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Primary Care Division
The Scottish Executive
St. Andrew's House
Regent Road
Edinburgh EH1 3DG

28 February 2003

Dear Mr. Fraser,

**OFFICE OF FAIR TRADING REPORT: CONTROL OF ENTRY
REGULATIONS AND RETAIL PHARMACY IN THE UK**

Thank you for your letter of 22 January. This response comes on behalf of SPGC, which as you know, represents pharmacy contractors in Scotland in relation to the terms and conditions of their NHS activity. This response comes with the authority of the elected Standing Committee of SPGC.

In the light of "Partnership for Care", we hope that we can look forward to a continued partnership between the Scottish Executive and SPGC to deliver benefits for patients across Scotland.

Should you wish any further information, please do not hesitate to contact me.

Yours sincerely,



Frank Owens
Chair

**Regulating NHS community pharmacy: why the
current system should remain**

Response from the Scottish Pharmaceutical General
Council to the Office of Fair Trading Report "The control
of entry regulation and retail pharmacy services in the UK"

February 2003

	<i>Page</i>
Introduction	3
Summary	4
1. The benefits to stakeholders of the control of entry system	5
2. The impact of removal of the current system	8
3. Why the OFT's case is flawed	10
4. The Right Medicine	15
5. Conclusions	16

Annex 1: The control of entry regulations and retail pharmacy services in the UK – A critique, by Deloitte Touche, February 2003

Introduction

The Scottish Pharmaceutical General Council is the body recognised to represent Scotland's 1150 community pharmacy contractors and negotiates on their behalf with the Scottish Ministers on remuneration, terms and conditions of their NHS work.

SPGC's Standing Committee is elected by representatives from Scotland's local committees of pharmacy contractors, made up of independents, large and small multiples, and PLCs. This response represents a consensus amongst the elected Standing Committee and aims to reflect the opinions expressed by pharmacy contractors.

As the body responsible for negotiating the contract for pharmacists' NHS work, SPGC has received representations from contractors who, in the light of the OFT's report, are extremely concerned about the future sustainability of community pharmacy and its ability to provide high quality services to patients. Since the OFT began its investigation, we have seen a significant reduction in the confidence of pharmacy contractors about the future, resulting in sales of businesses, mainly by independent contractors.

SPGC is confident that the plans laid out in The Right Medicine represent a positive way forward for community pharmacy as a means of further enhancing NHS pharmacy services in all of Scotland's communities.

We look forward to the Scottish Ministers' bringing a swift end to the current uncertainty.

Summary

The control of entry system gives NHS Boards & Trusts the power to regulate the number and location of pharmacy services in their area. When pharmacy's core business is NHS business, this is right and proper. The current system has enabled the creation of an enduring pharmacy network in which pharmacies are distributed according to patient need. This network is of benefit to patients, to the primary care team, to the Scottish Executive looking to implement The Right Medicine, and to communities.

Removing the control of entry system poses risks and offers few benefits to patients. While supermarkets could be empowered to sell Pharmacy medicines more cheaply and offer one-stop shopping to patients with NHS prescriptions, existing pharmacies may become unviable even if they provide vital services to the community; staffing pressures may put a drain on pharmacists in secondary care; NHS access points may disappear; and an inappropriate distribution pattern of pharmacies would develop.

The OFT has looked at retail sales in community pharmacy today, rather than the future of community pharmacy which is being constructed by the implementation of The Right Medicine. If implemented, the OFT's recommendation would threaten the implementation of The Right Medicine.

The Office of Fair Trading's report is ill-conceived. The OFT's research fails to take account of the NHS activity carried out by community pharmacy, looking only at the small proportion of pharmacy turnover coming from sales of Pharmacy medicines, which we estimate to be on average less than 5% of turnover. The OFT ignores, in its recommendation, the NHS activity which makes up 80% of the turnover of the average pharmacy. Each of the OFT's four criticisms of the control of entry system are flawed and fail to understand the changing nature of pharmacy in Scotland.

The OFT's report glosses over the consequences of the removal of the control of entry regulations. It has failed to recognise the knock-on effect that its plans to open up the over-the-counter medicines sales sector would have on the provision of NHS services.

SPGC believes that the OFT's recommendation that the control of entry regulations be abolished **should not be implemented in Scotland**. To do so would be to risk losing the potential to deliver The Right Medicine and losing the benefits to patients of the current network of pharmacies.

1. The Benefits to Stakeholders of the control of entry system

In summary: The control of entry system gives NHS Boards & Trusts the power to regulate the number and location of pharmacy services in their area. When pharmacy's core business is NHS business, this is right and proper. The current system has enabled the creation of an enduring pharmacy network in which pharmacies are distributed according to patient need. This network is of benefit to patients, to the primary care team, to the Scottish Executive looking to implement The Right Medicine, and to communities.

The existing regulations, the NHS (Pharmaceutical Services) (Scotland) Regulations 1995, (regulation 5 (10))¹ enable NHS Boards & Trusts to regulate pharmacy services in their area. This is referred to as 'the control of entry system' or 'control of entry'.

SPGC believes control of entry is appropriate to the need of the NHS to control adequately and efficiently its scarce resources.

SPGC firmly believes that the future of community pharmacy lies squarely as a part of the NHS primary care team. We therefore believe that local NHS Boards & Trusts **should** have the power to plan and control the number and locations of community pharmacies. This enables NHS resources to be applied logically to meet the needs of public and patients.

SPGC believes that the control of entry has also created:

- A network of community pharmacies which are, by and large, **distributed according to patient need**, located in high streets and throughout communities
- An **enduring network** without a high turnover of pharmacies and without many changes in location of premises
- A **stable core role** for community pharmacist contractors, stability in the way they work and a stable source of their funding

Where there may be gaps in the system, we believe that these are best filled through the proposals outlined in The Right Medicine to develop 'toolkits' to assess local need for pharmaceutical services, and meet those needs.

This situation benefits patients, the primary care team, the Scottish Executive and communities. Each of these will be addressed in turn below.

¹ Which state that the decision to permit the awarding of a new contract must be because it is "necessary or desirable in order to secure adequate provision of pharmaceutical services in the neighbourhood".

1. The current situation benefits patients

The enduring nature of the pharmacy network means that patients know where to find their local pharmacies and can choose to return to them again and again for enhanced care. In addition, patients, most of whom are in poor health, are likely to appreciate a familiar face when they receive their medicines. Continuity of care and of the carer are important to give people confidence in their treatment.

The stability of the network enables patients to choose to build up a medication record with their chosen pharmacy, which in turn can improve the level of care which the pharmacist provides. If a patient should be unhappy with the pharmacy services he or she receives, he or she can visit another pharmacy instead. In the situations where a patient has no choice of pharmacy services, such as in rural areas, a free market, as proposed by the OFT, would not lead to new pharmacies opening.

Patients also are satisfied with the current location of pharmacies. This was illustrated by the Scottish Consumer Council in 2002², and previously by the National Statistics Office in 2002³.

The current system enables pharmacists to improve services to patients. The pharmacist's core role of safely dispensing medicines is currently stable. The platform this provides enables pharmacists to:

- invest in their premises, staff and services, for instance by installing quiet areas or space for confidential counselling, and provision for wheelchair access;
- offer advice to patients and consumers even when that advice does not result in a sale;
- offer services which do not result directly in payment, such as home delivery, or the filling of monitored dosage systems which are not covered by current payment schemes;
- plan and execute new services for patients, such as pharmacist prescribing for minor ailments, supplementary prescribing or repeat dispensing schemes, and others proposed in *The Right Medicine*.

Were pharmacists forced to be constrained by purely commercial considerations, such services would undoubtedly come under threat. Because these services do not result in an income for pharmacists they could not be secured by the market mechanism. Without a stable base of funding and security to operate from, pharmacists would find it

² Scottish Consumer Council, *Consumer Views of Community Pharmacy*, published November 2002

³ Scottish Household Survey bulletin 7, Scottish Executive 2002, published by Scottish Executive National Statistics, *The Convenience of Local Services*. This showed that on average 87% of adults find the situation of a chemist shop is either very convenient or fairly convenient, a level of satisfaction second only to post offices (90%) and grocery shops (91%).

extremely difficult to invest in the research and development work required to offer a wider range of services to patients. Contractors would also find it extremely difficult to continue to invest in improvements to their premises which benefit both the consumer and the NHS.

2. The current system benefits the Primary Care Team

Community pharmacists are involved in ensuring that primary care services deliver effective, holistic care for patients, by working with GPs and other members of the primary care team on pharmaceutical care services. If purely commercial imperatives constrained the work of pharmacists, time and resource limitations would mean that pharmacists would be unable to carry out this work.

Additionally, if pharmacists were forced to operate under purely commercial constraints and found themselves unable to advise patients unless that advice resulted in a sale (as outlined above), patients may turn instead to their GPs, who are already recognised as being under considerable pressure.

3. The current system benefits the Scottish Executive

The current system has provided a **stable platform** upon which the Scottish Executive has begun to implement The Right Medicine. Recent pilot schemes including direct supply of medicines and repeat dispensing may not have been possible were it not for the current system. The stability of the current system enables these schemes to be implemented with the added strength of **continuity of care** by pharmacists, which increases the confidence of patients in the care they receive.

4. The current system benefits communities

Pharmacies help keep high streets and small community services alive by giving people a reason to shop locally. The loss of pharmacies from the heart of communities could damage many neighbourhoods.

Instability in the system would also harm the interests of the 10,000 staff employed in Scotland's pharmacies, who have reasonable employment security and local job prospects because of the stability of the businesses they work for.

2. The impact of removal of the Control of Entry

In summary: Removing the control of entry system poses risks and offers few benefits to patients. While supermarkets could be empowered to sell Pharmacy medicines more cheaply and offer one-stop shopping to patients with NHS prescriptions, existing pharmacies may become unviable even if they provide vital services to the community; staffing pressures may put a drain on pharmacists in secondary care; NHS access points may disappear; and an inappropriate distribution pattern of pharmacies would develop.

The OFT's report glosses over the consequences of the removal of the control of entry system. Although we have no crystal ball, we consider the following scenarios to be likely.

We anticipate that existing non-contract pharmacies will dispense NHS prescriptions, and supermarkets will open pharmacies and do likewise. We anticipate that other new entrants to pharmacy will locate in 'clusters', in premises as close as possible to a GP's surgery, cutting off considerable amounts of business for surrounding existing pharmacies.

Research by the Scottish Consumer Council last year⁴ showed that 90% of people are happy with the location of their local pharmacy. When the NHS has such a high public approval rating for pharmacy, abolishing the system which has created the current distribution will be extremely risky.

Possible positive outcomes of removal of control of entry

- More supermarkets enter the market, giving patients and consumers greater choice of where to have their medicines dispensed or where to purchase Pharmacy medicines
- Supermarkets use their bulk purchasing power to deliver cheaper Pharmacy medicines to consumers⁵
- Supermarkets offering 'one-stop shopping' may see an increase in footfall when offering pharmacy services, although this effect may be spread very thinly if every supermarket opens a pharmacy

Those who argue that abolishing control of entry would enable new contractors to enter the market are, we believe, giving false hope to would-be contractors. Without the stability provided by control of entry, the cost of borrowing to finance the opening of a pharmacy will be likely to increase. While more pharmacies would open, there would also be rapid exits.

⁴ Scottish Consumer Council, Consumer Views of Community Pharmacy, published November 2002

⁵ However, we have some reservations that this will be the case. See page 11, section 1.

Possible negative outcome of removal of control of entry

- A reduced number of prescriptions dispensed in an existing pharmacy may lead to **marginal pharmacies becoming unviable**, even though such pharmacies may have patients who entirely rely on their services. We do not anticipate that a vast number of patients will switch from current pharmacy loyalty to new supermarkets. However, patients who do not require their medication 'there and then' may chose to retain their prescription until visiting a supermarket, for instance for their weekly shop.
- The current shortage of qualified pharmacists, combined with the need for more pharmacists to staff new pharmacies (supermarket pharmacies may require at least three full time pharmacists to cover their extended opening hours) may lead to independent contractors having to work continuously for 6 days a week every week. Such **contractors may well consider ceasing to be pharmacy contractors**, particularly when working for a supermarket presents them with an attractive salary and employment package.
- The current shortage of qualified pharmacists in the community may put pressure on pharmacists in other spheres, including hospital pharmacy. Lucrative packages offered by supermarkets may lure pharmacists in secondary care into primary care, leaving a **staffing crisis in our hospitals**.
- Were GPs to chose to open a pharmacy on their premises, **fewer prescriptions would leave the doctor's surgery**, seriously jeopardising the future of primary care in communities in any other location. This would run contrary to the current desire to develop more access points to the NHS⁶, and would make out-of-hours pharmaceutical care more difficult.
- Control of Entry was introduced because of a desire to bring some rationality to the siting of pharmacies, to prevent clustering around GP surgeries or in shopping areas with high pedestrian flow. It is our concern that were control of entry to be abolished, we would see a return to this **inappropriate distribution pattern**.
- In rural communities there tends to be a very good continuity of care in pharmacies, which patients value. The stability of rural pharmacies also enables very close working amongst the primary care team. In many rural areas, the pharmacy is one of very few local businesses. At a time when many rural businesses are closing⁷, the loss of a local pharmacy could be a significant threat to fragile communities.

⁶ "We want to see a fundamental change in the quality and accessibility of people's contact with the NHS. This means greater flexibility in both thinking and working. For example, traditionally, GPs have been seen as 'gatekeepers' to the NHS. In future, we want to provide people with 'gateways' to the NHS. Making best use of the skills of the whole healthcare team is key." – the Scottish Executive, Our National Health, December 2000.

⁷ For a fuller illustration of the dangers to communities of business closures, see Ghost Town Britain, New Economics Foundation, January 2003

3. Why the OFT's case is flawed

In summary: The OFT's case is fundamentally flawed because it fails to take sufficient account of the NHS activity which makes up 80% of the turnover of the average pharmacy. The OFT's four criticisms of the control of entry system are flawed and fail to understand the changing nature of pharmacy in Scotland.

The OFT concluded that the control of entry system must be removed. It reached that conclusion because it took the view that the current regulatory system:

1. Inhibits price competition
2. Stifles efficiency improvements and innovation
3. Limits the availability of pharmacy services
4. Imposes substantial regulatory burdens.

SPGC contends that the OFT's case is **fatally flawed** because it was **fundamentally ill-conceived**. The OFT investigated 'retail pharmacy' and reached its conclusions because of the possible effects of deregulation on that small segment of community pharmacy activity. SPGC estimates that the average pharmacy generates around 80% of its income from NHS work and only 4-5% from the sale of Pharmacy (P) medicines.

We also believe the OFT's report is flawed because **it looks at the economic outcomes of the pharmacy market rather than the health outcomes**. We believe that a health economics approach, rather than a traditional economic approach, would have better reflected the current situation in pharmacy.

In essence, the OFT wishes to see a free market for 'retail pharmacy'. However, 'P' medicines are currently available in a market regulated by professional standard, which is an appropriate regulator for medicines. Were control of entry to be abolished, the market for P medicines – the 'retail pharmacy market' would still not be 'free'.

Decisions based on 'retail pharmacy' will inevitably impact on the NHS aspects of community pharmacy. The question must be asked, what is in the best interests of NHS Scotland?

The OFT's report focuses on these four alleged effects of the current system, which here will be discussed in turn.

1. The current system inhibits price competition

Since there is already a free market for General Sales List medicines and no market for Prescription Only Medicines, the OFT is talking about Pharmacy (P) medicines.

SPGC does not accept that control of entry inhibits price competition. We estimate that **only 5% of turnover of the average pharmacy comes from sales of Pharmacy**

medicines. This is too low a percentage to be responsive to the free market. Even if competition increases, for instance if a new pharmacy opens nearby to an existing pharmacy, the most serious impact on the existing pharmacy will be the loss of dispensing, not the loss in sales of Pharmacy medicines.

Even if the OFT's prediction were correct and the free market for 'retail pharmacy' delivered benefits for consumers who self-care (buy medicines with or without the advice of a pharmacist) in the form of cheaper medicines, this represents only half of the population⁸, and offers no benefits for NHS patients. NHS patients pay a fixed price for their NHS medicines in the form of the prescription charge, or they receive medicines free. Thus competition cannot reduce the price of NHS care.

We believe that the relevance of price competition on Pharmacy medicines will decrease as the Scottish Executive rolls out the **direct supply of medicines** scheme, giving increased access to medicines for minor ailments on the NHS. Although this scheme will only apply to the 50%⁹ of patients who do not pay prescription charges, we expect to see a reduction in sales of medicines in favour of medicines provided by the direct supply of medicines scheme.

We believe that the OFT's method of costing medicines in a '**shopping basket**' of medicines is flawed. The shopping basket used by the OFT contains a limited range, within which there is a high proportion of known value items, which does not reflect the true nature of sales in pharmacies. Most pharmacies are likely to offer customers generic versions of known value items, which are always less expensive. It is inappropriate to encourage more medicine to be purchased than required, and indeed is prohibited for registered pharmacists by the Code of Practice of the Royal Pharmaceutical Society.¹⁰

We also believe that there are differences in the way that supermarkets sell medicines. Supermarkets have national pricing policies, according to the OFT's report¹¹ and this will not promote local competition. Additionally supermarkets promote nationally advertised products, whereas other pharmacies promote generic, better-value equivalents.

2. The current regulations stifle efficiency improvement and innovation

We do not accept the fundamental principle of the OFT that the free market will improve services to patients. Within the NHS the best way to improve service quality, while at the same time maintaining equity of service across Scotland, is to regulate. SPGC is

⁸ Since only 50% of people pay their prescription charge, we can assume that the other 50% will visit their GP for NHS treatment rather than self-care. "50 per cent of people do not have to pay for prescriptions – including the elderly and those on low incomes" – Susan Deacon, Health Minister, 16 March 2001.

⁹ "50 per cent of people do not have to pay for prescriptions – including the elderly and those on low incomes" – Susan Deacon, Health Minister, 16 March 2001, Scottish Executive press release, lowest percentage prescription rise for more than 20 years

¹⁰ Medicines & Ethics, Royal Pharmaceutical Society

¹¹ page 32, The control of entry regulations and retail pharmacy services in the UK, January 2003

committed to the implementation of The Right Medicine as the way to provide the step change in community pharmacy necessary to improve the patient journey.

Pharmacy provides services to patients which are not controlled by market forces, including healthcare advice which does not result in a sale, answering general questions on medicines and their safe use, and monitoring for adverse drug interactions through patient medication records. The free market would not be sensitive to these transactions and these vital services could suffer.

The destabilisation caused by the removal of the control of entry is more likely to see a **loss of the quality services provided by community pharmacists**. Non-NHS funded services such as home deliveries and ordering of repeat prescriptions are likely to be axed by contractors in an unstable climate. It is difficult to see how, when faced with such instability, pharmacy contractors would be willing to get involved in supplementary prescribing or direct supply of medicine schemes.

We believe that **pharmacies which do not improve to meet patient need or innovate to meet expectation should be a matter for NHS Boards**. At the moment it is the job of Primary Care Trust Chief Pharmacists to monitor pharmacies to ensure that they meet the criteria set down in the contract.

In the future we anticipate that **quality standards will be rigorously enforced** in pharmacies in Scotland. The Scottish Executive's plans to ensure that the new contract will include quality indicators are welcomed by SPGC. Whereas the OFT selected four arbitrary indicators of quality in relation to the retail aspects of pharmacy, the new contract will uphold patient-centred standards.

There is no impediment to a pharmacist wishing to open a **non-dispensing pharmacy, and offering a range of innovative, non-NHS health services**. While supermarkets argue that it is not viable to run a pharmacy without a contract to dispense, we have seen no evidence that supermarkets have explored other ways of supporting such a pharmacy.

On **efficiency**, we find it difficult to see how community pharmacy could be described as inefficient. The core role of pharmacy, dispensing NHS prescriptions, has been increasing year on year, resulting in a massive increase in prescription volume over the last 15 years.¹² This has been done by a broadly static number of pharmacies. While dispensing has increased, the size of the global sum has not increased by the same proportion. Thus the core pharmacy service has become increasingly more efficient and productive in recent years.

3. The current regulations limit the availability of pharmacy services

The OFT comes to this conclusion in spite of showing that **90% of the population consider access to a pharmacy from their home to be easy**, and 89% of the

¹² In 1987, 38.3 million prescriptions were dispensed in Scotland. In 2002, the figure was 63.5 million, plus more than 6 million instances of serial dispensing.

population consider access to a pharmacy from a GP's surgery to be easy. This is backed up by the results of the Scottish Consumer Council's research last year which showed that 90% of people in Scotland say their pharmacy is conveniently located, and that women, older people, people from lower socio-economic groups and urban backgrounds are more likely to think their pharmacy is conveniently located.

It seems then to be **unsubstantiated** to say that the control of entry system limits the availability of pharmacy services.

In areas where there are **gaps in provision of pharmacy services**, we believe that these are best filled through the proposals outlined in The Right Medicine to develop 'toolkits' to assess and meet local need for pharmaceutical services, in particular in rural and deprived areas. A free market will not encourage contractors to open pharmacies where to do so is currently economically unviable.

We have grave concerns that access to pharmacy services would be severely limited if control of entry is abolished and **GPs open pharmacies on-site at their surgeries**. While this may at first glance seem like an attractive option for many patients, such pharmacies would inevitably have shorter opening hours and reduce access to pharmaceutical care throughout the community. The result would be very few scripts being dispensed in the community and would lead to the inevitable closure of a significant number of pharmacies.

This would drastically reduce access to pharmaceutical care in the community, especially outside surgery hours. Effectively it would limit access to primary care to that of the GP surgery, which would go against the grain of 'Our National Health'.

4. The current system imposes a substantial regulatory burden

The OFT states that the regulatory burden of control of entry costs the NHS £10 million per year throughout the UK. We believe that regulatory costs are unavoidable and worth paying in order that NHS Boards & Trusts can plan and manage the number and location of pharmacies.

We foresee additional costs were the current system abolished, namely in increased costs to PSD to pay for the administration of pricing prescriptions from an increased and varying number of pharmacies; and the additional costs of paying a professional allowance to, at least in the medium term, an increased number of pharmacies.

In addition, SPGC commissioned Deloitte & Touche to produce a critique of the OFT report. As you will see from Deloitte & Touche's report included as Annexe 1, their conclusions are that it could be argued that:

- the stated benefits from deregulation are modest and are over reliant on evidence adduced by the supermarket chains;
- the benefits (as consumer savings from competition) are already small and may, at that, have been overestimated;

- the risks associated with open market competition have not been fully quantified;
- little attention was paid to the health promotion role of community pharmacists as part of the primary health care team;
- some of the research evidence presented in favour of deregulation is ambiguous and limited.

4. The Right Medicine

Summary: *The OFT has looked at community pharmacy today, rather than the future of community pharmacy which is being constructed by the implementation of The Right Medicine. If implemented, the OFT's recommendation would threaten the implementation of The Right Medicine.*

In February 2002 The Scottish Executive published its pharmaceutical care strategy "The Right Medicine", setting out its plans for the future of community pharmacy. SPGC has welcomed the opportunity to discuss with you a new direction of travel, one which puts both the patient and the community at the forefront.

"The Right Medicine" has highlighted a number of areas where community pharmacy could contribute to or substantially improve the patient's experience. However, any possibility of removal of the control of entry system greatly concerns SPGC. **It is our belief that disruption of the current stable network would markedly inhibit contractors' ability to implement the Right Medicine.** There would be no confidence to invest staff time and resources into developing new schemes, skills and practices. In addition, patients value our ability to deliver a continuity of care, and this would be jeopardised by disruption of the current network.

SPGC has welcomed the opportunity to commence discussions with the Health Department on the shape of a new contract for community pharmacy. Working in partnership, we need to develop a contract which will continue to encourage and acknowledge the use of the community pharmacist's professional skills on behalf of patients and allow us to deliver "The Right Medicine". Issues such as access, quality, workforce, equity and remuneration must also be examined, and the control of entry regulations must not be looked at in isolation.

It is our firm belief that **we need to work with you to deliver that new contract in a way which minimises turbulence and instability in community pharmacy.** That will not be possible for us to do against a background of instability brought about by deregulation. Indeed if deregulation were to occur, it is our belief that our ability to deliver enhanced pharmaceutical care services would be severely jeopardised not just in the short-term but for some considerable time to come.

5. Conclusion

SPGC believes that the current system of control enables the efficient use of NHS resources to deliver pharmaceutical care throughout communities in Scotland. The system provides a stable base for improved services, as envisaged in The Right Medicine.

SPGC contends that the OFT's case is **fatally flawed** because it was **fundamentally ill-conceived**, investigating "retail pharmacy" when average pharmacy generates around 80% of its income from NHS work and only 4-5% from the sale of Pharmacy (P) medicines.

Additionally, as appendix 1 shows, there are considerable questions raised about the accuracy of the OFT's economic analysis. The issues raised by Deloitte Touche's critique could usefully form the basis for further economic research by the Scottish Executive.

SPGC believes that improving and innovating in Scotland's pharmacy services is best done in partnership between the Scottish Executive and community pharmacy. When problems are identified, as has been the case in The Right Medicine, these can be addressed best by joint working within a regulatory framework.

SCOTTISH PHARMACEUTICAL GENERAL COUNCIL

**THE CONTROL OF ENTRY REGULATIONS AND
RETAIL PHARMACY SERVICES IN THE UK
(JANUARY 2003)**

A CRITIQUE

February 2003

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CONTENTS		Page
1.	INTRODUCTION	1
1.1	Background	1
1.2	Terms of reference	1
2.	BENEFITS ASSOCIATED WITH DEREGULATION	2
2.1	Current regulations inhibit price competition	2
2.2	Current regulations stifle efficiency improvements and innovation	4
2.3	Current regulations limit the availability of pharmacy services	4
2.4	Current regulations impose substantial regulatory burdens	5
3.	RISKS ASSOCIATED WITH DEREGULATION	6
3.1	Impact on pharmacy numbers	6
3.2	Impact of market competition	7
3.3	Impact on market composition	7
3.4	Impact on consumer access	8
4.	SUMMARY AND AREAS FOR FURTHER WORK	10
4.1	Summary	10
4.2	Areas for further work	10
5.	ANNEX 1: CONCENTRATION MEASURES	11

1. INTRODUCTION

1.1 Background

The Office of Fair Trading (OFT) launched an investigation into the provision of retail pharmaceutical services in the United Kingdom (UK) in October 2001. In particular, it was to examine whether the interests of consumers are best served by the current control of entry regulations. These regulations place restrictions on how and where contracts to dispense National Health Service (NHS) prescriptions in the UK are awarded.

OFT market investigations are evidence-based studies that examine whether markets are working well for consumers. The investigations are guided by the principle that competitive markets to which there are no barriers to entry generally serve the best interests of consumers.

The final OFT report, *The control of entry regulations and retail pharmacy services in the UK: A report of an OFT market investigation* was published in January 2003.

1.2 Terms of reference

Deloitte & Touche was commissioned by the Scottish Pharmaceutical General Council (SPGC) to undertake a short, high-level review of the OFT report and in particular to:

- read the report and appendices;
- draft a paper setting out our critique of the report. This would identify our high-level thoughts on the report and the areas that may merit further investigation or be worth highlighting to the Scottish Executive for consideration in its deliberations;
- meet with you to review our critique.

The following sections outline our critique of the report. Section one, considers the scope and scale of the benefits associated with market deregulation, section two highlights a series of potential risks associated with deregulation and in section three we summarise our conclusions and highlight areas for further research.

It should be noted that this paper is based on a short review and is, therefore, a high-level commentary to inform discussion and possible further work. We have not conducted any additional detailed analysis or empirical research. It is intended, as per our remit, as a discussion document for the SPGC and Deloitte & Touche does not accept any liability for its use by other parties for any other purposes.

2. BENEFITS ASSOCIATED WITH DEREGULATION

The Director General of Fair Trading outlined a number of key benefits associated with the removal of the control of entry regulations in *The control of entry regulations and retail pharmacy services in the UK: A report of an OFT market investigation* (referred to as the 'the OFT report' in the remainder of this paper).

In the following section we consider each of these potential benefits and the evidence presented within the OFT report.

2.1 Current regulations inhibit price competition

The report presented little evidence to illustrate that the current market is working against the interest of consumers, for example:

- there was no evidence of excess-profits in the sector based on work commissioned by the OFT¹; and
- deregulation would have no impact on the market for NHS prescriptions because prices are fixed. The NHS prescription market is valued at £6.8 billion per annum and accounts for approximately 80% of the total market.

The main focus of the OFT report was the indirect impact the control of entry regulations has upon the market for over-the-counter (OTC) medication. In particular, that the regulations restrict the market for pharmacy-only (P) medicines and to a lesser extent General Sales List (GSL) medicines. The OTC market is valued at £1.8 billion per annum, split equally between both types. The evidence that the current market arrangements inhibit price competition can be summarised in two points²:

- there was no evidence that the price of OTC medications is influenced by the level of local competition (as proxied by local measures of pharmacy density); and
- the prices of OTC medications were significantly lower in certain supermarkets than in independent or grocer pharmacies.

The first point illustrates that the OFT could find no statistical evidence that OTC medication prices were lower in areas of high pharmacy concentration. This, they argue, could be due to the current control of entry regulations inhibiting price competition, but could also be due to measurement error in the concentration measures used (see Annex 1).

The main finding of the OFT report was that certain supermarkets, in particular Asda and Tesco, had lower prices for a basket of P-list medicines compared to local community pharmacies. This finding is supported by the data presented, although, the result that some supermarkets are cheaper than local 'corner' shops is unsurprising as it is generally recognised as applying to a wide range of goods. However, we would be concerned that this finding was driven primarily from data from Asda (which accounted for only 17 out of the 838 observations in the analysis). We have no understanding of Asda's pricing mechanisms or whether within a supermarket environment OTC medications may be a loss leader, or receive cross-subsidisation from other products.

¹ Townsend, A. *Report to the Office of Fair Trading*. Orridge Business Sales Limited

² Frontier Economics. *The relationship between price and local competition measures. A report to the Office of Fair Trading*. November 2002.

Based on the finding that certain supermarket chains are cheaper than other retailers for OTC medication, the OFT report estimated the potential consumer savings associated with deregulation of the market. It assumed that between 400-500 supermarkets would enter the market following deregulation and that this would save consumers between £20-25m per annum. However, it was unclear to us how this figure was arrived at. For Scotland specifically, this figure would need to be re-calculated based on a number of pieces of information:

- the additional OTC market share captured by certain supermarket chains;
- the level of price reduction for OTC medications; and
- the value of the OTC market in Scotland.

Box 1 illustrates a hypothetical worked example of this type of calculation. The data contained within this example is illustrative and needs further refinement, but highlights that the OFT estimate of potential cost savings could be overstated.

Box 1. Example Calculation: OTC P-list savings post-market deregulation

Assumptions:

- the current P-list product market value is £900m;
- Asda and Tesco double their market share;
- Asda's prices are 30% and Tesco's 10% lower than existing retailers;
- it is assumed that P-list market share is in proportion to number of shops.

Savings if all P-list medication were dispensed in:

- Asda: 30% of £900m = £270m
- Tesco: 10% of £900m = £90m

Savings if Asda and Tesco double current market share:

- Asda doubles market share from 0.66% to 1.32% (80 out of 12,100 stores):
= $0.66\% * £900m * 30\% = £1.80m$
- Tesco doubles market share from 1.75% to 3.50% (210 out of 12,100 stores):
= $1.75\% * £900m * 10\% = £1.57m$

In this example, the total saving to consumers across the UK would be £3.37m. If Scotland accounts for 10% of the OTC market then savings to Scottish consumer would be £0.337m.

The figures presented in Box 1 assume that consumer savings would be realised immediately post-deregulation. However, due to the lack of pharmacists it would take a number of years for large supermarkets to open and staff these additional pharmacies. The analysis could be bounded further. For example, in the United States which is a deregulated market, the share

of pharmacy sales by supermarket pharmacies has remained relatively static at just over 10% between 1992 and 2001.

Similar investigation could be conducted for GSL products.

2.2 Current regulations stifle efficiency improvements and innovation

The second point raised by the OFT was that current regulations stifle efficiency improvements and innovation. However, it could be argued that this was not substantiated by the evidence provided. The key piece of evidence used to support this statement attempted to measure the impact of competition (local concentration) on a number of quality measures³.

The report measured quality and innovation using four main measures:

- pharmacy opening hours;
- whether the pharmacy had a separate consultation area;
- whether the pharmacy offered a home delivery service; and
- whether the pharmacy collected repeat prescriptions.

These quality measures were based on a survey of 233 pharmacies. The survey had a relatively low overall response rate of 35%. The response rate by supermarkets was even worse with only 9 (3.6%) responding. The poor response rate may limit the validity of the results.

The impact of type of pharmacy on these quality measures was ambiguous. Supermarket pharmacies reported longer opening hours whilst independent pharmacies were more likely to offer a home delivery service.

There was little statistical evidence linking these quality measures to the competition measures used. Again, this may be due to measurement error in the competition measures or measurement error in the quality indicators. A number of additional measures of innovation could have been used, for example, the range of pharmaceutical services offered. A key aspect of quality in the pharmacy market, and a factor in current health policy, is continuity of care and the provision of pharmaceutical advice. These quality indicators were not measured.

2.3 Current regulations limit the availability of pharmacy services

It could be argued that there is no compelling evidence that consumers have difficulty accessing community pharmacies⁴. In the vast majority of cases, the consumers' usual chemist was easy to get to from home (89%) and the doctor's surgery (86%).

The OFT report argues that market deregulation resulting in the entry of additional supermarket pharmacies would increase the accessibility of services due to supermarkets' longer opening hours. However, there is nothing stopping community pharmacies opening for longer under the current regulations. There is anecdotal evidence that pharmacies currently respond to the needs of consumers, for example, opening early if located close to a GP surgery and closing at times when demand is very low.

³ Frontier Economics. *The relationship between quality and local competition measures. A report to the Office of Fair Trading.* November 2002.

⁴ FDS International Ltd. *Office of Fair Trading: Survey on Usage of Prescription Pharmacies in the UK.* September 2002.

Although, supermarket opening hours may be longer, other aspects of access could be adversely effected if they cause displacement or net exit amongst smaller independent pharmacies (see below).

2.4 Current regulations impose substantial regulatory burdens

There are currently a number of costs associated with running the existing control of entry system. These include:

- business costs associated with applying for licences;
- appeal costs associated with legal challenges to the definition of the existing regulations; and
- administrative costs to the NHS to implement the current regulations.

The total value of the costs was estimated at approximately £26m. This would translate to just over £2m in Scotland.

It is unclear what proportion of these costs would translate into *realisable* cost savings to businesses and the NHS. The OFT report assumed administrative savings of £75,000 per Health Board or Primary Care Trust. However, it could be argued that this may be an overestimate, especially for the smaller Scottish Health Boards. Also, it is not clear how many NHS posts would become redundant following the removal of these regulations.

We would also still expect some business and administrative costs to be incurred with applying for pharmaceutical licences whatever entry system is in place.

Key Points: It could be argued that:

- there is no evidence of excess profits being made in the UK pharmacy market;
- deregulation will have no impact on the price of NHS prescriptions (over 80% of the market);
- the cost of OTC medication is lowest in certain supermarket chains, as it is for many other products compared with high street locations;
- there is no evidence linking local measures of concentration (competition) with reduced prices of OTC medication;
- the consumer savings associated with deregulation in the OTC market are modest and may be overestimated;
- there is no evidence that competition will increase innovation or quality;
- there is no evidence that consumers are unhappy at current levels of access to community pharmacies; and
- the scale of the realisable cost savings associated with reducing the regulatory burden are unknown in a Scottish context.

3. RISKS ASSOCIATED WITH DEREGULATION

There are a number of possible benefits associated with deregulation. However, it could be argued that there are also potential risks which were not directly quantified within the OFT report. Most of the risks were assumed to be relatively small based on a series of commissioned empirical studies. We highlight the potential key risks associated with deregulation in the following section.

3.1 Impact on pharmacy numbers

The OFT report appears to implicitly assume that the removal of current entry regulations will increase the number of pharmacies in the UK and stimulate competition. This assumption was based on two pieces of evidence:

- data from stakeholder supermarkets on potential supermarket pharmacy numbers; and
- empirical analysis of historical entry data⁵.

The empirical analysis concluded that new entrants into the pharmacy market did not displace existing pharmacies but resulted in net entry so increasing the overall number of pharmacies.

However, this analysis was conducted using data from 1997 to 1999 when the current regulation system was in force. The current system only allows entry if there is a proven 'need'. It would be unlikely that approval would have been granted if it was expected to displace another pharmacy, so it could be argued that this data is not reliable in predicting what would happen under a different entry regulation system.

Also, the analysis was not conducted using data on financial viability (this could be conducted using current prescription volumes as a proxy), so further limiting the analysis.

International evidence highlights that the impact of deregulation on the number of pharmacies in the market will be ambiguous⁶. The precise impact will depend upon the current number of pharmacies in the market. For example, deregulation of the pharmacy market in Norway resulted in net entry into the pharmacy market, however, this was from a very low base. On the other hand, in the United States, deregulation of the market has gradually seen the number of pharmacies reduce over time. The likely impact of deregulation will, therefore, depend upon the current number of pharmacies. So, areas such as Scotland (4,400 people per pharmacy) and Northern Ireland (3,300 people per pharmacy) with relatively high numbers of pharmacies may see a net loss of numbers, whilst England (5,000 people per pharmacy) may see net entry. This pattern would also be replicated within regions, with net entry in areas of growing population (which tend to be affluent) and net exit from areas with a decreasing population (which tend to be deprived).

It could be argued, therefore, that there is a *risk* following deregulation that pharmacy numbers will fall, especially in certain regions, having a direct impact on consumer access.

⁵ Frontier Economics. *The access implications of entry and exit of pharmacies. A report to the Office of Fair Trading*. November 2002.

⁶ Mossialos, E, Mrazek, M. *The Regulation of Pharmacies in Six Countries*. Report prepared for the Office of Fair Trading. LSE Health & Social Care and the European Observatory on Health Care Systems.

3.2 Impact of market competition

The OFT report assumes that between 400 and 500 supermarket pharmacies will open following market deregulation. If additional pharmacies entered the market (assuming current remuneration fees are capped) then some pharmacies must lose market share and share of total remuneration.

A pharmacy could respond to this loss of business or finance in a number of ways:

- it could absorb a loss of profitability and continue trading;
- it could reduce costs, the most obvious being related to staffing or opening hours. It is already widely accepted that Saturday opening can be unprofitable, so it would seem an obvious target for a reduction in opening hours;
- it could innovate and improve the quality and range of services offered, the response the OFT report implicitly considers most likely; and
- it could close or sell up to a rival. A case study presented in the OFT report⁷ highlighted a similar scenario, where additional competition caused all local pharmacies in an area to become less financially viable. In the case study, one of the two struggling pharmacies agreed to take over the other, so as a direct result of competition, one owner now has even more of a local monopoly.

It could, therefore, be argued that there is a *risk* that competition could have an adverse impact on opening hours or on local competition.

3.3 Impact on market composition

The UK pharmacy market has been changing rapidly over the past few years with an increasing trend towards 'chaining' or market consolidation. By definition this restricts competition and consumer choice as the number of independent players is reduced. More importantly, if the composition of the market shifts further towards a supermarket based model then the type of consumer service offered will change. Data from the OFT report highlights a number of issues associated with this shift in market composition:

- there is strong evidence of consumer loyalty with over 90% of people using their 'usual chemist'. This behaviour is particularly strong with independent pharmacies;
- anecdotal evidence suggests that supermarket pharmacies have high staff turnover rates and use locums more frequently which may reduce the continuity of patient care. The OFT report did not examine this issue;
- supermarkets are less likely to offer collection and delivery services which are highly valued by the elderly and infirm;
- supermarkets are used by a younger more affluent client base, so any increase in the number of supermarkets at the expense of independents or multiples would adversely affect the deprived, elderly and those without cars; and
- the closure of a local pharmacy would be a 'real problem or nuisance' for up to 45% of those responding to the consumer survey⁸ (the OFT report only reported this statistic as 19% for the first category). This proportion was even higher in the elderly (54%) and infirm (62%) categories.

⁷ Frontier Economics. *The impact of pharmacy entry: three case studies. A report to the Office of Fair Trading.* November 2002.

⁸ categories 'it would be a real problem for me' and 'it would be a big nuisance but there are alternatives'

It could be argued, therefore, that there is a *risk* that a switch in market composition towards a supermarket based model may adversely affect certain disadvantaged population subgroups.

3.4 Impact on consumer access

One of the most important issues examined by the OFT report was the impact of deregulation on consumer access to pharmacies. Access was defined in terms of physical access as well as in terms of longer opening hours etc.

The OFT commissioned detailed empirical research using scenario analysis to examine the impact of deregulation on consumer accessibility⁹. This report measured the impact on the distance travelled by consumers to their local pharmacy under a series of different scenarios. These scenarios were in broad terms:

- the impact of various numbers of supermarkets opening, with *no exit* on distance travelled from a 'ward population centroid' and from a GP practice;
- the impact of various numbers of supermarkets opening and *displacing the nearest pharmacy* on distance travelled from a 'ward population centroid' and from a GP practice; and
- the impact of various numbers of supermarket opening and *displacing the nearest two pharmacies* on distance travelled from a 'ward population centroid' and from a GP practice.

The OFT report concludes that under scenario one access would improve, under scenario two access would be unchanged, and under scenario three access would deteriorate. The OFT report considered that scenario three was a worst case scenario and unlikely to occur.

However, it could be argued that there is a *risk* that a 'scenario two type situation' could occur and in this scenario access would on average deteriorate. In this scenario, the average distance travelled from a GP surgery to a pharmacy would actually *increase* by between 140 and 210m. Careful examination illustrates that for those whose access would deteriorate, approximately 40% would face a deterioration of greater than 400m in distance (the OFT report states that 400m is an appropriate benchmark for consumer access).

The main OFT report does not present these data, it presents data based on distance travelled from home. However, the consumer survey clearly illustrates that most people travel to the pharmacy from the GP surgery, not home, and in any case using a 'ward population centroid' (from the 1991 census) could at best, be considered a rough proxy for 'home'.

It could be argued, therefore, that there is a *risk* that access could deteriorate as a result of greater supermarket entry and that this will impact differentially across areas.

⁹ Frontier Economics. *The access implications of entry and exit of pharmacies: A report to the Office of Fair Trading*. November 2002.

Key Points: It could be argued that:

- analysis of entry and exit scenarios was based on the current regulatory system and, therefore, is of limited use;
- no data on financial viability was used to assess the impact of entry and exit scenarios;
- international evidence suggests that the impact of deregulation on pharmacy numbers will be ambiguous. 'Over-pharmacied' areas will lose numbers whilst 'under-pharmacied' areas will gain numbers;
- additional competition could reduce current levels of service or create local monopolies;
- supermarkets serve a more affluent and younger market and offer less services valued by the elderly and infirm;
- 45% of people stated that closure of a local pharmacy would cause big problems; and
- scenario analysis of the impact of supermarket entry on consumer access illustrates that distance travelled could increase substantially in some areas.

4. SUMMARY AND AREAS FOR FURTHER WORK

4.1 Summary

It could be argued that the benefits associated with market deregulation are modest and based on over-reliance on data from supermarket chains.

It could also be argued that the benefits in terms of consumer savings from competition, which are already small, may be overestimated and that the risks associated with open market competition have not been fully quantified. Also, there was little or no attention paid to current public policy towards the health-promoting role of community pharmacists as part of the primary health care team.

It could be argued further that some of the research evidence presented in favour of deregulation is ambiguous and limited. Some of the concentration and quality measures could be improved, and there is a need to consider the impact of competition on market exit using data on financial viability.

4.2 Areas for further work

The OFT report raises a number of important questions, some of which may merit further attention, including:

- a more detailed breakdown of the cost savings to the Scottish consumer;
- a more detailed breakdown of the realisable cost savings to businesses and in terms of NHS administration;
- the development of more realistic quality and competition or concentration measures; and
- the use of data on financial viability or other proxies for viability to examine the impact of market deregulation on market exit.

5. ANNEX 1: CONCENTRATION MEASURES

Large aspects of the research commissioned by the OFT to support its recommendations were based on empirical research by *Frontier Economics*. The main research tool and measure of competition used throughout the report was based on the creation of an electronic map of pharmacy location¹⁰.

Although, we recognise the difficulty of measuring accessibility it is important to highlight a number of caveats around the use of GIS techniques including:

- concern about the size of some of the isochrones because the report states that drive times under 5 minutes can be unreliable;
- in rural areas, if a major road is impossible to reach an isochrone will not be constructed;
- a drive time of 15 minutes could potentially cover a very large area – up to a 12-mile radius in rural areas (based on 70km/hr);
- it was not clear what the relationship was between rurality or urbanity and the concentration measures; and
- the measures were not well correlated causing the researcher to develop a composite indicator of concentration. If the indicators were not well correlated then they must be measuring different things, so they cannot all be measuring concentration.

A more important issue would be that the 'density' measures do not represent a good proxy for competition. A better indication of competition would be the market share of each GP's prescription market a pharmacy captures. One pharmacy may capture all of one GP's business (no competition) or a GP's business may be shared over a number of pharmacies (greater competition).

It would be possible to construct such measures using data on prescriptions so that concentration could then be expressed using 'concentration coefficients', a much better measure. *Frontier Economics* state that such data was not available due to data protection. However, suitable anonymisation of data should allow this analysis.

The mis-measurement of competition or local market concentration may be one reason why the econometric methods failed to identify any significant relationships or why the models failed standard specification tests.

¹⁰ Frontier Economics. *Creating an electronic map of GB pharmacy locations: A report to the Office of Fair Trading*. November 2002.