department proposed that a proportion of savings generated through Category M would be paid where other services were delivered (as in England, Scotland and Wales). A subsequent disagreement over whether payments should have been made when these other services were not provided, culminated in legal challenge by CPCs. (Details of legal proceedings against the Department are set out in Appendix 2).

2.20 In 2010, a Judicial Review found in favour of the CPCs and concluded that the Department's continued use of the Scottish Drug Tariff did not meet the statutory obligation to provide fair and reasonable remuneration to CPCs. The Department and HSC Board subsequently took steps to put in place a lawful Drug Tariff. A subsequent Judicial Review in 2011 also found in favour of CPCs but crucially, the revised Drug Tariff was not deemed to be unlawful. In December 2012, the Department and HSC Board withdrew an appeal of the Judicial Review decisions and a further interim agreement was reached with Community Pharmacy Northern Ireland (CPNI).

The legal action has cost the Department £550,000. CPCs received compensation of some £6 million. A further £40 million was made available to CPCs over the seven year period to 2011

2.21 The Judicial Review process has cost the Department almost £550,000. In addition, and outside the Judicial Review process, the Department paid £6 million to CPCs in 2006-07. Following the outcome of the first Judicial Review, the Department negotiated an Interim Agreement with CPNI. As part of that agreement, the Department acknowledged the revised arrangements resulted in lower reimbursement rates and provided £40 million to CPCs over the seven year period to 2010-11 inclusive of previous payments that had already been made on account.

2.22 The Department has begun a NI Cost of Service Investigation (CoSI)[16] and anticipates that the data collection phase will be completed by April 2015. The outcome of the 2011-12 margins survey became available in May 2014. A 2012-13 margins survey is currently being undertaken. The Department expects that the results of that will be available by the end of 2014. The outcomes of these investigations and surveys will form the basis of further negotiations with CPNI. The decision to exclude multiples companies (as in the rest of the UK), however, will limit the extent of increased transparency.

16 The objective of the Cost of Service Investigation (CoSI) is to quantify the level of profit generated by CPCs.

Part Two:
Community Pharmacy Contractors' Reimbursement

2.23 While we accept that the Department faced considerable opposition to the implementation of Category M in the Northern Ireland Drug Tariff, in our view, many of the stumbling blocks should have been foreseen by the Department and overcome. In particular, the Department should have ensured that it was fully informed about the likely economic impact of introducing the revised tariff and should have completed a Regulatory Impact Assessment (RIA). Following the outcome of the first Judicial Review, it would have been prudent for the Department to have completed an RIA and investigation prior to enforcing further change. The Department told us that it completed, and consulted on an economic analysis which supported its view that no RIA was required. We note however, that this was not accepted as sufficient by the Court.

2.24 In addition to damaging relationships with CPCs, the Judicial Review process had a financial impact. While no financial remedy was imposed by the Courts, the Department told us that the total cost incurred through both Reviews amounted to £550,000.

2.25 We acknowledge that the Cost of Services Inquiry and Margins Survey will produce useful information on the level of profit generated by contractors. In our view however, the decision to exclude multiples (as in the rest of the UK) from the margins survey, will limit the extent of increased transparency. We recommend that the Department reconsiders this decision.

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

3.1 GPs use independent clinical judgement to decide which drugs to prescribe. A complex relationship of activities including procurement, selection, prescribing, dispensing, administration, monitoring and review of medicines impact on both clinical outcomes and cost. Research[17] has shown that GP prescribing behaviour is influenced by many factors, which operate at different levels in the health and social care system. At the national or international levels, clear evidence on treatments and drugs presented in authoritative journals is a significant influence. The Department has noted that it is therefore to be expected that an equally complex array of activities are required to ensure that optimal therapeutic gains can be achieved from investment in medicines while at the same time ensuring value for money.

3.2 At the HSC level, influences include local guidelines, newsletters, site visits by HSC Board Medicines Management Advisers, personalised contacts, and recommendations from specialist or consultants in the secondary health care setting. At the practice level, the professional experience of the GP, the clinical needs of the patient, patient demand, peer networks, and drug company representatives may influence prescribing. Decisions can, to an extent, be influenced by the HSC Board efficiency initiatives (see paragraph 4.2) and by several other factors. A number of examples are listed below.

- **Legislation:** The Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004 applies to prescribing by GPs and requires that a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient.

- **Guidance:** A GP's clinical decision as to whether a drug is required is complex. The General Medical Council[18] (GMC) requires GPs "*in providing clinical care [to] provide effective treatments based on best available evidence*". It is policy in NI to follow guidance provided by The National Institute of Health and Clinical Excellence (NICE) guidance which is evidence based and considered to be best practice. GMC also advises GPs "*To minimise waste, improve services and promote the effective use of resources, you should take financial responsibility for the delivery of your service at a level appropriate to your role*".

- **General Medical Services contract**[19]**:** The Quality and Outcomes Framework (QOF) is part of the General Medical Services (GMS) contract for general practices and was introduced on 1 April 2004. The QOF rewards practices for the provision of 'quality care' and helps to fund further improvements in the delivery of clinical care. Practice participation in QOF is voluntary

17 RAND Europe, Prescribing in primary care, Understanding what shapes GPs' prescribing choices and how might these be changed, 2006

18 General Medical Council Guidance: http://www.gmc-uk.org/index.asp

19 GMS Contract details are available at: http://www.nhsemployers.org/your-workforce/primary-care-contacts/general-medical-services

but most practices take part. Given that QOF provides incentives for better disease management, it may therefore have an influence on GPs' prescribing behaviour.

- **Access to information:** GPs' assessment of the clinical and cost effectiveness of the drugs they prescribe will be influenced by a range of factors. The Department has advised us that the Northern Ireland formulary[20] is in place and is an unbiased review of the medicines and recommendation for first and second line choices.

- **Interaction with representatives from the pharmaceutical industry:** In 2005, it was estimated that the UK pharmaceutical industry spends £1.65 billion a year on drug promotion and marketing[21]. It is likely, therefore, that marketing activities can have an influence on prescribing decisions.

- **Secondary Care Prescribing:** Another influence on GPs' prescribing is the secondary care sector. In some cases, hospital consultants specify a particular drug for a patient leaving hospital and/or an outpatient. While ultimately the decision to prescribe rests with the GP, it is likely that his decision will be influenced by the clinical opinion of the secondary care consultant.

The volume of prescribed drugs has increased at a steady rate over recent years but costs have fallen substantially since 2010

3.3 In 2000, over 23 million items were prescribed by GPs at a cost of just over £245 million. **Figure 6** shows that by 2010, the number of items prescribed had increased to almost 36 million at a cost of £440 million. Along with the influences set out in paragraph 3.1, the Department considers that the increase also reflects the impact of a steadily growing older population and the fact that they consume more medicines.

3.4 The Pharmaceutical Clinical Effectiveness (PCE) Programme[22] is a suite of medicines management initiatives, initiated by the Department in 2005 and now implemented by the HSC Board.

20 The NI formulary is available at: http://niformulary.hscni.net/Pages/default.aspx

21 House of Commons Health Committee, The Influence of the Pharmaceutical Industry 5 April 2005.

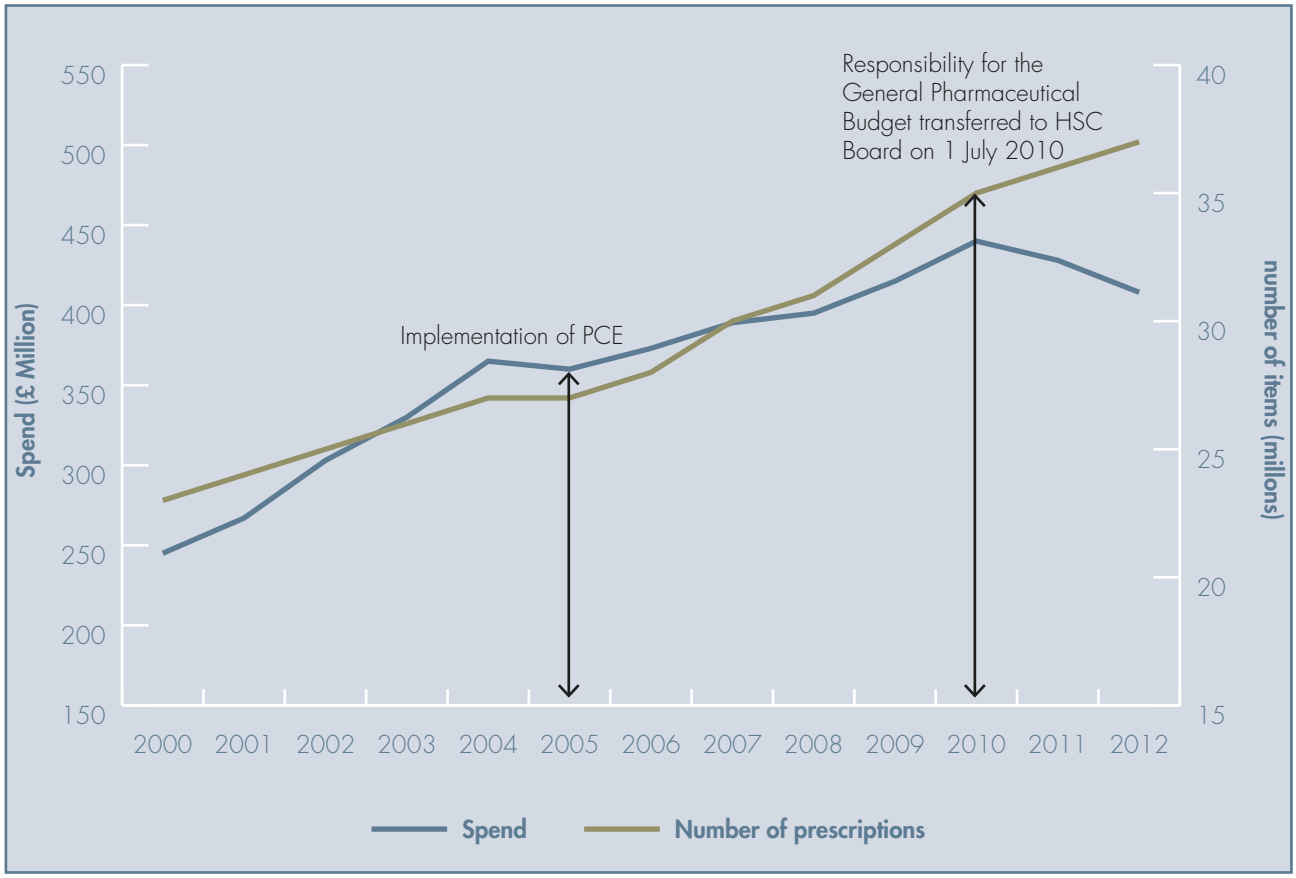
22 Pharmaceutical clinical effectiveness (PCE) is the outcome of the application of pharmaceutical skills directed to providing a systematic approach to rational product selection and use, consistently applied across secondary and primary care, taking account of clinical need, evidential product clinical performance, product presentation, safety characteristics and economic factors. The process can be applied to medicines, wound care and medical and surgical disposable products. It employs a multidisciplinary collaborative approach to reach consensus on the most appropriate clinical products and achieve the ownership and behavioural change necessary to make the decisions operational. Effectively, in medicines terms, it is the right medicine for the right patient at the right time and for the right cost. The PCE programme has been in operation since 2005 and represents the synergistic combination of a number of initiatives designed to optimise the implementation of the product selection process through effective procurement, prescribing policy and guidelines and pharmaceutical service improvements.

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

3.5 In the three year period, following the introduction of PCE the rate of growth in expenditure on drugs was reduced to less than 5 per cent per annum (see **Figure 6**) which, according to the Department, resulted in £75 million in savings having been made as part of the targeted Comprehensive Spending Review 2002-08 efficencies. The Department also told us that between 2006-13, the cost of prescribing was reduced in real terms by 18 per cent.

3.6 On 1 July 2010 responsibility for managing the General Pharmaceutical Services budget[23] was devolved from the Department to the HSC Board. Since 2010, while the volume of prescriptions continued to increase (by almost 5 per cent to 2012), the cost of prescribing these drugs has decreased by just over 7 per cent in the same period.

Figure 6: Percentage increases in the number and cost of items prescribed



Source: Business Services Organisation – Prescription Cost Analysis Reports

23 Responsibility for the entire Family Health Services Budget was devolved to the HSC Board on 1 July 2010. Family Health Services expenditure includes General Medical Services, General Dental Services, General Pharmaceutical Services and General Opthalmic Services.

There have been a range of influences which have helped to contain the cost of primary care prescribing

3.7 GP prescribing decisions are tightly regulated and monitored. Each year, GP practices are subject to prescribing reviews and repeat prescription audits. The purpose of these reviews and audits is to demonstrate that GPs have:

- implemented the National Institute for Health and Care Excellence (NICE) guidelines on prescribing and cost-effectiveness;
- selected only medicines listed in the NI Formulary; and
- implemented the Pharmaceutical Clinical Effectiveness Programme which sets key therapeutic objectives that GP practices are encouraged to implement which will deliver improved quality, safety, effectiveness and efficiency

3.8 Safe and cost-effective primary care prescribing requires that:

- GPs have access to up-to-date information about medicines;
- GP, hospital staff and pharmacy staff co-ordinate prescribing activity;
- all new prescribers and prescribing support staff receive sufficient, robust training;
- generic medicines are used where clinically appropriate; and
- medicine management advisers work in tandem with practices.

3.9 GP Prescribing Incentive Schemes played a part in influencing effective prescribing. The schemes, which were largely budgetary focused, were based upon the principle that savings made on the prescribing budget should be shared between GP Practices and their Local Commissioning Groups (LCGs). The savings were retained by GP Practices for reinvestment in services designed to improve or enhance patient care, without adding any additional layer of bureaucracy. The savings earmarked were also designed to assist in reinvestment with health and social care aimed at delivering improvements to patient care. It is essential, especially given the current financial constraints within which the public sector finds itself, that every opportunity to deliver efficiencies is pursued.

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

HSC Board Medicines Management Advisors have been instrumental in ensuring prescribing efficiencies are generated

3.10 Containing the cost of prescribing by GPs is primarily managed by the HSC Board's Medicines Management Advisers (MMAs) who seek to influence the prescribing behaviour of GPs. As qualified pharmacists, MMAs perform two main functions:

- each MMA monitors the prescribing patterns of an allocated number of GP practices (approximately 25 for a full-time MMA) with a focus on safety, effectiveness and efficiency. By identifying high value expenditure and variations in prescribing patterns, MMAs are well placed to highlight areas where financial savings could be generated without impacting on the quality and safety of care; and

- each MMA is responsible for reviewing prescribing patterns within given therapeutic areas (such as obesity or asthma). The MMA is set a specific effectiveness target for this area and influences prescribing practice by providing comprehensive, up to date advice to GPs on the most effective treatments.

3.11 In part, the success of MMAs is reflected in achievement against annual GP prescribing efficiency-saving targets which have been in place since 2010-11[24] (see Paragraph 4.2). By encouraging GPs to prescribe more cost-effectively by, for example, increasing the level of generic prescribing and identifying areas where cheaper alternatives (proven to have the same outcomes) can be used, MMAs have played an important role in helping to slow the year-on-year increase in the number of items dispensed and to reduce costs.

3.12 The ratio of MMAs per head of population has been used in Scotland to demonstrate that prescribing performance can be enhanced by increasing MMA capacity. Compared to Scotland[25], the ratio is lower here with 1 whole time equivalent (WTE) MMA per 130,000 of the population compared to between 3.5 and 6 WTE prescribing support staff (similar to the role of MMAs in NI) per 100,000 of the population in Scotland.

3.13 While the relative impact of various prescribing support activities is difficult to assess, in our view, MMAs play a key role in controlling prescribing costs by coordinating these activities. We recommend that the HSC Board should use available benchmarking data to inform their consideration of whether MMA staffing levels in NI are appropriate. The Department has informed us that it recognises the role of MMAs and will consider available evidence from NI and elsewhere to inform consideration of appropriate and affordable staffing levels.

24 Until July 2010, the Department had responsibility for the General Pharmaceutical Service budget. It set the efficiency target of £40 million for that year. Responsibility was then devolved to the HSC Board.

25 Audit Scotland Report: Prescribing in General Practice in Scotland 2013.

British National Formulary (BNF)

3.14 The British National Formulary (BNF) is a publication which contains information and advice on prescribing, dispensing and administering medicines. It is used by GPs and pharmacists to confirm drug dosages, indications, interactions and side effects. Medicines are classed in accordance with their therapeutic actions and are categorised against one of 15 BNF chapters. Some drugs, such as aspirin, appear in a number of BNF chapters since they can be used to treat several conditions. Basic net prices are given in the BNF to provide an indication of the relative cost of different drugs.

3.15 The NI administrative prescribing database, hosted by The HSC Sector Business Services Organisation (BSO), classifies medicines in accordance with the BNF format in order to report prescribing/dispensing activity by therapeutic areas. BSO include one additional section allocating unclassified[26] medicines. Typically over 60 per cent of the total cost of prescribing falls to one of four therapeutic areas (see **Figure 7**).

Figure 7: 2013 Expenditure in top four BNF Chapters

BNF Chapter	Conditions Commonly Treated	2013 Expenditure	Percentage of overall prescribing expenditure in 2013
BNF 4 – Central Nervous System	Depression, dementia, alzheimers disease, multiple sclerosis, pain	£113 million	28 per cent
BNF 2 – Cardiovascular System	Angina, heart attacks	£48 million	12 per cent
BNF 3 – Respiratory System	Asthma, emphyzema, chronic obstructive pulmonary disorder, acute respiratory distress, sinusitis, tonsillitis, laryngitis	£48 million	12 per cent
BNF 6 – Endocrine System	Diabetes, thyroid problems, osteoporosis	£45 million	11 per cent

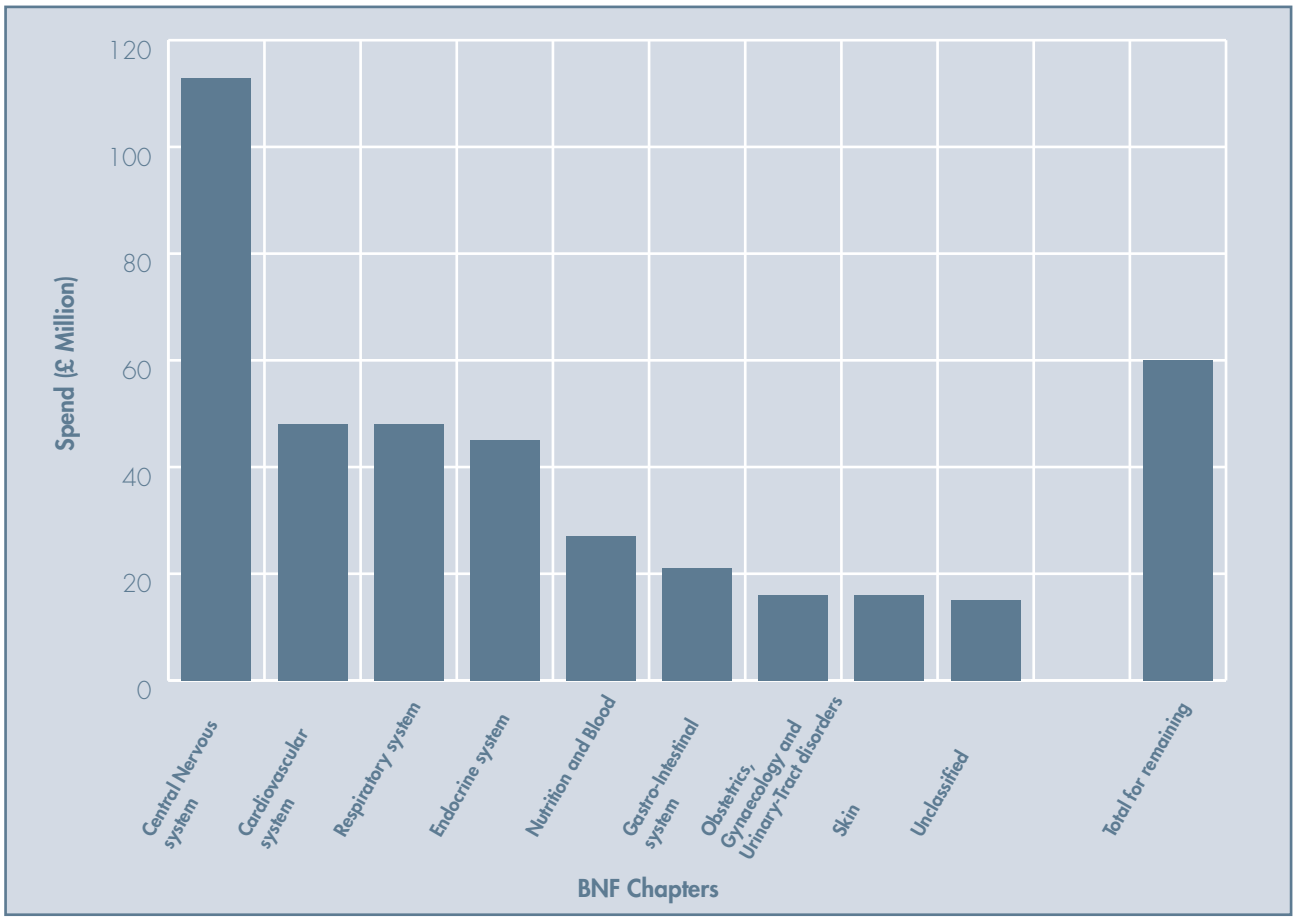
Source: Business Service Organisation

26 Unclassified are dispensed items for which there is no corresponding code in the NI Code book issued by BSO.

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

3.16 Around 20 per cent falls to a further five therapeutic areas, with four per cent of all prescribing expenditure allocated to 'unclassified' (see **Figure 8**).

Figure 8: Analysis of 2013 Expenditure by BNF Chapter

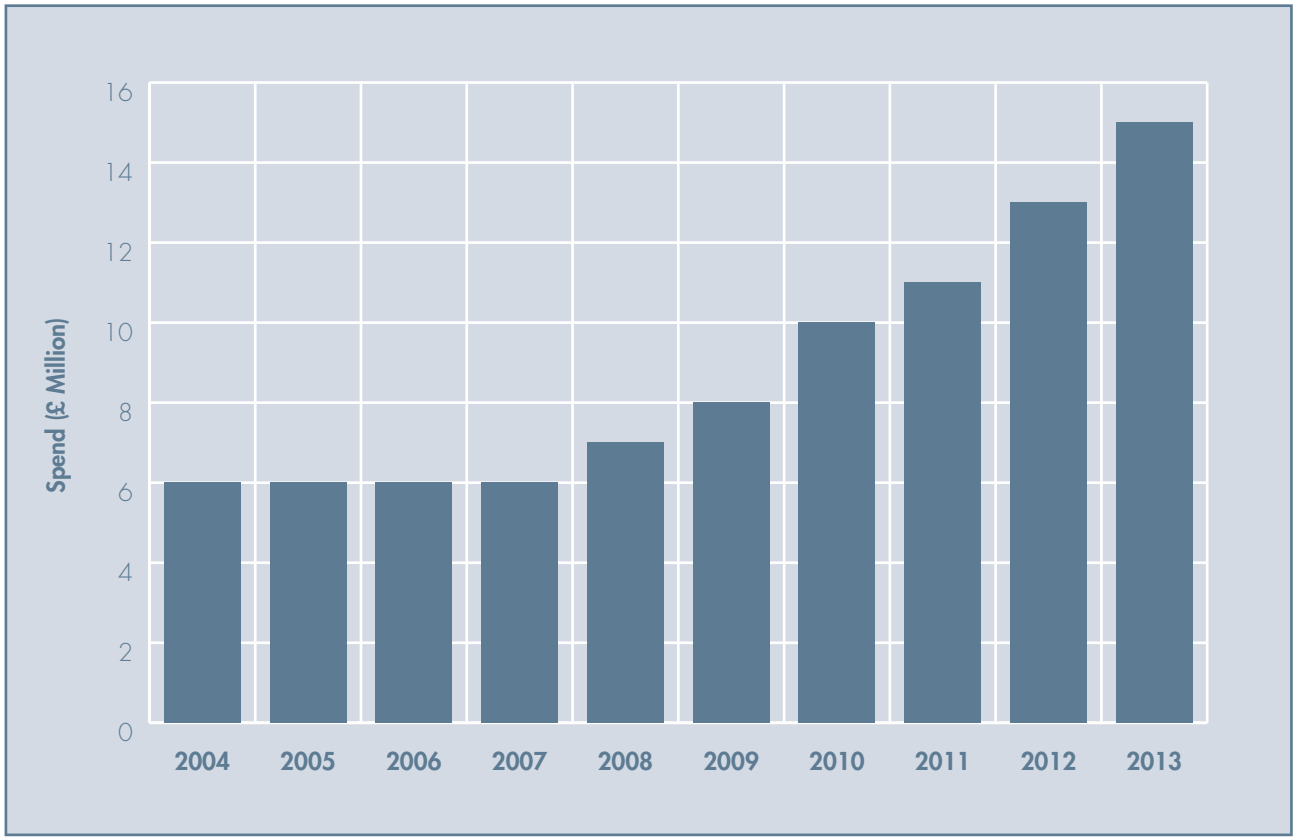


Source: HSC Board

The use of an 'unclassified' category prevents comprehensive analysis of prescribing patterns

3.17 Where a GP prescribes an unusual item or a liquid form of a routinely dispensed tablet, the items is allocated to the 'unclassified' category. In 2013, 250,000 prescription items costing £15 million were charged to the unclassified code. **Figure 9** shows that the level of unclassified expenditure has more than doubled in the 10 year period to 2013.

Figure 9: Spend allocated to the unclassified category in NI over the period 2004 to 2013



Source: HSC Board

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

3.18 It is, however, the view of the HSC Board that the inclusion of an unclassified category allows greater transparency and allows the quantification and interrogation of the use of these products. In Scotland, unclassified items (referred to as dummies in Scotland) represented less than two per cent of the prescribing costs. England and Wales do not use an unclassified category. All prescribed items are allocated to a BNF chapter/ therapeutic area.

3.19 We examined the top 100 most expensive items prescribed and allocated to 'unclassified' in December 2013. In our sample we identified that:

- Just over half of all items selected (costing £46,000) were liquid forms of routinely dispensed medicines;
- Pharmacists had been reimbursed between £622 and £1,230 for dispensing individual liquid (rather than tablet) doses of omeprazole. Tablet form omeprazole costs approximately £2.27;
- In one case, a pharmacist was reimbursed £220 for dispensing a '*special*[27]' suspension. We noted that this product was available on the market at a cost of £23.43; and
- An application for reimbursement relating to a 'special' item costing just over £400 was turned down by the HSC Board. The HSC Board advised the pharmacist to dispense the treatment in tablet form at a cost of £1.48.

3.20 The use of an unclassified cost in NI masks the overall cost of treating various conditions. We recommend that the HSC Board replicates the arrangements in England and Wales (where no unclassified code exists) by removing the unclassified code in an effort to improve transparency and monitoring. We note that BSO has introduced a new Family Practitioner Service payment system which will provide enhanced management information and permit more detailed classification of uncoded items.

3.21 Although we note that the HSC Board reviews applications for '*special*' product reimbursement, in our view, additional savings could be generated by strengthening controls. We recommend that the HSC Board continues to work closely with healthcare professionals to ensure that all possible alternatives are considered before a '*special*' item is dispensed.

27 Where a prescribed item or solution cannot easily be prepared by the pharmacist, it is categorised as a 'special' product. Specials tend to be unusual items, such as appliances designed specifically for the patient, solutions which combine various drugs or treatments which require an active ingredient at a level which is not available commercially. The pharmacist is reimbursed the full amount he is charged by the drug company.

Variations in regional prescribing rates which cannot be fully explained by differences in population demographics suggest that it may be possible to improve the quality of prescribing further.

3.22 Effective prescribing should ensure that the clinical needs of a population are met by prescribing a volume of drugs which is consistent with the prevalence of a disease. Paragraph 1.8 shows that the overall volume of items prescribed has been increasing across all UK countries over recent years. While research[28] has consistently shown health need here is much greater than elsewhere in the UK, data from other sources suggests that the relationship between health need and prescribing is not as straightforward as may be expected.

3.23 Data on the prevalence of specific diseases or health conditions are an important element of the Quality and Outcomes Framework (QOF) and according to the HSC Board[29]: *"(disease) registers are particularly valuable in recording both the number of patients known to have the condition and in calculating the prevalence locally and regionally. This can be extremely useful for assessing clinical need and planning service development.....QOF data can indicate variation in practice and potential unmet need within the population"*.

3.24 The Department has told us that it has been advised by the NI Statistics and Research Agency and the Health and Social Care Information Centre in England that QOF data is unsuitable as a measure of need in this context. The QOF is primarily designed to address primary care management not prevalence or need. QOF data is not statistically robust for this purpose. The limitations inherent in utilising QOF in this analysis include that no account is taken of the population structure across the four countries.Severity of disease or co-morbidities is not considered, all of which are contributory factors in level and cost of prescribing. Although QOF may be considered consistent in definitions across the four countries; the social and demographic characteristics of the population differ widely as will the recording and clinical behaviour of the GPs.

3.25 We recognise that accepted research shows there is additional health need in Northern Ireland which may range from 9 to 26 per cent. However, while we acknowledge the Department's view that QOF should be interpreted with caution[30], recent data shows that the prevalence of many of the main diseases does not appear to be in line with the general understanding of higher health need here. **Figure 10** shows the prevalence of specific diseases

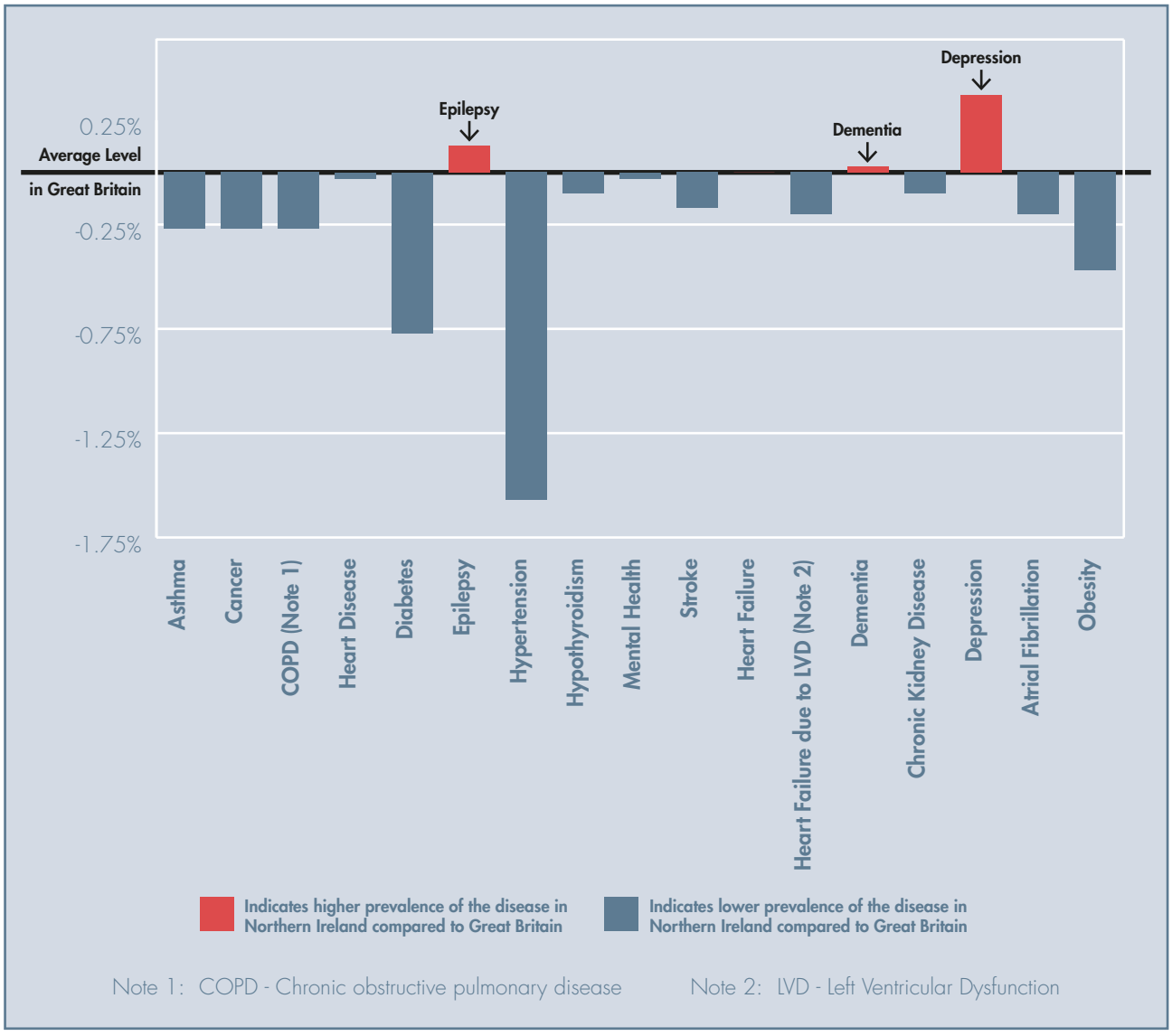
28 NAO, Healthcare Across the UK: A comparison of the NHS in England, Scotland, Wales and Northern Ireland.

29 Performance Review Report 2012-13,Pages 7 and 9, General Medical Services, HSC Board, 2013.

30 The Department considers that caution should be taken when interpreting QOF prevalence since the rates are simply the total number of patients on the register, expressed as a proportion or percentage of the total number of patients registered with the practice. They are not adjusted to account for patient age distribution or other factors that may differ between general practices. Furthermore, although registers may be restricted (e.g. to only include persons over a specified age) the QOF prevalence rate is based on the total number of persons registered with the practice (the practice list size) at one point in time.

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

Figure 10: Comparison of disease prevalence in NI with the average level in the rest of the UK in March 2012



Source: The Department/NIAO

and conditions here compared to the average in other parts of the UK at March 2012. Prevalence of epilepsy, depression and dementia is higher in Northern Ireland than the average level in GB. However, for the majority of categories, prevalence in NI is considerably less than the average for other parts of the UK.

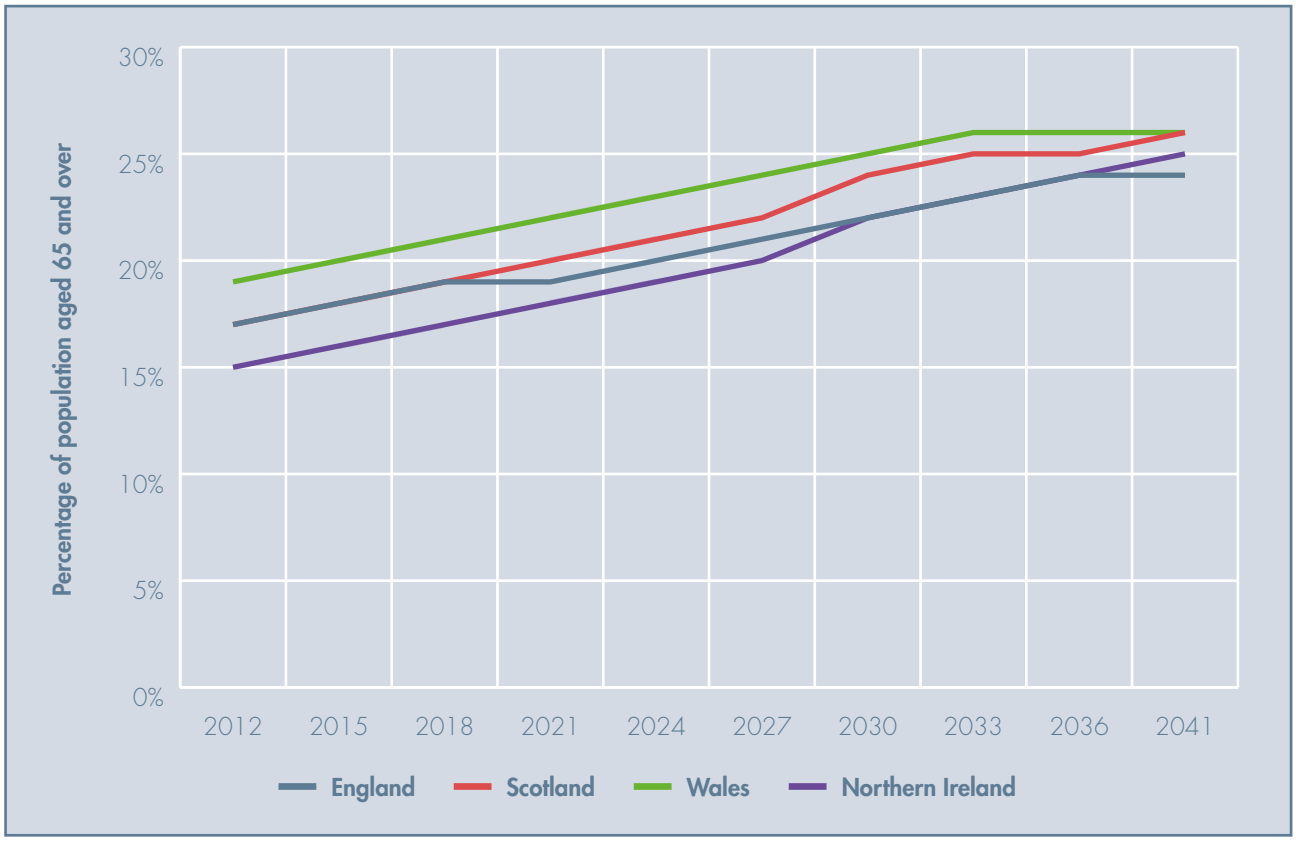
3.26 On the basis of the data presented in **Figure 10**, therefore, prevalence of a condition does not seem to fully explain the higher rates of prescribing here. Despite the caveats footnoted at paragraph 3.25, we consider that estimates of disease prevalence rates based on QOF data from GP practices provides an additional source of information which can help in providing as complete a picture of prescribing activity as possible, in order to identify the opportunities to improve standards and provide safer care as well as improving efficiency and effectiveness. In a period of unprecedented financial challenge, coupled with major transformational change, we would agree with the HSC Board (paragraph 3.23) that the use of QOF data could be helpful in focusing attention around optimising medicines use.

3.27 Information on long-standing illness and disability (based on people's subjective assessments of their own health)[31] also shows NI below the UK average – 18.4 per cent compared against 19.7 per cent. The Department told us that the use of patients' subjective assessments of their own health in reaching this conclusion is inappropriate as the data is unsuitable as a measure of need in this context. Moreover, while the likelihood is that people will suffer chronic illness increases with age, the age distribution of the population of NI reveals a relatively smaller share of older citizens than the rest of the UK (**Figure 11**).

31 The NI Statistics and Research Agency collects data relating to long standing illness and disability, based on people's subjective assessments of their own health. Independent healthcare providers would argue strongly that the incentives under which they operate ensure that their activities are well aligned with the public interest. The results are contained in the National Wellbeing Measures publication.

Part Three:
Trends in General Practitioner (GP) Prescribing Practice

Figure 11: Age distribution of the UK population – percentage of population aged 65 and over



Source: National Population Projections, 2012-based projections (Office of National Statistics)

3.28 Overprescribing represents a waste of resources. On the other hand, under-prescribing can indicate unmet need and potential future health complications. In order to identify the extent to which there may be opportunities for improving the value for money GPs get from their prescribing, we recommend that the HSC Board, along with GPs, should use the streams of data on disease prevalence, patients' self assessments and relative age distributions to further explore the relationship between prescribing rates and relative healthcare need.

Part Four:
The Scope for more efficient and effective prescribing

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The Scope for more efficient and effective prescribing

4.1 While the prescribing of drugs in primary care is a matter for GPs independent clinical judgement, the HSC Board can nonetheless seek to influence the choices made by GPs when prescribing, for example, between different drugs that have the same clinical effect but different prices. The scope for savings in prescribing choices arises because, for many conditions, there are a range of drugs that could be prescribed. When deciding to treat a patient with medication, a doctor will typically have a range of different options to choose from. Frequently, the cost of these varies considerably. It does so for two main reasons:

- many drugs are available in both branded and generic versions, the latter generally being cheaper; and
- there may also be more than one drug available for treating a given medical condition, also at different prices.

4.2 The management of spending on drugs in primary care has generally improved in recent years. For example, the HSC Board provided us with details showing annual GP prescribing efficiency savings of £132 million in the four year period to 2011-14 (**Figure 12**).

Figure 12: Annual Efficiency Targets and Achievement over the period from 2010-11 to 2013-2014

Year	Efficiency Target £ million	Efficiencies realised £ million	(Under)/ Over achievement
2010/11	£40	£26	(£14)
2011/12	£30	£40	£10
2012/13	£29	£34	£5
2013/14	£23	£32	£9
Total	£122	£132	£10

Note: These figures were calculated by the Department /HSC Board but were not validated as part of our review.

Source: Business Services Organisation

The Department, HSC Board and GPs are to be commended for the savings generated from improving the rate of generic prescribing

4.3 For many years the Department[32] and the HSC Board have been encouraging GPs to write prescriptions using a drug's chemical name, whether or not the product in question is out of patent. This is typically known as 'generic prescribing'. When a branded medicine's patent expires, the generic equivalents which appear on the market - containing the same active ingredient(s) - are usually cheaper. In 2013 the average cost of a generic drug was around £4.21 whilst the average cost of a branded drug was about £22.61[33].

4.4 Generic dispensing rates have improved considerably in NI over the past 10 years. In 2003-04, 41 per cent of items dispensed were generic rather than branded drugs. By March 2014, NI generic prescribing rates had risen to 80 per cent and generic dispensing rates[34] had risen to 71 per cent. **Figure 13** compares the generic rates in NI since 2003-04 against that elsewhere in the UK.

Figure 13: Generic Prescribing Rates across the UK from 2003 to 2013

Financial year	NI dispensing rate %	NI's prescribing rate[35] %	England %	Scotland %	Wales %
2003/04	41	-	78	79	76
2004/05	43	-	79	80	78
2005/06	46	-	80	81	80
2006/07	49	-	82	82	82
2007/08	53	-	83	82	84
2008/09	56	-	83	82	84
2009/10	58	-	83	82	84
2010/11	60	75	83	82	83
2011/12	64	78	83	83	83
2012/13	68	79	84	83	83
2013/14	71	80	84	83	83

Source: The Department and the HSC Board

32 In 2006 the Department launched the "*Go Generic*" campaign to increase public awareness of generic medicines and advocate their use. In July 2006 the Department launched a new Prescribing Incentive Scheme (PIS) for GP practices which included targets for generic dispensing. The PIS is no longer in operation.

33 Source: BSO.

34 By monitoring dispensing rates for generic drugs, NI is more closely identifying generic drug usage. Monitoring elsewhere in the rest of the UK is based on prescribing levels which do not accurately reflect what was actually dispensed.

35 Generic Prescribing rates for NI are only available since April 2011. Since April 2011 BSO records items prescribed and dispensed generically, previously it only recorded dispensed.

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4.5 The scope for achieving savings from generic prescribing had been highlighted in the past. For example, a report published in 2005[36] outlined that one of the main reasons for the higher unit cost of prescriptions in NI (relative to England) was the greater use of branded drugs. The report stated that if NI achieved the same generic rate as England, costs could be reduced by 18 per cent, saving £55 million. A more recent report, published in October 2012[37], estimated that £129 million savings could be generated in NI over the 4 year period to 2015 through the increased use of generic medicines. The HSC Board estimate that currently achievable savings from switching to generic drugs are likely to be modest at around £1.6 million when set against the overall drugs bill as most of the potential savings from generic switching have already been made.

There is wide variation in the cost of prescribing per head of population across individual GP practices locally

4.6 While we recognise the progress that has been made in how prescribing costs have been controlled over recent years, the Department and HSC Board acknowledges that prescribing costs per head of population here are still higher than they should be and are being addressed as part of the efficiency agenda. Reducing unwarranted variations in prescribing activity and cost is one area where there is potential to save on prescription costs. Given the factors set out in paragraph 3.2, the occurrence of some variation is not only inevitable but, on occasion, may also be necessary in terms of clinical practice. Therefore, while it can be difficult to determine why variations in prescribing patterns exist, unwarranted variations in activity and expenditure are causes for concern as they may reflect differences in quality of care and may lead to extra expense and potential waste of resources.

4.7 Age and level of deprivation are two of the principal determinants of the health of any population. They affect both the incidence of the disease (the number of new cases that develop in a year) and its prevalence (the number of people who have a chronic disease at any point in time).

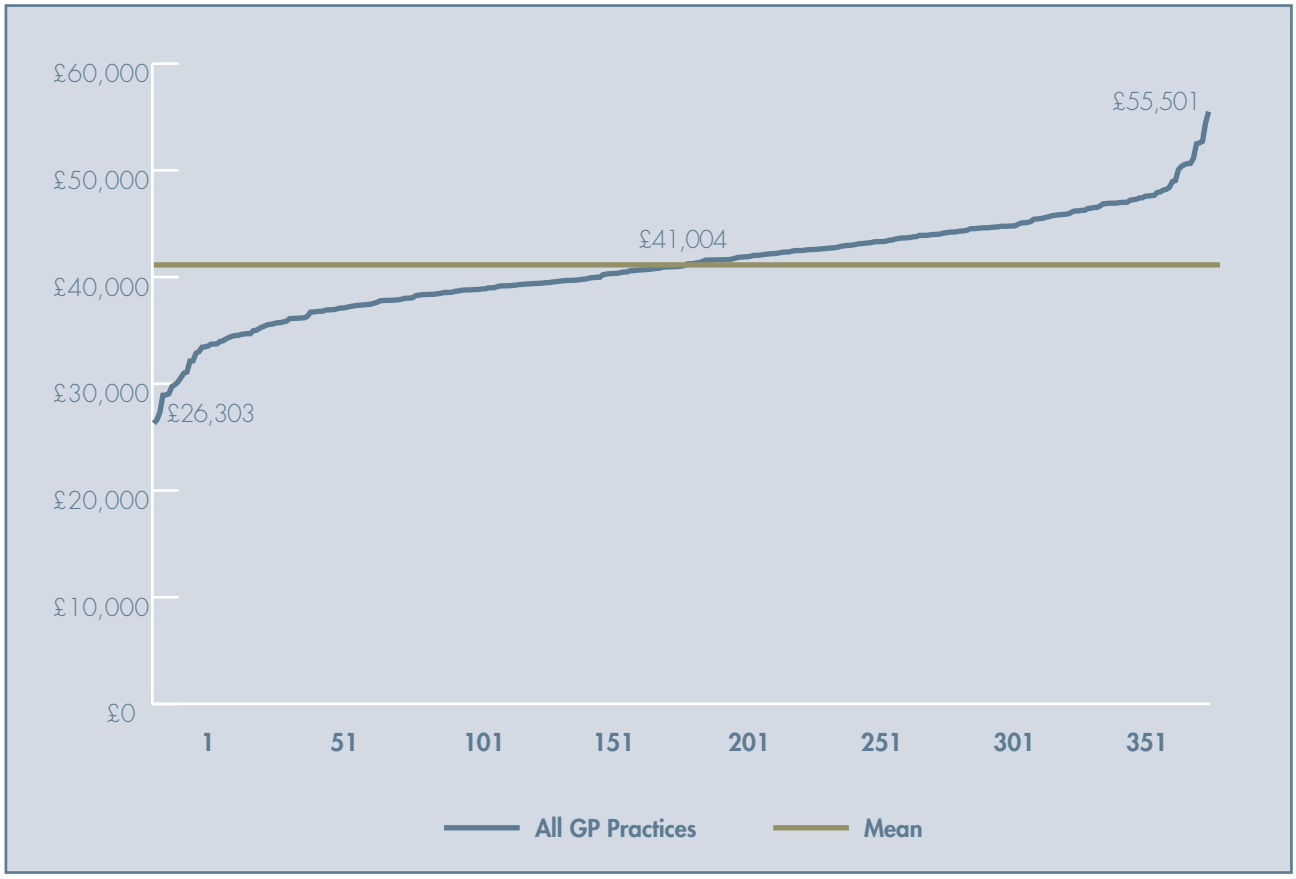
4.8 Local data has been adjusted for, among other things, social class and age distribution using 'prescribing units' (PUs) to standardise GP caseloads so that valid comparisons can be made. As **Figure 14** demonstrates, there can be a substantial degree of variation between GP practices after taking account of population differences.

4.9 We recognise that BSO together with GP practices have been working hard to understand variation and to mitigate unwarranted variation through the work

36 The Appleby Report examined the likely future resource requirements of the health & social care sector in Northern Ireland and the scope for resources to be used more effectively.

37 The Office of Health Economics for the Association of British Pharmaceutical Industries. UK NHS Medicines Bill projection 2012-15, Oct 2012.

Figure 14: Cost per 1000 NI Prescribing Units by GP practices in NI (2013)



Source: BSO

of MMAs (see paragraphs 3.10 to 3.12). The Department told us that in the period 2010 to 2013 the range of variation has reduced. However, **Figure 14** shows that in 2013 there was a variation of over 100 per cent between the GP practice with the lowest cost prescribing rate (£26,303) and that of the highest cost practice (£55,501). The differences in spending on GP prescribing among practices here may be due to differences in the amount of prescribing; differences in the choice of drugs prescribed and their cost; or a mixture of both. The precise causes of the variations require careful inspection to determine the extent to which they represent good quality practice.

4.10 As the NI PU system normalises prescribing data to enable a more balanced comparison within prescribing, this variation cannot reasonably be explained by population differences. We consider that this presents a significant opportunity for financial savings for the health and social care sector. For example, if GP practices performing above the average prescribing cost brought their prescribing costs to that of the average (£41,004), efficiencies of around £19 million could be achieved.

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4.11 The Department has commented that such an estimate is crude and does not take into consideration the other factors associated with prescribing, such as access to other services; the impact of cross-border workers; private healthcare. The Department considers that there will always be a degree of variability between GP practices and therefore the full quantum of such efficiencies will not be realisable. Despite this, we consider that a rolling target could be set to minimise the level of variation between GP practices. Further we consider that there is scope to reduce the average over time. For example, reducing the average by 10 per cent over a three year period would generate savings of £54 million.

4.12 The Department told us that, while it does not expect that all GP practices should be at the mean, it accepts that those with statistically significant variations (that is, beyond two standard deviations of the mean) should be investigated. The Department told us that it does not accept the analysis or conclusions in respect of the figure of £54 million, as being deliverable without further robust analysis.

4.13 We recommend that the HSC Board and BSO continues to compare and investigate the reasons for variations that are statistically significant in the NI PU between GP practices to assist in the identification of opportunities for achieving the potential saving levels set out in paragraph 4.10.

There is scope to make further savings from prescribing without affecting patient care

4.14 Perhaps the most important dimension in competition between medicines is that of the relative effectiveness of the drugs concerned. In principle, a difference in price between two drugs is understandable if the two products have very different effects. However, when the prices of prescription medicines do not reflect their relative therapeutic benefits, the health and social care sector may obtain poor value for money.

4.15 As outlined in paragraph 4.3, the price at which branded medicines are reimbursed does not change when they come off-patent and generic substitutes enter the market. In order to maximise the savings available when generic substitute drugs become available, therefore, it is essential that the HSC Board has arrangements in place to notify GPs well in advance of patent expiry dates and to provide them with clear guidance on the recommended generic replacements.

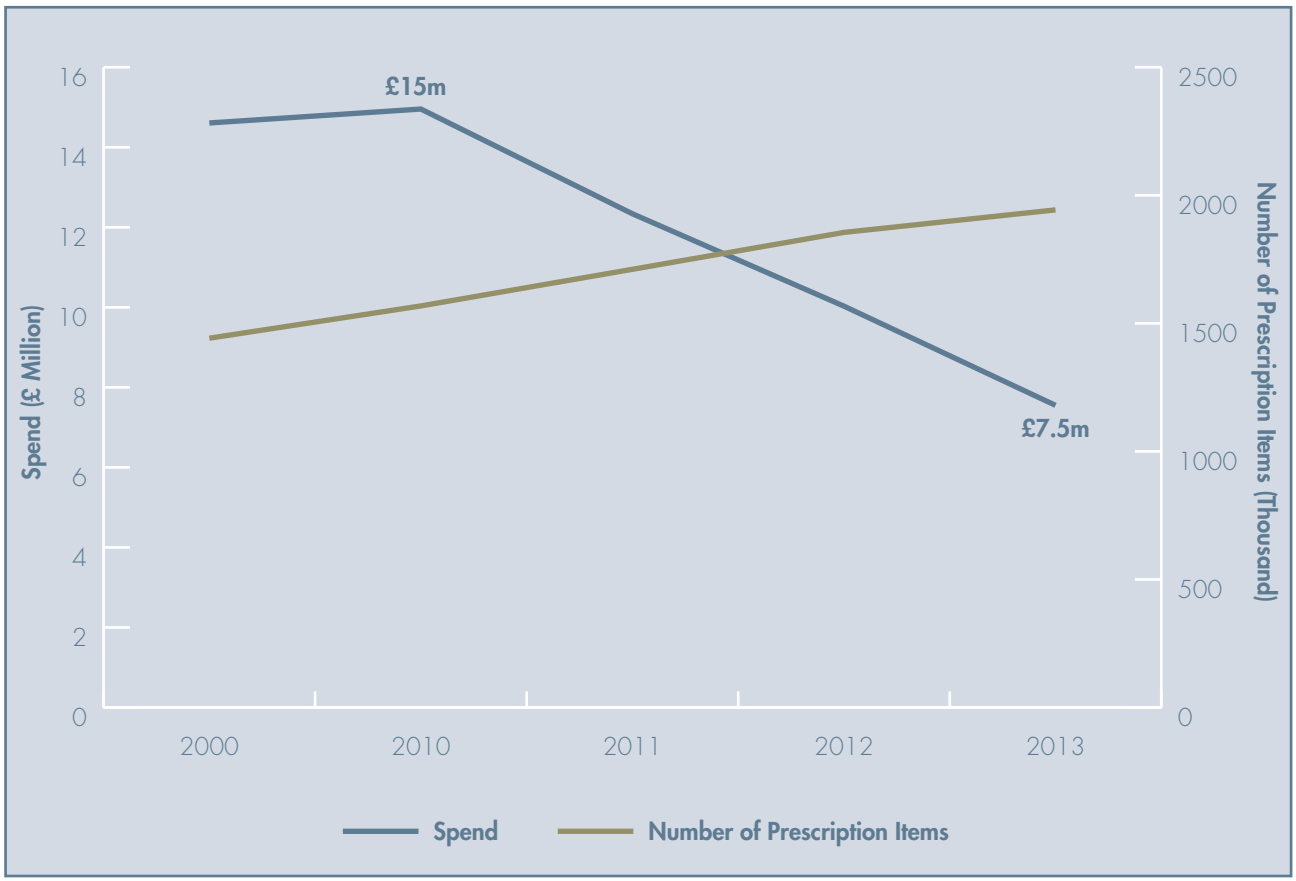
4.16 We examined the scope for efficiency improvements in three therapeutic areas which account for a significant proportion of the prescribing budget: Stomach Acid Treatments; Cholesterol-controlling Treatments (statins); and Depression Treatments. The drugs discussed were chosen for illustrative purposes to demonstrate the opportunity costs of failing to prescribe more cost effective alternatives.

Earlier switching to cheaper generic stomach acid treatments (Proton Pump Inhibitors (PPI)) would have resulted in additional efficiency savings of £2.2 million in 2012 and £1 million in 2013

4.17 Proton Pump Inhibitors (PPIs) reduce the amount of acid made by the stomach. They are used to treat acid reflux and treat and prevent ulcers of the stomach and duodenum. They are also prescribed to patients using non-steroidal anti-inflammatory drugs.

4.18 **Figure 15** shows that while the number of PPIs prescribed here has increased over the last five years, costs have decreased substantially. However, **Figure 16** shows that NI is still some way behind the rest of the UK in terms of the cost of PPI treatments per head of population.

Figure 15: The number and cost of PPI prescribed since 2009



Source: BSO

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Figure 16: Cost of PPI treatments per head of population in the UK over the 4 year period to 2013

Source: BSO

4.19 The higher cost per patient here reflects the fact that GPs have tended to prescribe lower volumes of a generic PPI substitute compared to other UK regions. Prior to 2002, PPI patients were treated with one of a number of branded drugs (such as Losec© or Nexium©). In 2002 the Losec© patent expired and a generic PPI, omeprazole, became available. In NI, the majority of patients who had been treated with the branded Losec© were transferred to omeprazole. However, few patients who had traditionally been treated with Nexium© (esomeprazole) were switched to omeprazole therefore a comparatively greater proportion of patients in NI continued to be treated with the branded drug Nexium© than the rest of the UK. During 2012, the cost of Nexium© was £17.03 compared with £2.27 for omeprazole.

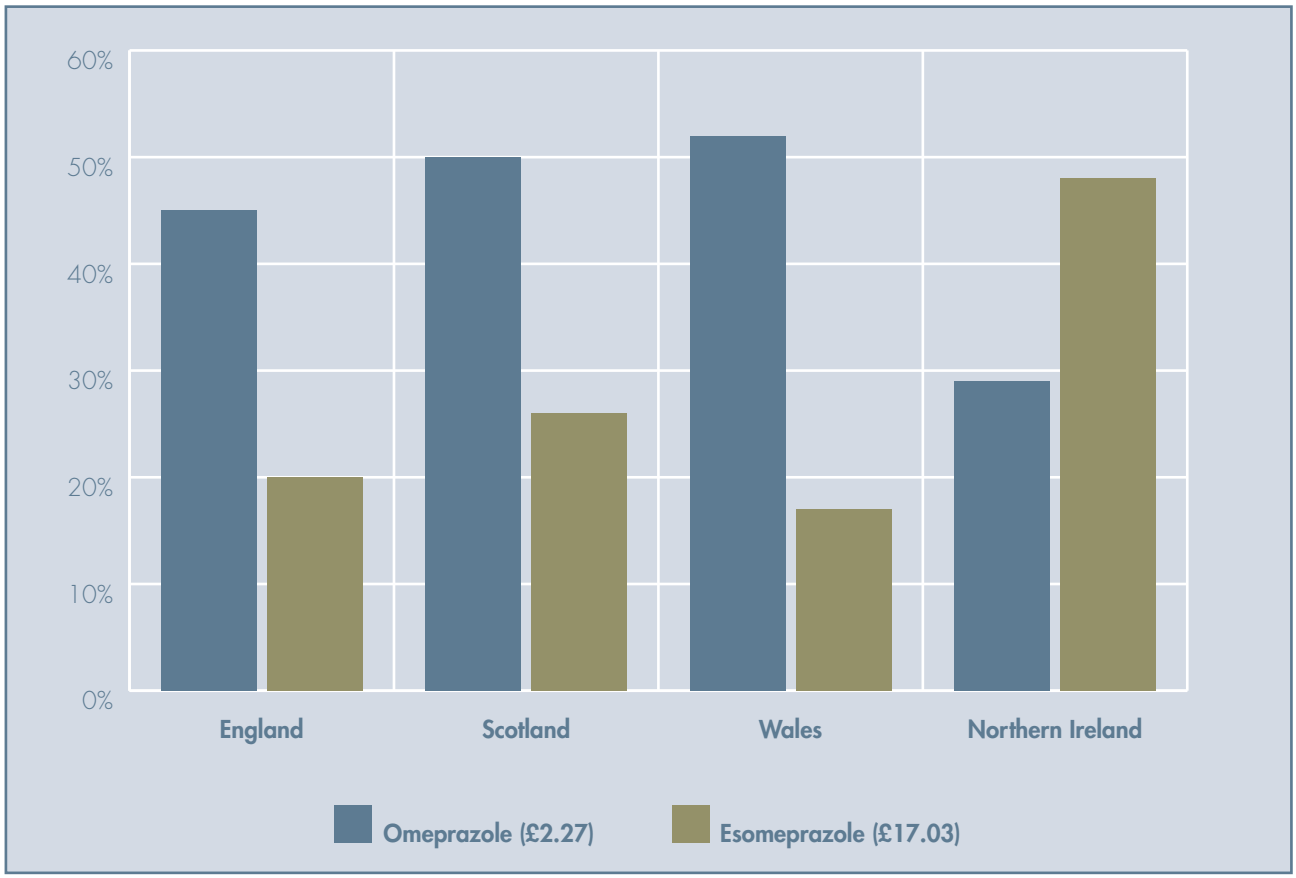
4.20 **Figure 17** shows that in NI in 2012, 48 per cent of the PPI spend related to branded esomeprazole. Only 29 per cent related to, the much cheaper, omeprazole. This is low compared to the level of omeprazole spend in other UK regions. Although NI GPs

prescribe more (low cost) omeprazole than esomeprazole, the proportion of esomeprazole prescribed in NI is higher than any other region of the UK. *In 2012, the opportunity cost to local health and social care services of not prescribing omeprazole at a similar rate as the rest of the UK was £2.2 million. During 2013 the opportunity cost was £1million.*

Switching to less expensive statins would have saved around £2.7 million in 2012 and £2.5 million in 2013

4.21 Statins lower cholesterol and are one of the classes of drugs employed to treat cardiovascular disease - the single greatest cause of death in the UK. High levels of Low Density Lipoprotein (LDL) or 'bad cholesterol' are a well accepted risk factor associated with the onset of coronary heart disease. Statins have a strong effect in reducing LDL cholesterol.

Figure 17: Comparison of the proportion of Omeprazole and Esomeprazole dispensed in the UK during 2012 based on Cost



Source: BSO

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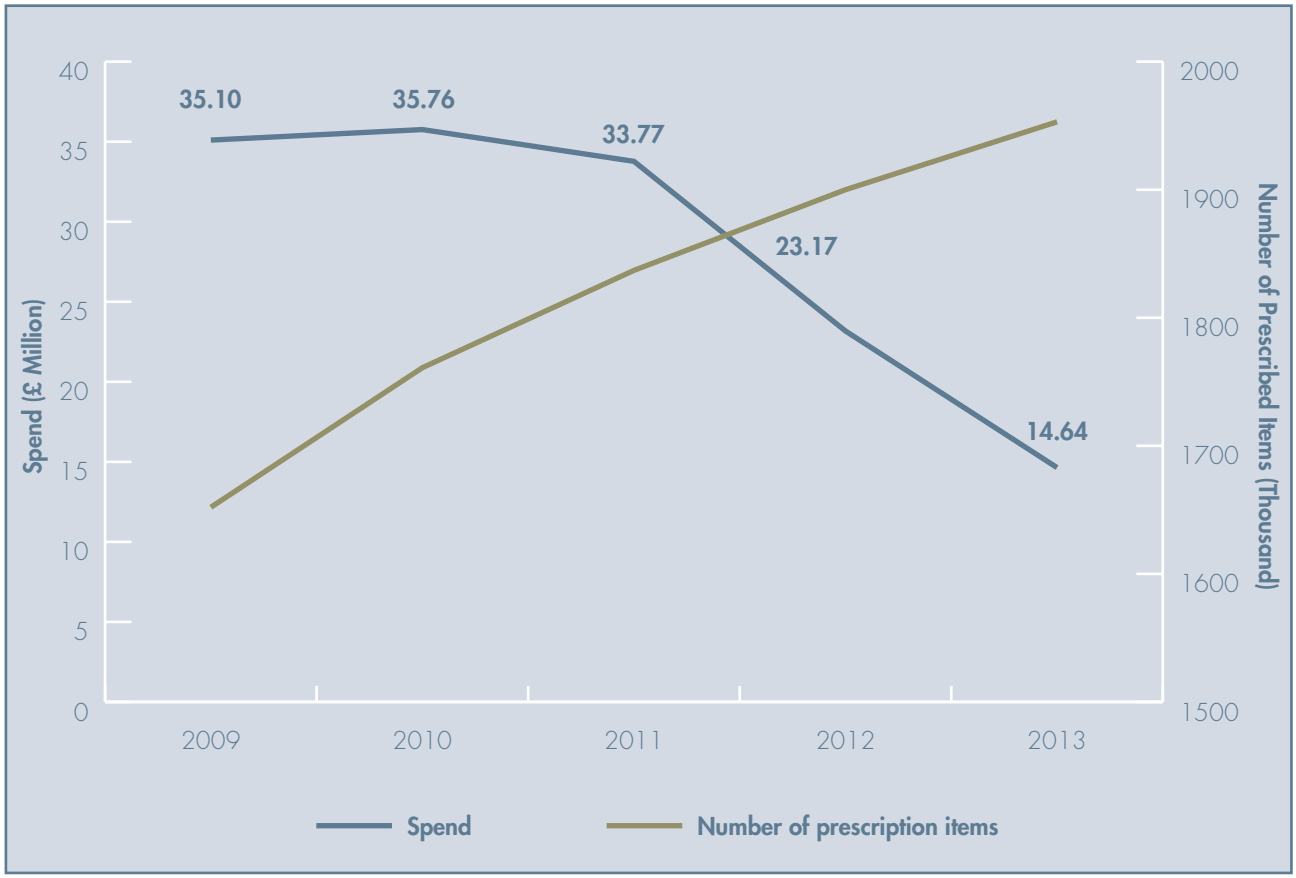
4.22 In an attempt to address rising rates of cardiovascular disease the number of statins prescribed by GPs has steadily increased over the last number of years. By moving from branded to generic statins, the HSC Board has managed to reduce unit costs (**Figure 18**). However, while **Figure 19** shows that the cost per head of population has successfully been reduced from £16 in 2010 to £5.32 in 2013, other regions of the UK have fared even better: during 2013 Wales spent £3.37 per head, Scotland £5.24 and England £2.88.

Figure 18: The number and cost of statins prescribed since 2009



Source: BSO

Figure 19: Cost of Statins per head of population in the UK over the 4 year period to 2013

Source: BSO

4.23 As with PPIs (paragraphs 4.17 to 4.20), analysis of the drugs dispensed across the UK demonstrate that GPs here tend to prescribe more expensive statins than GPs elsewhere. In particular, GPs here prescribe higher volumes of atorvastatin and rosuvastatin. Prior to coming off patent in May 2012, atorvastatin cost £38 per pack and rosuvastatin (which is not coming off patent until 2016) costs £32 per pack. By contrast simvastatin and pravastatin (both available generically since 2003) cost approximately £2.20 per pack. **Figure 20** compares the prescribing behaviour of GPs here with their counterparts in the rest of the UK and shows that, in general, they prescribe larger volumes of the more expensive statin drugs and therefore incur higher unit costs.

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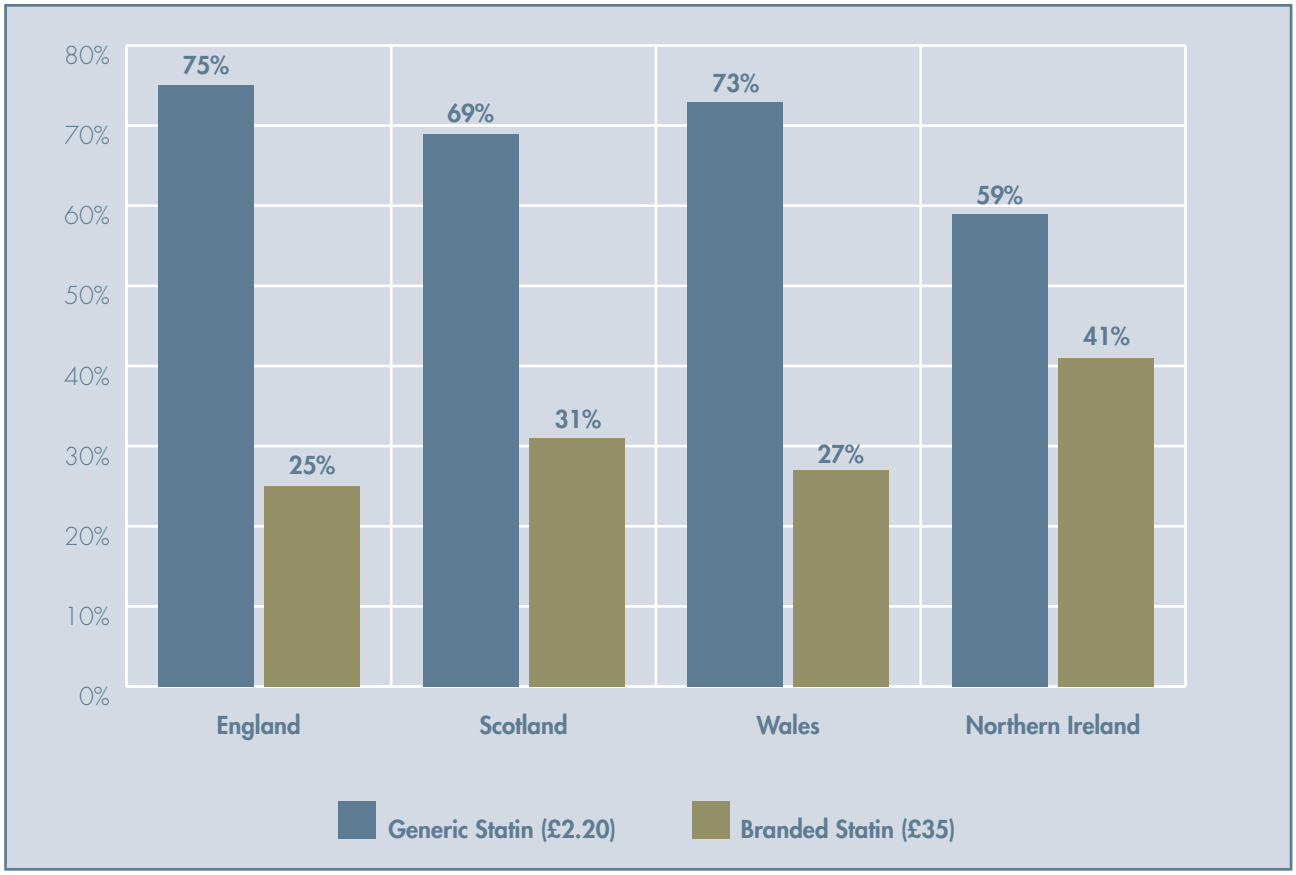
Figure 20: Comparison of the use of statins in the UK during 2012



Note The cost figure represent the average cost of statins during 2012

Source: BSO

4.24 In the absence of strong evidence that other statins achieve a better reduction in cardiovascular related deaths and illness in large populations than simvastatin, the fact that GPs here tend to favour the prescription of more expensive equivalents has a major budgetary impact.

4.25 Evidence on the comparative efficacy of statins was produced by the National Institute for Health and Care Excellence (NICE) in 2006[38]. In summary, this guidance recommended the use of a statin of lowest cost and at that time, this was simvastatin. In September 2011, The Scottish Medicines Consortium advised prescribers that rosuvastatin was not recommended within Scotland for the prevention of cardiovascular events. In November 2011, the All Wales

38 Statins for the prevention of cardiovascular disease, NICE, January 2006.

Medicines Strategy Group directed that rosuvastatin was not recommended for preventing major cardiovascular events in patients with a high risk as the clinical and cost effectiveness evidence provided was not sufficient to recommend it. Until April 2014, in Northern Ireland there was no body specifying what medicines ought to be or not be prescribed resulting in a higher proportion of the more expensive drugs being prescribed. Since this time though, the HSC Board has put in place the NI Formulary and a 'Managed Entry' process to deal with new medicines.

4.26 Atorvastatin is now available generically and now costs less than 10 per cent of the branded version. The NICE Clinical Guidance has recently been updated[39] and it now recommends the use of atorvastatin. However, it has been apparent that GPs here have been prescribing comparatively more expensive equivalents that have a major budgetary impact. *In 2012, the opportunity cost to local health and social care services of not prescribing simvastatin at a similar rate as the rest of the UK was £2.7 million. The total opportunity cost for not prescribing all statins at similar proportions to the rest of the UK was £4 million and during 2013 was £2.5 million.*

Earlier switching to alternative generic drugs in the treatment of depression would have resulted in additional efficiency savings of £2.7 million in 2012 and £1.6 million in 2013

4.27 QOF data (see paragraph 3.24) shows a slightly higher prevalence of depression in NI than other UK regions (see **Figure 21**). Therefore it is expected that NI will spend slightly more per capita on this type of medication. However, as previously noted, the Department considers that QOF data is unsuitable as a reliable measure of need in this context.

Figure 21: UK Disease Prevalence (as a % of GP Registered Population) Comparison March 2012

Disease Area	NI	England	Scotland	Wales
Conditions for Depression Screening	7.1%	Not available	7.8%	8.2%
Diagnosis of Depression	9.6%	9.2%	9.0%	9.5%

Source: DHSSPS

39 Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease, NICE, July 2014.

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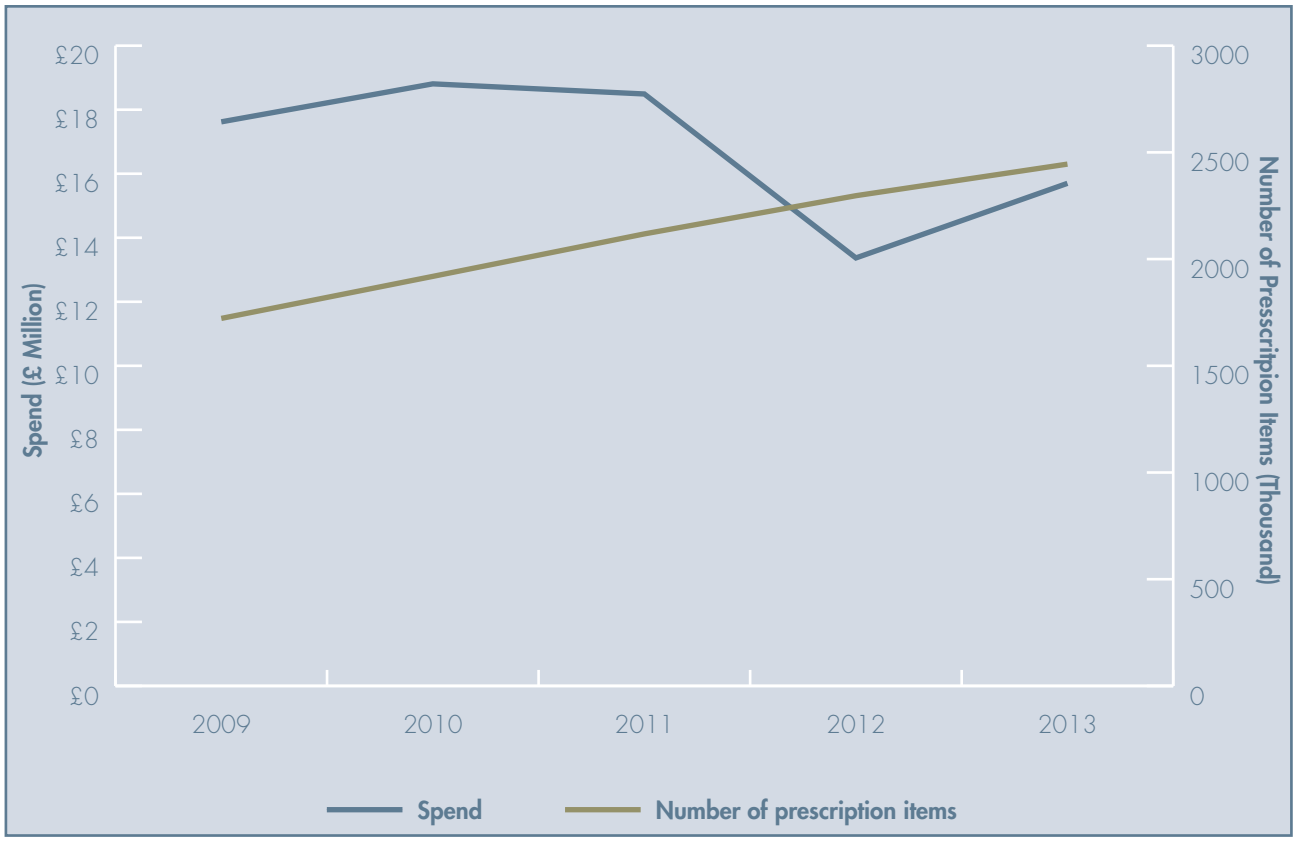
4.28 The volume of anti-depressant prescribing here has been steadily increasing over recent years. The cost of anti-depressants fell considerably during 2012 but rose again slightly in 2013 (see **Figure 22**). **Figure 23** illustrates that NI has consistently had significantly higher anti-depressant prescribing costs per capita than other UK regions.

Figure 22: The volume and cost of anti-depressants prescribed in NI since 2009



Source: HSC Board

Figure 23: The cost of anti-depressant prescribing per head of population in the UK over the 4 year period to 2013

Source: HSC Board

4.29 Comparison with the rest of the UK shows that in Northern Ireland there was a lower proportion of generic treatments being prescribed for depression which would, in part, explain the higher cost per head. In particular, escitalopram, one of the more expensive treatments for depression, is used more widely here than any other region of the UK. During 2012 prescribing costs per head of population was £1.71 here compared with £0.41 in Scotland and £0.26 in Wales.

4.30 While research suggests that there may be some slight differences between escitalopram and close equivalents (*which may make a difference in how the medicines work*), the drug citalopram is regarded as a close comparator. However, the price of these two drugs varies considerably. **Figure 24** shows that a higher proportion of (the more expensive) escitalopram is prescribed in NI than in the rest of the UK. *In 2012, the opportunity cost to local health and social care services of not prescribing*

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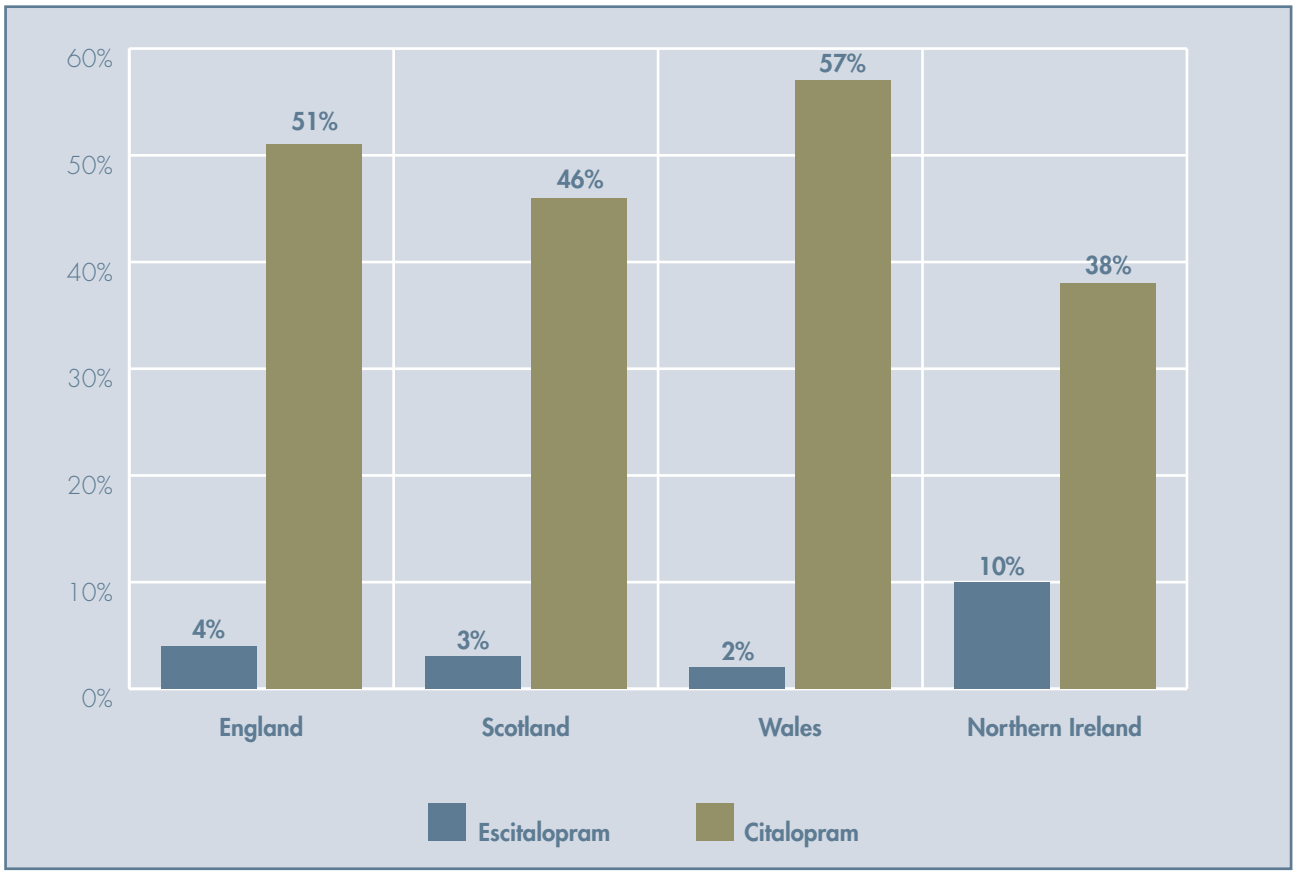
citalopram at a similar rate as the rest of the UK was £2.7 million. The opportunity cost in 2013 due to Northern Ireland prescribing patterns for anti-depressant medication not being similar to those in the rest of the UK was £1.6 million.

4.31 It should be noted that the HSC Board has advised that simply switching from a branded medicine to a different medicine that is available as a generic needs to be managed carefully. Given that the two medicines cited here are being used for depression and other mental health issues, the HSC Board has advised that such changes need to be worked through very carefully.

Figure 24: Comparison of the proportionate use of Escitalopram and Citalopram in the UK countries in 2012



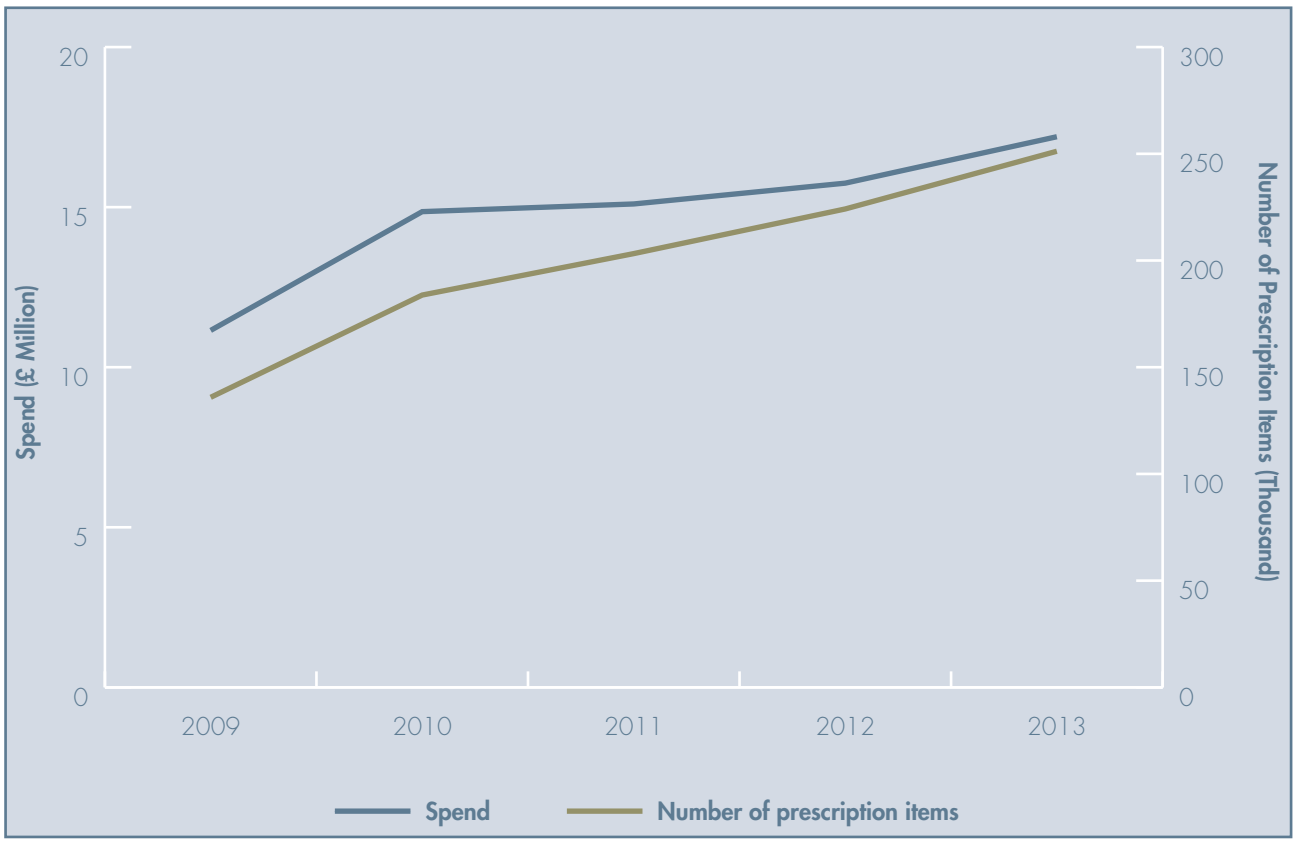
Source: BSO

More money is spent prescribing Pregablin in NI than on any other drug. Pregablin is more frequently prescribed in NI than elsewhere in the UK

4.32 Pregabalin[40] is a medicine used to treat epilepsy, neuropathic pain and generalised anxiety disorder. As an analgesic it works by reducing the volume of pain signals sent to the brain from damaged nerves. It can have a euphoric effect on patients and cases of abuse and misuse have been reported.

4.33 **Figure 25** shows a steep rise in the volume of pregabalin prescribed over the last six years and despite a slowing down of expenditure over this period, pregabalin currently costs the prescribing budget £17 million a year (see **Figure 25**). This level of expenditure is higher than any other single medicine prescribed by GPs. Pregablin is also more frequently prescribed in NI than in the rest of the UK. **Figure 26** shows that, during 2013, £9.43 was spent on pregabalin per head of population here compared to approximately £4 per head in the rest of the UK .

Figure 25: The number and cost of Pregabalin since 2009



Source: HSC Board

40 Pregabalin became available as a generic in October 2013.

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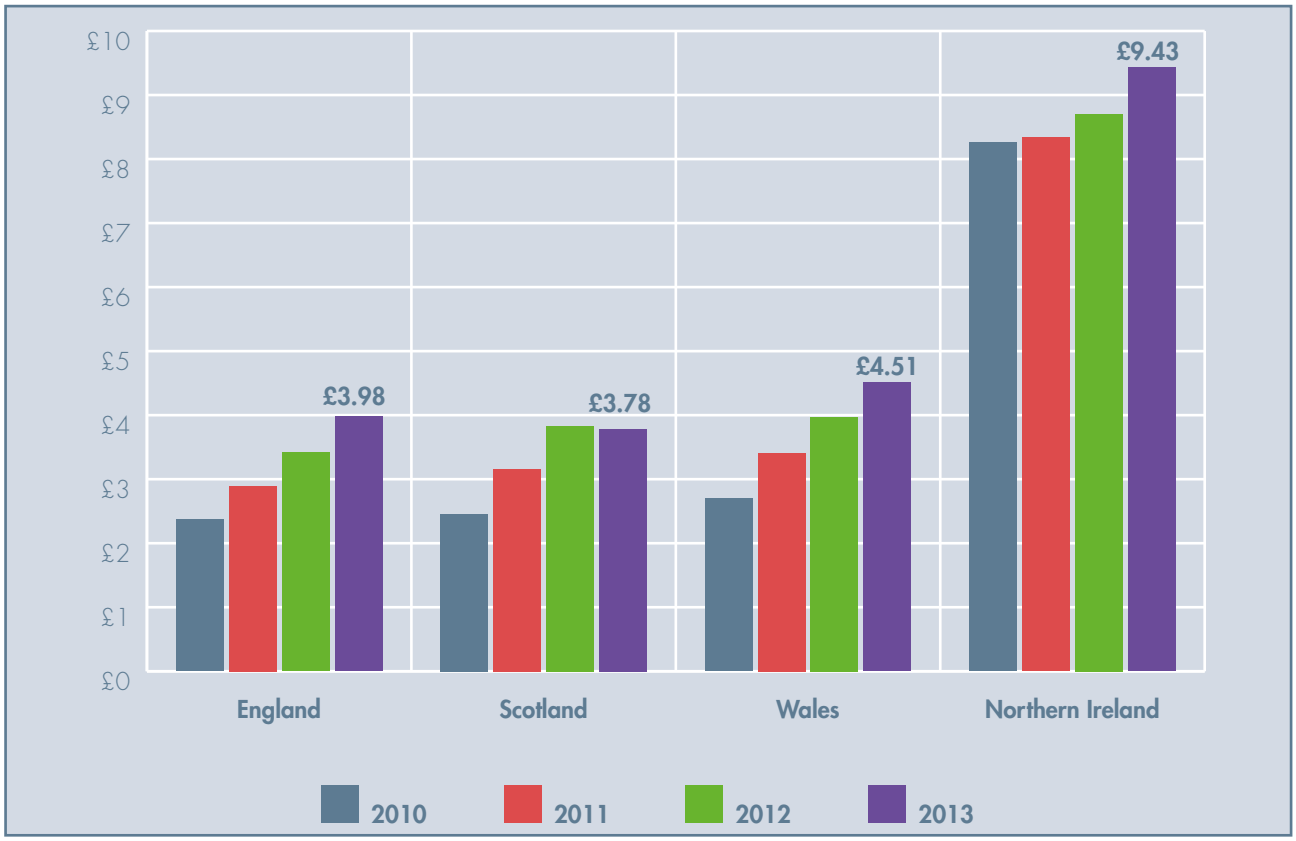
Figure 26: The cost of Pregabalin per head of population in the UK over the period 2010-2013



Source: HSC Board

4.34 NICE initially recommended pregabalin (or amitriptyline) as a first-line treatment in its early guidance on the pharmacological management of neuropathic pain published in 2010. But within 18 months withdrew this recommendation. Guidance subsequently published in 2013 is that pregabalin is one of three drugs to be considered in first line treatment.

4.35 Given the additional cost incurred by prescribing pregabalin, and the potential for it to be 'abused', it is not clear why pregablin is so heavily prescribed in Northern Ireland. *In 2013, the opportunity cost to local health and social care services of not prescribing pregablin at a similar rate as the rest of the UK was £9.7 million. During 2012 it was £8.5 million.*

4.36 BSO monitors the level of pregabalin use in NI. In view of its concerns that usage in NI is higher than is necessary, it has set a target to reduce total pregabalin spend by approximately £1million during 2014. BSO anticipates that MMAs will play a significant role in ensuring this target is achieved.

4.37 We note that the HSC Board has set a target to reduce usage of pregabalin in NI by £1 million during 2014. However, in our view, this target is not sufficiently challenging. We consider that, with the assistance of MMAs, GP practices in NI could move much more quickly to prescribing levels elsewhere in the UK.

4.38 We acknowledge that GPs have succeeded in generating significant savings in prescribing costs over recent years by moving from branded to generic drugs. However, it is clear also, from the variations we have found between prescribing practice here and the rest of the UK, that there is potential to increase the quantum of savings even further by focusing on conditions where there are suitable drugs available at differing prices. For instance, on the small range of drugs we have examined in paragraphs 4.17 to 4.36 we have calculated that the opportunity cost to health and social care services here of not prescribing in a more cost effective way was over £17 million in 2012 and £15 million in 2013.

4.39 An integrated approach, encompassing all stakeholders, is needed to optimise the use of clinically-appropriate and cost-effective medicines. It is essential the HSC Board continues to build on the work it has been undertaking in the promotion of efficient prescribing.

Appendices:

Appendix 1
Generic Drug Categories (paragraph 2.12)

	Definition	Price Basis
Category A	Drugs which are readily available.	Weighted average of the prices listed by the following manufacturers and suppliers: AAH, Alliance Healthcare (Distribution) Ltd, Teva UK and Actavis.
Category B	Drugs whose usage has declined over time.	Price lists from the following manufacturers or suppliers are considered strictly in the following order: Alliance Healthcare (Distribution) Ltd, AAH, UCB Pharma and Thornton & Ross. The Tariff price is the list price for the item is that quoted by the first manufacturer or supplier.
Category C	Drugs which are not readily available as a generic.	Based on the price of a particular proprietary product, or as listed by the manufacturer or, as the case may be, supplier.
Category E	Extemporaneously prepared items, made up of two or more products listed elsewhere in the Tariff.	The Tariff price is the sum of the Tariff prices of the components.
Category M	Drugs which are readily available.	The Tariff price is set by the Department of Health based on information submitted by manufacturers under Scheme M[41].

41 Scheme M is a voluntary scheme for generic manufactures which is designed to assist the Department of Health, England gather information to support the revision of Category M prices.

Appendix 2
Legal challenge to new Drug Tariff (paragraph 2.19)

The PCC sought to have the Department's decision to introduce the new Drug Tariff in Northern Ireland judicially reviewed in 2010. The legal challenge brought by the PCC was successful.

In January 2010 the lawfulness of the Department's arrangements for remunerating community pharmacies for dispensing drugs was the subject of a High Court Judicial Review. The legal challenge was brought by the Pharmaceutical Contractors Committee (the PCC)[42] and two companies which own and operate community pharmacies in Northern Ireland.

The judge concluded that the 1994 agreement to follow the Scottish Drug Tariff (which was based on the English Drug Tariff) reflected the view of the Department and the PCC that it fairly remunerated pharmacists. He noted that by 2001, the Department had become concerned that the remuneration being provided to pharmacists was excessive. However, he considered that the Department's decision to make a compensatory payment of over £6 million in 2006-07 was evidence that it accepted that the revised arrangements did not fairly reimburse pharmacists.

The judge considered that once it became apparent to the Department that the Drug Tariff was not fulfilling its statutory purpose, it had a legal obligation to resolve the situation. While accepting that the Department took steps to remedy the position, the judge was critical of the Department for failing to calculate and offer a compensatory amount for the 2007-08 and 2008-09 financial years.

The judge ruled that the failure to reach agreement with the PCC did not excuse the Department from its obligation to provide reasonable remuneration to pharmacists (for past and future periods). Concluding that the Department was continuing to fail in complying with its statutory obligations, he declared that the arrangements at that time were unlawful.

The 2010 Judicial Review led to extensive negotiations between the Community Pharmacy Northern Ireland (CPNI)[43] and the Department. This resulted in the signing of a provisional agreement in July 2010. The provisional agreement provided for interim, non-recurrent monthly payments to contractors from 1 April 2010 to 31 March 2011. The agreement highlighted that it was incumbent on all relevant parties to work to have a fair and reasonable remuneration model in place by 31 March 2011. Finally it was made clear that if agreement could not be reached the Department would be legally obliged to implement a fair and reasonable solution.

No agreement could be reached and, on 1 April 2011, following consultation on the outcome of an external review of community pharmacy remuneration in NI which recommended the introduction of the English Drug Tariff in NI, the Department introduced a revised Drug Tariff. In December 2011, the CPNI brought a second judicial challenge against the Department.

42 On 15 June 2005, the Pharmaceutical Contractors Committee (PCC) became a Company Limited by guarantee. On 24 March 2011, the company changes its name to Community Pharmacy NI (CPNI) to reflect and represent its expanded remit.

43 The CPNI represents all of Northern Ireland's community pharmacy contractors negotiations on services, the pharmacy contract and remuneration and reimbursement with the Health and Social Care Board (HSCB) and the Department of Health, Social Services and Public Safety (DHSSPS).

Appendix 2
Legal challenge to new Drug Tariff (paragraph 2.19)

The CPNI sought a second Judicial Review of the Department's decisions when it unilaterally introduced a revised Drug tariff in 2011. This second legal challenge brought by PCC was also successful.

The Department, having an awareness of the importance of obtaining access to reliable and up-to-date market information employed an external consultant[44] to provide advice. The consultant was tasked with developing a methodology, model and working prototype:

- to support the development and ongoing maintenance of a new NI Drug tariff which could be adapted or reviewed to reflect changing circumstances; and
- to support the assessment of the return on investment required by community pharmacists to achieve fair and reasonable funding for the delivery of their NHS service contract.

In October 2010, the consultant reported that any amended NI Drug Tariff should adopt the English model as a reference source. It acknowledged that the model would require adjustment to reflect the different conditions in Northern Ireland and highlighted that there were various areas were Northern Ireland-specific data would need to be gathered in order that appropriate, informed adjustments could be made.

Having considered the evidence the judge concluded that:

- the Department failed to carry out sufficient consultation and investigation to enable it to compile and publish a Drug tariff which complied with statutory objectives, including the objective of ensuring fair and reasonable remuneration for pharmacists, in particular, it failed to carry out any costs surveys or any margins survey, or to use available alternative powers to establish key information about the costs and profits of pharmacy business in Northern Ireland;
- the respondents failed to carry out sufficient consultation and investigation to enable them to identify the need for (and arrange for the implementation of) any necessary adjustments to the English Tariff model in light of conditions in Northern Ireland, with the objective of ensuring fair and reasonable remuneration for pharmacists here; and
- the Department erred in failing to carry out a Regulatory Impact Assessment (RIA) and that error constituted a breach of the applicant's legitimate expectation that an RIA would be conducted in the present case and resulted in potential loss of relevant information.

44 NI - True Costs of NHS Pharmacy, The Tribal Report, 13 January 2011.

In summary the legal challenge brought by the CPNI was successful. While the judicial review clarified the Department's statutory obligation to provide fair and reasonable reimbursement and remuneration, the judge did not quash the extant NI Drug Tariff (as requested by the CPNI) or impose any financial penalty on the Department.

As a consequence of the second Judicial Review, the Department was required to conduct a Cost of Service Inquiry and an On-going Margins Survey for NI. These exercises are on-going.

The Department and CPNI agreed an interim financial arrangements covering the two year period to 31 March 2013. Agreement was also reached that no RIA was required for this period.

The NI Drug Tariff continues to reflect reimbursement costs in England and Wales and is key to ensuring that the cost of medicines in NI is not excessive (compared to other UK regions). The application of English Tariff prices supports the current policy position that NI is part of a UK-wide Drugs Markets with access to the same medicine prices as the rest of the UK.

Community Pharmacists received £6 million compensation in 2006-07. Additional non-recurrent remuneration of some £40 million was paid to community pharmacists over the period 2007 to 2011.

Since the implementation of Category M in NI in 2006, CPCs have received £6 million in compensation in recognition that the revised arrangements have resulted in lower reimbursement rates for community pharmacists. Additional non-recurrent remuneration of some £40 million was paid to community pharmacists as part of an agreed interim position covering the period 2007 to 2011.

Further agreement was reached following the outcome of the second judicial review. On the eve of an Appeal Hearing, community pharmacists agreed to participate in the Cost of Service Inquiry and the On-going Margins Survey and waived the need for the Department to produce an RIA. Elements of the funding provided under this further agreement remain subject to retrospective clawback subject to the outcome of the on-going reviews.

Additional Payments to Pharmacy Contractors over the period 2006 to 2013

Year	Additional Payments (£ million)
2006-07	6
2007-08 to 2010-11	40
Total	**46**

Source : DHSSPS

NIAO Reports 2013-2014

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