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Committee of Public Accounts

Procurement of vaccines by the Department of Health

Fifteenth Report of Session 2003–04

Report, together with formal minutes, oral and written evidence

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The Committee of Public Accounts

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Contents

Report

Summary

Introduction

The Department of Health (the Department) and the National Health Service in England spent £195 million on routine vaccine procurement in 2001–02. Of this, the Department's national vaccine programme cost £83 million.[1]

The limited number of vaccine manufacturers in the market, and the complex manufacturing processes involved, results in shortages in the supply of some vaccines in the UK. So there is a risk that manufacturers may charge higher prices as they will have a near monopoly of supply for certain vaccines.[2]

In April 2002, the Department, with the Ministry of Defence, let a contract for £32.5 million, excluding value added tax, with PowderJect Pharmaceuticals PLC for the supply of 20 million doses of smallpox vaccine. The Department used the exemptions under European Union regulations and the Public Supply Contracts Regulations 1995 that, on grounds of national security, enabled it to adopt confidential procurement procedures for these supplies. Concerns had been raised among some suppliers, and in Parliament and the media, about the Department's handling of the procurement and about any link between the political donations made by the then Chief Executive of PowderJect and the award of the contract.[3]

On the basis of a Report by the Comptroller and Auditor General[4] and a memorandum from the Department of Health,[5] we examined the Department on the robustness of its central purchasing arrangements, the lessons to be learned from the procurement of smallpox vaccine, and the measures it has put in place to avoid or mitigate the impact of vaccine shortages in general.

1 C&AG's Report, *Procurement of vaccines by the Department of Health* (HC 625, Session 2002–03), para 1.4

2 *ibid*, paras 19–20

3 *ibid*, para 1.5

4 C&AG's Report, *Procurement of vaccines by the Department of Health* (HC 625, Session 2002–03)

5 Ev 15

Conclusions and recommendations

1. **The Department failed to act promptly on a number of reviews of its procurement processes which would have provided an opportunity to achieve significant financial savings much earlier.** For example, the Department's procurement unit was under-resourced and had not been able to introduce management information systems to provide readily available data on what was being spent with a particular supplier.

2. **The Department claims general procurement savings of some £5 million per year but has also identified scope for a further £5 million which has yet to be realised.** These additional savings arise from the introduction of a new financial and business management system, the co-ordination of procurement activity under the auspices of a newly appointed Commercial Director and a strengthening of its Procurement Policy Advisory Unit. The Department will need to be able to demonstrate that it has achieved the financial savings from successful implementation of these initiatives.

3. **At around the same time the Department was letting a contract for the purchase of the smallpox vaccine, political donations were made by the successful bidder. We found no evidence that these donations had influenced the award of the contract.** As in this case, however, officials dealing with contracts need to see that proper procedures are followed and that there is a clear audit trail, so that decisions on the award of contracts can always be shown to follow from an objective evaluation of tenders.

4. **Increasing dependence on a small number of suppliers entails a growing risk of interruptions in the supply of vaccines.** To help mitigate this risk, the Department needs to encourage suppliers to stay in the market and make the necessary investment to assure long term vaccine supplies. Greater opportunity for suppliers to influence the development of the Department's immunisation policies, perhaps through the Joint Committee on Vaccination and Immunisation, might enable them to plan more strategically to meet the Department's medium and longer term vaccine requirements.

5. **Vaccines have been very effective in controlling or eliminating major diseases, but important risks remain to be managed.** Tuberculosis, for example, is again emerging as a threat, and the Department and the NHS will need to work closely with other agencies, including the Home Office, Prison Service, Immigration Services, and local authorities to tackle it. The Chief Medical Officer is shortly to publish an action plan setting out the efforts needed to keep this disease under control.

1 Improving the Department's procurement procedures

1. The NHS as a whole spends over £13 billion a year on goods and services, ranging from complex medical diagnostic equipment to examination gloves and stationery. Most is spent by NHS organisations, mainly NHS acute trusts. They deal directly with suppliers for most of their procurement, but around £4.8 billion of NHS procurement expenditure is made through, or with advice from, the NHS Purchasing and Supply Agency (the Agency), an executive agency of the Department. One of the Agency's core functions is to negotiate national framework contracts on behalf of the NHS, ensuring good practice, compliance with European Union regulations and economies of scale. The Department itself spends some £367 million a year on commercial contracts and deals with around 1,700 suppliers. The Department also uses the Agency to procure vaccines as part of its routine vaccination programme.[6]

2. Deficiencies in the Department's procurement procedures were pointed out in four separate Internal Audit reviews carried out between 1997 and 2000. Many of the same weaknesses were again highlighted in May 2001 by an independent external review commissioned from a consultant recommended by the Office for Government Commerce.[7] This review reached the following conclusions:

- Procurement practices within the Department were variable, depending on the importance and interest attached to them by local management.
- The Procurement Policy and Advisory Unit was under-resourced and the role afforded to it was at variance with other government departments. For example, the Unit did not have systems to provide readily available data on what was being spent with a particular supplier and the goods or services received, or develop e-commerce for procurement purposes as required across Whitehall.

3. The review recommended that the Department enhance the role of the Unit to cover the monitoring of procurement activity within business units; to promote collaboration where beneficial; to pursue the e-commerce agenda; and to maintain professional standards. An enhanced Unit taking these initiatives forward had the potential to achieve better value for money, estimated at savings of some £5–6 million of public money a year.[8]

4. In October 2002, the Department commissioned the Deputy Chief Executive of the Office of Government Commerce to lead a review of its commercial and procurement activities, which was completed in March 2003. The review's key recommendation was that the Department should appoint a Commercial Director to provide a strong focus for the procurement activity of the Department and the NHS, and this appointment was made in August 2003.[9]

6 C&AG's Report, paras 1.2–1.3

7 Qq 2, 62–65; C&AG's Report, para 2.12

8 Q 4; C&AG's Report, para 2.14

9 Qq 62, 66–67; Ev 15

5. The Department acknowledged that action in response to these reviews might have been taken more quickly, and that savings would have been realised sooner as a result. It had not been able to take action earlier because there had been some changes in the Department and under-resourcing of its Procurement Policy Advisory Unit. In the last year, however, the Department believed it had made a number of improvements which would enable it to achieve the savings of between £5 and £6 million a year predicted by the 2001 review.[10] These changes included:

- the strengthening of the Procurement Policy Advisory Unit and the appointment of the Commercial Director to link the relatively small amount of procurement done within the Department with the very large amount of procurement in the NHS;
- the introduction of Office of Government Commerce Gateway review procedures for all major projects which include procurement and procurement activity; and
- the implementation, from April 2004, of a new financial and business management system which will give the procurement group a supplier database and increased control over procurement activity.

6. The Department also reported to the Committee that it had identified additional savings of £4.8 million in 2000–01, £5.1 million in 2001–02, and £5.6 million in 2002–03 by the application of good procurement practice to the Department's commercial expenditure.[11]

On procurement arrangements

7. Procurement arrangements within the Department are highly devolved to business units within the Department. Procurement activity within each business unit is supported by Corporate Development Teams based in each Directorate, many of which have still been developing their procurement role. The Department's central Procurement Policy Advisory Unit disseminates procurement policy and best practice and provides direct support to business units on major procurement exercises. Following recommendations made in the internal and external reviews, the Department has expanded the Procurement Policy Advisory Unit from seven to ten staff. In August 2003, the Department also appointed a Commercial Director who is responsible for all the Department's commercial activity. These changes are also expected to develop better links between the relatively small amount of procurement activity in the Department and that done in the NHS as a whole.[12]

8. Since 1 April 2003, the Office of Government Commerce Gateway Project Review Process has applied to all high risk investment and procurement programmes and projects within the Department and the NHS. It is not mandatory for all procurements undertaken locally by individual hospitals. In assessing whether or not to use the Gateway process, bodies assess the level of risk associated with a potential project using a model which takes into account whole life cost, complexity, experience of the client and contracting

10 Qq 2–6, 49–52, 69–71; Ev 19

11 Ev 15

12 Qq 50–51, 71; C&AG's Report, paras 2.7–2.8

organisations and other significant risk factors. The assessment of risk is not solely based on the capital cost of a programme or project.[13]

On financial and business information systems

9. The Department has recognised that its own financial and business information systems are not satisfactory and do not provide all the information that is needed. A new information system, provided by Oracle at a forecast cost of £4.3 million, is due to be in place in April 2004.[14]

10. The Department is in the process of reforming the NHS specifically to devolve as much responsibility as possible to local health bodies. The Department recognises that there is always tension between achieving the benefits of local autonomy in purchasing decisions and exercising the considerable negotiating power of a buyer as large as the NHS. Achieving the right balance depends on establishing appropriate incentives for local bodies to be part of any national system. For example, in its current development of the NHS Programme for Information Technology, the Department does not intend to pay local bodies for participating in the national systems, but will incentivise them to use these by allowing them to keep savings made as a result of being part of the national network. The Department has also maintained pressure on overhead costs throughout the NHS, and will challenge organisations whose costs are rising faster than others.[15]

11. The NHS Purchasing and Supply Agency too has identified weaknesses in its contract management arrangements. These include a lack of information routinely available on its contract portfolio, multiple supplier databases maintained by buyers, from which the Agency was unable to analyse supplier information that might have improved its negotiating position, and an inadequate monitoring system. The Agency has been developing a single supplier database that will be accessible to buyers across the Agency.[16]

13 Qq 71, 112–117; Ev 20

14 Qq 43–51; C&AG's Report, para 2.16

15 Qq 53–56

16 Q 52; C&AG's Report, paras 2.17–2.18

2 The procurement of smallpox vaccine

12. Although smallpox was eradicated worldwide in the 1970s, the UK, like some other countries, continued to hold a contingency stockpile of the vaccine. Following the attack on the World Trade Centre on September 11 2001, the Department reviewed its ability to deal with terrorist attacks, including biological terrorism. With the advice of a sub-group of independent experts convened by the Joint Committee on Vaccination and Immunisation, the Department and the Ministry of Defence decided on 18 December 2001 to purchase up-to-date stocks of smallpox vaccine as a means of strengthening the country's defence against possible biological terrorist attacks.[17] For the purchase of a first tranche of smallpox vaccine, the Department used confidential procurement procedures, allowed under European Union rules on the grounds of national security. The procurement was not advertised and the Department held confidential discussions with five potential suppliers, selected from a list of twelve, with known production capabilities in the UK and Europe.[18]

13. A contract was awarded to PowderJect Pharmaceuticals PLC in April 2002.[19] The National Audit Office found no evidence of impropriety in the conduct of this procurement exercise, but the fact that the Chief Executive of PowderJect had made political donations coinciding with the evaluation and award of the contract prompted concerns over propriety amongst some suppliers, in Parliament and in the media. The Department did not have a system to identify donations made by companies participating in the bidding. Instead, the donations became public only late in the process as a consequence of Stock Exchange disclosure rules, once officials had completed their assessment and recommended the choice of PowderJect to Ministers. The Department told us that, had it known about the donations earlier, it might have involved Ministers less in the decision-making process and thought more carefully about the relationship with the supplier.[20]

14. Suppliers consulted by the National Audit Office raised further concerns that the Department's procurement process for that first tranche of smallpox vaccine had not been transparent. They claimed that the Department had not clearly specified that it was interested only in the 'Lister' strain of the vaccine, and had not revealed the procurement criteria and timelines to be applied. They also claimed that companies had been expecting a second stage to the procurement process, at which point bidders would have received full specifications against which to bid and that, although companies had been expected to consider licensing issues and clinical trials, they had not been informed of the Department's decision to accept an unlicensed product. The Department believed that these views were unjustified, and had not been shared by all the bidders. In discussions with the bidders, issues of procurement criteria, timescales, scope of the contract and strain of the vaccine had all been covered in detail, and the Department had followed a standard script to ensure that all the companies were provided with exactly the same information. However, the Department recognised that, as a result of the unusual nature of this

17 C&AG's Report, para 3.9 (case study C)

18 *ibid*, para 3.14 (case study E)

19 Qq 12, 18–19, 21, 126; C&AG's Report, para 3.24

20 Qq 22–23, 86–89, 120–126; C&AG's Report, para 3.25

procurement, there might have been a mismatch between the information provided and its interpretation by the companies concerned.[21]

15. The Department had wished to move quickly because of the need to prepare the country adequately against any terrorist threat. The Department had held early discussions with individual companies for supply of vaccine, but it had not been an open market and at that stage the Department had little knowledge of what vaccine was available and how quickly companies would have been able to prepare it. The Department recognised that, if companies had to start from scratch, it would have taken them from 18 to 24 months to develop vaccine. Nonetheless, the Department had made clear in discussions that they had wanted to buy supplies of vaccine as soon as possible.[22]

16. Expert advice sought from a specially formed sub-group of the Joint Committee on Vaccination and Immunisation had been that two alternative strains of vaccine—the Lister strain and New York City Board of Health (NYCBH) strain—showed no real difference in efficacy. However, the expert sub-group recommended that, since the authorities in the United States had stocks of the NYCBH vaccine, the United Kingdom should opt for a different strain so that both could fall back on the other vaccine should either prove to have problems.[23] When the Department had invited companies to tender, they had not specified the Lister strain to the exclusion of other options because they did not know what was available, and would have risked being unable to source any supply of vaccine. However, the Department had made clear in discussion with the companies that the Lister strain was the preferred option if this could be obtained. Of the five companies invited to bid, three had the capacity to produce the Lister strain using the new manufacturing process required and, of these, PowderJect had been able to supply vaccine the fastest.[24]

17. In October 2002 the Department advertised a follow-up procurement exercise in the Official Journal of the European Community. Having augmented emergency stocks of vaccine, timescales for the next stage had been less urgent. The Department also wished to be as transparent as possible, and this route allowed them to follow as closely as possible normal procurement rules without compromising national security. This contract was won by Aventis, on the grounds that in the Department's judgement it best matched the required standards for safety, efficacy, availability, price and the degree of experience of the company.[25]

18. All vaccines routinely used in this country are required to have a valid Marketing Authorisation, or licence, but there was no licensed smallpox vaccine available from any supplier at the time. Normally, before a vaccine can be licensed, the manufacturer carries out trials with people who might have the disease, but in the case of smallpox such trials were not possible because the disease has been eradicated. The vaccine was given to some healthcare workers who volunteered, but while this might test the immunity the vaccine

21 Qq 7, 10–11, 26–27, 38–40; C&AG's Report, paras 3.19–3.21

22 Qq 12, 57–58

23 Qq 13–15; C&AG's Report, para 3.9 (case study C)

24 Qq 9, 12, 28–29; C&AG's Report, para 3.17 (case study F)

25 Qq 16–17, 24, 32–33, 59–60; C&AG's Report, para 3.15

appeared to give and whether it was safe, it could not show how the vaccine would respond to the disease itself.[26]

19. The Department explained that, in the first-round procurement for smallpox vaccine, they had known there were no licensed products but had made clear that they were willing to accept an unlicensed vaccine in the short term. Because the vaccine was unlicensed, the Department provided PowderJect with an indemnity against liabilities arising from possible side effects. The Department estimated the potential liability to be £30 million, but no payments have needed to be made so far. In the second-round procurement the Department asked for a vaccine that was licensable, recognising that achieving a product licence would take time. Work to establish the conditions under which a smallpox vaccine might be licensed is ongoing between the United Kingdom licensing authority and European and American licensing authorities.[27]

26 Qq 33, 109–111; C&AG's Report, para 3.22

27 Qq 32, 61, 109

3 Avoiding or mitigating the impact of vaccine shortages

20. The Department relies on ten different suppliers for sixteen essential vaccines. The main reasons for the narrow market are the high and increasing cost of vaccine development and production, mergers between manufacturers and a relatively low profit margin compared with other pharmaceutical products. The vaccine industry is global, and it is hard to prevent companies from narrowing their product line or leaving the market. Limited competition, and near monopolistic conditions for supply of some vaccines, have made it more difficult to secure competitive prices and value for money. Furthermore, reliance on a single supplier has made the Department more vulnerable to interruptions in supply. Where possible, the Department aims to award contracts to more than one supplier, subject to their satisfying qualifying criteria for safety, efficacy, availability and price. Even so, in eleven cases the Department is still dependent on a single supplier **(Figure 1)**.[28]

Figure 1: The extent of the Department's reliance on a single supplier for vaccines

Vaccine	Aventis Pasteur MSD	Baxter	Berna Biotech	CAMR	Chiron Behring	Evans/ PowderJect	GlaxoSmithKline	Solvay	Statens Serum Institut	Wyeth
Influenza (contingency stock)	✓							✓		✓
Meningitis C		✓			✓					✓
Absorbed Diptheria and Tetanus vaccine for paediatrics (DT)	✓				✓					
Smallpox	✓					✓				
Measels/Mumps/Rubella (MMR)	✓						✓			
Absorbed low dose diphtheria vaccine for adults combined with Tetanus (Td)	✓									
Haemophilus influenzae type b, Diphtheria, Tetanus, wholecell Pertussis (Hib/DTwP)	✓									
Inactivated polio vaccine (IPV)	✓									
Low dose diphtheria for adults			✓							
Anthrax				✓						
Tuberculin PPD						✓				
Diphtheria Tetanus and acellular Pertussis (DTaP)							✓			
Haemophilus influenzae type b (Hib)							✓			
Oral Polio (OPV)							✓			
Rubella (German Measles)							✓			
BCG Intradermal (Tuberculosis)									✓	

Source: National Audit Office

28 Qq 92–93; 119; C&AG's Report, paras 3.28–3.29, Figure 10

21. In most cases the Department's suppliers have delivered vaccines as required, but there have been instances, for example with Measles, Mumps and Rubella (MMR), and Bacillus Calmette-Guerin (BCG) vaccines, when there have been supply shortages. The Department manages the vaccine supply by monitoring stock levels and comparing the rate at which vaccines are being drawn down, mostly by GPs, with forecasts from manufacturers, on at least a monthly basis, on their ability to satisfy contracts. If stocks appear likely to be threatened, the Department has a capacity to switch from a demand ordering system, under which GPs order vaccine, to a system under which GPs receive a weekly allocation of vaccine according to the size of the population for which they are responsible. This system guards against excessive ordering that might otherwise occur when there are shortages. However, vaccines are biological products that are difficult to make, and sometimes faults are only identified at the end of the manufacturing process. Recovery from failure of a production batch can take months, and because of the increasing centralisation of manufacturing could rapidly lead to an international vaccine shortage. So, while current UK stocks are fairly healthy, the Department is unable to guarantee that there would never be shortages.[29]

22. A key part of the Department's strategy to manage the risk of shortages is to establish alternative sources of supply. For one of the most important vaccines given to babies when they are 2, 3, and 4 months old (Haemophilus influenzae type b, Diptheria, Tetanus, and wholecell Pertussis), disruptions in supply during 1999 were overcome by finding an alternative supplier, and there was no disruption to the vaccination programme.[30] Similarly, shortages in supply of the MMR vaccine were met from the Department's existing stockholding until further supplies could be obtained from an alternative manufacturer.[31]

23. There has been one case, however, where in the last recourse the Department suspended part of the vaccination programme. The Bacillus Calmette-Guerin (BCG) vaccination is part of the Department's childhood vaccination programme against Tuberculosis (TB). It is also offered selectively to higher risk groups, such as babies born into ethnic groups at higher risk of tuberculosis, and new entrants from, and visitors to, parts of the world where the disease is prevalent. In September 1999, the Department suspended the routine schools-based vaccination programme because manufacturing problems had left insufficient supplies to maintain both this and the targeted vaccination of higher-risk groups. The immunisation programme finally recommenced in September 2001. Because the BCG vaccination, given to children between the ages of 10 and 14, is not as age-dependent as the infant vaccination programmes it was possible to recall children who had previously missed out. In this example, the manufacturer had experienced increasing difficulties in making vaccine that reached specifications, and had indicated that they would be unable to continue production without a substantial investment in the manufacturing plant, which would have led to a correspondingly large increase in the price of the vaccine. The Department was ultimately able to find an alternative supplier, although this still left them dependent on a single company.[32]

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29 Qq 34–37, 82–84, 91; C&AG's Report, para 3.30

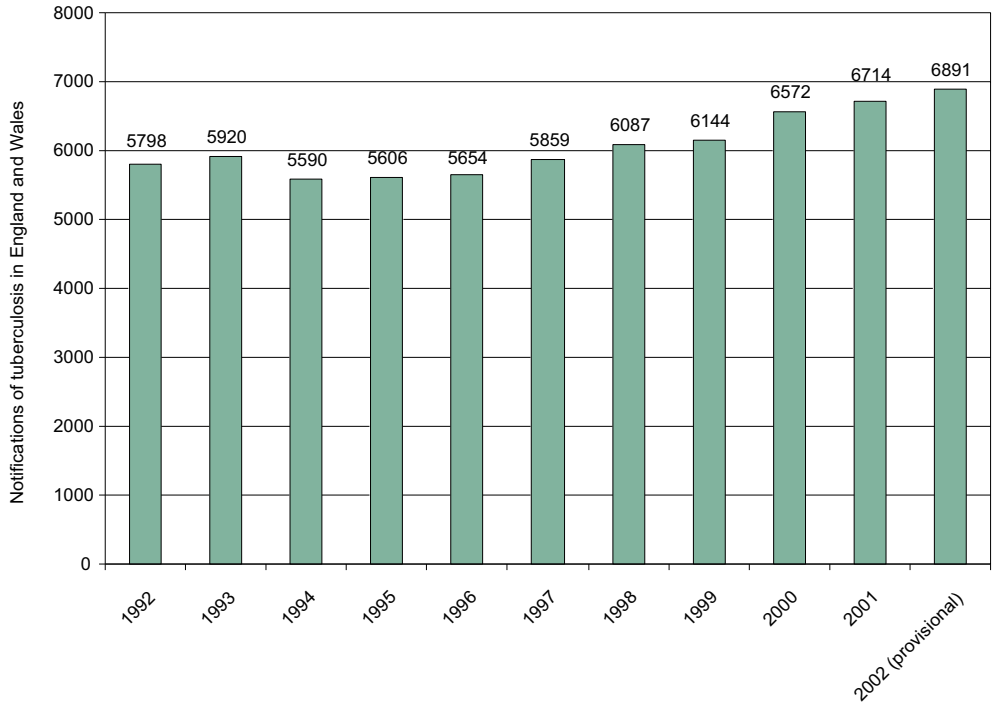
30 Qq 20, 82, 35; C&AG's Report, para 3.33 (case study J)

31 Q 118; C&AG's Report, para 3.31 (case study H)

32 Qq 35–36; C&AG's Report, para 3.32 (case study I)

24. Notwithstanding the BCG programme, the Department concedes that the recent increase in the incidence of tuberculosis is worrying. Until about five years ago there were about five and a half thousand cases a year, but this has risen to almost seven thousand cases a year **(Figure 2)**. The strains of tuberculosis now being seen have also come from different parts of the world than have previously been found, and there are different patterns in different parts of the country. The Department has been trying to work with colleagues internationally to map, using DNA profiles, incidences of different strains of the disease. Some indigenous tuberculosis has never gone away, but there have been a number of cases originating from sub Sarahan Africa and Asia, particularly the Indian subcontinent. However, the vaccine has always had a limited effect, and a small amount of drug-resistant tuberculosis has also started to appear.[33]

Figure 2: The incidence of tuberculosis in England and Wales since 1992



Source: Department of Health

25. Containment of the disease is particularly difficult because it is necessary to keep people on treatment for six months. This is hard to maintain when working with less stable populations, such as people going in and out of prison, or with the occasional individuals who decline treatment. The Home Office has been running a pilot scheme at Dover to monitor people entering the country for tuberculosis, but this is not straightforward, as people do not always show symptoms when they arrive. The Department is exploring a number of ways, however, to identify and treat people early, before it becomes an established disease. The Department recognises that a substantial effort is needed to keep the disease under control and the Chief Medical Officer is publishing an action plan to carry forward the work.[34]

33 Qq 94–102

34 Qq 105–108

Formal minutes

Monday 8 March 2004

Members present:

Mr Edward Leigh, in the Chair

Mr Richard Allan	Mr Gerry Steinberg
Jon Cruddas	Jon Trickett
Mr Ian Davidson	

The Committee deliberated.

Draft Report (Procurement of vaccines by the Department of Health), proposed by the Chairman, brought up and read.

Ordered, That the Chairman's draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 25 read and agreed to.

Conclusions and recommendations read and agreed to.

Summary read and agreed to.

Resolved, That the Report be the Fifteenth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the provisions of Standing Order No. 134 (Select Committees (Reports)) be applied to the Report.

Adjourned until Wednesday 10 March at 3.30 pm

Witnesses

Monday 20 October 2003

Page

List of written evidence

List of Reports from the Committee of Public Accounts Session 2003–04

First Report	Tackling fraud against the Inland Revenue	HC 62
Second Report	The new electricity trading arrangements in England and Wales	HC 63
Third Report	The Sheep Annual Premium Scheme	HC 64
Fourth Report	Improving service delivery: the Forensic Science Service	HC 137
Fifth Report	Warm Front: helping to combat fuel poverty	HC 206
Sixth Report	Department of Trade and Industry: Regional Grants in England	HC 207
Seventh Report	Progress on 15 major capital projects funded by Arts Council England	HC 253
Eighth Report	The English national stadium project at Wembley	HC 254
Ninth Report	Review of grants made to the National Coalition of Anti-Deportation Campaigns	HC 305
Tenth Report	Purchasing and managing software licences	HC 306
Eleventh Report	Helping consumers benefit from competition in telecommunications	HC 405
Twelfth Report	Getting it right, putting it right: Improving decision-making and appeals in social security benefits	HC 406
Thirteenth Report	Excess Votes 2002–03	HC 407
Fourteenth Report	Inland Revenue: Tax Credits	HC 89
Fifteenth Report	Procurement of vaccines by the Department of Health	HC 429

The reference number of the Treasury Minute to each Report will be printed in brackets after the HC printing number

Oral evidence

Taken before the Committee of Public Accounts

on Monday 20 October 2003

Members present:

Mr Edward Leigh, in the Chair

Mr Richard Bacon
Mr Ian Davidson
Mr Frank Field
Mr Brian Jenkins
Jim Sheridan
Mr Gerry Steinberg
Mr Alan Williams

Mr Tim Burr, Deputy Comptroller and Auditor General, **Mr Jeremy Colman**, Assistant Auditor General, and **Mr Steven Corbishley**, Director of Financial Audit: Health, further examined.

Mr Brian Glicksman, Treasury Officer of Accounts, HM Treasury, further examined.

REPORT BY THE COMPTROLLER AND AUDITOR GENERAL:

Procurement of Vaccines by the Department of Health (HC 625)

Witnesses: **Sir Nigel Crisp KCB**, Permanent Secretary/NHS Chief Executive, **Dr Pat Troop**, Chief Executive of the Health Protection Agency, and **Dr David Salisbury**, Principal Medical Officer, Department of Health, examined.

Q1 Chairman: Good afternoon and welcome to the Committee of Public Accounts where this afternoon we are discussing the Comptroller and Auditor General's Report on the Procurement of Vaccines by the Department of Health and, once again, we welcome back Sir Nigel Crisp, the Permanent Secretary of the Department and the NHS Chief Executive. Would you like to introduce your colleagues, please.
Sir Nigel Crisp: I am accompanied by Dr Pat Troop who was at the time and up until April the Deputy Chief Medical Officer; she is now Chief Executive of the Health Protection Agency but she was, in her former role, responsible for counter measures to deliberate release of biological matters. I am also accompanied by Dr David Salisbury who is head of the immunisation group of the Department.

Q2 Chairman: Sir Nigel, I have two or three questions to ask you first of all and could I ask you to look at the Comptroller and Auditor General's Report and look particularly at paragraph 2.12 where you will see that deficiencies in the procurement process have been pointed out in five separate reports since 1997. Why has it taken you so long to act on these issues?
Sir Nigel Crisp: I think there has been a series of reasons early on which were to do with things like some changes in the Department and some under-resourcing of the unit involved. What we have actually done in the last year—and indeed some of this is in a note that I sent to your clerk very recently[1]—has actually moved this on very considerably. So, I think we have finally perhaps in this last year addressed most of those issues.

[1] Ev 15-18

Q3 Chairman: That is a very honest answer. So, it has basically taken you three years where you could have got to it in one year if you had taken note of these internal audits.
Sir Nigel Crisp: In summary, yes.

Q4 Chairman: That is fair enough. It is nice when people apologise. Can we then turn to the following page, page 15, and looking at paragraph 2.14 where we see in the bottom part of that paragraph that the Department could have been saving up to £5 to £6 million on procurement every year and presumably you agree with that because you signed up this Report.
Sir Nigel Crisp: Yes.

Q5 Chairman: Why was such a golden opportunity to save public money missed out on?
Sir Nigel Crisp: In fact, we have actually saved that money in both of the last two years. As I have said, a number of changes happened in the last year and one of them is that we are actually beginning to see these results, so last year, 2002–03, we actually had a saving of £5.1 million based, may I say, on the NAO recommendations as to how you calculate that saving.

Q6 Chairman: Yes, but you will be the first to admit that you missed out on achieving the full potential. I think you have already admitted that.
Sir Nigel Crisp: In the early years but not the last two.

Q7 Chairman: You are aware of course of the criticisms levelled at you by people who failed to get the contract for the vaccines. How many of these criticisms could have been met if there had been much more clear and consistent advice and help given to potential suppliers? Is this a fair question?

Sir Nigel Crisp: I think there are two parts to that. Firstly, I do not think that the criticisms are fair if you are talking about the specific criticisms about the purchase of the smallpox vaccine. I can very happily go through our comments on the criticisms that have been made. Secondly, I do not think that any of these changes would have made a difference to that particular procurement which was a one-off procurement done in that particular way. I think these recommendations about money and so on are actually about how we handle the much bigger volume of procurement across the Department.

Q8 Chairman: Can I look at this in some more detail, please. If you turn to page 24 and look at paragraph 3.19, you will see there that these criticisms are listed as bullet points. "The Department did not clearly state that it was interested in the Lister strain only . . ." etc, etc. So, these are not valid criticisms, are they?
Sir Nigel Crisp: Could I actually ask one of my colleagues to address that?

Q9 Chairman: Perhaps Dr Troop might answer these points.
Dr Troop: Certainly. If we take the first one, we did use in the documentation the word "preferred". Perhaps I should explain that, first of all, before we sent the documentation, colleagues from the Department did hold face-to-face meetings with individual companies and take them through the issues. We made it very clear in those meetings that we wanted to have the Lister vaccine. However, we also recognised that, at that time, we did not actually know what was out there and therefore, if we had put a complete cut-off against anything else, we might have found ourselves with no vaccine, but we made it very clear to the companies that we wanted to buy the Lister vaccine should it be available as well as the discussions that would follow up questions coming back from the companies and that was made clear to them in those follow-up discussions.

Q10 Chairman: What worries me is that, if you go down to paragraph 3.20, you will see that these companies felt, "(following confidential meetings with the Department of Health)" that they were given "limited information on procurement criteria, timescales, scope of the contract and the strain of vaccine." It seems to me that you had a pretty poor relationship with the companies and this has led to a lot of these criticisms.
Dr Troop: In the discussions that were held with them, all those issues were taken through in great detail. There was a standard set of points raised on an equal basis with every company which covered all those issues. In terms of the timescale, again, we were in a situation—

Q11 Chairman: So, what the companies are saying here is wrong, is it?
Dr Troop: I think it is not a fair representation of the discussions that we had with the companies. In terms of the timescale—

Q12 Chairman: You see, what I have suggested to you is that you have not acted improperly but that, if you had worked more closely with your suppliers, you might have got more out of them because clearly they feel aggrieved, do they not?
Dr Troop: We did work very closely with them. We were in a situation when we started this process of, first of all, as you know, we were trying to move very quickly because it was just after September 11 and we were trying to put our countermeasures programme together because we felt that the country was inadequately prepared and we wanted to move very fast. We had very early discussions with individual companies but, before those discussions, we really did not know what was available. Normally when you go out to this kind of tendering, you usually have some indication of what is on the market. We did not know what was on the market and we did not know how quickly they could prepare it. In the discussions, what we said was that if they were to start from scratch, we recognised that it would take them 18 to 24 months and that was why we suggested that timescale and that was because, at that stage, we did not know whether there was any that was available, if you like, off the shelf because it was not an open market. The discussions that were held with each company went through a standard set of questions and a standard set of points which made it very clear that we wanted to buy the vaccine as soon as possible; we recognised that, if they had to start from scratch, that may take them 18 to 24 months; we made it very clear that our strong preference was Lister if we could obtain it, and that information was verified in follow-up conversations that happened afterwards.

Q13 Chairman: Can we now look at the difference between Lister and the New York strain and this is dealt with in Case Study C which you will find on page 19. We know that you chose Lister but we know that both these strains are equally effective. So, what I really want to know is whether your justification for your choice of Lister was sufficiently robust.
Dr Troop: The previous vaccines that we used were equally effective but they were vaccines made in a different way. We took advice from an independent expert group—the Joint Committee of Vaccination and Immunisation co-opted the country's experts on smallpox—and their advice was that the previous vaccines had shown equal effectiveness. However, the vaccines we were about to purchase were based on a different manufacturing process and therefore we did not have any pre-knowledge of which of the vaccines might be effective or which ones might have problems. Therefore, they recommended that, as the Americans were going for the New York strain, we should go for an alternative strain should either of the vaccines demonstrate any problems. That way, both of us would be able to fall back on the other vaccine. That was the clear advice which they sent in their minutes to us.

Q14 Chairman: So, it was not just that because the Americans were going for the New York strain, they might have used up all the supplies?
Dr Troop: No, it was not that at all.

Q15 Chairman: It was because you thought that there might be a problem with it.
Dr Troop: Because the new vaccines were manufactured in a way in which we had never done it before, we could not guarantee that either of them would be as effective as we wished them to be even though they were using those strains. Therefore, the advice from the Committee was that we should make sure that we had an alternative should that be necessary and that was their clear advice which they minuted and sent to us.

Q16 Chairman: Can I look at the tendering process itself and refer you to page 24 and paragraph 3.15. We know that the second tendering process was obviously handled differently from the first and that there have been fewer complaints, but the terrorist threat remains, so why was the process handled differently? If the terrorist threat was the same, why was the process handled differently?
Sir Nigel Crisp: I think the position was that the circumstances were different in that the first procurement, as Dr Troop has said, was in the immediate aftermath of September 11 and we wanted to make sure that we created a sufficient supply early on, always with a view, as I think we said publicly at that time, to have a second procurement later on for the further vaccine and, by the time we came to that second vaccine, then the same positions of urgency did not apply or urgency and secrecy did not apply. So, in discussion with ministers, we took the view to do it through the normal route.

Q17 Chairman: But the terrorist threat is still out there, is it not? So, as you are now proceeding in a different way, are you at risk of compromising national security?
Sir Nigel Crisp: No, we do not believe we are because, in the first instance—

Q18 Chairman: If that is the case, why did you not act in this way the first time round? Could not some people suggest that in fact, after September 11, you panicked, you moved too quickly, you battened down the hatches and you did not do a sufficiently robust tendering process? I have to put that to you.
Sir Nigel Crisp: People may make all kinds of suggestions and I am delighted that the National Audit Office, in looking at all the information, has come up with the view that we behaved perfectly properly—

Q19 Chairman: I am not suggesting that you behaved improperly.
Sir Nigel Crisp: I am just calling a witness in aid which is the National Audit Office that, having gone through all the papers and looked at all the details, they have come to the view that we behaved perfectly appropriately, which is that it was appropriate to have a quick response.

Q20 Chairman: Finally, do you think there are lessons to be learnt from this whole process and that perhaps there is a case to be made for having a closer partnership with the industry in order that we avoid some of these complaints in the future?
Sir Nigel Crisp: I am quite sure that, in any circumstance, you will get some disgruntled suppliers. I do not think it was all the non-winning suppliers who made the complaints. I understand it was mainly one organisation. Secondly, it is part of our process to try and be as close to organisations as possible and to understand what is happening and indeed that is part of the strategy which Dr Salisbury and others adopt to try and make sure that we always have alternative sources of supply of vaccines for the future. However, I take the point that we can always do more on that.

Q21 Mr Field: Sir Nigel, can I turn to the PowderJect settlement. The chairman of PowderJect gave the Government £100,000 and they won a major contract from you. There is a fair amount of uproar as a result of that and they do not win the next contract from you. To the outsider, it looks as though the Department caved in on the first one, became scared the second time round and therefore decided to punish PowderJect. It is good that the National Audit Office found in your procurement that there were no links between the monies to the Government and your decision, but if we continue to have a system whereby political parties are financed to a very large extent by large industrial donations, it is clearly important that the system is as open and as clear as possible. I wonder if you could tell us something about how you in the Department protect yourself and the public realm against the accusation that people can buy political influence.
Sir Nigel Crisp: The generality of it is that we try to be as clear as possible both within the Department and externally in what our processes are. So that, for example, on something like procurement, Dr Salisbury and others will try to be in contact with the whole field of suppliers as much as possible though, as the Chairman said, we can probably pursue that even further. So, there is the part about complete openness. There is also the ability to audit our decisions and, on both of these two decisions where the process itself may have been different for reasons that we have just talked about, there is a clear audit trail and a clear mechanism through the National Audit Office to be able to come in and review it and see if there were any links, and I will bring in Dr Salisbury in here in a moment, if I may. I think that openness, ability to have audit, making sure that you are minuting decisions and that you have a proper record are all the sort of things that we would have within the Department and I am pleased in this particular case that, at the point that somebody spotted the donation, we immediately went in to assist them to try and reassure ourselves that we were doing the right thing.

Q22 Mr Field: Before Dr Salisbury comes in, could I just keep you on that. You said that somebody "spotted the donation". Thanks to recent reforms, we now have the list—it is published as to who supports which political parties and to what extent. Do you have a system whereby that information is used in your Department, so that you know you would have to be particularly careful in certain circumstances because this person has managed to donate £100,000 to the Government?
Sir Nigel Crisp: The straightforward answer is that I do not think we have a complete system and I think that perhaps we should have one and, sir, I will come back to you on that. I will check whether we have a complete system which actually makes sure that, for all procurement, we understand that.[2]

Q23 Mr Field: The point I was also getting at was that, if I were a member of your staff helping to make these key decisions and there were players out there, some of whom had given the Government a large donation, I would want my position in the Department to be strengthened in that it would be common knowledge in the Department that at least one of the players had made a major political contribution and I just wondered whether you used the register which is published by both the major political parties of their donations, I think to feed it in at the beginning of this process.
Sir Nigel Crisp: I think that we do not. I will have to check and, if we do not, I can see the sense in doing so.

Q24 Mr Field: I am sorry, I interrupted Dr Salisbury who wanted to say something.
Dr Salisbury: I was just going to pick up the point about the awarding of the first contract to one company and awarding the second to another. On all of our adjudications, we follow very strict criteria of safety, efficacy, availability, price and experience of those companies against previous contracts and we always work through these criteria for all of our contracts. For the first contract, the company that matched those criteria the closest was awarded the contract. When it came to the second, it was not the same, it was quite different in terms of the products that were being offered and, when it came to the second contract, the company that was successful the first time did not match those criteria as closely as the one to whom it was awarded. So, we do have independent criteria against which we award contracts and, on this occasion, the second was quite different to the first.

Q25 Mr Field: Could I ask the National Audit Office for their comments on what changes they would propose to ensure that staff were properly and fully protected against what both the public or an individual minister might wish in influencing a decision.

Mr Corbishley: I think that the use by the Department of the Electoral Commission's Register of such donations as part of their procurement process could be an effective means of being informed as to who are the key players in terms of any particular procurement decision. It could help provide an early warning sign of any potential problems. These problems can then be headed off during the next part of the procurement process. That would be a very good idea to consider taking forward.
Mr Field: That is what Sir Nigel has promised he is at least going to look at.

Q26 Mr Steinberg: Clearly, the questions that have been asked up to now are the main thrust of the Report and I basically want to continue along the same line that the questions have been asked because I get the impression, frankly, that if the Labour Party had not received the £100,000 in a donation and then PowderJect had not got the contract, we would not be doing this report this afternoon. That is no criticism of the National Audit Office, I can assure you. I have no trouble with that at all, absolutely none whatsoever. If suspicions are aroused, then it is only right that they should be looked at. It is exactly the same as pre-1997 when the last government was in power and ex-ministers became directors of privatised firms and ministers became directors of firms that were getting huge contracts and the privatised industry was giving donations to the Tory Party. There were suspicions then. Now, as long as it is open and transparent and it is seen that nothing is wrong, I have no trouble with that at all. However, there are things that worry me and things that have to be explained to ensure that people are satisfied that there was nothing funny going on at the time. The Chairman covered in particular on page 24 the four main points which immediately put doubts in our mind that there were certainly worries about the procedures and you have explained that. I am not allowed to put words into your mouth but would you say that this Report came clearly after everything was revealed and after the contract had been awarded and would you say that the other companies were just peeved at not getting the contract and were looking for ways to criticise the Government and criticise the way things were done or do you see them as genuine criticisms?
Sir Nigel Crisp: Can I just respond to your first point by saying that I too welcome this Report because I do not want doubts cast on the professionalism of the staff on the left and right of me and I think this Report shows that we have a thoroughly professional approach to buying vaccines which brings in all the experts in the country and indeed I know that colleagues provide advice to other governments externally. So, I think it is a thoroughly professional operation, as I say, to the left and right of me. In terms of the particular criticisms which I think it is fair to say came mainly from one company, to some extent, it is what you get after a tender is let. It does not necessarily surprise me to hear that some people who did not win a contract are complaining afterwards. It happens.

[2] Ev 21

Q27 Mr Steinberg: Can you assure us, for example, that PowderJect did not get any extra information than the other companies had? In other words, that PowderJect had exactly the same information and exactly the same treatment as the other companies had and there was no sort of private, confidential talks with PowderJect and there was no other information given to them? Can you tell this Committee that, as far as you are aware and as far as you are concerned, every company that was interested had exactly the same information and were treated in exactly the same way?
Sir Nigel Crisp: Can I assure you that my colleagues work to a script in terms of meeting people and that absolutely, to the best of my knowledge and that of my colleagues here, there were no other meetings outside those. It is a standard script.

Q28 Mr Steinberg: Was the Lister strain for the vaccine that we were talking about only provided by PowderJect or was it possible to be produced by the other companies? Did they have a monopoly at the time?
Dr Troop: They were the only ones who could provide it in the short term. The others indicated that they might be able to produce it but they did not and, picking up the point of trying to make sure that we had this protection early, to be able to obtain vaccine that met the new manufacturing standards as early as possible seemed to us very important if we were going to protect the country.

Q29 Mr Steinberg: So, what you are saying is that other countries could have produced exactly the same vaccine as PowderJect. PowderJect did have a monopoly on this and basically they were the only company that could provide the Lister strain.
Dr Troop: In the timescale. There was an issue about timing here. We made it very clear to all the companies that we wanted to obtain the vaccine as soon as possible and PowderJect were able to come forward with a supply of vaccine in the very short term which would enable us to enhance our stocks very quickly and we felt that was important to protect the population.

Q30 Mr Steinberg: Frank also made the point, which I agree with and which came to my mind, as it did to him when he was reading the Report, that, once there had been this uproar about PowderJect and the awarding of the contract, the natural reaction then is to say, "We will make damn sure that they do not get another contract because we are not going to go through that again." So, it could work out to be unfair to PowderJect in the next tendering procedures because they are being denied the opportunity on the basis that perhaps it was not done right in the first place. Are we given a guarantee that that did not happen?
Dr Troop: I should add that we do buy other vaccines from a number of these companies including PowderJect. They have been awarded other contracts.

Q31 Mr Steinberg: We are aware of that.
Dr Troop: So, it depends on the particular criteria. If that were the case, we would not have been awarding the subsequent contracts which we have done. So, as Dr Salisbury said, it made no difference in this particular one and certainly they have been able to enjoy contracts since then.

Q32 Mr Steinberg: What struck me was that, in the Report, it keeps saying—and let me get this right—that the fact that they could not guarantee delivery did not mean that they were not going to get the contract in the first instance. Yet, you said to Frank and in the Report that the reason why PowderJect did not get the contract in the second place was because they could not guarantee delivery. So, that is a little contradictory from the first contract.
Dr Troop: In the first contract, they were able to provide for us vaccine from Bavarian Nordic which met the modern manufacturing processes. For the second round, we were asking for a vaccine that would be licensable and—

Q33 Mr Steinberg: Can I just butt in there because I am sure that I am going to run out of time very quickly. In the new contract—and that is Aventis—they have not licensed the product yet and there is no guarantee that they will get the licence. So, you have awarded a contract to a company that say they can deliver but with an unlicensed product and ignored a company that has a licensed product that might not be able to deliver.
Dr Troop: No. The one from PowderJect is not licensed. There are no licensed products out there at the moment from anyone.

Q34 Mr Steinberg: I think you have now explained that very well. In the last few minutes that I have, I want to change the subject slightly and I would like you to turn to page 30 and Case Study 1. This is quite worrying, is it not? If you take the background to the situation, we have seen an increase of 21% in the cases of TB and, in 2001, there were approximately 7,000 new cases diagnosed, but you are having great difficulty getting the vaccine. Then, in the next study on the following page, which worries me to death as well, it says that with one of the most important vaccines given to babies at two, three and four months, there were manufacturing problems and disruptions in availability. I have just had a baby grandson and he has just been vaccinated, but I would be horrified if I were to take him to the doctors and was told that there was no vaccine. It is a little like a third-world country, is it not? Are we going to start getting donations from Bangladesh and Ethiopia to ensure that our kids are being immunised? Why is there a shortage and what, in the name of Heaven, are you going to do about it?
Sir Nigel Crisp: I will ask Dr Salisbury to address the wider point of how we maintain supply of vaccines with these two as examples.
Dr Salisbury: First, we do have strategies to do our utmost to maintain continuity of supplies of vaccines. Vaccines are difficult to manufacture; they are biological products and sometimes it is only at

the very end of the whole of the manufacturing process that you find that there is a fault with the product and then they have to start all over again. They are not straightforward things to manufacture and this is true of any part of the world with any suppliers.

Q35 Mr Steinberg: But you have been doing this for donkey's years, have you not?
Dr Salisbury: Sometimes that is true and other vaccines change, but that does not stop the problem. They are biological products and sometimes there are manufacturing problems that are unexpected. Where the DTP vaccine is concerned, that is the one that is given at two, three and four months, what I think perhaps you have not appreciated from this is that actually there were no interruptions in supply because we found an alternative supplier and made sure that we did have continuity of supply. We do our utmost to make sure that we have more than one supplier wherever possible, so that if one manufacturer has difficulties, we can turn to another to make good. Sometimes, that is not possible where there is only a single licensed supplier. That was the case for BCG. There was only one supplier and they had increasing difficulty in making vaccine that matched the specifications. I think it is fairly convoluted to work out but it is in fact the same company we are talking about for the smallpox vaccine, as it happens. In the event, they made it clear that if they were to be able to continue to manufacture vaccine, BCG, that matched the good manufacturing practice requirements, they would require a huge investment in their Merseyside manufacturing plant and they clearly saw that the consequence of that would be an enormous increase in the price. We then immediately took steps to try to find alternative suppliers. Alternative suppliers have to have a product which is either licensed or licensable before we can go forward in buying it and we approached one other European company that said that, although they had the product, they were not interested in bringing it to the UK market. There are reasons for that, probably to do with the very old data that they had that would not suffice for a current licence. We therefore scoured all of the markets to look for alternatives and we found that the State Serum Institute in Denmark was able to produce vaccine and we were therefore able to go ahead and get supplies. With the BCG programme, I can assure you that nothing upsets me more than having no vaccine.

Q36 Mr Steinberg: It upsets parents, I suspect.
Dr Salisbury: I feel very responsible if there are shortages, but the BCG vaccine programme is not quite so age dependent as the infant programme with DTP. Of course it is a problem if we have to suspend part of the programme and, as I say, it is something that we would do our utmost to avoid, and we found an alternative supplier, came back in with extra quantities of vaccine and used our computerised databases in order that we could identify the children who had missed out the year before and they were called back and then we were able to catch up the programme. It is difficult sometimes when there are shortages.

Q37 Mr Steinberg: That was a very long and comprehensive reply for which I am very grateful but, in a very, very short answer, can you therefore reassure me, my colleagues and parents in this country that they have nothing to fear?
Dr Salisbury: Vaccine is a biological product. We cannot guarantee that they will always be available. For the last two years, the United States has had severe vaccine shortages that we have not faced. We do our utmost to ensure continuity, we have strategies to deal with shortcomings such as stockpiling of vaccines, but we cannot guarantee that there will never be a problem.
Mr Steinberg: That is not all that reassuring.

Q38 Chairman: Sir Nigel, in answer to Mr Steinberg, Mr Field and myself, you said that one company did all the complaining. What was that company?
Sir Nigel Crisp: I cannot remember its name, actually.

Q39 Mr Field: It did not make much impression then! It is really bad news for it, is it not?
Sir Nigel Crisp: It was a company called Acambis.

Q40 Chairman: Have they had any business from you since?
Dr Salisbury: They have no routine vaccines; they have never produced nor provided the UK market with vaccines; this was their first attempt to come to the UK market.

Q41 Mr Bacon: Sir Nigel, I gather that you received my fax.
Sir Nigel Crisp: I have it here and I will catch you later.
Mr Bacon: I will not dwell on it but do you agree that, in a situation where apparently there is a chronic shortage of nurses where 50,000 are going to retire, where even to maintain numbers let alone increase them and where you are reliant on agency nurses, not employing somebody with two years' training and eight years' experience is a little odd and will you look into it?
Chairman: Is this related to vaccines, Mr Bacon?
Mr Bacon: Absolutely.

Q42 Chairman: Then if you would like to answer that question in relation to vaccines.
Sir Nigel Crisp: I am happy to have a discussion outside the Committee.

Q43 Mr Bacon: If you would turn to page 15, in paragraph 2.16, it says that you are getting a new financial and business information system which is due to be established next year in April 2004.
Sir Nigel Crisp: Yes.

Q44 Mr Bacon: Could you tell me how much that system has cost?

Sir Nigel Crisp: No, but I can let you know.[3]

Q45 Mr Bacon: Do you know who the computer contractor is for it?
Sir Nigel Crisp: On this particular one, no, I do not.

Q46 Mr Bacon: It is not Fujitsu, is it?
Sir Nigel Crisp: I do not think so, no.

Q47 Mr Bacon: That is a relief!
Sir Nigel Crisp: I can certainly let you know. I understand that it is Oracle. I do not know the number yet but I may know the number.

Q48 Mr Bacon: It is a relief that it is not Fujitsu because you have a chance of it going right! It is presumably the case that, until it is up and running, the integrated business information and financial information that is going to be provided is not available and that is the implication of that paragraph.
Sir Nigel Crisp: Yes.

Q49 Mr Bacon: In the absence of that, how do you know whether your current procedures are robust and whether they are providing value for money?
Sir Nigel Crisp: We would not be buying the system if we thought our current arrangements were satisfactory. They are not satisfactory. That means that we do not have all the information that we would want. I think there are probably two answers to that. One is that that means that individuals have to make more of the connections, so that people in our procurement group have to do all the working in working with other people and seeing what is happening around the Department rather than having a database that they can use.

Q50 Mr Bacon: Is your procurement group within the Department?
Sir Nigel Crisp: Yes.

Q51 Mr Bacon: It is not a loose network of procurers across the NHS?
Sir Nigel Crisp: No. I can come back to that if you wish, but we actually have a small group that is actually focused on the spend that we spend in the Department. I think the first point is that they have to do more than they would do if they had a better system to support them within that. The other check which is extremely encouraging and is a point I made in reply to the Chairman earlier is that, in the last two years, we have actually made savings against procurement of the order that the Report said we should have done and, in measuring those savings, we have used the NAO methodology for it. So, we are clearly making progress.

Q52 Mr Bacon: In the next paragraph at paragraph 2.17, it says that the Agency has identified weaknesses in its contact management arrangements including a lack of and it goes on to talk about routine contract information and "One supplier database. Buyers maintain their own supplier databases . . ." When you have this new business information system up and running, will that change or will they continue to be buyers running their own supplier databases?
Sir Nigel Crisp: No, I understand that we will actually have one-supplier database. I understand that we will then be able to see the database right across the Agency.

Q53 Mr Bacon: The cry at the moment is to give more autonomy to local centres within the Health Service and yet it runs exactly counter to improving your negotiating position with major suppliers. The tension is inherent; it is always going to be there. How do you specifically go about addressing that tension in order that you get the local . . . I know that this is a very broad question—how do you manage something as large as the Health Service?—but how do you, specially in relation to procurement, go about getting the benefits of local autonomy and the negotiating power of a large buyer?
Sir Nigel Crisp: You are absolutely right, that is the constant tension that you are fighting with, as it were, and one of the ways that we do it here, as indeed with introducing an IT system across the whole of the NHS because it is the same issue, is about getting the incentives in the right place, so that if people are actually seeing benefits from the procurement activity, then they are more likely to be willing to not just work with a central buying system but they will actually be enthusiastic about it if they are actually seeing the savings coming through into their own organisation that they can use for other things.

Q54 Mr Bacon: Are they actually paid in that way or are you just saying that they get greater resources that they can use for other things?
Sir Nigel Crisp: That if they can save 10% on their purchasing from their own budget as a result of being part of the national network, then that is a good thing to do.

Q55 Mr Bacon: But they are not remunerated according to participating in the central . . .?
Sir Nigel Crisp: No, but we do have—

Q56 Mr Bacon: Have you thought of doing that?
Sir Nigel Crisp: I think that we actually do it in two slightly different ways. One is that actually the savings made in this will stay with the unit which is a very big incentive, providing they believe they can get the savings in that way, but I think the second thing is that we do keep the pressure on overhead costs throughout the NHS. So, if people are actually showing that their expenditure is rising on their non-paid costs faster than others in the NHS, then they will get asked questions about it. So, that is the stick rather than the carrot, but we do not actually pay people to be part of the purchasing arrangements.

[3] Ev 19

Q57 Mr Bacon: Can I ask you to turn to the second column on page 24 in paragraph 3.19, it mentions at the second bullet point, "The Department did not reveal the procurement criteria or timelines. There was no indication that the supplies were required in 2002." What was the reason for that?
Sir Nigel Crisp: This is the point that Dr Troop was making earlier.

Q58 Mr Bacon: About national security?
Sir Nigel Crisp: That we did not know exactly what people had, so we went out initially with a fairly open-ended group of questions about what they could supply.
Dr Troop: We said that we wanted "as soon as possible" if it is available but we acknowledged that, if they had to start from scratch, this was how long it would take them and that is where the 18 to 24 months came in.

Q59 Mr Bacon: Dr Troop, in the third bullet point, it says, "Companies were expecting a second stage . . ."
Dr Troop: And this has happened.

Q60 Mr Bacon: It has happened?
Dr Troop: Yes. We had always said that there would be the second stage of purchasing. We were looking for short term and then a longer term programme and that has now happened and that is what second procurement is.

Q61 Mr Bacon: With regard to the fourth bullet point, were there documents that led them to believe that they would be considering licensing issues and not that the Department would consider accepting an unlicensed product?
Dr Troop: We knew that there were no licensed products there and therefore it was made very clear that we would be willing to accept a vaccine in the short term. For our second round of procurement, we said that we want to try and move towards a licensable vaccine. We recognised that it would take time to get the licensable vaccine, we have always recognised that, but we did not want to wait that long before we could get any vaccine. So, if it were possible to get a vaccine in the short term even though it was not licensed for emergency use, we said that is what we would want to do.

Q62 Mr Bacon: Sir Nigel, I think you have now done three reviews: one internal, one external and now a third that is ongoing.
Sir Nigel Crisp: Yes. They were slightly more connected than that.

Q63 Mr Bacon: Do you mean that they are not separate reviews?
Sir Nigel Crisp: The internal audit which was on a wider set of issues raised some questions here, so we asked somebody to come in from OGC to look at it.

Q64 Mr Bacon: The external one was OGC?
Sir Nigel Crisp: Yes.

Q65 Mr Bacon: So, you did not pay an external consultant?
Sir Nigel Crisp: No.

Q66 Mr Bacon: No consultants like PriceWaterhouse receiving fat fees?
Sir Nigel Crisp: No. The third one was again OGC on implementation. Having made some recommendations, we then asked them, "How can we implement it?"

Q67 Mr Bacon: I think that is terrific. You are phoning up the OGC and asking them for advice. I hope you followed their advice.
Sir Nigel Crisp: It was good advice.
Mr Bacon: That is actually quite encouraging. Finally, if I could have a conversation with you afterwards about nursing, I would be grateful.

Q68 Mr Jenkins: This should not take long insofar as the Report is concerned; it is a good Report in almost all respects, but there is one thing about the Report that did worry me when I was reading it and I am sure you can clarify it for me. When the Chairman began, he asked you a question regarding paragraph 2.12 with regard to deficiencies and your answer—and I am paraphrasing—was, "We would address the problem. All the problems are now addressed. We have extra resources in the Department. Everything is fine." When I look at paragraph 3.20, a report from Dr Troop, the companies are saying that is not strictly accurate. In paragraph 3.21, it goes on to explain why it was not strictly accurate and therefore completes that element of the report. In paragraph 2.12, the answer was, "We would address the problems", but there is nothing in the report to show why you have addressed the problems. Later on, we had a letter from you which highlights the tremendous improvements in what you have done but it is not clear to me how or why these improvements were brought in. Were they brought in due to the audits you ran internally, were they brought in due to the NAO's review, were they brought in due to the external review 2001 or were they brought in due to the external review 2002? Exactly what was the process that led you to bring in these improvements? Why do you sign a document off without having the improvements listed? Were the improvements in place when this inquiry was taking place?
Sir Nigel Crisp: Some but not all.

Q69 Mr Jenkins: Why were they not put in the Report?
Sir Nigel Crisp: This Report was work done in September to December last year and we would have last seen it in about February and it was signed off or I should say published on 3 April. Most of what I am talking about has happened in the last year. Shall I just tell you what they are? Would that be helpful? Then you will see why they are slightly more time efficient.

Q70 Mr Jenkins: I think you should have the opportunity to flesh out exactly what improvements and what developments you had made because I do not want to come back in three years' time and find that some of the things you said have been improved are now still awaiting implementation.
Sir Nigel Crisp: Shall I do that?

Q71 Mr Jenkins: Yes.
Sir Nigel Crisp: Four quick points then. The first one is that the earlier review on the internal audit and the following one said that we should strengthen the purchasing unit. We did that but we have now gone further and appointed a commercial director who is responsible for all our commercial activity and what has gone beyond this review is the Department of Health and NHS. So, we are linking in the relatively small amount of procurement done in the Department of Health with the very large amount of procurement done in the NHS and making sure that we have that all linked in properly. The second one refers back to OGC and we have now put in place gateway procedures—and I suspect you will have the OGC in front of you though I am not sure—for all major projects which include procurement. We now have that in place. They are not just about procurement but they apply to procurement activity as well. The third one is this new system which will be coming in which we touched on. The fourth one is that we have started to make the savings. So, I think there is quite a broad-based set of changes under way and I am happy to read them into the minutes for you to review in three years' time.

Q72 Mr Jenkins: That is excellent. You sent us a letter on general procurement arrangements and you say in that half-way down that savings are to be identified and the first saving you give is £4.8 million in 2000–01.
Sir Nigel Crisp: Yes.

Q73 Mr Jenkins: Once again, in the body of the Report, although I have paragraph 2.13, recommendations from the external review where it says that savings up to £5 million to £6 million a year can be made, there is nothing in the Report to tell me—and this Report was done after the 2000–01 figures were available . . . Why is it not in the Report that you saved £4.8 million in 2000–01?
Sir Nigel Crisp: I am afraid that I do not know.

Q74 Mr Jenkins: Well, I do not know and in fact I am worried about the consistency and the accuracy of this Report.
Sir Nigel Crisp: I do not know why those particular figures were not in there.

Q75 Mr Jenkins: They are obviously not available. You did not make them available. You signed off this Report. You read this Report. Why did you not put it in the Report yourself?
Sir Nigel Crisp: I did not write the Report and those figures will have been available. Those figures, as it says, are achieved under the NAO approved methodology. I do not know why we did not include them in the Report. I would rather have seen them in the Report.

Q76 Mr Jenkins: I will ask the NAO, why were these figures not included in the Report? What sort of investigation was done?
Mr Corbishley: We would have liked to have seen those in the Report and to have had the opportunity to bring them into the Report at the time of the clearance process, but the Department did not make the data available to us.

Q77 Mr Jenkins: You cannot sit there and say, "It's not me, Gov" because someone is responsible for this Report and it is not accurate.
Sir Nigel Crisp: It is accurate in the sense that the NAO have reported on a review, the external review undertaken by the Department, and reported the review's findings, which was that there would be a potential for those savings and reported accurately what the review did set out.

Q78 Mr Jenkins: I am sorry, but there is not a potential for savings if the savings have already been made and they were made in 2000–01 of £4.8 million. Are you saying that there is another £5.5 million to be made or does that include the £4.8 million?
Sir Nigel Crisp: These are savings each year within this. My earlier comments were that some improvements have been made as this Report has said but it has taken time for them to come through. Some improvements were being made earlier on because, again, if you look at paragraph 2.12—

Q79 Mr Jenkins: My last question is, would you have thought that it would be beneficial to the roundness of this Report if those figures had been included in the main body of the Report to show what progress you have been making and to take away this figure of £5 million to £6 million that will be saved when we have already saved the vast majority of it?
Sir Nigel Crisp: I would much rather have seen the figures in and I do not know why they did not come in; it would have been much better if they had been there.

Q80 Chairman: Was the information provided to the National Audit Office? Perhaps it came too late, I do not know. What is the reason for it?
Sir Nigel Crisp: I do not know. Can I check that for you? I simply do not know the answer to that.[4]

Q81 Chairman: We have had this before and it is very important if we are going to have worthwhile hearings that the Department, with a moving situation like this, does keep the National Audit Office fully informed in order that it can have a proper discussion.
Sir Nigel Crisp: I fully accept that. I am sorry that we did not do that.

[4] Ev 19-20

Q82 Mr Jenkins: I will move on to the next point, shortages of vaccines. Although the Report says that we may have a shortage for a short period of time, when would you decide that a shortage for a short period of time is exceeding that short period of time? It is now in the long-term strategy. We now have a problem. What is your strategy for dealing with that situation to ensure the health of this country?
Dr Salisbury: First of all, we have regular forecasting undertaken by my own group and colleagues from PASA when we are able to look at the stockholding that we have which we can do on a day-to-day basis, we can look at the drawing down of vaccine as it is being taken by the NHS on a day-to-day basis and we also have information from manufacturers on at least a monthly basis as to how they are matching the specifications of their contracts. Within the contracts, we do not just say that we want 10 million doses, we actually tell them how many doses we want per month and when we want them and so on. So, we get indications very quickly if there is any sign that the manufacturing process is not keeping up with the contract specification. We then have to look at our stockpile in order that we can make judgments on the size of the stockpile and the time it will take for that to be eroded and we then use intelligence from the manufacturers about when they will replace the shortfall. If the shortfall is going to be replaced whilst the stockpile is still healthy, then we have no need to take action. However, as soon as that position appears in any way threatened or compromised, then we can switch from demand ordering to an allocation ordering base. We are the only country in the world that can do this. Instead of GPs putting in their orders for vaccine, we hold the database of every GP in the country and the number of children of every age on their list and, as soon as we can see that our stockholding is in any way at risk, we switch to allocation and that means that we do not take any orders from GPs for vaccine. Once a week, they will receive vaccine according to their calculated needs for the size of their population. This means that we do not get asset stripped by people putting in excessive orders and we can manage the availability of vaccine according to supply. Where the long term is concerned—and clearly we get feedback from manufacturers and that requires a regular dialogue that we hold—if we get feedback from manufacturers that there is going to be a serious problem and that they cannot fulfil a contract, then the next recourse is to look for an alternative manufacturer who may have stock that we can take to keep our supply going. Clearly, if all of those fail, then we will continue to press to try to get stock but we may, on occasion—and that was the circumstance with the BCG programme—have to suspend that part of the programme, but that is, by and large, a very late stage and our experience in recent years has been that it is very rare that we have to go to that extent. That has not been the circumstance, for example, in the United States in the last couple of years where they have had severe vaccine shortages and do not have the ability to go to an allocation system to control distribution.

Q83 Mr Davidson: I wonder if I could just follow up that point about asset stripping and the like. Can you clarify for me whether or not the establishment of foundation hospitals, presumably free to order as they wish, could result in exactly the sort of asset stripping that you indicated was a danger?
Dr Salisbury: The arrangements that we have for distribution of vaccines are essentially towards primary care, because the provision of the immunisation routine programme is a primary care derived function. Almost by far the greater part now of our distribution goes from our one distribution holding centre to individual general practices on a weekly or two weekly basis, so very little actually goes through a hospital. There are still a few community service pharmacists that draw vaccine and then distribute it within their locality, but for the greater part our vaccines go direct to GPs.

Q84 Mr Davidson: Are you satisfied that the marketisation of the Health Service would not lead to a situation where exactly the sort of asset stripping that you were mentioning might take place?
Dr Salisbury: I do not believe that will happen because this is a primary care driven phenomenon, and increasingly we seek to provide the vaccines free to GPs.

Q85 Mr Davidson: On the Bacon principle of raising any issue that you feel like and asking to see you afterwards—
Sir Nigel Crisp: At least he gave me warning!

Q86 Mr Davidson:—can I say that I have a sore elbow and I want an opportunity for a consultation once this meeting has finished! But if we are being told now that everything was okay and there was effectively no problem with the awarding of this contract, are you happy, Sir Nigel, with the way in which this was dealt with by your Department at the time? I understand, of course, the merits of having somebody external looking at that, but presumably they have looked at it using information provided by yourselves. Were you happy with everything that you were able to assess at that time, and is there a change that needs to be made in the Department about responsiveness?
Sir Nigel Crisp: I am happy in the sense that my colleagues went about this in a thoroughly professional way. At a very late point we suddenly realised there had been a donation and therefore we had to look at it again in a different way and I got involved personally in looking at that, and that seems to be the right way to do it. The only point I would make is the one that Mr Field made that maybe there should be some way of identifying potential donors earlier in the system, and then we would have handled it differently as a result of that.

Q87 Mr Davidson: But this broke and ran for some time, as I recall, and you were not able to nail it down at the time, if I recall correctly. Now, I am not quite sure exactly why that was—partly obviously because you did not have somebody external and impartial

to confirm it, but were there any other internal difficulties that prevented you being believed? There was an air of suspicion around at that time.
Sir Nigel Crisp: The other issue that was there was the fact that we were doing this quietly and, as I recall it, it came into the public domain through the stock market so we did not make an announcement about this; this was suddenly revealed through the stock market, which means that therefore people thought we were hiding something or something like that and it moved that way. Now, I think in retrospect that is always a difficult balance. If you are doing something that you have chosen to do quickly after the terrorist attack and doing it in a way, as has been said here, where we did not want to reveal anything about what our precautions were to any potential terrorists or whatever, then the issues of secrecy come in, so I think that is the only thing which probably fed this more than it might have in other circumstances.

Q88 Mr Davidson: So just following up that point as well, I understand the point you make for the need for secrecy and not to flag things up to terrorists, so basically Stock Exchange rules of disclosure are unhelpful in these circumstances since presumably the companies have to disclose that information even though you might not have wanted to?
Sir Nigel Crisp: Certainly that was the issue, and I suppose what you would then say is why had we not thought of that in advance—

Q89 Mr Davidson: That was my next question!
Sir Nigel Crisp: I think that must be one of our learning points.

Q90 Mr Davidson: In terms of stocks of vaccines am I right in thinking that the only one where you have any difficulties at all is the BCG, and everything else we can be reassured is all hunky dory?
Sir Nigel Crisp: In terms of commonly used vaccines—
Dr Salisbury: That was using the two case studies that were here. Our BCG shortage that we did have from that particular company was overcome by going to an alternative supplier.

Q91 Mr Davidson: And other vaccines?
Dr Salisbury: At the moment our portfolio is fairly healthy.

Q92 Mr Davidson: I thought I understood earlier on that you were often going to multiple suppliers for security yet in the supplementary sheet that you gave us about the second smallpox vaccine procurement I see it seems only to have been awarded to a single company. How do these two points marry?
Dr Salisbury: Certainly where our routine procurement contracting is concerned we would look to more than one supplier but we would expect them to have matched the criteria that we identify, so they would have equal data on safety, efficacy, availability, price and so on. If they did not, we would be uncomfortable about giving them a contract. In the case of the two smallpox contracts, where the first one is concerned it was very clear that one company matched those criteria far better than the others. To have brought a second company in to share that first contract would have been at a considerable disadvantage in terms of the criteria that we were trying to match. The same happened in the second round where the company who won the contract was way ahead of the alternative company who were only talking about constructing a new factory, and had no physical vaccine experience that was going to supply that contract. So if two companies had matched the criteria equally, then that would have been different.

Q93 Mr Davidson: So what you are saying is that a spread of suppliers is desirable but not essential?
Dr Salisbury: Yes.
Sir Nigel Crisp: And it is more desirable on routine purchases where you are buying some every year.

Q94 Mr Williams: I have a few questions just on bits and pieces—very little to do with the main subject. I think it has been interesting in any case to have been brought up to date on the sort of problems you are facing, and very informative. Looking at case study I, Tuberculosis and so on, the point made there—and Gerry referred to this—is that there has been a 21% increase, but that is between 1987 and 2001 so fourteen years, at first sight perhaps only just 1.5% a year but I suspect that has not been consistent. What has been the rate of increase in, say, each of the last three years, or whatever you can give me in recent years?
Sir Nigel Crisp: Can we come back and give you those figures? I think we would be guessing at the moment in terms of knowing that. We can come back and give you a ten year history, if you like, but it is a worry.[5]

Q95 Mr Williams: But it would be a false presumption to assume a steady level of increase?
Sir Nigel Crisp: Yes.

Q96 Mr Williams: So how dramatic, impressionistically, has been the increase in recent years?
Dr Troop: Until about five years or so we are at a fairly level rate.

Q97 Mr Williams: Do you remember offhand approximately what that would be? There were 7,000 new cases last year.
Dr Troop: Yes. We were down to about 5,000.

Q98 Mr Williams: So it has been about 2,000 a year?
Dr Troop: Yes, and that has been a fairly recent phenomenon, and the pattern of the TB has changed as well.

Q99 Mr Williams: You mean the strain of TB?
Dr Troop: No. There are many different strains of TB and certainly the strains we are seeing now come from different parts of the world than some of our

[5] Ev 20

previous ones we saw. We are now able to do pretty sophisticated typing and we find that we can trace back to whether or not they are indigenous ones or ones that have originated from different parts of the world. We have been doing that work—that is what my new organisation does—and the pattern of TB is different than the pattern in London. Also, whereas before there was a fairly standard pattern across the country because it was something that was longstanding, we now find different patterns in London from Birmingham or from Bradford, so it is a much more complex epidemiology than it was just even five years ago. Part of the work we do now is to understand precisely what those strains are, precisely where they are coming from, so we are able to try and work with the local population and the Health Service to enable them to put in the right strategies.

Q100 Mr Williams: So would the strains tend to be localised as well? Is there a sort of strain map?
Dr Troop: Yes. We are now DNA-mapping strains, and you find that very often where you think you have one outbreak you have many different strains and therefore they are not linked. But what we are doing is working with the Health Service to do this mapping for them and that way they can work through how to deliver the most appropriate response, and it is very important that we also link with lots of colleagues overseas and internationally, because what we are getting is part of a global picture of TB and therefore we have to work internationally if we are going to tackle this, and that is what we are trying to do.

Q101 Mr Williams: So where is the primary source at the moment?
Dr Troop: There are multiple sources. We have some indigenous TB of our own because that never went away in this country, it got down to about 5,000 new cases, but we do have quite a number of cases coming from sub Saharan Africa and from other parts of Asia, particularly the Indian subcontinent—we have them in a number of different places where we can find them coming from, but it is such a mixture. It is also not clear when people come whether or not they get their TB when they come because they come often into poor areas and come into contact in those areas with people with TB, so it is a complex picture that we are trying to unravel at the moment.

Q102 Mr Williams: And are the newer strains you are identifying containable with the existing vaccines?
Dr Troop: The vaccine has always had a limited effect for Tuberculosis, so we have always been aware of that. In fact, my new organisation does quite a lot of research in trying to find a new TB vaccine. At Porton Down we have quite a big vaccine programme to find new candidates for better vaccines, but at the moment the vast majority of TB is amenable to drugs that are there, although there is a small amount of drug resistant TB that we are, I think, beginning to face that is beginning to creep up.

Q103 Mr Williams: I suppose more worrying than the fact that it is coming in would be if it is now spreading once it is here. How far is containment working?
Dr Troop: It is quite difficult with TB because you have to keep people on treatment for six months, so to maintain that level of treatment often in communities which are not stable is quite difficult, but in London they have been doing a huge amount of work on a sector basis and they have set up databases of people so they can follow and work with them and go into their communities to work with them to help them continue with their treatment. We are finding problems as well with people going in and out of prison, and that is another problem we have with TB.

Q104 Mr Williams: When you say "going in and out", I would have thought it would be easier to sustain a treatment pattern for somebody who goes into prison because they are under control and can be medicated?
Dr Troop: Well, people go for short terms and come out again. TB is always more difficult to contain when you are working with mobile populations, and our previous TB tended to be with more stable populations and therefore you could follow people up. When you are working with less stable populations it becomes a more complex problem, and what we are trying to do with the NHS is give them sufficient detail so they can work with those populations and communities enabling people to follow up their treatment. People want to complete their treatment; it is just not always easy for them to do it.

Q105 Mr Williams: I do not want to lead you into saying things you do not want to say, but are you satisfied at the moment that you are containing the problem?
Dr Troop: I think we are doing pretty well. We had a big outbreak in Leicester a couple of years ago and we were able to contain that; it was a huge outbreak. More recently with the DNA testing we were able to nip a similar thing much earlier, now we have this specialised testing, so we were able to contain it at a much earlier stage than we were even two or three years ago. Perhaps I could say that the CMO in his strategy *Getting Ahead of the Curve* is about to publish an action plan to follow up a lot of the work in there, and certainly I think we all recognise that we need to make a big effort in this area if we are going to keep it under control.

Q106 Mr Williams: I know the Home Office has been running a pilot scheme at Dover, if I have it correct, for monitoring incomers for TB. Have you any information on this? Is it effective? Is it giving any worthwhile information? Is it something that looks as if it might be worth replicating elsewhere?

Dr Troop: It is something that is being explored. It is not straightforward because when people arrive in the country with any disease they do not always show the symptoms, and if somebody does not show the symptoms when they arrive it is not always easy to pick them up. There are a number of different ways, however, that are being explored to see whether or not people can be identified and treated at an early stage rather than wait until it becomes an established disease, and we are working with them to see how effective that might be.

Q107 Mr Williams: If you identify someone as having TB, are you able to oblige them to have treatment?
Dr Troop: No. You cannot oblige people to have treatment. What you can do is, if somebody is unwilling to be treated, you can oblige them to remain in hospital, but you cannot oblige them to take treatment.

Q108 Mr Williams: Do you find much resistance? There are social attitudes to things like medication. Are you finding resistance in any sectors to medication?
Dr Troop: The vast majority of people want to have their treatment and they want to get better, so that is not a broad problem. There are occasionally individuals, not from any particular sector, who decide they do not want treatment and then we do have quite a problem of maintaining them in hospital. We can keep them there for a long time but we cannot force them to take treatment. There have always been a few individuals in that situation ever since I have been involved in public health, so this is not a new situation but we have always recognised this as a difficulty.

The Committee suspended from 5.41 pm to 5.50 pm for a division in the House of Commons.

Q109 Mr Williams: Switching slightly to the smallpox vaccine and case study G on page 25, why is it that still no smallpox vaccine is currently licensed in the United Kingdom?
Dr Troop: There is no licensed vaccine anywhere. Licensing will be a problem with any vaccine because normally, before you license a vaccine, you do human trials where you test it against people who might have the disease, and as there is no disease it is quite difficult to do the trials. There is, therefore, work with our own licensing authority and with the European and the American licensing authorities on what would be acceptable to be able to license a vaccine so that in itself is a very unusual situation for licensing something. But also, if you are going to put a licensed portfolio together, it can take a couple of years to do that, to collect the kind of detailed information that will satisfy the licensing authority, so it is not surprising that at this stage nobody has yet got a licensed vaccine, even given the kind of special conditions the authorities might wish for.

Q110 Mr Williams: I see that in the main paragraph there it is pointed out that you had the indemnity which the Committee was told about previously of £30 million against liability, and that that might be on the low side because it was assessed on the basis of a different vaccine. £30 million seems quite a lot of money—and I am not sure in this context, and you can tell me from your experience because I have no experience in this area—but then you are vaccinating a lot of people. Have you had to pay anything out yet, or would it be too early to expect to do so?
Dr Troop: No. The only people who have been vaccinated thus far are some healthcare workers who have volunteered to be vaccinated so they could be in the front line should they be needed, and they have been screened very carefully because there is no personal benefit to them and they were doing it for the benefit of the population, and therefore we have been extremely careful to screen out anybody who might have possible side effects, including, for example, children having a problem like eczema or something like that. We have been very careful to make sure that only people we felt were robust could have the vaccine.

Q111 Mr Williams: Does this not present us with a bit of a conundrum if there were a need for a mass programme, because it would essentially be advantageous to have had experience on which to be able to assess the likely range of reactions?
Dr Troop: Certainly people can give vaccine to volunteers but that only tells you the kind of immunity it appears to give and the safety it has. What it cannot do is tell you how it responds to the disease, which is what you would normally do for a vaccine. You normally test it against the disease and we have not been able to do that—and we will not be able to do that because there is no smallpox in the community.
Mr Williams: Thank you.

Q112 Mr Bacon: Just a quick question: you mentioned the OGC gateway review process which I take it is used for procurement of a wide range of different characters for different bits of services. Is the OGC gateway process used for all NHS IT procurement?
Sir Nigel Crisp: It is used for all the IT procurement as part of the national programme.

Q113 Mr Bacon: What does that mean? The Department of Health?
Sir Nigel Crisp: That means the big one. What it means is we do not use that process in every hospital every time they are buying a small system, but we do use it for the major national systems.

Q114 Mr Bacon: So is there a threshold of an amount of value below which you would not put it through the OGC?
Sir Nigel Crisp: I am sure there would be a sensible threshold but at the moment what we have done is we have extended the gateway process to a series of major national programmes. We have not said it is

mandatory through the NHS for every procurement but it includes all the major procurements we have under way at the moment, which is not just IT.[6]

Q115 Mr Bacon: But if I am an IT director of a hospital, do I know that there is a guideline, a threshold, for a procurement in my hospital—what you call a small system, a certain amount of millions of pounds—above which it stops being small, and that I have to put it through the OGC gateway process, or do I not because it is not "national"?
Sir Nigel Crisp: Beyond a certain figure, and I can obviously give you the figure, there are all kinds of things that come in, including how you have to structure the business case and everything else that needs to be done above a certain lifetime cost. At the moment there is no requirement on the NHS for local IT systems to go through the gateway process.

Q116 Mr Bacon: Irrespective of the cost?
Sir Nigel Crisp: I believe that is the case but I will check that.[7]

Q117 Mr Bacon: If you could give the Committee a note I would be grateful.
Sir Nigel Crisp: Because OGC, as you know, was only about national expenditure originally. We have extended it to the national projects in the NHS but not to local projects in the NHS.

Q118 Chairman: Thank you. I have a couple of questions on case study H on page 29 dealing with the MMR vaccine. I do not want to get involved in all the medical controversy this afternoon but I do note that there were production problems and Aventis were unable to supply all the doses contracted for. I take it that the fact that we are insisting on MMR is not producing any supply difficulties, is it? It would not be any easier if people were given the choice, would it?
Dr Salisbury: Quite the opposite. The circumstances were that in this case study one vaccine manufactured in the States by Merck that was then being distributed by Aventis was in short supply but we had a second contractor: we had sufficient stocks from our stockpile to see us through, and we were able to get more vaccine from the alternative supplier which was GSK. That was not the circumstance in the United States where they had a monopoly supplier; they exhausted their stockpile; and they were not able to turn to a second supplier. So single vaccines would not have helped one bit.

Q119 Chairman: But we seem to have a problem with fewer and fewer and larger and larger suppliers. What are you doing in the Department to stimulate the vaccine supply market?
Dr Salisbury: The best we can do is make sure we have regular dialogue with the manufacturers, both to bring to their notice what our policy requirements are and, equally, to hear from them what their development plans are both for existing and new products. The vaccine industry is in effect a global industry nowadays: it is very rarely country specific, so these are major market issues. Sometimes the decisions are made clearly at board level within companies where they have made a judgment that the return on vaccines may not be as good as the return on other pharmaceutical products, and in those circumstances it is very difficult. I was at a meeting in the United States last week looking at global vaccine shortages working closely with US colleagues who face exactly the same difficulties, and we all acknowledge that, where companies decide either to narrow their product line or even to leave the market, it is very hard to prevent that happening. The best we can do is ensure that our policy requirements are clearly conveyed to the industry, and the other thing is that it has to be a healthy industry financially otherwise they will not stay in it.

Q120 Chairman: Lastly, Sir Nigel, you told Mr Davidson that you did not know about this donation to the Labour Party until late in the day and then, once it became public, you had to look at it personally; it was obviously sensitive at that stage. I think you said that if you had known about it then you would have done things differently. What things would you have done differently if you had known about this donation from day one?
Sir Nigel Crisp: I think I need to think just a bit more about that answer but I suspect the two areas we would be thinking about is, firstly, the role of ministers in decision-making and whether there was any question of whether they should have been as involved as they were in this.

Q121 Chairman: Perhaps they should not have been involved?
Sir Nigel Crisp: Perhaps. That might well have been one of the things that we would have done.

Q122 Chairman: But they were involved in this case?
Sir Nigel Crisp: They were involved right the way through the process in terms of recommendation.

Q123 Chairman: So you might have said to them, "Minister, I am afraid you should know a donation has been made and therefore I do not think you should take the decision"?
Sir Nigel Crisp: Yes.

Q124 Chairman: What else would you have done differently?
Sir Nigel Crisp: The other thing I think that we would have done I suppose was just to think about our relationship with the particular supplier and whether we were absolutely double-checking everything and making sure that we knew how we were going to handle this if we ended up having the decision that we were going to go with somebody who had given a donation to the Party—

Q125 Chairman: What do you mean double-checking everything? Presumably you double-check everything anyway?

[6] Ev 20
[7] ibid

Sir Nigel Crisp: That is what I did subsequently, if you see what I mean.

Q126 Chairman: And you were satisfied everything had been double-checked?
Sir Nigel Crisp: I sat down with Dr Troop and colleagues; I went through the paperwork; I looked at it all in detail and asked the sort of questions your Committee has been asking about why the Lister strain, why now, why are we doing it through a restricted process—that sort of question.

Chairman: Thank you very much. I think it has been a useful inquiry. The National Audit Office can confirm—and I am sure we can—that there has been no impropriety here and therefore it has been a useful process in the democratic system. However, you have said that you have learned some lessons and certainly, irrespective of the controversy about one company, I think you have learned some lessons about the general procurement process which we can return to in our report. We are very grateful to you and your colleagues for coming to talk to us this afternoon. Thank you.

Letter and memorandum to the Committee from the Department of Health

I am writing in connection with my appearance at the Committee's hearing on 20 October on the procurement of vaccines.

As it is some time since the NAO published its Report I thought it might be helpful to provide the Committee with a note (below) of developments in the Department's general procurement arrangements and the second smallpox vaccines procurement process.

General Procurement Arrangements

The March 2003 procurement review uncovered a similar, but improving, situation to the detail covered in the Internal Audit report of 2000 and the external review "the *Passemard Report*". The *Passemard Report* and the March review were both initiated by DH to provide drive and impetus to the improvements being progressed following the Internal Audit review in 2000. The most notable change since the March Review has been the appointment of the Commercial Director in August which yields a strong central focus to DH and NHS procurement activity.

The main changes are set out below and other changes are noted as updates to the table included in the NAO's April Report.

- The Purchasing and Policy Advice Unit has been grown on from 7 to 10 posts.
- The process of Accrediting units of the Department to manage procurement and contract manage was commenced in 2002 and will be vigorously pursued continued by the Commercial Director appointed in August this year.
- Savings have been identified since changes were made and the procurement structure was enhanced. Since the Internal Audit and Passemard reports DH has reported procurement savings to the Office of Government Commerce (under and NAO approved methodology) of £4.8 million in 2000–01, £5.1 million in 2001–02 and £5.6 million in 2002–03. A recent example of early involvement of PPAU in the negotiations for the Independent Complaints Advocacy Service resulted in savings of £1.3 million.
- Co-ordination with OGC, PASA and other Government Departments continues. The use of cross Government Contracts has been adopted increasingly by DH (notably the G-Cat and S-Cat contracts).
- The Department continues to advance the "e" commerce agenda jointly with the Office of Government Commerce, for example, electronic travel booking and increased use of the Government Procurement Card.
- Increased control of Departmental procurement will be available once the Departments new financial system is installed in April 2004.
- Commercial Director will add impetus to the drive for savings and better procurement structure.
- Commercial Director is instituting a full "forward look" on all major procurements to enable a more effective procurement co-ordination across the Department and NHS (via PASA and NHS logistics). The Department has adopted the OGC gateway review process and requires fully costed business cases for all major purchases.

In *italics* are the changes since the NAO Report in April 2003.

Recommendation	*Progress*
Contract Management	
Guidance should emphasise EC constraints, allowing managers to highlight the associated implications in their business cases.	Requirement undertaken and is available on the departmental intranet. Intranet pages receive constant attention and are updated. Linkage of procurement needs to Ministerial submissions to be enhanced in next update. *Departmental Guidance has been enhanced and the whole of the Department's intranet site is the subject of an overhaul and update. The Department appointed a Commercial Director in the Summer of 2003 which, in part, is specifically targeted at increasing commercial awareness across the Department and the wider NHS. The Commercial Director is responsible for both Departmental procurement and the Purchasing and Supply Agency (PASA). In terms of vaccines procurement this change addresses all the market other than that directly purchased by GP's and not covered by PASA.*
Easily accessible guidance should be made available to staff covering the pre-procurement stages of a needs assessment: — Business case preparation — Options appraisal And given equal status with the Department's procurement guidance.	Noted initially that this recommendation was not uniquely within the procurement discipline. Was further addressed in the "*Passemard Report*" and will be further clarified by the investigation being undertaken by the OGC deputy chief executive (report due March 2003). The Department has accepted the discipline of business case preparation and the appraisal of options this entails. The Office of Government Commerce gateway process is now increasingly being applied across the Department. *The process of "Gateway" review, initiated by the Office of Government Commerce, has been accepted as the methodology for major projects within the Department. The Department has a dedicated Gateway team and has an internal Departmental training programme for its dedicated gateway review teams.* *Business cases are required by the Department for all-major new schemes and purchases. Guidance and advice is available from the Department's Finance unit and in particular from the section dealing with PPP/PFI. Option appraisal is a constituent part of the requirements called for in respect of business cases presentation. Business Case operation passes through an outline and final business case phase to secure ongoing control.* *Publication of guidance is targeted through the Departments intranet system.*
The Department's guidance should be amended to reflect the weaknesses in standard conditions that we identified.	Recommendation complied with. The terms and conditions in the guidance cover the general environment faced by units in the Department. For specific and particularly detailed contracts conditions of contract are drafted to meet the needs—but will follow the basic requirements contained in the "general" terms and conditions of contract. *The requirement has been fully met to satisfy Internal Audit.*
Easily accessible guidance on drafting specifications should be made available to staff.	This requirement has been undertaken and guidance is available on the Departmental intranet.
Minimum requirements for administrative instructions, together with proformae and system guidance should be included in departmental guidance.	This requirement has been undertaken and guidance s available on the Departmental intranet.

Recommendation	*Progress*
Guidance on post-contract award management should be incorporated into departmental guidance.	This requirement has been undertaken guidance is available on the Departmental intranet.
Sourcing potential suppliers, competition and value for money	
The need to consider the financial stability/track record of potential tenderers should be highlighted in the Department's guidance.	This requirement is addressed in outline on the Departmental intranet. The placing of EU advertisements through the "on line" system employed by the Department imposes this requirement on all potential suppliers and the Departmental units submitting such advertisements.
Guidance should identify those staff to be excluded from a tender exercise.	This requirement is addressed through the separation of duties requirement noted on the Departmental intranet. The requirement is addressed in the "accreditation" process adopted by the Department subsequent to the *Passemard Report*. Risks now considered to be slight but the issue remains under review. *Departmental reorganisation has limited the scope for accreditation into 2003. The Department is, therefore, preparing a middle to senior managers training event (jointly with the Civil Service College) to address specific issues such as those highlighted in the Internal Audit report.*
Guidance should state the requirement for a review of tenders against pre-determined tolerance levels to be considered as part of the recommended wash-up meeting.	This requirement was considered under the Passemard review and report. The Department has actively addressed the requirements of the *Passemard Report.* *The Departmental guidance available on the intranet addresses issues of objectivity and economy during the evaluation process as a matter of policy.*
Contract Management	
Guidance should stipulate that tenderers chosen for contract award should be required to prove their financial stability (eg by supplying company accounts covering the past three years).	The placing of EU advertisements through the "on line" system employed by the Department imposes this requirement on all potential suppliers and the Departmental units submitting such advertisements. The topic is addressed in the Departmental intranet in general terms. *The Department contracts with a commercial company to financially check it's potential and actual suppliers.*
Guidance should stress the importance of tender document retention as evidence of an adequate management trail.	This requirement has been undertaken guidance is available on the Departmental intranet.
Departmental policy, control and guidance	
Appropriate training programmes should be identified and established.	This requirement has been fully addressed and continues on a Departmental wide basis. Training sessions for none procurement staff are regularly offered and undertaken. *The Department also offers training events to its supplier base either directly through "meet the buyers events" or participation in commercial seminars.*
The corporate structure for strategic management, and the provision of expert advice to managers, should be strengthened.	Noted initially that this recommendation was not uniquely within the procurement discipline. Was further addressed in the *Passemard Report* and will be further clarified by the investigation being undertaken by the OGC deputy chief executive (report due March 2003). *The Department has increased PPAU staff numbers as recommended in the* Passmard Report. *The creation of the Commercial Director post has significant potential to strengthen the corporate structure and expert advice provision into the future.*
PPAU or SOL Commercial should maintain a central register of all contracts.	This requirement is being addressed through the Departments replacement of its financial systems. It is expected that the replacement system will be able to maintain a contracts register.

Recommendation	*Progress*
Contract Management	
All Departmental business plans should identify expenditure potentially/subject to contract. These should be co-ordinated by the Department's central procurement unit.	Noted initially that this recommendation was not uniquely within the procurement discipline. Was further addressed in the "*Passemard Report*" and will be further clarified by the investigation being undertaken by the OGC deputy chief executive (report due march 2003). *Has now become subject to the Commercial Director and his command (including the PPA Unit). The requirement requested is also incorporated into the guidance available on the Department's intranet.*
Guidance should provide sufficient information to enable devolved managers to be clear on time-scales, and alternative courses of action (eg open or negotiated procedures, or the use of framework contracts).	This requirement has been undertaken guidance is available on the Departmental intranet. Will be further clarified by the investigation being undertaken by the OGC deputy chief executive (report due March 2003). *Revised guidance is now being placed on the Department's intranet.*
The status of electronic and hard copy guidance should be clarified to staff.	The status of the electronic copy confirmed as Departmental policy. The paper copy has been withdrawn and has been supplanted by the Departmental intranet version.
PPAU should amend the desk-guide and manual to provide improved advice and links between the two.	This requirement has been undertaken guidance is available on the Departmental intranet.

SECOND SMALLPOX VACCINE PROCUREMENT

In the follow-up procurement announced in October 2002, on advice from the Department's Permanent Secretary, Director of Finance and Investment and the Procurement and Supply Agency, the Minister of Health agreed that grounds of urgency no longer applied and it would be inappropriate to set aside the normal EU procurement rules because the Department:

— having augmented its emergency stocks, timescales for the next phase were less urgent;

— wanted to be as transparent as possible about its purchase of smallpox vaccine; and,

— wanted to follow as closely as possible the normal route of procurement. The Official Journal of the European Community (OJEC) route would allow this to be achieved without compromising national security and would ensure that any potential new suppliers were identified.

The procurement was advertised in the OJEC on 23 October 2002 and expressions of interest were received by 29 November. All but one of the original companies responded (PowderJect, Acambis, Aventis Pasteur MSD and RIVM). One other company also responded. Tender documentation was sent out on 20 February 2003, following a pre-tender meeting with the companies on 10 January. Included in the specification was the requirement for a licensed form of Lister strain cell-derived vaccine. Three bids were received on 1 April 2003, the deadline for submissions.

The Department of Health confirmed its intention to award a contract to Aventis Pasteur for new supplies of smallpox vaccine at the end of July 2003. The contract is for a licensed second generation vaccine of the Lister Strain.

Sir Nigel Crisp

16 October 2003

Supplementary memorandum submitted by the Department of Health

Question 44 (Mr Bacon): How much will the new financial and business information system, which is due to be established in April 2004, cost?

The Business Case was costed at £4,453,475.00

The current forecast is £4,284,820.00

Actual spend to date is £2,570,034.00

Business Case (including VAT)	
Hardware	£983,475.00
Software	£470,000.00
Software Implementation	£1,600,000.00
Project Management	£300,000.00
Business Process Re-engineering	£600,000.00
Contingency	£500,000.00
Total	£4,453,475.00

Question 80 (Chairman): Was the savings information provided to the National Audit Office?

The information on procurement savings included in the Department's note to the Committee was available for 2000–01 and 2001–02 at the time of the National Audit Office's (NAO's) study in the form of annual returns to the Office of Government Commerce (OGC). The return for 2002–03 was not made to the OGC until after publication of the NAO's report and was not therefore available at the time of the NAO's study. Unfortunately, the Department did not specifically draw attention to the availability of the general procurement savings information.

Part 2 of the C&AG's Report provides an overview of the Department's central purchasing arrangements in order to place vaccine procurement into context. It was not meant to be a value for money review of the effectiveness of these general procurement arrangements. The National Audit Office reported the conclusions of key procurement reports, including an external review (the Passemard review), to provide context and background and to highlight the lack of progress that until recently there had been on a number of the reviews' key recommendations. The Department accepts that it would have been helpful to have made the figures available and included as part of the National Audit Office's Report to provide further context of the Department's drive to secure savings wherever it can.

Prior to Question 80, Brian Jenkins MP asked a number of questions (Question 73–79) about the actual savings already achieved and the savings potentially achievable from improvements to the Department's procurement arrangements. The following further clarification may be helpful to the Committee.

The savings identified in the Department's note to the Committee covers estimated savings arising from the application of good procurement practice. However, the savings identified in the C&AG's Report at paragraph 2.14 are estimated additional savings which may arise once the Department fully implements the initiatives suggested as part of the Passemard review which reported in May 2001.

Using an Office of Government Commerce methodology, the Department had achieved savings totalling an estimated £4.8 million in 2000–01, £5.1 million in 2001–02 and £5.6 million in 2002–03. These figures are an estimate of value for money gains achieved by application of good procurement practice to the Department's commercial expenditure. Value for money gains are defined as improvements in how costs and quality are combined in meeting user requirements. They are secured as a result of positive action by staff involved in commercial transactions for example through negotiation of an improved deal with a supplier (such as lower prices or improved quality for the same price), or through reduced staff time spent procuring goods and services. The figures therefore represent efficiency gains that may result in resources being released for deployment elsewhere.

As a separate initiative, the Department commissioned the independent Passemard review to, inter alia, identify how purchasing arrangements could be strengthened taking into account the highly devolved nature of the Department. The review concluded in May 2001 that procurement practices within the Department were variable depending on the importance and interest attached to them by local management. It recommended that the Department enhance the role of its Procurement Policy Advisory Unit (as distinct from applying procurement best practice in general) to cover the monitoring of procurement activity within business units, promote collaboration where beneficial, driving forward the e-commerce agenda, and maintain professional standards. The review estimated that an improved Advisory Unit could have the potential to realise savings of £5–6 million a year.

The changes recommended by the Passemard review have not all been fully implemented, so the potential savings have yet to be achieved. However, the Department believes that recent expansion of the number of staff in the Advisory Unit, the recruitment of a commercial director in August 2003, and the work currently

in progress to replace, by April 2004, financial and management information systems with a new Oracle-based system, together have the potential to realise additional savings on the scale estimated by Passemard. The Department agrees that further savings might have been realised sooner if it had acted more promptly to implement recommendations included both in internal audit reports and 2001 Passemard review (Questions 2–3).

Question 94 (Mr Williams): What has been the rate of tuberculosis in recent years?

Since 1992, for England and Wales, the notifications of tuberculosis are as follows:

Year	*Notifications*
1992	5,798
1993	5,920
1994	5,590
1995	5,606
1996	5,654
1997	5,859
1998	6,087
1999	6,144
2000	6,572
2001	6,714
2002	6,891*

* provisional figure

Questions 114–116 (Mr Bacon): Is the OGC gateway process used for all NHS IT procurement, or is there a threshold of an amount of value below which you would not put it through?

The Office of Government Commerce (OGC) Gateway process is mandatory for all high risk NHS investment and procurement programmes and projects. The level of risk of programmes and projects is assessed using the OGC Gateway Project Profile Model (PPM). The PPM takes into account whole life cost, complexity, experience of the client and contracting organisations and other factors in assessing the risk profile of the programme or project. The assessment of whether or not to use the OGC Gateway reviews is not based on the capital cost of a programme or project.

More specifically, the PPM is intended to provide a standard set of high level criteria against which Senior Responsible Owners (SROs)/Project Owners (POs) can assess the intrinsic characteristics and degree of complexity of a proposed procurement project, in order to establish the appropriate: control structures; risk profile and corresponding risk strategy; and, design approach.

The PPM produces a score that is validated by the OGC.

- 30 or less—indicates that the project is relatively low risk. Gateway Reviews will be managed by the departmental Centre of Excellence or Gateway Co-ordinator.
- 31–40—indicates the project is medium risk. Gateway Reviews will require a Review Team Leader nominated by the OGC Gateway Team and independent of the department.
- 41 or more—indicates that the project is high risk and will require both a Review Team Leader and Review Team Members nominated by the OGC Gateway Team and independent of the department.

It should also be noted that any IT enabled Business Change project using a "Big Bang" and/or implementation approach or any IT enabled Business Change project that has been prioritised as "Mission Critical" will automatically result in it being classed as high risk.

Any IT enabled Business Change project identified as high risk will need an identified responsible Minister and an SRO and Project Manager with good relevant track records. In addition, before the project commences it is assessed against the NAO/OGC list of common causes of failure.

23 December 2003

Letter to the Committee from HM Treasury

At the Committee's hearing on 20 October, Mr Field asked, in relation to procurement decisions in general, whether the department had a system for checking the public registers of political donations *(Question 22)*. As this question is relevant to all government departments, I agreed with Sir Nigel Crisp after the hearing that I would seek the views of the Cabinet Office and the Office of Government Commerce. I am sorry for the delay in replying.

Having looked into this in consultation with the Cabinet Office and OGC, a number of difficulties have been identified. Although details of political donations over £5,000 are published quarterly, there can be significant delay in reporting them and many individuals make donations on a personal basis so their links to individual companies will not be obvious. Linking donations and tenderers would therefore be difficult, time-consuming and uncertain. There are also problems of whether to apply a time cut-off, whether to include donations by close family members and how to cover other types of political connection (eg former Ministers on the boards of companies). Any checking process of registers of donations would therefore only be a partial and unreliable response to the issue discussed at the hearing.

It must also be borne in mind that the public procurement procedures themselves provide significant protection to Ministers and officials. Officials handling contracts are required to make sure that the correct procedures have been followed and that the award recommendation follows from the evidence of the evaluation of tenders. All contract award decisions must be based on value for money, normally through competition (a requirement of Chapter 22 of Government Accounting). The EC procurement directives, and the Regulations which implement them in the UK, must also be followed for contracts above certain financial thresholds (approximately £100,000 for supplies and services). Even for contracts below those thresholds or otherwise outside the scope of the directives (concessions for example), EC Treaty principles of equal treatment and transparency apply. The directives require appropriate advertising of contracts and other transparency mechanisms, including the need to provide an explanation to any unsuccessful bidder who seeks it. Aggrieved bidders may complain to the courts or the European Commission if they consider that they have been treated unfairly and, in that event, the purchasing department has to justify its actions. A detailed audit trail is therefore required for all public procurements, which provides evidence in the event that procurement decisions are challenged or questioned. Officials who feel that some additional substance to the audit trail is required, for whatever reason, may refer the case to their Accounting Officer and/or to Internal Audit to verify that the procedures have been correctly conducted.

Aside from the public procurement laws, Ministers and officials are also expected to observe the Seven Principles of Public Life set out in the first report of the Nolan Committee and the requirements of the Ministerial Code and the Civil Service Code as appropriate. Any decision by Ministers to overturn a recommendation by officials on a public procurement contract would have to be fully recorded and explained in the documentation. Where officials consider that a decision cannot be defended on grounds of propriety, Government Accounting requires an Accounting Officer to seek a written instruction and to inform the Treasury and the Comptroller and Auditor General.

In the light of these considerations, we are therefore of the view that it would not be appropriate to introduce such a checking system into the procurement process. However, the Treasury will write to Departments to remind them of the above points.

I am copying this letter to Sir Nigel Crisp and to the C&AG.

Brian Glicksman
Treasury Officer of Accounts

3 March 2004

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