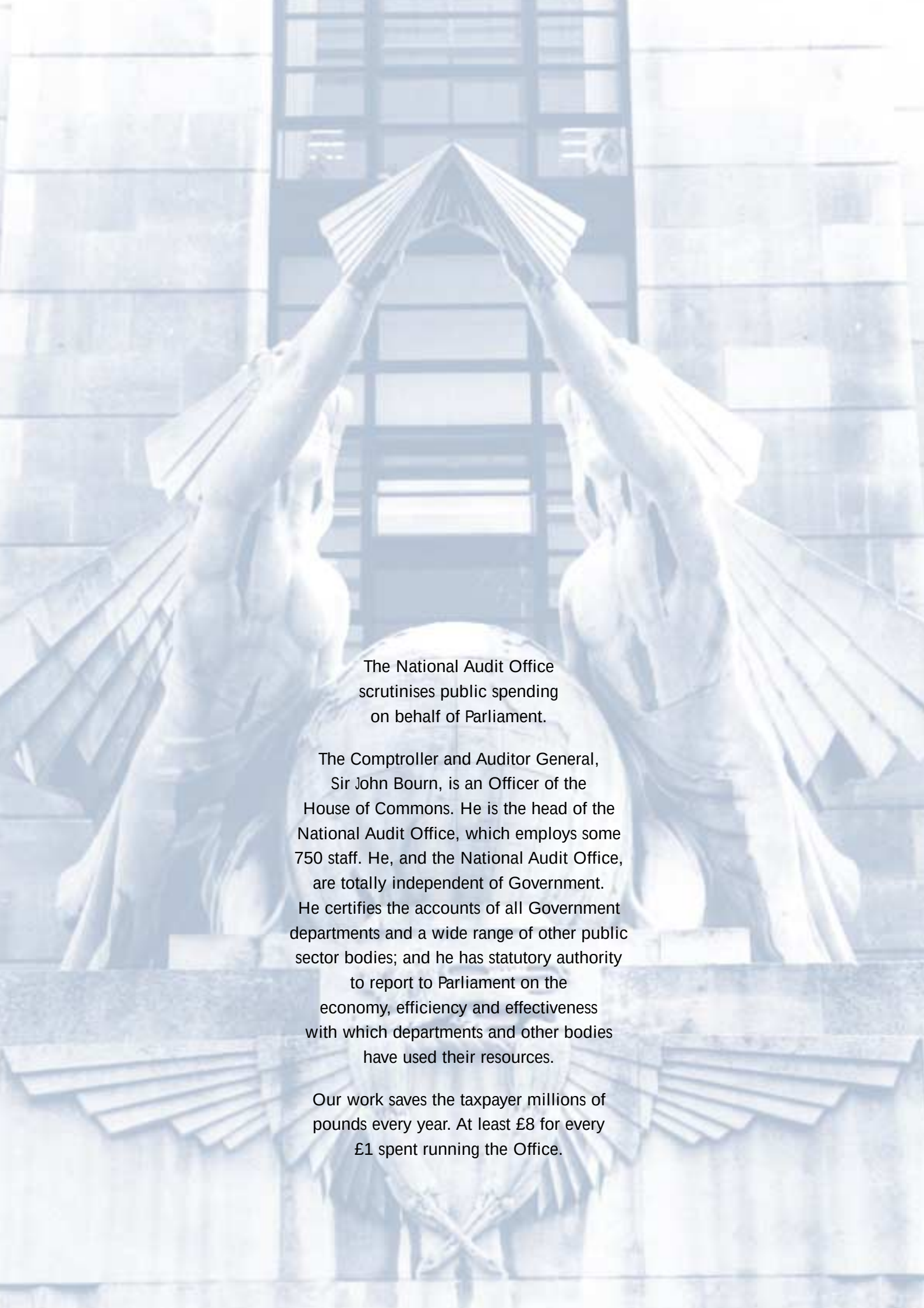
NATIONAL AUDIT OFFICE

Procurement of Vaccines by the Department of Health

REPORT BY THE COMPTROLLER AND AUDITOR GENERAL
HC 625 Session 2002-2003: 9 April 2003



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John Bourn
Comptroller and Auditor General

National Audit Office
4 April 2003

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Introduction and scope

1 From its annual budget of £54 billion (2002-03), the Department of Health (the Department) funds NHS hospital and community health services (£48 billion) and payments for family health services to General Practitioners, opticians and dentists and prescription charges (£5 billion). The remainder (£1 billion) is spent on directly funded health services (£0.7 billion) and the Department's administration (£0.3 billion).

2 Part of these funds is spent on the procurement of vaccines - in 2001-02, £195 million. Of this, the Department's national vaccine programme costs £83 million. In addition, General Practitioners purchase vaccines to meet local needs, such as the influenza vaccine for patients in 'at risk' groups. NHS trusts also purchase a limited amount of vaccine via national pharmaceutical contracts for the immunisation of staff or patients considered to be 'at risk'.

3 In April 2002, the Department contracted with PowderJect Pharmaceuticals PLC for the supply of 20 million doses of smallpox vaccine. This was a joint contract with the Ministry of Defence, costing £32.5 million excluding value added tax. The Department used the exemptions allowable under European Union (EU) regulations and the Public Supply Contracts Regulations 1995 on grounds of national security, enabling it to adopt confidential procurement procedures to purchase these supplies.

4 Following Parliamentary and media concerns about possible links between donations made by the Chief Executive of PowderJect to the Labour Party and the award of the contract, we examined the robustness of the Department's arrangements for buying vaccines (Part 3 of this report), including smallpox, within the context of their central purchasing arrangements (Part 2). Our methodology is summarised in paragraph 1.9.

5 We did not question the choice of particular strains of vaccines, since these are matters of clinical, and in case of medical countermeasures against bio-terrorism, national security judgements. Nor did we look at procurement arrangements in NHS organisations, since the Audit Commission examined procurement arrangements in acute hospital trusts in 2002, in its report *Procurement and Supply*.

On the Department's general procurement arrangements

6 The Department and the NHS Purchasing and Supply Agency (the Agency) buy goods and services under EU procurement directives. They have issued guidance to staff on procurement practices, and this incorporates key elements of guidance issued by the Office of Government Commerce on the application of EU rules, the need for competition and securing value for money.

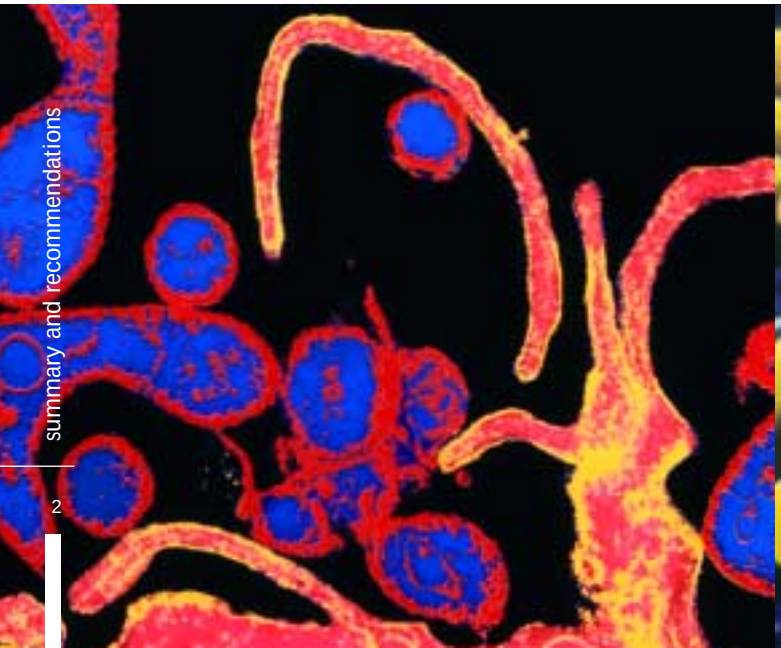
7 The Department and Agency use EU restricted procedure as the norm for most routine UK public sector procurements because it limits the number of suppliers invited to submit a full tender to those most likely to meet requirements and avoids burdening commercial suppliers with unnecessary tender costs. Sixty per cent of all public sector procurements used restricted procedures in 2001 and open procedures were used in over 20% of cases. For vaccine contracts, half followed restricted procedures and over a third open procedures.

8 The Department's procurement arrangements are highly devolved, and are currently being strengthened and improved following recommendations in 2000 from Internal Audit and in 2001 by an independent external review. They both identified areas requiring attention including better central co-ordination, ensuring consistent application of procurement practices and compliance with guidance, better resourcing of the Department's Procurement Policy Advisory Unit, and setting up effective monitoring and management information systems to provide readily available data on what was being spent with a particular supplier.

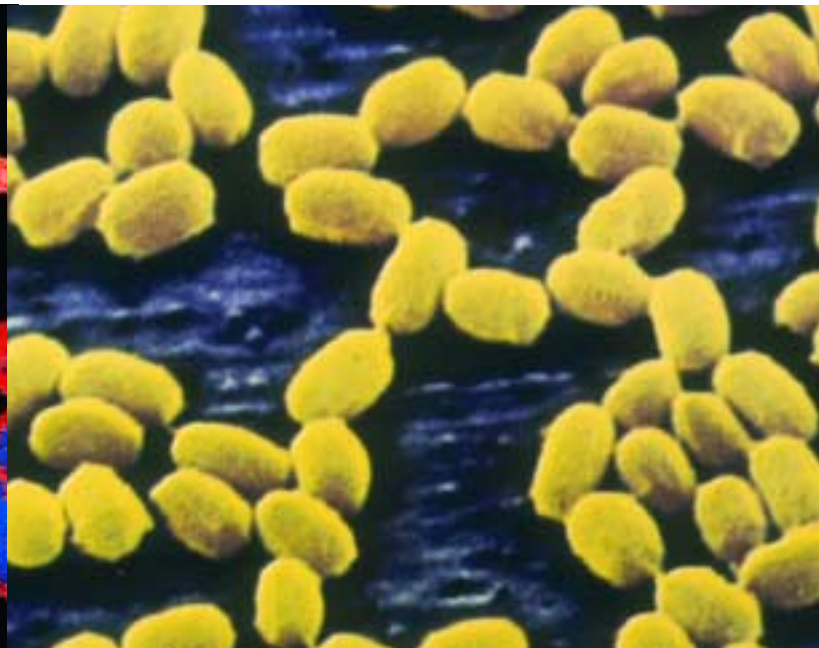
9 The external review also concluded that a more effective and better co-ordinated procurement operation should be able to achieve value for money improvements of between 2.5 and 3 per cent of the spend over which the Department has influence. This could be in the form of improved quality, or cash savings of up to £5-6 million a year on commercial spend of £200 million.

10 In October 2002, the Department commissioned a more fundamental review of its procurement arrangements. This was completed in March 2003. The Director of Finance and Investment and the Permanent Secretary are currently considering the review's recommendations on the future procurement structure, resourcing of a Commercial Division, including its relationship with the NHS, and a job and person specification of a Commercial Director.

Measles viruses



Anthrax bacteria spores



11 Given our focus on vaccine procurement, we did not examine in depth the procurement systems and arrangements in the Agency. However, the Agency has identified weaknesses in its contract management, including a lack of information routinely available on its contract portfolio and contract usage by NHS organisations, and lack of a single supply database. Consequently, the Agency is not easily able to analyse information to improve its negotiating position with major suppliers nor adequately monitor its procurement activities. The Agency is in the process of acquiring a single contract management system that will address these issues. This new system is expected to be implemented in April 2003.

On the procurement of vaccines

12 The Department buys vaccines, such as Polio and Meningitis C, for its national vaccination programme and supplies as a contingency measure to protect against suppliers failing to deliver, for example, in the case of the Influenza vaccine in 2001-02 and 2002-03. In addition, it purchases supplies to address actual or potential emergencies, such as smallpox and anthrax as countermeasures to bio-terrorism.

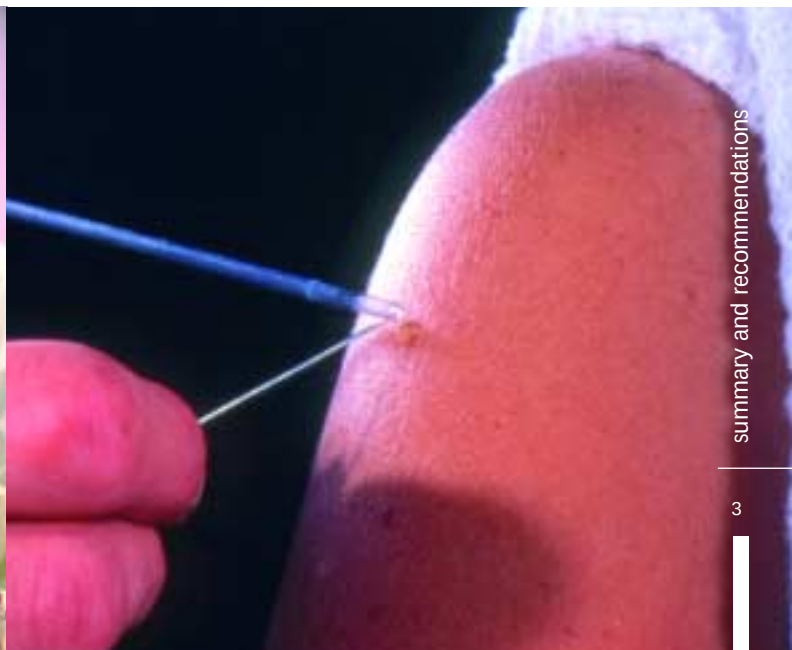
13 The Agency plays a key role in the tendering and contracting process for childhood vaccines, but the procurement of the first tranche of smallpox vaccine was arranged in-house by the Department's Communicable Disease Branch with advice provided by the Procurement Policy Advisory Unit. The Agency is, however, undertaking the procurement exercise for the second tranche of the vaccine.

14 The Joint Committee on Vaccination and Immunisation (JCVI), a Non-Departmental Public Body, advises the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation. The Committee's remit covers routine as well as specific matters and, in formulating advice and recommendations, it considers the need for and impact of vaccines, their quality and strategies to ensure maximum benefit from their most appropriate use. A sub-group of experts under the auspices of the JCVI played an important part in the decision to purchase smallpox vaccine and in the choice of the Lister strain.

PowderJect Pharmaceuticals plc laboratory

Photograph: *Courtesy of PowderJect*

Patient being given smallpox vaccination



15 For the vaccine contracts that we examined, the Department acted properly in awarding these contracts by complying with appropriate EU procurement regulations, encouraging sufficient competition and evaluating tenders fairly. The procurement arrangements for emergency supplies of smallpox vaccine were unusual as the Department chose not to adopt standard competitive procedures for national security reasons, which is allowable under EU regulations.

16 For both low dose diphtheria and anthrax vaccines, the Department holds the Market Authorisations (product licences) and the manufacturers are named on the licences. Therefore, full EU procedures, including advertisement in the Official Journal of the European Community (OJEC), were not appropriate, although the market was tested in the case of low dose diphtheria. Anthrax was purchased directly from the Centre for Applied Microbiology and Research (the executive arm of the Microbiological Research Authority, a Special Health Authority).

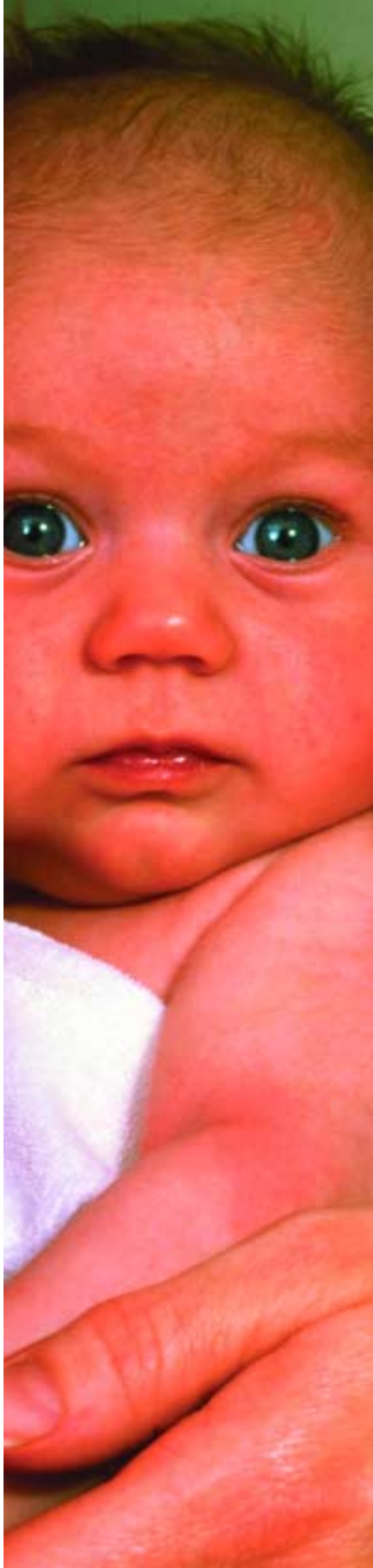
17 Generally, costs are secondary to public health and national priority issues. This is particularly the case for vaccines purchased for emergencies, for example the purchase of smallpox and anthrax vaccines, where national priorities are paramount. Submissions are made to Ministers setting out the risks to public health of not purchasing, quantities needed, costs, and funding arrangements.

18 All vaccines routinely administered in the UK are required to have a Marketing Authorisation (product licence) valid in the UK. All the vaccines we examined had this, with the exception of smallpox. All vaccines carry risks to the receipient when administered and could lead to the manufacturer being sued for damages. As the smallpox vaccine was unlicensed, the Department bore this risk by indemnifying PowderJect for up to £30 million against damages and notified the Committee of Public Accounts of this contingent liability on 26th March 2002.

19 Ensuring competition in the vaccine market is difficult in view of the limited number of suppliers resulting in few expressions of interest in each contract advertised and there is a risk of relatively higher prices as there are near monopolistic conditions for some vaccines. The main reasons for the narrow market relate to the high and increasing cost of vaccine development and production, mergers of manufacturers and the relatively low profit margins compared with other pharmaceutical products.

20 The limited number of vaccine manufacturers and the complex manufacturing process has resulted in shortages of supply of certain vaccines. For example, in the UK, shortages have been experienced for vaccines such as the Measles, Mumps and Rubella (MMR), Bacillus Calmette-Guérin (BCG), and Hib, Diphtheria, Tetanus, wholecell Pertussis (Hib/DTwP). Production problems including batch failures are common reasons. Recovery from a major batch failure may take months and, with the increasing centralisation of manufacturing, can rapidly lead to an international vaccine shortage.

21 The Department's strategy to deal with potential supply shortages has been to award contracts to more than one supplier where possible. For example, in December 2002, the Department placed a contract for the supply of the MMR vaccine with the only two suppliers with Market Authorisations (product licences) valid in the UK - Aventis Pasteur MSD and GlaxoSmithKline - to ensure continuity of supply. This prudent approach enabled supplies to be met when, due to production problems and international demand, Aventis rationed their supply to each country and the Department obtained an increased proportion of their needs from the other supplier.



On the procurement of smallpox vaccine

22 Decisions on the strain of vaccine to purchase, speed of delivery, and security of supply (a preference for a UK manufacturing company was initially stated by Ministers), together with the small number of companies operating in this market, limited the number of suppliers able to compete for this contract.

23 The choice of vaccine strain was crucial. A specially convened sub-group of experts, set up under the auspices of the JCVI, concluded that the Department should buy the Lister strain although there was no real difference between its efficacy and that of the New York City Board of Health strain. The Lister strain was chosen because it was preferred by the Ministry of Defence (MoD) on intelligence grounds, was proved to be effective in protecting people against smallpox in Africa and India in the 1970s, and was used by the Israeli military. Moreover, using a different strain from that used in the United States offered the greatest safeguard by ensuring that the alternative strain could act as a fallback.

24 The Department used the exemptions available under EU rules to conduct a confidential procurement process. It used this route so as not to reveal any UK vulnerabilities in its bio-terrorist strategy that might be valuable to potential terrorists. For example, disclosure could alarm the public at a time when there was a heightened risk of terrorism and provide terrorists with information on the number of doses being purchased and where they would be stored.

25 Nevertheless, the Department went further by seeking to establish a degree of competition by exploring with a number of companies whether they could meet its requirements. It held confidential meetings in January and February 2002 with five potential suppliers with a UK or European based manufacturing capability. In the event, only PowderJect could supply the required doses against the Department's criteria in the time-scale specified, but only through its partnership with Bavarian Nordic based in Germany. The Department signed a contract with PowderJect in April 2002.

26 The suppliers consulted told us that they considered that the procurement process was not transparent. The Department did not reveal to the companies the procurement criteria or timelines. For example, the Department did not clearly indicate that supplies were required in 2002, or that it was willing to accept an unlicensed product. Hence the prices quoted by some of the companies included licensing and clinical trial costs. Nor did the Department clearly specify that it was interested in the Lister strain only (since they used the terms "preferred" or "favoured" throughout the procurement process) and this misled them. Consequently, the suppliers felt that their proposals, at the confidential meetings and subsequently, were based on limited information on procurement criteria, timescales, scope of the contract and the strain of vaccine.

27 The Department's view is that they were consistent in the information that they provided to each company and gave as complete information as they felt able to give under the circumstances. The Department recognises that there may have been a mismatch between the information provided and the interpretation of this by the companies and this arises because of the unusual nature of this procurement as highlighted in paragraph 24.

28 The appointment of PowderJect, linked with the Department's decision not to reveal details of the procurement to the public, also raised concerns amongst some suppliers, in Parliament and the media about propriety. Donations were made by the Chief Executive and Chairman of PowderJect, Dr Paul Drayson, to the Labour Party in July 2001 and January 2002 (£50,000 each), the second of which coincided with the timing of the smallpox procurement exercise. It was

between 7 January to 18 February that officials shortlisted companies, set procurement criteria, held confidential meetings with companies, assessed the companies and prepared a submission to the Minister recommending PowderJect.

29 The officials involved, including the Deputy Chief Medical Officer, confirmed to us that they first knew of the donations on 18 February 2002 when the Minister's private office informed them having seen their submission to the Minister. It was then that the Minister's private secretary made the connection between the company recommended and recent media reports (on 17 February 2002) about the donations. This was after the procurement assessment had been completed and the supplier selected by officials. Furthermore, having been made aware of these donations, the Minister, proceeded carefully taking account of the possible sensitivities that might be associated with the award of the contract to PowderJect, required the Permanent Secretary to examine the officials' proposal. The Permanent Secretary endorsed the recommendation on the grounds that in the short-term the only source of the cell derived Lister strain smallpox vaccine in the UK was from PowderJect. The key factors in award of the contract, therefore, were the Lister strain, speed of delivery and national security issues.

30 Although price was not the key criteria in the Department's decision to appoint PowderJect, PowderJect did offer one of the lowest quotes. However, each supplier's quote was different in terms of vaccine strain and type and the elements of costs included. Prices were therefore not directly comparable.

31 For the second procurement exercise, announced in October 2002, the Department used the normal EU restricted procedure, because it considered that this could be done without compromising national security, the procurement of supplies was less urgent, and wanted a more transparent process. Five companies expressed an interest and all were invited to tender. Three bids were received on 1 April 2003, the deadline for submissions.

Recommendations

32 The Department should:

(i) give greater priority to strengthening its general procurement arrangements. Addressing the concerns raised by Internal Audit in 2000 and the external review in 2001, would improve compliance with good practice, put in place effective monitoring arrangements and enable the early identification of emerging problems, improve central management and information systems and offer the prospect of significant financial savings.

(ii) look at ways, such as its website, to make more widely available the process of vaccine procurement and the criteria required for contract award. EU Directives prohibit discriminatory specifications, which would include the obligation to issue invitations to, and consider offers from, suppliers in other Member States. Information on the procurement process is already available publicly via OJEC but this is unlikely to be readily available to members of the public who want information on how the Department obtains vaccines for routine use.

(iii) develop protocols in relation to procurements addressing specific threats, including guidance specifying when the national security over-ride should be considered. This would increase public and supplier confidence in the Department's arrangements and introduce greater transparency.

(iv) consider the need for a more proactive approach, including a long-term strategy, to address the threat of supply shortages for some vaccines given the limited and continuously decreasing vaccine market, to minimise disruption to immunisation programmes and the public health consequences.

Part 1

Background and introduction

1.1 The Department of Health (the Department) has an annual budget of £54 billion (2002-03). The majority funds NHS hospital and community health services (£48 billion) and payments for family health services to General Practitioners, opticians and dentists and prescription charges (£5 billion). The remainder (£1 billion) is spent on directly funded health services (£0.7 billion) and the Department's administration (£0.3 billion).

Each year, the NHS in England spends over £13 billion on goods and services procured from the private sector

1.2 Of the total annual expenditure, the NHS spends over £13 billion on goods and services, ranging from complex medical diagnostic equipment to examination gloves and stationery. The majority is spent by NHS organisations, mainly NHS acute trusts. They deal directly with suppliers for most of their procurement, but some purchases are through 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 (EU) regulations and economies of scale. The Department also uses the Agency to procure vaccines as part of its routine vaccination programme. The Agency manages some 3,000 national contracts and currently influences around £4.8 billion (37% of total procurement expenditure) of NHS expenditure on commercial procurement each year **(Annex A)**.

1.3 The Department itself spends some £367 million a year on commercial contracts and deals with around 1,700 suppliers.

Each year the Department and the NHS in England spend some £195 million on routine vaccine procurement

1.4 In 2001-02, total expenditure on vaccine procurement was £195 million. Of this, the Department's national vaccine programme costs £83 million. In addition, General Practitioners purchased vaccines to meet local needs, such as the influenza vaccine for patients in 'at risk' groups. NHS trusts also purchased a limited amount of vaccine via national pharmaceutical contracts for the immunisation of staff or patients considered to be 'at risk', **Figure 1**.

1 Expenditure on vaccines, 2001-02

	Total value (£ million)
Department of Health national programme	83
NHS acute trusts	2
General Practitioners (excluding private prescriptions)	110
Total	**195**

Source: Department of Health; NHS Logistics; and Prescription Pricing Authority

We studied the Department's procurement procedures for vaccines, following concerns in Parliament and the media about the arrangements for buying doses of smallpox vaccine in 2002-03

1.5 In April 2002, the Department contracted with PowderJect Pharmaceuticals PLC for the supply of 20 million doses of smallpox vaccine. This was a joint contract with the Ministry of Defence and the contract value was £32.5 million excluding value added tax. The Department used the exemptions allowable under EU procurement regulations and the Public Supply Contracts Regulations 1995 on grounds of national security, enabling it to use confidential procedures to purchase this vaccine.

1.6 Following Parliamentary and media concerns about possible links between the Chief Executive of PowderJect's donations to the Labour Party and the award of the contract, we examined whether the Department acted properly in awarding this contract to PowderJect. Furthermore, we examined the robustness of the Department's arrangements for the purchase of vaccines (Part 3 of this report), within the context of their central purchasing arrangements (Part 2). This included whether there was compliance with statutory competition and EU procurement regulations.

1.7 We did not question the choice of particular strains of vaccines, since these are matters of clinical, and in some cases, national security judgements. Nor did we look at procurement arrangements in NHS organisations, since the Audit Commission examined procurement arrangements in acute hospital trusts in 2002, in its report *Procurement and Supply*.

1.8 Finally, we did not examine the purchase of travel vaccines because, although they are part of the Department's national immunisation policy, they are not part of the centrally funded childhood programme and, therefore, the vaccines are not procured centrally.

Methodology

1.9 We used a variety of methods to examine these issues. We:

- Interviewed key personnel in the Department and the Agency responsible for procurement policy and arrangements, vaccine policy, and public health issues. At the Agency we also held discussions with key buyers.
- Examined other reports on the Department's procurement procedures.
- Developed, using EU and Treasury procurement rules, criteria for assessing vaccine procurement contracts, and tested all current vaccine contracts against these criteria, based on file examination at the Department and the Agency.
- Consulted all five companies short-listed for the smallpox procurement, and held face to face discussions with PowderJect Pharmaceuticals and Acambis, regarding their views of the Department's procurement procedures, particularly in the context of the smallpox vaccine contract.

Part 2

General procurement arrangements

2.1 The Department's policy, as set out in the document *Procurement Management Policy 2002*, is to be scrupulously fair in all its dealings with suppliers, to use best practice and to continuously seek to achieve better value for money. This part of our report reviews the procurement procedures used by the Department and by the Agency when contracting on its behalf.

Purchasing by the Department and the NHS Purchasing and Supply Agency is subject to detailed rules and guidance, including Treasury Guidance and EU Directives

2.2 The EEC Treaty requires fair and open competition between member states in the pursuit of trade. EU procurement directives set out the requirements for all large value procurements of works, supplies and services to be acquired through competition to ensure best value for money, openness, transparency, equal chances for all irrespective of nationality and non-discriminatory specifications. The directives have been brought into UK law via statutory instruments, the most relevant of which is the Public Supply Contracts Regulations 1995, and have been incorporated into the Office of Government Commerce's, guidance on procurement practices[1], applicable across all government departments. Breaches of EU directives are actionable in law.

2.3 Both the Department and the Agency issue their own guidance to staff involved in procurement, which incorporates the key elements of the Treasury guidance on the application of EU procurement rules. The Agency also provides guidance to NHS staff involved in procurement.

2.4 EU regulations require that contracts with values above specified thresholds must be advertised in the Official Journal of the European Community (OJEC), unless exemption clauses apply, for example, for reasons of national security, **Figure 2**. The exemption clauses are framed in general rather than specific terms in the EU regulations, Treasury guidance, and the Public Supply Contracts Regulations 1995, leaving what falls within national security open to interpretation.

2 EC Procurement Thresholds for the public sector from 1 January 2002

	Supplies	Services	Works
Entities listed in Schedule 1 (S.I. 1995/201)[1]	£100,410	£100,410[2]	£3,861,932
Other public sector contracting authorities	£154,477	£154,477[2]	£3,861,932[3]
Indicative Notices	£464,024	£464,024	£3,861,932[3]
Small Lots	Not applicable	£49,496	£618,698

NOTES

1. Schedule 1 of the Public Supply Contracts Regulations 1995 lists central government bodies subject to the World Trade Organisation's Government Procurement Agreement. These thresholds will also apply to any successor bodies.
2. Some services have a threshold of £123,740, such as Research & Development Services (Category 8) and Television and Radio Broadcast services.
3. For subsidised works contracts under regulation 23 of the Public Works Contracts Regulations 1991 the threshold is £3,093,491.

1 The procurement guidance is commonly known as the Central Unit on Procurement - CUP guidance.

3 European procurement rules and their application

Procedure	Key milestones	Key features and when applicable
Open	Allow 52 days from the advert to the submission of tenders. (36 days if a prior indication notice has been published).	All respondents to the advert may submit a tender. All tenders submitted before the closing date must be fully evaluated by the purchaser. Open procedures provide the purchaser with the opportunity to test markets where there are a limited number of known suppliers and the contract specification is straightforward.
Restricted	Allow 37 days for applicants to register an interest. Allow 40 days from the issue of tender documents to the submission of completed tenders. (26 days if a prior indication notice has been published).	Enables the purchaser to select preferred bidders from contractors registering an interest, based on an assessment of the capacity of the respondent to meet the contract specification. Both the Department of Health and the Agency routinely use restricted procedures.
Negotiated	Allow 37 days for applicants to register an interest. No deadline is required for submission of completed tenders.	Negotiated procedures **with a call for competition** (requires an OJEC advert and the purchaser is required to negotiate with at least 3 bidders) may be used when the nature of the purchase does not permit overall pricing or when specifications cannot be drawn up with sufficient precision to permit the use of open or restricted procedures. Negotiated procedures **without a call for competition** (does not require an OJEC advert or negotiation with a specified number of bidders as above) are permitted for technical or artistic reasons or for the protection of exclusive rights pertaining to the contractor. Negotiated procedures enable the purchaser to ensure that their requirements are fully understood and can be met by the supplier and generally means the supplier is potentially in a strong bargaining position. Procedures must be justified by the buyer and approved by a senior member of staff in accordance with the Department of Health's or the Agency's scheme of delegation.
Accelerated	A prior indication notice must have been placed in OJEC giving potential suppliers advance notice of the purchasing organisations broad requirements. Allow 15 days for applicants to register an interest. Allow 10 days from the issue of tender documents to the return of completed tenders.	Applicable where there is genuine urgency as a consequence of circumstances outside the purchaser's control. The Agency routinely places prior indication notices, the Department of Health does not. Procedures must be justified by the buyer and approved by a senior member of staff in accordance with the purchasing organisation's scheme of delegation.

Source: The Department of Health, CUP guidance and NAO

2.5 **Figure 3** sets out the procedures to be followed under EU procurement rules, the circumstances where these are appropriate and the key milestones and features.

2.6 Neither the Department nor the Agency currently routinely analyse information on the number of times they use each of the different procurement procedures. Both the Department and the Agency told us that the restricted procedure is the norm in the public sector, used in 60 per cent of cases, because it limits the number of suppliers invited to submit a full tender to those most likely to meet requirements and avoids burdening commercial suppliers with unnecessary tender costs. Open procedures are used in 22 per cent of procurements, 12 per cent use negotiated procedures, and 6 per cent accelerated. **Case study A** illustrates the key features of the restricted process and **Case study B** the open process.

Case study A - National Joint Registry contract using EU Restricted Procedures

Background

This contract is for the development of a database of hip and knee joint replacement operations. The benefits are expected to include better monitoring of implanted prostheses, and earlier identification of those that perform poorly. The development of the Registry follows recommendations made by the National Audit Office *(HC 417)* and the Committee of Public Accounts *(HC 513, Session 1999-2000)* in their reports on "Hip Replacements: Getting it right first time" in 2000.

The contract is divided into four stages:

- developing an IT based solution to the collection and analysis of activity data surrounding hip and knee joint replacements;
- establishing the operations, systems and processes concerned with the Registry;
- the management of the Registry, collection of levies imposed on Trusts but paid to Association of British Health Industries manufacturers and the provision of secretariat support to the NJR Steering Committee; and,
- the management of the Registry including the transfer of services when the contract expires.

This is a new contract let for a period of two and a half years with the option to extend by 15 months. The tender submitted by the successful bidder was for £3.9m.

The procurement timetable

15 February 2002 - date advertised in the Official Journal of the European Community

26 March 2002 - deadline for the return of expressions of interest from the advert

30 April 2002 - invitations to tender issued to contractors

28 June 2002 - deadline for the return of tender documents

16 September 2002 - award of contract

16 September 2002 - commencement of the contract

The EU procurement timetable was met.

The procurement process

Eight contractors out of the 30 expressing interest were invited to tender. They were selected on the basis of their financial standing and demonstrable ability to meet the contract specification. Discussions regarding this initial selection took place between interested policy leads and was overseen by members of the Policy Procurement Advisory Unit and the head of performance management for the specialist health services' Corporate Development Team.

Four suppliers submitted a bid. The evaluation involved scoring each one against pre-determined criteria. The tender evaluation panel consisted of policy leads overseen by the Corporate Development Team. The contract was awarded to the supplier who, while not the cheapest bidder, was considered to have put in the best bid overall to ensure the success of the Registry. The Parliamentary Under-Secretary of State (Lords) ratified the award on 12 September 2002.

Case study B - Purchase of the influenza vaccine for contingency stock using EU Open Procedures

Background

Influenza immunisation has been part of the national public health programme since the late 1960s. The vaccine is purchased directly from suppliers by General Practitioners to meet local needs. However, demand is unpredictable and increases in response to public speculation about the illness. Demand can, therefore, sometimes exceed supply. Also, as the manufacture of the vaccine is complex, manufacturers are not able to respond to unexpected demands at short notice. Delays in delivery of the vaccine to GPs were experienced in 2000-01.

Against this background, in 2001-02 and 2002-03, the Department decided to purchase contingency stocks in case any supplier had serious manufacturing problems that would result in the vaccine being unavailable for the season rather than just delayed. We examined the tendering of the 2002-03 contract.

The procurement timetable

- 10 June 2002 - date advertised in the Official Journal of the European Community
- 17 June 2002 - deadline for the return of expressions of interest from the advert
- 3 July 2002 - invitations to tender issued to contractors
- 6 August 2002 - deadline for the return of tender documents
- 9 September 2002 - award of contract
- 1 September 2002 - commencement of the contract

The EU procurement timetable was met.

Procurement process

The contract, valued at £1.2 million, was for one year, with delivery required in September 2002 for the winter campaign. EU open procedures were followed. Six suppliers responded to the OJEC advert and 5 tendered. The evaluation criteria included availability, quantity, and timescales for delivering the vaccines and price. Prices quoted varied depending on the quantity the suppliers could manufacture (the larger the quantity the lower the price-economies of scale). The contract was split between three suppliers and awarded on the basis of how quickly delivery could be made, cost and the desire to avoid supply failures. The three suppliers chosen best met these criteria.

The Department of Health is implementing improvements in its procurement procedures to ensure compliance with its guidance and improve oversight, but progress has been patchy and this may put corporate governance and value for money at risk

2.7 Procurement arrangements within the Department are highly devolved and there are many different players **(Annex B)**. Overall responsibility lies with the **Director of Corporate Affairs** and day to day responsibility is devolved to business units within the Department's 11 Directorates. Procurement activity within each business unit is supported by directorate based **Corporate Development Teams** (formed in November 2001), many of which are still developing their procurement role.

2.8 The **Procurement Policy Advisory Unit**, within the Department's Information Services Group, disseminates procurement policy and best practice and also provides direct support to business units on major procurement exercises. The Unit has to be involved when procurements over £50,000 are set up but thereafter, and for lower value procurements, usually has no involvement.

2.9 The **Business Unit** for vaccines is the policy team responsible for immunisation and communicable disease. The team does not usually procure vaccines itself, although there are a few exceptions. Vaccine procurement is normally undertaken by the Agency on behalf of the Department and financial and logistical matters emanating from vaccines procurements are the responsibility of the **NHS Logistics Authority**.

2.10 The Department's procurement guidance is held electronically on the intranet, but compliance by staff is not routinely monitored by the Procurement Policy Advisory Unit. In 2000, the Department's Internal Audit Unit carried out a comprehensive review of contracts and found significant weaknesses in the Department's procurement strategy, performance management and contract management procedures. Internal Audit could not provide the Department with assurance that proper control was being exercised in the formation and management of contracts, or that value for money was being achieved. Their recommendations are in **Figure 4**, and **Annex C**.

2.11 The Agency has adapted its own guidance for use by NHS Trusts and made this available via its website, but compliance is not mandatory.

4 Key recommendations of the Department's Internal Audit Report, 2000

- **Departmental Policy, Control and Guidance -** Procurement Policy Advisory Unit or the Department's solicitors should maintain a central register of all contracts; the Department should strengthen strategic management and provision of expert advice to managers; and, identify appropriate training programmes for all relevant staff.
- **Contract management and documentation -** Guidance: should be available on how to prepare business cases, appraise options and draft specifications in an easily accessible form; should emphasise EC constraints, allowing managers to highlight the associated implications in their business cases, such as how to deal with Ministerial priorities; Standard conditions should be strengthened; and, should include administrative instructions, together with proformae, and post-contract award management systems.
- **Potential suppliers, Competition and Value for Money -** Guidance: should highlight the need to consider the financial stability/track record of potential tenderers; state the requirement for a review of tenders against pre-determined tolerance levels to be considered; stipulate that tenderers chosen for contract awards should be required to prove their financial stability; and, stress the importance of tender document retention as evidence of an adequate management trail.

Source: Internal Audit Review: Department of Health procurement - the formation of associated contracts and decentralised contract management, 2000

2.12 The Department commissioned an independent external review of the Department's procurement arrangements, which reported in May 2001, and largely endorsed the devolved structure[2]. However, the review also repeated many of the weaknesses previously highlighted by Internal Audit in the implementation of best practice, policy and procedures. The main findings were:

- General procurement practices and compliance with guidance issued by the Department were variable depending on the importance and interest attached to them by local management. Deficiencies had repeatedly been found by Internal Audit (1997, 1998, 1999 and 2000).
- The Procurement Policy Advisory Unit was under-resourced and its approach to procurement, and the role and authority afforded to it was at variance with other major government departments. For example, the Unit had not been able to introduce management information 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.
- Closer liaison was required with the Agency to ensure that procurements that started in the Department and transferred to the NHS for execution were fully supported at all stages.

2.13 A summary of the external review's recommendations and progress made are at **Annex D**. Three key recommendations were implemented but progress has been slow:

- **The role of Procurement Policy Advisory Unit should be enhanced and expanded to raise awareness, improve and monitor procurement practice, and drive forward the e-commerce agenda within the Department.** The review recognised that the Unit did not have sufficient resources to meet its existing commitments and that interim measures would be required before its role could be developed further. The Department has attempted to boost staff numbers, with limited success. It restructured the Unit into two teams, one to provide support to business units on major procurements and the other to develop and oversee the implementation of the procurement management policy and implement the Government's e-commerce agenda. Staff shortages have meant that the focus has been on supporting business units rather than on addressing longer term issues.
- **The Department should accredit business units' procurement activities** whereby they are permitted to operate within defined parameters depending on their level of expertise. A pilot exercise was completed in June 2002.
- **The Department should produce and implement a procurement management policy.** A policy was produced and approved by the Department's Management Board. It was issued to Directors and Corporate Development Teams in February 2002 and placed on the Department's intranet. But implementation has been slow. For example, the policy requires the Unit to prepare an annual report on the Department's procurement performance but it has so far been unable to do so, in part due to the staff shortages and weaknesses in management information systems.

2 *The review, Department of Health: Procurement Review, May 2001 was conducted by a consultant recommended by the Office of Government Commerce. The Deputy Chief Executive of the Office of Government Commerce was on the Steering Group for this review.*

2.14 The external review also pointed out that one of the key benefits of an enhanced Procurement Policy Advisory Unit would be better value for money. In their view, a more effective and better co-ordinated procurement operation across the Department should be able to achieve value for money improvements of between 2.5 and 3 per cent of the spend over which they have influence. This could be in the form of an improvement in quality or cash savings of up to £5-6 million a year based on the estimated commercial spend at the time of the review, which was £200 million.

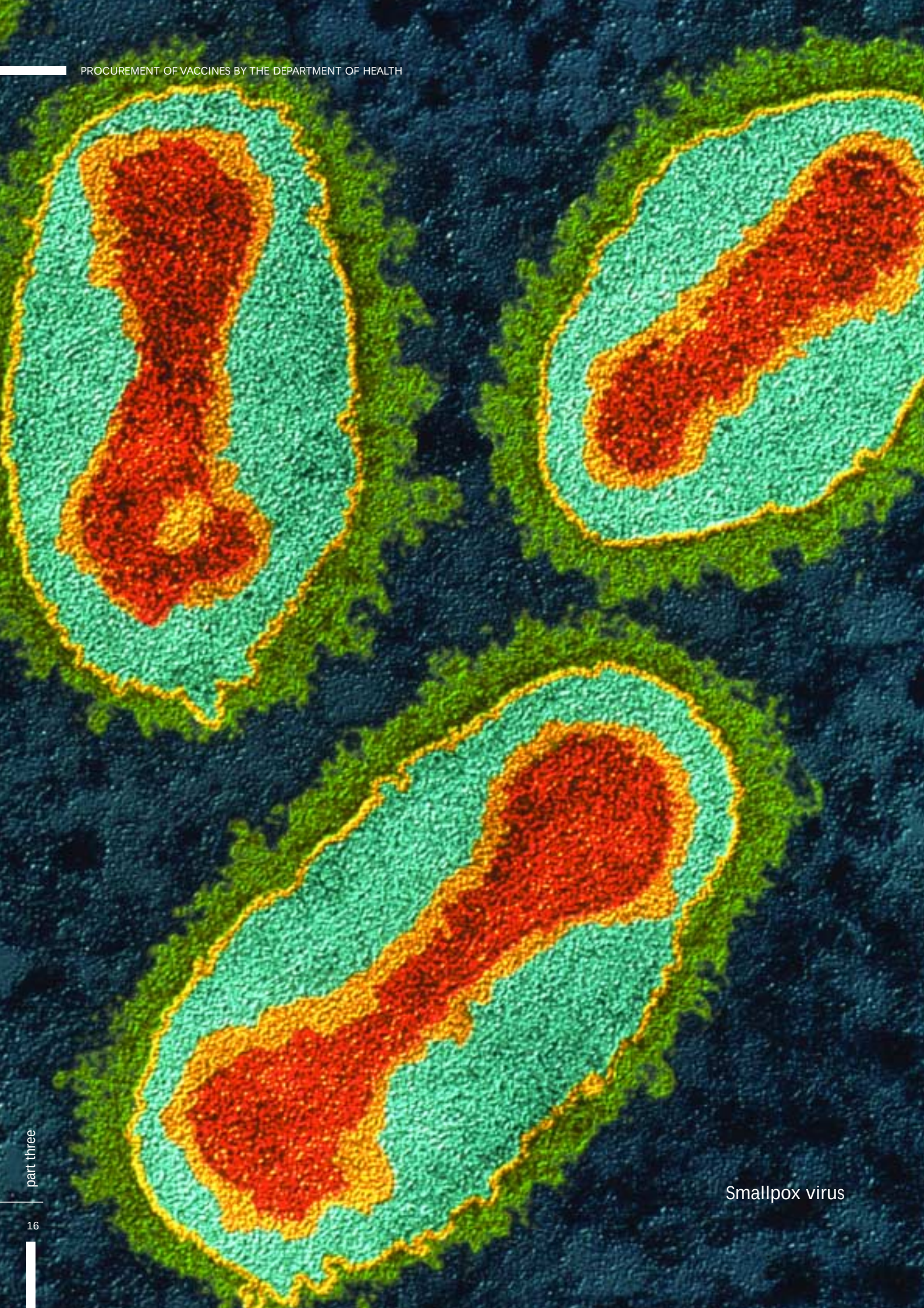
2.15 In October 2002, the Department commissioned the Deputy Chief Executive of the OGC to lead a review of its commercial and procurement activities in its support to the NHS. Recommendations for the future procurement structure, resourcing of a Commercial Division, including its relationship with the NHS, and a job and person specification of a Commercial Director were made to the Director of Finance and Investment and the Permanent Secretary in March 2003 for them to consider.

2.16 The Department also plans to improve management information on contracts as part of the implementation of a new financial and business management system due to be established on 1 April 2004.

2.17 Given our focus on vaccine procurement, we did not examine in depth the procurement systems and arrangements in the Agency for other areas of procurement activity. However, the Agency has identified weaknesses in its contract management arrangements, including a lack of :

- Information routinely available on its contract portfolio; and contract usage by NHS organisations, as data supplied by private sector contractors is variable;
- One supplier database. Buyers maintain their own supplier databases and the Agency is not easily able to analyse supplier information which in some cases could improve its negotiating position with major suppliers;
- An adequate monitoring system to identify potential instances of non-compliance with procurement rules while procurements are in progress. However, files are reviewed on an ad hoc basis to check compliance with EU procurement rules and Agency guidance.

2.18 The Agency is in the process of improving its procedures through the introduction of a single contract management system that will address the weaknesses outlined above. It plans to implement this by April 2003.



Smallpox virus

Part 3

Procurement of vaccines

3.1 This part of our report examines the Department's procurement of vaccines as part of its national immunisation programme and for emergencies and contingency.

As well as buying vaccines within a national vaccination programme, the Department purchases supplies as a contingency measure and to address actual or potential emergencies

3.2 The Department is responsible for determining the need for vaccines and strategies for its childhood and other immunisation programmes. The Department's Communicable Disease Branch develops vaccine policy and programmes of immunisation **(Figure 5)**, which are set out in the publication *Immunisation against Infectious Disease, 1996*[3] (the Green Book), currently being updated. This covers all types of vaccines, including those not included in the national immunisation programme. Revisions to policy and the programme of vaccination are announced in Chief Medical Officer letters.

3.3 As well as buying for the national vaccination programme, the Department buys vaccines for contingency and emergency use:

- **Influenza**[4]- Contingency supplies have been held for the last two years (2001-02 and 2002-03) in case manufacturers failed to supply on time, thereby causing delays to the national influenza programme, or to supply sufficient quantities to meet unexpected need.
- **Smallpox**[5] - New supplies were procured in 2002 as a countermeasure to a deliberate release of the disease (bio-terrorism) following the events of 11 September 2001 in the United States. And a further procurement exercise was announced in October 2002.
- **Anthrax**[6] - Additional supplies were procured in 2002 as a countermeasure to bio-terrorism.

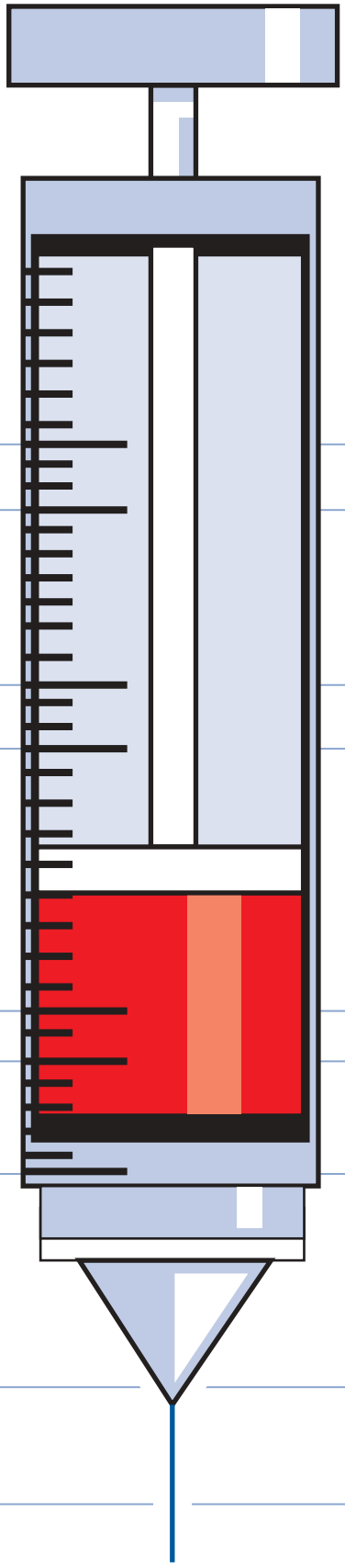
3.4 The Joint Committee on Vaccination and Immunisation has a responsibility to advise the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation. Its remit covers routine as well specific matters and, in formulating advice and recommendations, it considers the need for and impact of vaccines, their quality and strategies to ensure maximum benefit from their most appropriate use.

Procurement is undertaken within an agreed strategy, based on business cases developed when circumstances change or there is new medical evidence

3.5 Public health policies drive the need to purchase types and strains. Where policies or objectives remain unchanged and there are no changes in supply or availability of routine vaccines, business cases for the procurement of vaccines, including risk and cost-benefit analysis, are not routinely undertaken prior to each re-tendering exercise. National policy regarding continued use of most routine vaccines has been reviewed in the last three years usually by the Joint Committee on Vaccination and Immunisation.

3 *The Chapter on Meningococcal vaccines was updated in 1999, when a new policy was introduced and other policy changes have been announced in Chief Medical Officer letters.*
4 *See Glossary, page 33.*
5 *See Glossary, page 33.*
6 *See Glossary, page 33.*

5 The Department of Health's immunisation programme



National Childhood Programme	
Polio Haemophilus influenzae type b, Diphtheria, Tetanus, wholecell Pertussis, (Hib/DTwP) Meningitis C	Two, three and four months old
Measles, Mumps and Rubella (MMR)	Around 13 months old
Polio Diptheria, Tetanus and acellular Pertussis (DTaP) Measles, Mumps and Rubella (MMR)	Three to five year olds (pre-school)
BCG and Tuberculin (for skin testing)	10 to 14 year olds (and sometimes shortly after birth)
Tetanus and low dose diphtheria (Td), Polio	13 to 18 year olds
Contingency and at risk immunisation	
Hepatitis B	Those at risk
Pneumococcal	Those at risk
Influenza	For 65 year olds and over - and at risk groups of all ages (respitory, asthma, heart disease, renal disease, diabetes, and immunosuppression)
Emergency vaccines	
Smallpox	Emergency stocks for use in event of terrorist attacks
Anthrax	For those at risk due to their occupation and emergency stocks for use in event of terrorist attacks

NOTE

See Glossary, Page 33, for desciption of diseases

Source: Department of Health

Case study C - The decision-making process for the need and strain of the smallpox vaccine

Although smallpox was eradicated from the world in the 1970s, the UK, like other countries, holds a contingency stockpile of the vaccine (over 4 million doses of calf skin derived Elstree Lister). Following the events of 11 September 2001, the Department reviewed their ability to deal with terrorist attacks, including biological terrorism and convened a sub-group of experts, under the auspices of the JCVI, to discuss smallpox issues. At its first meeting on 27 September, the sub-group concluded that:

- Existing stockpiles were inadequate to provide the full population with protection in the event that this might be needed;
- Application with bifurcated needles would increase available stocks four-fold but this was still insufficient for the whole population;
- The existing stock, although still potent, was past its expiry date (30 years old) and no longer licensed but was suitable for use in an emergency situation;
- There was an immediate need to identify other potential sources of smallpox vaccine; and,
- In the longer term a completely new vaccine should be developed that would also be capable of being licensed.

At its second meeting on 30 September, the sub-group considered the appropriate strain to purchase. It concluded:

- There was no real difference in efficacy between the Lister strain and the New York City Board of Health (NYCBH) strain chosen by the US;
- A final decision would involve availability, licence and cost; and,
- Using a different strain from that used in the US, and one in use by the Israeli military, offered the greatest safeguard if difficulties arose with the production of either strain ensuring that the alternative strain could act as a fallback.

Subsequently, the sub-group recommended the Lister strain.

On 18 December 2001, the Department and MoD officials met and agreed that the Lister strain should be pursued based on the UK's experience in the past, its provenance as an effective vaccine strain, and the MoD's strong preference. On the same day, following discussions with the Minister, the Deputy Chief Medical Officer gave officials the go ahead to begin talks with potential suppliers on their ability to meet the Department's needs.

The Department outlined to Ministers on 18 February 2002 its recommendations to purchase the Lister strain, its short and long term procurement strategies, and its assessment of potential suppliers. The Minister subsequently challenged the choice of the Lister strain over the NYCBH strain. However, following further submissions, the Minister approved the Department's strategy on 5 March 2002.

3.6 Detailed cost-benefit analysis is undertaken prior to introducing a new vaccination programme, for example the Meningitis C vaccine programme in 1999, or when there are major changes to the programme, for example, the introduction of Diphtheria, Tetanus and acellular Pertussis vaccines in the pre-school booster immunisation programme in 2001. These are prepared to help justify additional funds.

3.7 Generally, costs are secondary to public health and national priority issues. This is particularly the case with regard to vaccines purchased for emergencies where national priorities are paramount. In these cases, submissions were made to Ministers setting out the risks to public health of not purchasing, the quantities needed, costs, and funding arrangements.

3.8 We looked at the adequacy of the Department's policy making process, using the example of the new Meningitis C vaccination programme, in our report Modern Policy-Making: Ensuring Policies Deliver Value for Money, 2001, (HC 289 Session 2001- 02). We concluded that the policy was developed and delivered satisfactorily.

3.9 **Case study C** provides another example of decision-making. It shows that a sub-group, convened under the auspices of the Joint Committee on Vaccination and Immunisation, played an important part in the decision to purchase smallpox vaccine and in the choice of the Lister strain.

6 Key players and their responsibilities within the vaccine procurement process

The Department of Health

PH6, the business unit within the Department with responsibility for immunisation and communicable diseases:

- policy responsibility for immunisation
- co-ordination of NHS Purchasing and Supply Agency and NHS Logistics in relation to vaccine contract activity
- budget holder for vaccine purchase and supply
- purchase and supply of other contingency pharmaceuticals for public health use

Joint Committee on Vaccination and Immunisation

- Non-departmental public body (NDPB)
- Considers the need for and impact of vaccines, their quality and immunisation strategies
- Makes recommendations to UK Health Ministers

NHS Purchasing and Supply Agency

The Agency with responsibility for vaccine procurement on behalf of the Department:

- tenders contracts
- stock control and monitoring of delivery schedules
- management and monitoring of contracted vaccine suppliers
- communication on supply with end users in the NHS

NHS Trusts

Purchase own supplies of adult vaccines

General Practitioners

Purchase own supplies of adult and travel vaccines direct from suppliers

NHS Logistics

The Authority with responsibility for financial and logistical matters emanating from vaccine procurement:

- financial administration of goods and services
- financial reporting to the Department on stocks and cash for resource accounting and audit
- financial forecasting for budgetary planning and management

Contractors for storage & distribution (Farillon for childhood vaccines)

Cold storage and distribution of vaccines

Source: Department of Health; National Audit Office research

3.10 Once the Department has established a need for a particular vaccination programme, it arranges for the purchase of vaccines through a series of agencies. The Purchasing and Supply Agency plays a key role in the tendering process for childhood, contingency and at risk vaccines. The respective roles of the various agencies are outlined in **Figure 6.**

Vaccine procurement is subject to the Department of Health's general procurement procedures

3.11 We examined 18 recently let vaccine contracts against assessment criteria agreed with the Department. With the exception of smallpox and anthrax vaccines, contracts were arranged by the Agency and the procurements were subject to general procurement rules described in Part 2. In the following paragraphs we summarise our findings under key criteria. **Annex E** shows our findings on each procurement.

Childhood, contingency and at risk vaccine procurements complied with EU procurement rules

3.12 All childhood, contingency and at risk vaccine procurements were subject to EU procurement rules. We found that the contracting procedures for these procurements complied with the rules and were advertised in the Official Journal of the European Community (OJEC). Open or restricted procedures were followed in the majority of cases, **Figure 7**.

Emergency vaccine procurement procedures were different

3.13 Full EU procedures, including advertisement in OJEC, were not appropriate for the anthrax vaccine because the Department itself holds the Marketing Authorisation (product licence) for this vaccine. The licence relates to one specific manufacturer, the Centre for Applied Microbiology and Research (the executive arm of the Microbiological Research Authority, a Special Health Authority). The vaccine was purchased under a Service Level Agreement **(Case study D)**. The US is the only other producer of this vaccine worldwide, although the type of strain is slightly different, and produced specifically for use by the US military.

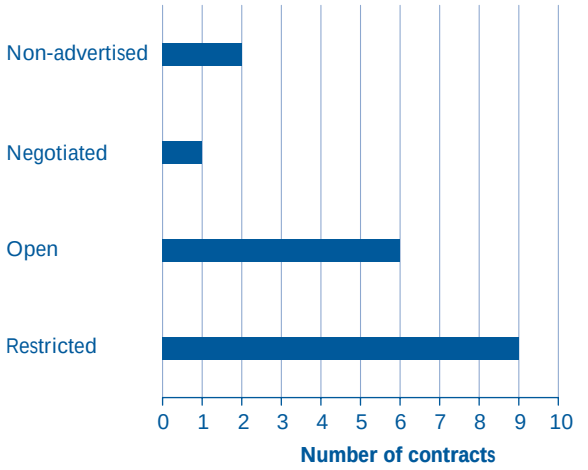
3.14 For the purchase of the first tranche of smallpox vaccine in 2002, the Department used the exemptions allowable under the EU rules for reasons of national security **(Case study E)**.

Case study D - Anthrax vaccine was purchased from the only manufacturer of this vaccine in the UK

Anthrax vaccine is supplied by the NHS only to those at occupational risk of the disease. The vaccine is produced by the Centre for Applied Microbiology and Research (CAMR). In January 2002, the Department asked CAMR to supply anthrax vaccine for emergency stockpiles as a countermeasure to possible bio-terrorist attacks, at a cost of £5 million. The Department intends to purchase further quantities over the next two years with the aim of substantially increasing stocks.

The contract was placed by single tender, under a Service Level Agreement. The Department did not negotiate on price. Following September 11, CAMR has received enquiries about supplying other countries including the US Department of Defence who want to enhance their stocks.

7 Types of tender procedures followed for vaccine contracts



Source: NAO examination

Case study E - In purchasing the first tranche of smallpox vaccine in April 2002, the Department used the exemption under EU rules on the grounds that it was necessary to protect the basic interests of the security of the UK

The decision to purchase up to date stocks of smallpox vaccine was taken on 18 December 2001 as a means of strengthening the UK capability against possible biological terrorist attacks. The Department decided to use confidential procurement procedures, as allowed for under EU rules for reasons of national security. The Department's solicitors advised that the exemption under the Public Supply Contracts Regulations 1995 (Regulation 6(c)) was appropriate.

The relevant EU exemption regulation was Article 223.1(b) of the EEC treaty (measures necessary for the protection of the essential interests of a Member State's security which are connected with the production of, amongst other things, countermeasures to biological agents). The basis were the urgency of supply, the fact that smallpox has been eradicated, and the purchase was needed as a medical countermeasure for use in response to a bio-terrorist attack.

The procurement was not advertised. Confidential discussions were held with five potential suppliers, selected from a list of twelve, with known production capabilities in the UK and Europe.

Case study F - Decisions on the strain, timescale, security of supplies limited the number of companies competing for the contract for smallpox vaccine in January 2002 to one company

The Department's overriding procurement requirements when they began the procurement process were to:

- buy the new cell-derived Lister strain vaccine for smallpox (in line with safety advice from the European Agency for the Evaluation of Medicinal Products (EMEA) that the new vaccine should be cell-culture derived);
- ensure the security of its supply; and,
- ensure the speed of its delivery in the short term.

However, although a consensus had been reached in December 2001 to pursue the new cell derived Lister strain, at the meetings with the potential companies in January and February 2002, the Department stated a "preference" for the Lister strain rather than a definitive requirement. This was partly because the Department wanted to keep its options open in the event there was no supplier of a cell derived form of the Lister strain.

With regard to security of supply, Ministers had initally expressed a preference that the vaccine should be manufactured in the UK because this would give the best guarantee of delivery and production of vaccine in the event of bio-terrorist attacks in the UK and elsewhere. However, following advice from Departmental officials, Ministers accepted that this would not be within the rules of fair competition and that, in any event, there was no UK manufacturing of smallpox vaccine. Nevertheless, Ministers advised that UK based companies should be approached initially.

The Department selected 12 potential suppliers based on their knowledge of the vaccine industry. On 7 January 2002, a group of officials from the Department and the MoD, chaired by a Principal Medical Officer, short-listed 5 potential suppliers, based on a review of each of the twelve companies to manufacture smallpox vaccine within the Minister's parameters. The shortlisted companies were PowderJect, Acambis, GlaxoSmithKline, Aventis Pasteur MSD and RIVM. In addition, the Department joined the MoD in a visit to Bavarian Nordic's plant in Germany on 30 January 2002, but Bavarian Nordic declined to deal directly with the Department as it had an exclusive partnership with PowderJect.

At the Department's invitation, four of the companies attended confidential meetings, whilst a confidential teleconference was held with another. The companies were not given any information prior to the meeting. After signing confidentiality agreements, each was asked specific set questions on their ability to supply such quantities of vaccine and time-scale. The manufacturers were reassured that any information they provided would be dealt with confidentially.

The key areas discussed during the confidential meetings were:

- Vaccine strain and type of manufacture (e.g. cell culture)
- Production capability
- Potential for licensed vaccine
- Time-scales (for the short-term, first tranche purchase the vaccine had to be available by the end of 2002) and quantity
- Costs

The companies were subsequently asked to provide written information against these key areas for the short and long terms, as well as the availability of immediate "off the shelf" supplies. Three companies provided this information within the deadline, and one submitted a presentation which the Department accepted. The Department was able to obtain all the information it needed to assess all the companies.

The Department evaluated the companies' information on 13 February and made its recommendations to the Minister on 18 February. This evaluation showed that:

- Aventis Pasteur MSD and RIVM had "off the shelf" supplies, but they were calf-skin based and would therefore, not satisfy the new EU regulations, particularly in relation to TSE (Transmissible Spongiform Encephalopathy).
- PowderJect, Acambis and RIVM had the capability to produce the new cell derived Lister strain. Aventis Pasteur MSD had the capability to produce the old type Lister vaccine but was not interested in producing the new cell derived Lister strain vaccine at that time. GSK were not planning to produce the Lister strain vaccine in the short-term.
- PowderJect was the only company with the potential to manufacture in the UK. It would transfer technology to manufacture smallpox vaccine from Bavarian Nordic to its factory in Speke in the longer term. But for the first tranche, short-term purchase, manufacture would take place in Germany. RIVM did not have a UK base which would make security of supplies difficult to achieve. Acambis had a UK base but manufacture would be in the US.

- PowderJect could supply new cell-derived Lister strain vaccine the fastest. It could supply a quantity by June 2002 and the remainder by September. Acambis could have supplied the Lister strain but in a comparatively longer time frame. However, Acambis could have supplied the NYCBH strain quicker than it could the Lister strain, but not until the third quarter of 2002.
- The Department accepted that for the purposes of the emergency stockpiles, the first tranche, short-term purchase of smallpox vaccine would be unlicensed.
- In terms of cost, although PowderJect's quote was one of the lowest, prices were not directly comparable as quotes were based on different vaccine types and strains and cost elements.

The Department told us that PowderJect provided the best match to their overall requirements.

The contract between PowderJect and the Department was signed on 11 April 2002.

PowderJect Pharmaceuticals Plc's manufacturing facility in Liverpool

Photograph: Courtesy of PowderJect.

3.15 In the follow-up procurement announced in October 2002, on advice from the Department's Permanent Secretary and Director of Finance and Investment and the 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 OJEC route would allow this to be achieved without compromising national security and would ensure that any potential new suppliers are identified.

3.16 The procurement was advertised in the Official Journal of the European Community 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 is the requirement for a licensed form of Lister strain cell-derived vaccine. Three bids were received on 1 April 2003, the deadline for submissions.

Key decisions on conditions attached to the first smallpox procurement exercise inhibited competition

3.17 For the smallpox vaccine contract, decisions on strain and security of supply (a preference for a UK manufacturing company was initially stated by Ministers), together with the small number of companies operating in this market, limited the number of companies able to compete for this contract. The Department held confidential meetings in January and February 2002 with five potential suppliers with a UK or European based manufacturing capability (PowderJect, GlaxoSmithKline, Acambis, Aventis Pasteur MSD and RIVM). In the event, only PowderJect could supply the required doses against the Department's criteria in the time-scale specified, but only through its partnership with Bavarian Nordic **(Case study F)**.

3.18 Although price was not the key criteria in the Department's decision to appoint PowderJect, PowderJect did offer one of the lowest quotes. However, each supplier's quote was different in terms of vaccine strain and type and the elements of costs included. Prices were therefore not directly comparable.

3.19 Whilst the Department tested the market to ensure a level playing field for all competitors, the companies told us that they felt that the procurement process, including criteria, was not transparent. The particular points they made were:

- The Department did not clearly state that it was interested in the Lister strain only (as it used the terms "preferred" or "favoured" throughout the procurement process) and this was misleading;
- The Department did not reveal the procurement criteria or timelines. There was no indication that the supplies were required in 2002. The timescales specified in the "points to consider" document were 18 to 24 months, which were interpreted variously by companies. Definitions of short, medium and long-term were, therefore, unclear;
- Companies were expecting a second stage to the procurement process whereby they would receive full tendering specifications against which to put in formal bids; and,
- Companies were expected to consider licensing issues and clinical trials but were not informed of the Department's decision to accept an unlicensed product. This would have had a significant impact on the prices quoted by some companies.

3.20 Consequently, companies felt that they had prepared their written proposals (following confidential meetings with the Department of Health) with limited information on procurement criteria, timescales, scope of the contract and the strain of vaccine.

3.21 The Department's view is that they were consistent in the information that they provided to each company and gave as complete information as they felt able to give under the circumstances. The Department recognises that there may have been a mismatch between the information provided and the interpretation of this by the companies and this arises because of the unusual nature of this procurement as highlighted in **Case study E**.

Contracts were awarded to those at least meeting the tender specifications

3.22 All vaccines routinely administered in the UK are required to have a Marketing Authorisation (product licence) valid in the UK. All the vaccines we examined did, with the exception of smallpox. The current suppliers of other older vaccines received their Marketing Authorisations when the licensing requirements were less stringent. In some cases these were granted as licences of right to products on the market before the Medicines Act 1968 was fully enacted in the late 1970s, for example, BCG, Diphtheria Tetanus (combined and separate) and Oral Polio vaccines. New producers of older vaccines also require a licence, and this can be a barrier to widening competition, especially where, for example, the full clinical trial data required for an application is not available.

3.23 There is no UK licence for the smallpox vaccine. All vaccines carry risks to the receipient when the vaccine is administered of possible side-effects. This could, in turn, lead to the manufacturer being sued for damages. In the case of smallpox vaccine, which was unlicensed, the Department bore the risks by indemnifying PowderJect against the potential for such damages **(see Case study G)**.

Propriety

3.24 For the vaccine contracts that we examined, the Department acted properly in awarding these contracts by complying with appropriate EU procurement regulations, encouraging sufficient competition and evaluating tenders fairly.

3.25 However, the purchase of smallpox vaccine from PowderJect raised concerns amongst some suppliers, in Parliament and the media about propriety. Dr Paul Drayson, Chief Executive and Chairman of PowderJect, made donations to the Labour Party on 25 July 2001 and 11 January 2002 of £50,000 each. The second donation and media coverage relating to the first donation coincided with the timing of the smallpox procurement exercise, raising suspicions about a possible link between the donations and award of the contract. It was between 7 January to 18 February that officials short-listed companies, set procurement criteria, held confidential meetings with companies, assessed the companies and prepared the Ministerial Submission recommending PowderJect. A chronology of events leading to the award of the smallpox contract is at **Figure 8 and Annex F**.

3.26 The officials involved in making the recommendations to appoint PowderJect, including the Deputy Chief Medical Officer, confirmed to us that they first knew of the donations on 18 February 2002 when the Minister's private office informed them having seen their submission to the Minister. It was then that the Minister's private secretary made the connection between the company recommended and recent media reports (17 February) about the donations and acted by informing officials and the Minister. This was after the procurement assessment had been completed and the supplier selected by officials.

Case study G - No smallpox vaccine is currently licensed for use in the UK

PowderJect began supplying quantities of smallpox vaccine from June 2002 with the final deliveries completed in March 2003. The vaccine was tested by the National Institute for Biological Standards and Control for potency and stability before delivery.

As this smallpox vaccine is an unlicensed product, the Department indemnified the vaccine supplier against damages arising from any side-effects caused by using an unlicensed vaccine.

An indemnity of £30 million was estimated as the contingent liability arising out of the use of the newly purchased unlicensed vaccine. Although complication rates for the Lister strain were available, the Department based its contingent liability assessment on rates reported by the Centre for Disease Control in the US, specific to the NYCBH strain. The Department told us that complication rates for the Lister strain tend to be higher. Therefore, there is a risk that the contingent liability calculated was lower than it should have been because it was based on a different vaccine strain, with lower complication rates.

The Department notified the Committee of Public Accounts of the contingent liability on 26 March 2002.

8 Chronology of events leading to the award of the smallpox vaccine contract

Date	Event
11 September 2001	Terrorist attacks in US
18 December 2001	Department and MoD decide to purchase smallpox vaccine (jointly) and to pursue the Lister strain. The initial steer from Ministers is that a UK company is preferred for security of supply reasons
December 2001	PowderJect enter a collaboration with Bavarian Nordic to supply the Lister strain smallpox vaccine - first stage formalised
7 January 2002	Department and MoD meeting to discuss way forward and companies to short-list given no UK companies known to be making smallpox vaccine. Criteria established for the purchase of vaccine
11 January 2002	Dr Paul Drayson's (Chief Executive of PowderJect) second donation to the Labour Party
22 January 2002	Confidential meeting with PowderJect to discuss the Department's smallpox requirements
28 January 2002	Confidential meetings with Acambis and Aventis Pasteur MSD (full team not present, second meeting requested) to discuss the Department's smallpox requirements
30 January 2002	Department joins MoD in site visit to Bavarian Nordic
6 February 2002	Second confidential meeting with Aventis Pasteur MSD to discuss the Department's smallpox requirements
7 February 2002	Publication of the first donation to the Labour Party by Dr Paul Drayson (Chief Executive of PowderJect) by the Electoral Commission
12 February 2002	Confidential teleconference meeting with RIVM to discuss the Department's smallpox requirements
13 February 2002	Meeting of officials to discuss responses from the companies
17 February 2002	Media coverage of donation by Dr Paul Drayson (Chief Executive of PowderJect) to the Labour Party
18 February 2002	Submission to Deputy Chief Medical Officer and Minister. Minister's office informs Minister and officials of donations
5 March 2002	Permanent Secretary endorses advice of the officials to purchase Lister strain and to purchase from PowderJect Minister approves contract with PowderJect for first tranche procurement following additional submissions on the relative merits of the Lister and NYCBH strains of vaccine
11 April 2002	Contract signed
12 April 2002	Partnership between PowderJect and Bavarian Nordic announced
April 2002 onwards	Further media coverage of donation by Dr Paul Drayson, Chief Executive of PowderJect, to the Labour Party
7 May 2002	Publication of the second donation by Dr Paul Drayson (Chief Executive of PowderJect) by the Electoral Commission

Source: NAO examination (Annex F); Department of Health; PowderJect Pharmaceuticals PLC

3.27 Having been made aware of these donations the Minister proceeded carefully taking account of the possible sensitivities that might be associated with the award of the contract to PowderJect and required the officials' recommendation to be put to the Permanent Secretary. The Permanent Secretary endorsed the recommendation on the grounds that in the short-term the only source of the cell-derived Lister strain smallpox vaccine in the UK was from PowderJect. The key factors in award of the contract, therefore, were the cell-derived Lister strain, speed of delivery and national security issues.

Ensuring competition in the vaccine market is difficult in view of the limited number of suppliers resulting in few expressions of interest for each contract advertised and there is a risk of relatively higher prices

3.28 There are limited suppliers and manufacturers in the vaccine market and the near monopolistic conditions for some vaccines mean that only one or two suppliers generally express an interest when contracts are advertised. The main reasons for the narrow market relate to the high and increasing cost of vaccine development and production, mergers of manufacturers and the relatively low profit margins compared with other pharmaceutical products, **Figure 9**.

3.29 Limited competition makes it more difficult to get competitive prices and secure value for money. The Department's procurement strategy is to award a contract to more than one supplier where possible. **Figure 10** shows the Department's current suppliers of vaccines. In four cases, the Department awarded contracts to more than one supplier in order to ensure continuity of supply and competition **(Case studies B, H and I)**. For example, in purchasing contingency supplies of the influenza vaccine the Department awarded contracts to three tenderers, mainly to cover for eventualities such as supply shortages, as experienced in 2000 **(see Case study B)**.

9 Main reasons for the limited number of suppliers and manufacturers in the vaccine market

- Vaccine manufacture is a complex and time-consuming process that requires significant investment in plant and research, and carries greater risk than traditional sterile or non-sterile pharmaceutical manufacturing. Unlike pharmaceuticals, which are usually synthesized from chemicals, most vaccines are produced from or use living biological organisms. Cultivation for many viral vaccines begins with almost laboratory scale culture and is progressively scaled up to larger and larger culture vessels. Each step takes a finite time and cannot be accelerated, as the cultures have to grow naturally. It can take 2 to 3 years to achieve licensure and thereafter, a typical production schedule, including growing the antigen, purifying, testing, packaging, and performing final quality checks can take between 1 to 2 years depending on the type of vaccination being produced, viral or bacterial, live or inactivated.
- Many manufacturing plants are dedicated facilities, built and maintained to produce specific vaccines and cannot easily be expanded or switched to produce other vaccines.
- Rationalisation by manufacturers worldwide to reduce costs and to concentrate production, marketing and research to specific vaccine types.
- Mergers and acquisitions have reduced the number of vaccine manufacturers.
- Many larger pharmaceutical companies have been exiting the vaccine market as it not as profitable as drugs. Vaccines have to compete with pharmaceutical products within a manufacturer's portfolio. Factors such as relatively long research and development period, the need to maintain production facilities to meet regulatory standards and the relatively fixed market size may hinder the competitive position of some vaccines relative to other pharmaceutical products.
- Regulators such as the Food and Drug Administration in the US, the European Medicines Evaluation Agency (EMEA), and the Medicines Control Agency in the UK have increased the quality standards for vaccines in recent years. Complying with standards is much harder and more costly when dealing with biological as opposed to chemical processes.

Source: NAO research; NHS PASA; Childhood Vaccines: Ensuring an adequate supply poses a continuing challenge, USA General Accounting Office, September 2002.

10 Current suppliers of vaccines

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

NOTE

See Glossary, page 33, for an explanation of diseases.

Source: NAO examination of contracts; NHS PASA

The limited number of vaccine manufactures and the complex vaccine manufacturing process has resulted in supply shortages of certain vaccines, thereby jeopardising the immunisation programme

3.30 In most cases suppliers have met delivery requirements, including quality. However, for vaccines, such as Measles, Mumps, Rubella (MMR), and Bacillus Calmette-Guerin (BCG), where there are a small number of vaccine manufacturers or sole suppliers with licences for the UK, supply shortages have occurred. Production problems including batch failures are common reasons. Recovery from a major batch failure may take a number of months and with the increasing centralisation of manufacturing can rapidly lead to an international vaccine shortage.

3.31 The Department's strategy has been to award the contract to more than one supplier where possible. For example, in December 2002 the Department placed a contract for the supply of the MMR vaccine with the only two suppliers with product licenses valid in the UK - Aventis Pasteur MSD and GlaxoSmithKline - to ensure continuity of supply. As **Case study H** shows, this prudent approach enabled supplies to be met.

3.32 As **Case study I** illustrates, the Department adopts a flexible approach when there is a risk that its immunisation programme may become too dependent on one particular supplier. In the case of BCG, the Department encouraged a second supplier to seek a UK licence to ensure the continuity of its supply as it already had problems with its existing supplier.

3.33 In the case of Haemophilus influenzae, Diphtheria, Tetanus, and wholecell Pertussis (Hib/DTwP)[7] vaccine **(Case study J on page 31)**, the Department experienced supply problems despite awarding the contract to more than one supplier. The Department were able to switch between products to maintain supplies.

3.34 The Department is also reviewing the length of contracts and whether there is sufficient time between contract award and start dates. Generally it has placed contracts for one or two years for childhood vaccines, with the option of an extension in most cases. Using shorter contracts allows the Department to make changes to its programme quickly and minimise the risk of unwanted vaccine stocks, as well as enabling the market to be tested regularly. But using shorter contracts, and the insufficient time between notifying the award and the actual start of the contract, can create uncertainty with suppliers and hesitancy in expressing an interest. As manufacturing lead times are sufficiently protracted, suppliers may not have vaccines ready when required if awards are made with inadequate notice. The Department told us that it reviews each contract on its own merits when deciding on contract length.

Case study H - Measles, Mumps and Rubella (MMR) vaccine

Background

Measles, Mumps and Rubella (also known as German Measles) are diseases caused by viruses, spread when the viruses are passed from an infectious person to someone who is not immune.

The MMR contract

After an OJEC competition, the Department placed contracts for the supply of the MMR vaccine in December 2000, to run from April 2001 to March 2002 (i.e. one year) with an option for a further year. There are only two suppliers with product licenses valid in the UK - Aventis Pasteur MSD and GlaxoSmithKline - and the Department awarded contracts to both, to ensure continuity of supply.

Supply difficulties

600,000 doses were ordered from each company. Due to production problems, Aventis were unable to supply all the doses contracted for. As they also supply other countries, they are rationing supplies. Due to having contracts with 2 suppliers, the Department was able to increase supplies from GlaxoSmithKline, who currently meet 75% of the UK requirement.

Source: NHS PASA

Whilst the Department has taken steps to ensure continuity of supply, there may be scope to do more

3.35 The potential for recurring shortages will remain because of the complex nature and lengthy vaccine production process. Severe vaccine shortages were experienced in the US at the beginning of 2001. The National Vaccine Advisory Committee has considered ways of strengthening the supply of routinely used vaccines in the US. This highlighted the need for proactive short and long-term strategies, as summarised in **Figure 11 on page 31**. Some of these may be of relevance to the UK also.

7 *See Glossary, page 33.*

Case study I - Tuberculosis (TB) and the Bacillus Calmette-Guérin Vaccination (BCG)[8]

Background

Tuberculosis (TB) is a disease of the respiratory system, which is caused by a bacterium that spreads through the air. The incidence of TB in the UK is continuing to increase, between 1987 and 2001 there was a 21% increase in cases of TB and in 2001 approximately 7,000 new cases were diagnosed.

Within the UK, the Bacillus Calmette-Guérin (BCG) vaccination is part of the Department of Health's childhood immunisation programme. The programme covers school children between the ages of 10 to 14; in addition there is selective vaccination of higher risk groups, for example babies born into ethnic groups at higher risk of TB and new entrants from, and visitors to, high prevalence areas of the world.

Procurement arrangements for BCG

The Purchasing and Supply Agency procures BCG vaccine on behalf of the Department of Health. The last tendering exercise took place in June 2000 for contracts to run from 1 October 2000 to 30 September 2002, with the option to extend to 30 September 2004. Whilst the tendering process commenced for a new contract to be in place for a 1 October 2000 start date, the contract was eventually awarded in March 2001. This was due to a much higher price quoted by Celltech Medeva, the then owners of the Evans Vaccines manufacturing facility in Speke where the BCG was being produced. Departmental officials were concerned about the escalating price and were exploring other options and seeking Ministerial approval on the way forward. During the procurement process, PowderJect acquired Evans Vaccines in October 2000.

Both Evans/PowderJect and Statens Serum Institute (SSI) were awarded contracts for the supply of BCG in March 2001, because the Department recognised the risks to the vaccination programme of dependence on a single supplier, and the need to catch-up with and maintain the schools immunisation programme in the future. The Evans/PowderJect contract award was subject to availability of supplies and the SSI award was subject to the company obtaining a UK licence. SSI were granted a UK license on 9 September 2002.

Supply difficulties

There has been a history of problems with the supply of BCG from Evans Vaccines. In September 1999, the Department suspended the routine schools-based part of the immunisation programme as there was insufficient vaccine supply to provide for this and those at higher risk. This was because of a manufacturing problem at the Evans Vaccine manufacturing site at Speke. The immunisation programme fully recommenced in September 2001, once Evans/PowderJect's BCG vaccine production was sufficient to allow the whole programme to re-instate.

In August 2002, however, Evans/PowderJect withdrew all batches of their BCG vaccine voluntarily after tests on a single batch of BCG supplied to Ireland showed that the product's end of shelf life potency test was below specification. The Department has now ceased to purchase their BCG vaccine from Evans/PowderJect and has received an undertaking that it will receive a refund for the unused BCG vaccine it currently holds.

Consequently, SSI is now the sole supplier of BCG vaccine in the UK and the risks associated with dependence on one supplier remain. PowderJect indicated to us that whilst it aims to re-introduce its BCG vaccine in the UK, the current tender structure of short-term contracts and the high level of investment required to produce biological products may not make this a viable proposition.

8 *See Glossary, page 33*

Case study J - Supplies shortages experienced despite contracting with more than one manufacturer of the Haemophilus influenzae type b, Diphtheria, Tetanus, and wholecell Pertussis (Hib/DTwP) vaccine

During the latter part of 1998 and throughout 1999, the UK experienced severe shortages of key vaccines from different manufacturers. These difficulties sometimes led to interruptions in the childhood immunisation programme that were unwelcome to health professionals and to parents. If no vaccines were available, such interruptions could endanger public health leaving children without protection against potentially lethal diseases. The disruptions were most significant for those vaccines where there was only one source of supply.

One of the most important vaccines, Hib/DTP (given to babies at 2, 3, and 4 months of age) was of particular concern. Although contracts were let with two manufacturers, both experienced manufacturing problems for different reasons, at the same time. This lead to protracted disruptions in availability. However, the Department were able to switch between products and companies and were able to continually keep sufficient vaccine available for issue to meet demand. For example, when shortages of the combined product first occurred the Department were able to switch to an alternative supply of separate Hib and DTwP vaccines already let against a different contract to keep the primary schedule running.

However, supply of the combined product continued to be severely disrupted throughout 1999. This was for different reasons. Both of the manufacturers experienced repeated batch failures (for unrelated reasons) and one of them also had a problem with a filling plant (resulting in the production cessation of a novel type of dual chamber syringe). With forward forecasting, the Department was able to identify that the UK would have no stock left by the end of December 1999.

On 2 December 1999, a Chief Medical Officer letter (PL/CMO/99/5, PL/CNO/99/9, PL/CPHO/99/4) was sent to the profession detailing these problems and what steps had been taken to maintain supply. The key change was to alert the profession that once the current supply of combined Hib/DTwP was exhausted, the UK would be using a different vaccine containing acellular pertussis (Hib/DTaP) instead of the hitherto used wholecell type. The first issues of the combined Hib/DTaP commenced at the end of December 1999. From then on, the Department was able to provide a continued supply of combined product to the profession of either or both Hib/DTwP and Hib/DTaP.

Source: Department of Health

11 Ways of dealing with shortages of routine vaccine supplies suggested by the National Vaccine Advisory Committee of the US

1 Increase funds for vaccine stockpiles to include all routinely administered vaccines in sufficient quantity to be used for amelioration of supply problems or surge demands.

2 Require vaccine manufacturers to provide advance notification to the Department of Health and Human Services regarding intent to withdraw from the market.

3 Increase the availability of accurate information about vaccine supply for opinion leaders and consumers. Appropriate information about vaccine supply can be communicated by a website containing current information about the availability of vaccines.

4 Enhance the valuation of vaccines by initiating a national campaign to emphasize the safety and efficacy and great benefit of recommended vaccines for the public good.

Solutions that are more complex and will require more study include the following:

1 Convene a multi-disciplinary group to evaluate the nature of appropriate incentives for manufacturers to sustain the supply of existing vaccines and stimulate development of new vaccines.

2 Streamline and strengthen the regulatory processes and the activities of the FDA, including a) support the work of international harmonization for mutual recognition of lot releases of various vaccines; and b) review the implementation of current Good Manufacturing Practices to assure that science-based decisions regarding vaccine safety and efficacy are made.

Source: Strengthening the supply of routinely recommended vaccines in the United States: A report of the National Vaccine Advisory Committee, October 2002


M
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Glossary

Anthrax	An acute bacterial disease affecting the skin (and rarely the lungs or gastro-intestinal tract). The disease most commonly occurs in herbivores, which are infected by ingesting spores from the soil, but all mammals are susceptible to infection.
BCG (Bacillus Calmette-Guérin) vaccine	Provides protection against Tuberculosis (TB) disease.
Bifurcated needles	A specialised two-prong needle for smallpox vaccination.
Centre for Applied Microbiology and Research (CAMR)	Is the executive arm of the Microbiological Research Authority, a Special Health Authority, funded by the Department of Health, whose role is to conduct research on microbial hazards associated with healthcare and to develop and manufacture products to counteract these hazards.
Clinical Trial	Testing of a new drug on humans before marketing. It may involve either healthy volunteers or patients.
Diphtheria	Diphtheria is an infectious disease affecting the upper respiratory tract and occasionally the skin. It is characterised by a throat membrane which forms across the tonsils and can block the airway.
DTaP	A combination vaccination of Diphtheria/ Tetanus/ acellular type of Pertussis.
DTP or DTwP	A combination vaccination of absorbed Diphtheria/Tetanus/wholecell type of Pertussis.
DT	A combination vaccination of absorbed Diphtheria/Tetanus.
Hib/DTP	A combination vaccination providing protection against Haemophilus influenzae type b (Hib), Diphtheria, Tetanus, and Pertussis.
Efficacy	The extent to which a medicine has the beneficial effect intended.
EU procurement procedures	Open - All respondents to the advert may submit a tender. Open procedures provide the purchaser with the opportunity to test markets where there are a limited number of known suppliers and the contract specification is straightforward. Restricted - Enables the purchaser to select preferred bidders from contractors registering an interest, based on an assessment of the capacity of the respondent to meet the contract specification. Negotiated with a call for competition - require an OJEC advert and the purchaser is required to negotiate with at least 3 bidders. They may be used when the nature of the purchase does not permit overall pricing or when specifications cannot be drawn up with sufficient precision to permit the use of open or restricted procedures. Negotiated procedures without a call for competition - do not require an OJEC advert or negotiation with a specified number of bidders. They are permitted for technical or artistic reasons or for the protection of exclusive rights pertaining to the contractor. Accelerated procedure - Applicable where there is a genuine urgency as a consequence of circumstances outside of the purchaser's control.

European Medicines Evaluation Agency	The central body responsible for evaluating applications for Europe-wide marketing authorisations and coordinating European medicines regulation.
Farillon Ltd	A company contracted by the Department of Health and NHS Purchasing and Supply Agency to hold the NHS storage and distribution contract for childhood vaccines to GPs and hospitals in the UK.
Haemophilus influenzae type b (Hib)	Is a bacterial infection which can cause serious illnesses including meningitis, blood poisoning and pneumonia.
Hepatitis B	A virus affecting liver function which is transmitted parenterally and sexually through the exchange of blood or body fluids.
Inactivated Polio Vaccine (IPV)	Manufactured from an inactivated form of the polio virus which has been purified and killed with a chemical.
Intradermal	Administered by entering the skin.
Influenza	A viral infection of the upper air passages. It can cause death, especially in the elderly or infirm.
Lister strain	A strain of vaccine against smallpox. It is one of the two most common strains of vaccinia and originated from the Lister Institute, England. It was propagated as a seed virus to be used in vaccine manufacture by National Public Health Institute of the Netherlands.
Market Authorisation	A licence to market a medicine, granted in the UK by the Licensing Authority or in Europe by the European Medicines Evaluation Agency.
Measles	Measles is a highly contagious viral illness that causes a distinctive rash and fever.
MMR vaccine	Measles, Mumps and Rubella - a combination vaccine protects against measles, mumps and rubella (German measles).
Meningitis	Meningitis is an inflammation of the membranes known as the meninges that line the brain and the spinal chord. Symptoms are varied and complications can include blood poisoning and brain damage. It can be caused by either viruses or bacteria. There are two main types of bacterial meningitis - meningococcal and pneumococcal.
Meningitis C	A particular strain of meningitis caused by a bacterium which can lead to meningitis and/or septicaemia (blood poisoning) for which there is a vaccine.
Mumps	A viral infection of the parotid salivary glands. In adolescent boys and men it may also affect the testes.
Mutual Recognition Procedure	The decentralised procedure by which a marketing authorisation obtained in one EU country is recognised by the others, allowing marketing of the medicines across the EU.
NHS acute trusts	Hospitals which are managed by their own Boards and which provide acute beds linked to medical and surgical intervention.
NHS Logistics Authority	Is the supply channel for consumable healthcare products to the National Health Service.
NHS Purchasing and Supply Agency (PASA)	The NHS Purchasing and Supply Agency is an executive agency of the Department. Its core function is to negotiate national framework contracts on behalf of the NHS.

New York City Board of Health (NYCBH)	A strain of vaccine against smallpox. It is one of the two most common strains of vaccinia. It was propagated as a seed virus by Wyeth Laboratories, Pennsylvania, US.
Office of Government Commerce (OGC)	An independent Office of the Treasury. It was set up to lead a wide-ranging programme to modernise procurement in government, and deliver value for money improvements.
Oral Polio Vaccine	Administered in drops by mouth. It contains a weakened form of live polio virus.
Pertussis	Is commonly known as whooping cough. It is a highly infectious bacterial disease causing severe coughing. Complications can lead to bronchopneumonia and brain damage. Acellular and wholecell are types of Pertussis vaccines.
Pneumococcal	A bacterial disease causing pneumonia, bacteraemia and meningitis.
Polio	Is an infectious illness following invasion of the gastro-intestinal tract by one of three types of polio virus. Symptoms can range from headaches, vomiting and fever to paralysis.
Public Supply Contracts Regulations 1995	A statutory instrument to incorporate EU Directives on procurement procedures into national law.
Public Works Contracts Regulations 1991	A statutory instrument to incorporate EU Directives on procurement procedures into UK national law.
Rubella	(German Measles) Is a highly contagious virus usually causing a mild rash and raised temperature. However it can cause serious birth defects in a foetus if contracted by a pregnant woman.
Smallpox	A viral disease unique to humans caused by the variola virus, marked by fever and skin rash. It is highly infectious and can be passed on through direct contact, infected body fluids and contaminated objects. Natural smallpox was declared eradicated in the 1980s after a global mass vaccination campaign.
Service Level Agreement	A proxy contract between one part of the Department (including its agencies) with another, or between Departments, to record a formal agreement between the parties with regard to the provision of a service.
Td	A combination vaccine of absorbed tetanus and low dose diphtheria for use in adults and children over 10 years.
Tetanus	An infection of the central nervous system caused by a bacterium, (Clostridium tetani) getting into the body and found in cultivated soil and manure. Symptoms include muscular spasms and rigidity.
Tuberculin skin test	Conducted prior to a BCG vaccination to assess an individual's sensitivity to the tuberculin protein. A positive test indicates that the individual should not be given BCG.
TB (Tuberculosis)	A bacterial infection which can affect the lungs, lymph nodes, skin or bones.
Vaccine	Modified micro-organism of any disease used in vaccination.

Annex A

Scope and estimated annual value of commercial contracts arranged by the Department of Health and the NHS Purchasing and Supply Agency

Category	Department of Health[1] £M	NHS Purchasing and Supply Agency[2] £M
Facilities management & utilities	17[3]	359
Other buildings related costs	24	0
Office services	17	68
Information technology	19	663
Professional services	7	212
Outsourcing	0	52
E-commerce	0	14
Staff related expenditure	16	0
Pharmaceutical (including vaccines)	128[4]	548
Medical and surgical		203
Rehabilitation		170
Food, textiles and domestic goods	124	93
Diagnostic medical equipment		94
Consumable healthcare products		485
Other health and NHS related expenditure		1861[5]
TOTAL	**352**	**4,822**

1. *Except where otherwise noted, estimated contract values are based on the Department of Health's commercial expenditure, excluding expenditure by its agencies, during 2001-02.*
2. *Expenditure under NHS Purchasing and Supply Agency contracts is incurred directly by NHS organisations, mainly acute NHS Trusts.*
3. *Includes the NHS retained estate.*
4. *Includes £117 million spent directly by the NHS.*
5. *In addition to the contracts it arranges on behalf of the NHS, the NHS Purchasing and Supply Agency directs £1,861 million of annual NHS expenditure through the provision and support and advice to the Procurement Department's of NHS organisations. Therefore, the Agency currently influences NHS expenditure of approximately £4,822 million per annum.*

Annex B

Department of Health: General Procurement Roles and Responsibilities

Director of Corporate Affairs: The Board Member with responsibility for procurement across the Department:

- approves procurement policy on behalf of the Board
- represents and champions procurement interests and needs at Board level
- monitors procurement effectiveness and governance.

Head of Information Services Group: Accountable for effective delivery of the procurement policy, either directly through the central procurement unit, or through liaison with the Heads of the Corporate Development Teams.

The Procurement Policy Advisory Unit: Accountable for execution of the procurement policy and practices with a focus on the higher risk, strategically important procurements. Specific areas of activity will include:

- development of procurement policy
- development of procedures, instruction and guidance
- dissemination of best practice
- development of E-commerce strategy
- management of procurement systems
- external reporting of procurement information for the Department

Business Units: Business units are responsible for all procurement activity in their business area. Directors, for the most part via Corporate Development Teams, are responsible for ensuring control and good practice are maintained in their areas of responsibility.

Corporate Development Teams: Normally accountable to their Director for monitoring procurement activities in their business units in accordance with approved policy and practice:

- operation within accredited limits
- development of forward procurement plans
- provision of procurement related data

Corporate Development Board: The Board comprises senior representatives from the Corporate Development Teams and is chaired by the Director of Corporate Affairs. The Board will be consulted on proposed changes to the Departmental Procurement Management Policy and significant changes to procurement procedures.

Source: Department of Health, Procurement Management Policy

Annex C

Recommendations of the Department's Internal Audit Report and progress to date

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.
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. The Department fully accepts 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 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.
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 is available on the Departmental intranet.
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 independent external review. Risks now considered to be slight but the issue remains under review.

Recommendation	Progress
Tender Evaluation	
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 independent external review and report. The Department has actively addressed the requirements of this report.
Guidance should stipulate that tenderers chosen for contract award should be required to prove their financial stability (e.g. 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.
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 non procurement staff are regularly offered and undertaken.
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 independent external review and will be further clarified by the investigation being undertaken by the OGC's Deputy Chief Executive (report completed March 2003).
PPAU or SOL Commercial should maintain a central register of all contracts.	This requirement is being addressed through the Department's replacement of its financial systems. It is expected that the replacement system will be able to maintain a contracts register.
All Departmental business plans should identify potential expenditure 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 and was further addressed in the independent external review in part through implementation of the accreditation processes.
Guidance should provide sufficient information to enable devolved managers to be clear on time-scales, and alternative courses of action (e.g. open or negotiated procedures, or the use of framework contracts).	This requirement has been undertaken and guidance is available on the Departmental 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 and guidance is available on the Departmental intranet.

Annex D

Recommendations of the independent external review

Department of Health: Procurement Review, 2001

Proposed additional roles for the Procurement Policy Advisory Unit (PPAU)

While acknowledging the devolved nature of the Department's operations the review recommended that the role of PPAU should be enhanced in its current areas of activity and expanded to cover the following additional activities across all procurements within the Department (including PFI, IT and Project Gateways).

Monitoring of procurement activity with business units

Monitoring should be a 'light touch', not day-to-day and typically consisting of a constructive six-monthly two-way review of successes and issues and an assessment of future needs and activities.

The Department introduced its *Procurement Management Policy*, setting out clear roles and responsibilities for procurement. Since the report, the Department has worked more closely with business units providing awareness training and identifying areas where their procurement capability needed strengthening. The Department is looking at ways to improve the routine monitoring of procurement activity in areas where there is significant commercial expenditure.

Assessment and accreditation

Assessment and accreditation of business units to carry out procurement. Beyond the parameters set, business units need to seek PPAU help. As has been identified there is not a 'one size fits all' need. Some business units need significant help, others much less.

The assessment would define: the needs of the business unit taking into account the risk and level of spend; the experience/ qualifications required within the business unit; and, any gaps to be addressed.

As a result of the assessment the business unit would be accredited to operate up to agreed spending limits without referral to PPAU.

The Department employed consultants, specialising in procurement, to carry out a pilot assessment and accreditation review of the Policy Directorate. A similar external review is about to be undertaken of a second Directorate as part of a rolling programme.

Co-ordination

Facilitating co-ordination of procurement activities and promoting collaboration where beneficial:

- Within the Department to exploit opportunities for aggregation and supplier management;
- With external organisations and other government departments; and,
- With the NHS Purchasing and Supply Agency to handle procurements that start with the Department of Health but then transfer to the NHS for execution.

The Department has been exploring opportunities with other Departments as part of its normal business. Action has been targeted in the more general areas (for example: stationery and travel) and the Department now purchases from NHS contracts for electricity, arranged by the NHS Purchasing and Supply Agency.

Government e-commerce agenda

Driving forward the e-commerce agenda within the Department should be a management, co-ordination role as many of the actions will be in other parts of the Department.

The Department piloted the OGC led initiative for e-tendering. OGC is reviewing the results of this exercise and the Department is waiting to see how this will be taken forward. In the meantime, the Department is continuing to look at ways of increasing the proportion of low value transactions carried out electronically.

Professional standards

Maintaining professional standards in procurement across the Department and ensuring continuous professional development. The Head of Procurement should act as head of profession for the Central Department.

All PPAU staff have procurement qualifications and the Department encourages its buyers to gain the full Member of the Chartered Institute of Purchasing and Supply (MCIPS) qualification. PPAU staffing levels have increased by 50% but there has been a steady loss of trained staff on promotion. With increasing emphasis on procurement capability in government generally, it has become more difficult to recruit replacements from within the government community and the Department is recruiting externally.

Management Information

Improved management information will be a spin-off from the move to e-commerce. It is recommended that development of the required management information systems is held until there is clarity about what will become available through the e-commerce route.

Progress has been slow on e-tendering. This has meant that the accounting records remain the most reliable source of expenditure incurred by the Department directly. This will be augmented in time by information from the accreditation process.

Annex E

Examination of vaccine procurement procedures

We examined the eight most recent procurement exercises for the purchase of both programme and non-programme vaccines. The results of our examination of each of these eight exercises are presented in this annex. Procurement exercises routinely involve a number of suppliers tendering for the supply of a combination of vaccines. From these eight exercises, 18 contracts were awarded to 10 suppliers.

Our examination involved reviewing vaccine files held by the NHS Purchasing and Supplies Agency and the Department of Health and discussions with vaccine buyers and the Department's Immunisation and Communicable Disease Team. Each procurement process, with the exception of Anthrax and Smallpox, was undertaken by NHS PASA on behalf of the Department of Health. See table on pages 43-47 for details.

Assessment criteria	General Vaccines: Diphtheria absorbed (D)[1], Oral polio, Hib, Low dose diphtheria/ Tetanus (Td), Diptheria and Tetanus (DT), DTaP Rubella, BCG, Tuberculin	Tetanus (T) and Td	Men C, Hib and DTP and MMR	Flu contingency stock	Low dose diphtheria (d)	General Vaccines: Rubella, Td, Hib, DTaP	Anthrax	Smallpox Phase 1
DID THE DEPARTMENT COMPILE A BUSINESS CASE SUPPORTING ITS NEED TO PURCHASE THE VACCINE?								
Were the objectives of the procurements specified by the Department of Health?	Yes	Not applicable	Yes	Yes	Yes	Yes	Yes	Yes
For **new** vaccines, was a business case (including risk analysis) carried out?	Undertaken for DTaP in 2000 for introduction in 2001.	Not applicable	Undertaken for Men C introduced in 1999.	Undertaken for contingency arrangements in 1999.	Not applicable	Not applicable	The Department prepared a submission to ministers covering risks to public health and other factors.	The Department prepared a submission to ministers covering risks to public health and other factors.
For **older** vaccines, when was the last policy review?	Vaccines were last reviewed as follows: Hib in 2002 (reviewed since contract commenced); DTP in 2000; Polio in 2001 (reviewed since contract commenced); BCG 2002 (reviewed since contract commenced); Rubella - the Department could not confirm last review date	Not applicable. This contract was set up by the Agency for use by NHS trusts.	Vaccines were last reviewed as follows: Hib in 2002 (reviewed since contract commenced); DTP in 2000; MMR in 1996	Not applicable.	(d) was last reviewed in 2002	Vaccines were last reviewed as follows: Rubella - the Department could not confirm last review date; Td in 2000; Hib in 2002; DTaP in 2000	Not applicable	Not applicable

Assessment criteria	General Vaccines: Diphtheria absorbed (D)[1], Oral polio, Hib, Low dose diphtheria/ Tetanus (Td), Diptheria and Tetanus (DT), DTaP Rubella, BCG, Tuberculin	Tetanus (T) and Td	Men C, Hib and DTP and MMR	Flu contingency stock	Low dose diphtheria (d)	General Vaccines: Rubella, Td, Hib, DTaP	Anthrax	Smallpox Phase 1
When did the contracts commence?	October 2000	April 2001	April 2001	September 2002	October 2002	October 2002	Manufacturing began in April 2002	April 2002
What was the length of the contract?	Between one and two years with options to extend for some contracts	One year with the option to extend for one year	One year with the option to extend one year	One year	Two years with the option to extend for one year	One year with the option to extend for one year	The doses required were ready by March 2003	Six months
Did the Department comply with appropriate procurement regulations?								
Was the estimated contract value greater than the OJEC threshold?	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable, as the vaccine is manufactured in-house	Yes
Is the contract exempt from EU procurement regulations? On what grounds?	No	No	No	No	No	No	Not applicable as provided by an in-house supplier	Yes. On national security grounds
Was the invitation to tender advertised in OJEC?	Yes	Yes	Yes	Yes	Yes	Yes	Not applicable	Not applicable
Was the invitation under open, restricted, negotiated or accelerated procedures?	Restricted	Open	Restricted	Open	Negotiated	Open	Not applicable	Not applicable. Negotiated through private discussions with suppliers

Assessment criteria	General Vaccines: Diphtheria absorbed (D)[1], Oral polio, Hib, Low dose diphtheria/ Tetanus (Td), Diptheria and Tetanus (DT), DTaP Rubella, BCG, Tuberculin	Tetanus (T) and Td	Men C, Hib and DTP and MMR	Flu contingency stock	Low dose diphtheria (d)	General Vaccines: Rubella, Td, Hib, DTaP	Anthrax	Smallpox Phase 1
Did the Department do enough to maximise competition between suppliers?								
How many potential suppliers were identified?	Five	One	Seven	Six	One	Three	One	Twelve. Five short-listed
How were potential suppliers identified?	OJEC advert	OJEC advert	OJEC advert	OJEC advert	By the Agency as there was no response to the advert	OJEC advert	By the Department of Health	By the Department of Health, JCVI and MoD
How many suppliers actually tendered?	Between zero and two for different vaccine combinations	One	Five	Five	Not applicable	Between one and two for different vaccine combinations	One	Five
Was the response from suppliers as expected?	Yes	Yes	Yes	Yes	Not applicable	Yes	Not applicable	Yes
Were large variations (+/- 10%) in tender prices investigated?	Yes	Not applicable	Not applicable	Yes	Not applicable	No for DTaP and Hib. Yes for Rubella and Td	Not applicable	Yes
Does the relationship allow for rapid reaction to new threats?	Yes	Yes, through a framework agreement	Yes	Yes	Yes	Yes	Yes	Not applicable

Assessment criteria	General Vaccines: Diphtheria absorbed (D)[1], Oral polio, Hib, Low dose diphtheria/ Tetanus (Td), Diptheria and Tetanus (DT), DTaP Rubella, BCG, Tuberculin	Tetanus (T) and Td	Men C, Hib and DTP and MMR	Flu contingency stock	Low dose diphtheria (d)	General Vaccines: Rubella, Td, Hib, DTaP	Anthrax	Smallpox Phase 1
Did the Department properly award the contract and purchase what they specified at the business needs stage?								
Is the vaccine licensed for UK?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Was a full evaluation of tenders undertaken prior to award of contract?	Yes	Not applicable	Yes	Yes	Not applicable	Yes	Not applicable	Yes
Has the Department met its original objectives?	Yes. Apart from the supply of the Diphtheria absorbed vaccine where no supplier was identified	Not applicable	Yes	Yes	Yes	Yes	Yes	Yes
Did the Department comply with the standards of propriety?								
Did the Department comply with EU procurement regulations?	Yes, apart from one minor error due to the OJEC advert being placed late and consequently the 37 days required for expressions of interest to be submitted was reduced to 30 days. This had no impact on the contract award	Not applicable	Yes	Yes	Yes	Yes	Not applicable	Yes

Assessment criteria	General Vaccines: Diphtheria absorbed (D)[1], Oral polio, Hib, Low dose diphtheria/ Tetanus (Td), Diptheria and Tetanus (DT), DTaP Rubella, BCG, Tuberculin	Tetanus (T) and Td	Men C, Hib and DTP and MMR	Flu contingency stock	Low dose diphtheria (d)	General Vaccines: Rubella, Td, Hib, DTaP	Anthrax	Smallpox Phase 1
Did the Department comply with the standards of propriety?								
Did the Department encourage competition?	Yes, through contract awards to a combination of suppliers	Yes, through compliance with procurement regulations and testing the market through open procedures	Yes, through compliance with procurement regulations and contract awards to a combination of suppliers	Yes, through compliance with procurement regulations, testing the market through open procedures and contract awards to a combination of suppliers	Yes, through compliance with procurement regulations	Yes, through compliance with procurement regulations and contract awards to a combination of suppliers	No, in order to ensure the supply of a UK licensed product within a realistic timescale the Department purchased from an in-house supplier	Yes - the Department did not need to seek competition under the EU procedures adopted. However, they, through discussions with companies, did establish alternative potential suppliers
Did the adjudication panel's award recommendation report evaluate each tender against the same criteria?	Yes	Not applicable	Yes	Yes	Not applicable	Yes	Not applicable	Yes

NOTE:

1 For Diphtheria absorbed vaccine no contract award was made as there were no offers received.

Source: NAO examination

Annex F

Award of the smallpox vaccine contract: Chronology of events

Date	Event
25 July 2001	First donation of £50,000 from Dr Paul Drayson, Chief Executive of PowderJect, to Labour Party
11 September 2001	Terrorist attacks in US
27 September 2001	First meeting of expert sub-group of JCVI set up to examine issue of strain of vaccine, medical counter-measures and outbreak control issues for smallpox - need discussed
30 September 2001	Second meeting of the expert sub-group - strain discussed. Concluded no difference between the strains. Sub-Group recommend Lister strain to Departmental officials
December 2002	Minister meets with industry groups - UK Vaccine Industry Group, Bio-Industry Association and Association of British Pharmaceutical Industry - to discuss UK capability for manufacturing smallpox vaccine. Lister strain discussed
18 December 2001	Department and MoD decide to purchase smallpox, jointly. Consensus to pursue Lister on the basis of advice from JCVI, UK experience with Lister strain in the past and its provenance as an effective vaccine strain and the MoD preference for Lister strain
	Deputy Chief Medical Officer (DCMO) decides the procedures to follow for the smallpox procurement. Steer is that a UK company is preferred for security of supplies reasons
December 2001	Powderject enters into an agreement with Bavarian Nordic - first stage formalised
7 January 2002	Department of Health/MoD meeting to discuss companies and way forward given there are no UK companies producing the vaccine
	Criteria established for the purchase of vaccine
8 January 2002	DCMO steer that UK companies should be approached in the first instance
11 January 2002	Dr Paul Drayson's (Chief Executive of PowderJect) second donation of £50,000 to the Labour Party
22 January 2002	Confidential meeting with PowderJect to discuss the Department's smallpox requirements
28 January 2002	Confidential meetings with Acambis, GlaxoSmithKline and Aventis Pasteur MSD (full team not available, second meeting requested) to discuss the Department's smallpox requirements
30 January 2002	Department joins MoD in site visit to Bavarian Nordic
6 February 2002	Second confidential meeting with Aventis Pasteur MSD to discuss the Department's smallpox requirements
7 February 2002	Publication of the first donation to the Labour Party by Dr Paul Drayson (Chief Executive of PowderJect) by the Electoral Commission
8 February 2002	Deadline for written submissions from companies
12 February 2002	Confidential teleconference meeting with RIVM to discuss the Department's smallpox requirements

13 February 2002	Meeting of officials to discuss responses from companies and to determine the options to be put to Ministers for procurement
17 February 2002	Media coverage of donation by Dr Paul Drayson (Chief Executive of PowderJect) to the Labour Party
18 February 2002	Submission to Deputy Chief Medical Officer and to the Minister
	Minister's Private Secretary informs Departmental officials and Minister of Chief Executive of PowderJect's donation to the Labour Party
	Minister approves in principle the officials' strategy and the contract with Powderject for phase 1 procurement (and the suppliers of phase 2 to be considered in the light of developments) subject to a copper bottomed case for choosing the Lister strain and consideration of other options in the light of the donations
1 March 2002	Submission to the Minister regarding the choice of Lister strain rather than NYCBH
5 March 2002	Minute to Permanent Secretary setting out procurement strategy and the reasons for Lister strain choice. Alerts Permanent Secretary of the donations and confirms that officials did not know about the donation until after the submission of 18 February
	Permanent Secretary endorses advice of the officials to purchase Lister strain and to purchase from PowderJect
	Minister formally approves contract with PowderJect for first tranche following additional submission on the relative merits of the Lister and NYCBH strains of vaccine
11 March 2002	Secretary of State confirms the option to purchase smallpox vaccine with PowderJect
21 March 2002	Officials meet Ministers to discuss contingent liability indemnity for the company for the use of unlicensed vaccine
21 March 2002	Treasury consultation over the PowderJect indemnity
27 March 2002	Letter to the Committee of Public Accounts informing them of the contingent liability arising from smallpox vaccine
5 April 2002	Contract finalised and ready for signing
9 April 2002	Deputy Chief Medical Officer agrees contract
11 April 2002	Contract signed
12 April 2002	Partnership between PowderJect and Bavarian Nordic announced
April 2002 onwards	Further media coverage of donations by Dr Paul Drayson, Chief Executive of PowderJect, to the Labour Party
7 May 2002	Publication of the second donation by Dr Paul Drayson (Chief Executive of PowderJect) by the Electoral Commission
	Further media coverage of the donations by Dr Paul Drayson, Chief Executive of PowderJect, to the Labour Party

Source: NAO examination; Department of Health; Powderject Pharmaceuticals PLC.