

Procurement of Vaccines by the Department of Health



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

summary & recommendations

In this section

| | |
|--|---|
| Introduction and scope | 1 |
| On the Department's general procurement arrangements | 2 |
| On the procurement of vaccines | 3 |
| On the procurement of smallpox vaccine | 5 |
| Recommendations | 6 |

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.

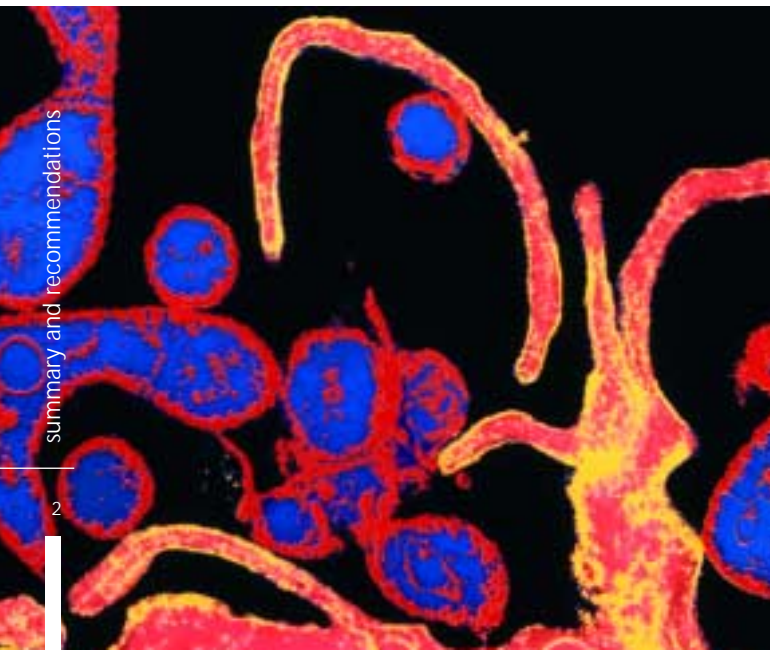


- 4 Following Parliamentary and media concerns about possible links between donations made by the Chief Executive of PowderJect to the Labour Party and the award of the contract, we examined the robustness of the Department's arrangements for buying vaccines (Part 3 of this report), including smallpox, 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 recipient 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.