

B THE COST OF ADMINISTERING THE CONTROL OF ENTRY REGULATIONS

Costs to business

Costs to business at the Health Authority stage

- B.1 We distinguish two types of costs to business associated with dealing with the regulations at the Health Authority/ Board stage:
- management time
 - administration costs (letters, faxes telephone calls etc).
- B.2 In the year 2000/2001 there were 1,517 applications received across all Health Authorities/Boards in the UK. In England and Wales there were 1,395 applications, in Scotland there were 67 applications and in Northern Ireland there were 55 applications.^{11,12,13}
- B.3 From discussions with various pharmacy businesses, it is apparent that a significant amount of management time is spent dealing with the control of entry regulations¹⁴ in each jurisdiction. This may be for a new contract application, a minor relocation or merely lodging an objection to a competitor's application. Given that an average application at first instance (at Health Authority stage) takes approximately six to eight months, we estimate that around 300 hours of management time, spread over the six to eight month period, is spent on the control of entry regulations per application. This estimate is based on information obtained through consultations with specific players in the industry and also a detailed breakdown carried out by the OFT of the time spent by managers dealing with the application process. This breakdown includes:
- time spent perusing and preparing the application to the health authority, including research and advice
 - internal meetings and liaising with colleagues on the progress of the application

¹¹ Figures taken from the Department of Health Bulletin 2001/34 published December 2001.

¹² Figure provided by the Scottish Executive.

¹³ Figure provided by the Northern Ireland Department of Health, Social Services and Public Safety (DHSSPNI).

¹⁴ NHS (Pharmaceutical Services) Regulations 1992 (England and Wales), NHS (Pharmaceutical Services) (Scotland) Regulations 1995 and Pharmaceutical Services Regulations (Northern Ireland) 1997.

- communicating developments and advice, and
- liaising with the Health Authority.

B.4 Mid management will be involved in assessing the prospect of an application, liaising with consultants, preparing detailed maps, visiting sites, reading and responding to correspondence, consulting other managers within the business and attending the initial hearing. We estimate that the hourly rate for staff at mid management level is approximately £27.00 per hour.¹⁵ This includes an allowance of 50 per cent to cover such things as general expenses, pension and NI.

B.5 In addition, one has to take account of administration costs to the business. We estimate the average administration cost will be in the range of £500 - £800 per application: and this includes the cost of letters, stationery costs, telephone charges, and faxes etc. This is a notional estimate¹⁶. For the purposes of this assessment we shall take the average administration cost to be £650.

B.6 Thus, management costs and administrative costs can be calculated approximately as follows:

Management costs: 300 hours @£27.00 per hour = £8,100 per application.

$£8,100 \times 1517 = £12,287,700$, or, **£12 million**

Administration costs $£650 \times 1517 = £986,050$ or **£1 million**

Total cost £13 million

Cost to business of using the appeals system

B.7 In the year 2000/2001 392 appeals were received in the UK. In England and Wales there were 362 appeals, in Scotland there were 18 and in Northern Ireland there were 12 appeals.^{17,18,19}

B.8 This cost to management is in addition to the management costs incurred by businesses when making their original applications. There are additional administration costs involved as well, over and above the administration costs of the original application which gave rise to the appeal.

¹⁵ Based on New Earnings Survey 2002, Office for National Statistics. Average hourly pay excluding overtime for full time general managers on adult rates (employees only).

¹⁶ A notional estimate is one which is based on certain factors the value of which can be easily and accurately estimated.

¹⁷ Family Health Services Appeals Authority Annual Report 1 April 2000 – 31 March 2001.

¹⁸ Figure given by the Scottish Executive Health Department.

¹⁹ Figure confirmed by Northern Ireland DHSSPNI.

B.9 It is estimated that an additional 200 hours of management time will be spent dealing with the appeal and liaising with the lawyers, consultants and the appeal authority and attending the appeal itself. This estimate is based on information obtained from consultations with specific players in the industry who have been involved in the appeals process. A notional average estimate of £500 will be incurred in administrative costs over and above the administrative costs incurred during the original application.

Thus:

Management costs of appeal:	200 hours @ £27.00 =	£5400
	£5400 x 392 appeals =	£2,116,800
	or	£2 million
Administrative costs:	£500 x 392 appeals =	£0.2 million
Total		£2.2 million

Legal costs at appeal

B.10 Due to the control of entry regulations the retail pharmacy sector faces costs over and above the 'usual' legal costs²⁰ of entering a market.

B.11 Legal costs are mainly aligned with the appeals process, and are incurred by a small proportion of pharmacies engaging legal experts to help them through the appeals procedure (some pharmacies engage legal experts at the earlier stage of applying for a new contract but for the purposes of this assessment we assume that legal costs are incurred at appeal stage only).

B.12 Legal costs can be high in this market due to the complex nature of the regulations. Given the specialist nature of this area of work, a senior solicitor will often be retained. The hourly rate for a senior solicitor is typically around £120 per hour.²¹

B.13 The OFT estimate that a solicitor will need to carry out around 50 hours of work to prepare for the appeal. This will involve taking initial instructions from the client, reviewing documentation from the initial application, drafting the appeal and skeleton arguments, telephone calls and correspondence and in some instances, instructing counsel. This and other estimates have been obtained through the OFT's consultation with those players who have been involved in the appeals process.

²⁰ Usual legal costs covers such things as conveyancing costs and other commercial legal costs of entering a market that most, if not all, undertakings pay whenever there is entry in the market.

Costs of administering the control of entry system

Cost of Health Authorities

B.19 The McKinsey & Co analysis is based on the following figures:

- The annual cost of one full time equivalent and a secretary in each Health Authority is £2.52 Million. The annual cost of the Health Authority sub-committee meeting every six weeks in each Health Authority is £0.16 Million. Thus, McKinsey calculate that the overall annual cost of running the control of entry regulations at Health Authority stage is approximately £2.68 Million.
- The OFT considers this to be an underestimate. In 2001 there were 104 individual health authorities in England and Wales, 16 health boards in Scotland and 4 in Northern Ireland.^{24,25,26} Each health authority or Board will require at least one full time member of staff and secretary in order to carry out the functions required under the control of entry regulations. It is recognised in this assessment that the Health Authorities have other functions and the necessary adjustments have been made. There is also the cost to each health authority of the sub-committee meeting every six weeks as well as the administration costs. The annual cost factors to each health authority can be broken down as follows:
 - Staff salaries £60,000²⁷
 - Administration costs (letters, faxes telephone, stationery etc) approximately £15,000²⁸

Total approximately £75,000

B.20 Our estimate of the total cost to the taxpayer of the health authorities' administration of the control of entry system in the UK is, therefore:

£75,000 x 124 Health Authorities in UK = **approximately £9.3 million**

²⁴ Figure confirmed by the Family Health Services Appeal Authority: England (99), Wales (5).

²⁵ Figure confirmed by the Scottish Executive.

²⁶ Figure confirmed by the Northern Ireland DHSSPNI.

²⁷ Figure obtained from the New Earnings Survey 2002, Office for National Statistics. Average hourly pay excluding overtime for full time general managers on adult rates (employees only).

²⁸ This figure is purely for the work carried out by the Health Authorities in administering the control of entry regulations. The figure is an OFT estimation.