The Publicly Funded Vaccines Market in the UK

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Jon Sussex, OHE[1]
Koonal K. Shah, OHE

Corresponding author:

[1]12 Whitehall, London, SW1A 2DY, Tel: +44 (0)20 7747 1412, E-mail: jsussex@ohe.org

This OHE Consulting Report presents a report that was prepared as a case study for the Federal German Ministry of Health (Bundesgesundheitsministerium), who funded the project. The full report of the wider study of vaccines markets, to which the OHE's case study of the UK contributes, is entitled "Gutachten zur Verbesserung der Wirtschaftlichkeit von Impfstoffen in Deutschland " ("Review for the improved efficiency of vaccines provision in Germany"), June 2010, and is available at:
http://www.bundesgesundheitsministerium.de/cln_160/nn_1168248/SharedDocs/Publikationen/DE/Forschungsberichte/gutachten-impfstoffe,templateId=raw,property=publicationFile.pdf/gutachten-impfstoffe.pdf

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1. Background and Institutional Overview

1.1. Features of the UK health care system

The UK National Health Service (NHS) provides comprehensive health care coverage, including preventive services such as vaccination, for all residents of the UK. Nearly 99% of NHS funding comes from general national taxation and just over 1% from user charges. Most services, including vaccination other than travel vaccines, are provided free of charge to patients. The large majority of UK residents are each registered with a General Medical Practitioner (GP), who is a physician responsible both for providing primary medical care and for referring patients to specialist ('secondary') care services including hospital inpatient and outpatient services. But even those people who have not registered with a GP are entitled to the same NHS services as anyone else.

The administrative and organisational details of the NHS have for decades varied between the four countries of the UK: England, Northern Ireland, Scotland and Wales. But in 1999 the scope for differences increased greatly. In that year the UK government introduced political devolution to the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly. Health policy in Northern Ireland, Scotland and Wales was devolved as part of this. English health policy is the responsibility of the UK Parliament. As a consequence of devolution, the different countries of the UK have pursued a variety of divergent health care policies since 1999.

However, although there is the scope for the four countries to pursue different policies towards immunisation and/or different approaches towards obtaining supplies of vaccines and the prices paid for those vaccines, the four jurisdictions have so far chosen to adopt (for the most part) a common approach. This approach is described below, with the occasional sub-UK variations highlighted where they arise. It is worth noting that in terms of population, England is ten times the size of Scotland, which in turn is larger than Wales and Northern Ireland combined – see Table 1.

Private sector immunisations are, in the UK, mainly focused on providing travel vaccines and vaccines not offered on the NHS, e.g. seasonal flu vaccines to non-high risk groups of the population. The private vaccines market in the UK is trivial in scale by comparison with NHS use of vaccines and is not discussed further here.

Table 1: UK Population (2007 mid-year)

	Population	% of UK total population
England	51.092m	83.8%
Scotland	5.144m	8.4%
Wales	2.980m	4.9%
Northern Ireland	1.759m	2.9%
Total	*60.975m*	

Source: Office for National Statistics. Annual Abstract of Statistics 2009 (Table 5.1)

1.2. The national immunisation programme and how vaccines reach patients

The immunisation programme offered by the NHS throughout the UK is published by the Department of Health in *"Immunisation against Infectious Disease"* [widely known as *"The Green Book"*] (Department of Health 2006, updated 2009). The routine childhood immunisation programme as specified there is set out in Figure 1. There are also a number of selective childhood immunisation programmes which target children at particular risks of certain diseases, principally:

- Hepatitis B
- Influenza ('flu')
- Pneumococcal
- Tuberculosis

From September 2008 immunisation against human papillomavirus has been added to the routine national programme. HPV immunisation is now routinely offered to girls aged 12/13 and a catch-up programme to immunise all girls aged under 18 is currently under way – three separate doses are administered, via one injection each time (Department of Health 2006, updated 2009).

There is no legal obligation for children to be immunised, however, and neither is immunisation a school entry requirement.

In addition to being able to complete any unfinished courses of childhood vaccinations, adults are offered the following immunisations on the NHS:

> "Older adults (65 years or older) should be routinely offered a single dose of pneumococcal polysaccharide vaccine, if they have not previously received it. Annual influenza vaccination should also be offered.

Selective vaccines should also be considered for young adults unprotected against diseases including measles, mumps, rubella and meningococcal C. Other vaccinations should be considered for any adult with underlying medical conditions and those at higher risk because of their lifestyle. These vaccinations include Hib, MenC, influenza, pneumococcal and hepatitis B." (Department of Health 2006, page 82)

The UK national immunisation programme set out in the *Green Book* can be thought of as effectively a 'positive list' of vaccines available free of charge to UK residents. Licensed vaccines not on the NHS programme may be purchased privately by patients out of their own pockets but will not be reimbursed by the NHS.

Figure 1: Schedule for the UK's routine childhood immunisations*

When to immunise	What vaccine is given	How it is given
Two months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Hib (DTaP/IPV/Hib)	One injection
	Pneumococcal (PCV)	One injection
Three months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Hib (DTaP/IPV/Hib)	One injection
	MenC	One injection
Four months old	Diphtheria, tetanus, pertussis (whooping cough), polio and Hib (DTaP/IPV/Hib)	One injection
	MenC	One injection
	PCV	One injection
Twelve months old	Hib/MenC	One injection
Around 13 months old	Measles, mumps and rubella (MMR)	One injection
	PCV	One injection
Three years four months to five years old	Diphtheria, tetanus, pertussis and polio (DTaP/IPV or dTaP/IPV)	One injection
	Measles, mumps and rubella (MMR)	One injection
Thirteen to 18 years old	Tetanus, diphtheria and polio (Td/IPV)	One injection

* Additionally, since September 2008, human papillomavirus (HPV) vaccination is provided for all 12/13 year old girls.

Source: Department of Health 2006, updated 2009

The majority of immunisations are administered to patients by staff at GP practices, although some are delivered in schools by school nursing services or in clinics run by NHS Trusts.

Vaccine purchase, storage and distribution together cost the NHS in England approximately £300 million (€340 million) in 2009/10 financial year, although this excludes the cost of swine flu (H1N1) vaccination, which is being paid for from a separate special government budget for pandemic flu (source: interview with David Salisbury, DH). As England has 84% of the total UK population (Table 1), this implies that the equivalent cost for the whole UK (excluding H1N1 vaccine) is approximately £360 million (€410 million). This sum excludes payments to GPs for administering vaccines and for reaching targeted immunisation rates among the patients registered with them.

The figure of £300 million for England in 2009/10 compares with the £195 million for England in 2001/02 financial year that was reported by the National Audit Office (2003). The greater than 50% growth in the cost of vaccines over 8 years partly reflects general inflation (the GDP deflator increased 23% over that period) but also the expansion of the immunisation programme, most recently to include HPV vaccination.

1.3. Organisations involved in vaccines policy, evaluation and procurement

The development and implementation of immunisation policy in the UK is led and coordinated by the English **Department of Health (DH)** in London, on behalf of all four countries of the UK. The devolved administrations in Northern Ireland, Scotland and Wales have the right to make their own decisions on immunisation policy but hitherto have always chosen to adopt that proposed by the Department of Health in England.

The DH and the health departments of Northern Ireland, Scotland and Wales are advised by the **Joint Committee on Vaccination and Immunisation (JCVI)**. Founded in 1963, the JCVI is a statutory expert committee with the terms of reference: "To advise the Secretary of State for Health and Welsh Ministers on matters relating to communicable diseases, preventable and potentially preventable through vaccination and immunisation." (http://www.dh.gov.uk/ab/JCVI/DH_094787, accessed 2 February 2020). Although advising Northern Ireland and Scotland is not a part of JCVI's statutory responsibilities, both those countries' health ministers have hitherto chosen to act in accordance with JCVI advice and have not established alternative sources of expert advice on vaccination and immunisation.

The JCVI has, at the time of writing (February 2010), 16 members, most of whom are medical experts across the range of relevant disciplines, and also two nursing experts and a lay member. The JCVI advertised in January 2010 to recruit up to five new members including up to two lay members and, for the first time, a health economist. The absence of specific health economics expertise on the JCVI has been a source of criticism by vaccines manufacturers (source: interviews). Minutes of the JCVI's meetings are published on its website

(http://www.dh.gov.uk/ab/JCVI/index.htm?ssSourceSiteId=en). The medical and scientific expertise of the JCVI is widely and highly respected across the UK, as evidenced by our interviews with manufacturers and with the Scottish health department as well as the DH.

The JCVI considers the need for and impact of vaccines, their quality and immunisation strategies. It also horizon-scans to identify likely longer term prospects in vaccine research and development. However, the most recently published long-term strategy for immunisation in the UK dates from 2002: "Getting Ahead of the Curve" (Department of Health 2002). The absence of an up to date strategy, discussed with vaccines manufacturers, was identified by our interviewees at the UK Vaccines Industry Group (UVIG) as a weakness of current arrangements. The DH monitors the burden of infectious disease but there is no formal mechanism to reconcile the consequent public health priorities with the R&D plans of the vaccines industry (Parliamentary Office of Science and Technology 2008).

The government introduced on 21st January 2009 a formal constitution for the NHS in England. It has not so far been replicated in the other countries of the UK. The NHS Constitution states various legally enforceable rights of patients in England, including:

> "You have the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation recommends that you should receive under an NHS-provided national immunisation programme."

It is the responsibility of the DH to ensure that the JCVI's recommendations are implemented, including finding the funds from within the overall health care budget in England. The health departments of the devolved administrations in Northern Ireland, Scotland and Wales are responsible for implementation and funding from within their allocations of public spending in their respective jurisdictions.

The JCVI obtains advice on the cost-effectiveness of vaccines usually from the Health Protection Agency (HPA). The HPA is a publicly funded non-governmental organisation covering the UK, which also undertakes vaccine research, epidemiology and surveillance of the national immunisation programme and of vaccine-preventable diseases. The JCVI can also obtain advice from other experts. The DH may choose also to conduct in-house analyses, but these will not necessarily be purchased (Welte et al. 2005). The specifics of how such cost-effectiveness analysis is undertaken and its role in determining access to and pricing of vaccines are explained below.

The Immunisation Branch at the DH in London is responsible for developing immunisation policy and supporting the NHS in implementing it. The Branch has a staff of about 35 and includes teams that are responsible for expert scientific input and policy development, communications, informatics, finance and the central purchase, stock management and logistics of vaccine distribution. As is explained in more detail in the following pages, a number of other organisations are involved in the procurement and supply of vaccines:

- The DH's **Procurement, Investment and Commercial Directorate (PICD)** has recently (autumn 2009) taken over some of the functions of the former **NHS Purchasing and**

Supply Agency (PASA). PASA previously had the responsibility to procure both the vaccines themselves and the distribution of those vaccines, on behalf of the DH and, in practice, for the health departments of the other UK countries too. This will now be run out of the PICD.

- A single private sector logistics company, currently **Movianto UK Ltd**, is responsible throughout the UK for collection from manufacturers, cold storage and distribution of vaccines to the end users. The logistics company is selected via competitive tender in a periodic procurement exercise managed previously by PASA but henceforth by PICD.

- Vaccines are supplied to **GP practices, school health services and NHS clinics** for administering to patients. The latter two types of organisations are run by 152 NHS Primary Care Trusts in England, five Health and Social Care Trusts in Northern Ireland, 14 Health Boards in Scotland and seven Local Health Boards in Wales. Each of these NHS bodies has responsibility for school health services and NHS clinics in particular geographic areas, so that the whole of each country is covered.

Thus, overall, the UK approach to determining which vaccines are to be made available on the NHS is highly centralised. The DH in London, advised by the JCVI, develops and implements policy, and procures vaccines and the associated logistics; and it does so on behalf of all four countries of the UK.

2. Methods of Cost Benefit Analysis of Vaccines

Economic evaluation is central to health care decision making in the UK. The National Institute for Health and Clinical Excellence (NICE), the organisation responsible for providing advice on the use of health care resources in England and Wales, endorses a particular form of cost benefit analysis whereby the benefit of an intervention is measured in terms of quality-adjusted life years, or QALYs (NICE 2008). NICE takes the view that for the use of a particular intervention in the NHS to be considered cost-effective, its incremental cost-effectiveness ratio (ICER) should not exceed £20,000 to £30,000 per QALY gained, specifically:

> "6.2.23 Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the technology as an effective use of NHS resources will specifically take account of the following factors.
>
> - The degree of certainty around the ICER. In particular, the [Appraisal] Committee will be more cautious about recommending a technology when they are less certain about the ICERs presented.
> - Whether there are strong reasons to indicate that the assessment of the change in HRQL [health related quality of life] has been inadequately captured, and may therefore misrepresent the health utility gained.
> - The innovative nature of the technology, specifically if the innovation adds demonstrable and distinctive benefits of a substantial nature which may not have been adequately captured in the QALY measure.
>
> 6.2.24 As the ICER of an intervention increases in the £20,000 to £30,000 range, the Committee's judgement about the acceptability of the technology as an effective use of NHS resources will make explicit reference to the relevant factors listed above.
>
> 6.2.25 Above a most plausible ICER of £30,000 per QALY gained, the Committee will need to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources, with regard to the factors listed above."
>
> (NICE 2008; available at http://www.nice.org.uk/niceMedia/pdf/TAP_Methods.pdf)

NICE is unlikely to recommend the use of an intervention whose ICER exceeds this threshold range unless there are special grounds for approval (Rawlins and Culyer 2004). However, NICE is not responsible for providing guidance on vaccines.

Similarly, the remit of the Scottish Medicines Consortium (SMC), Scotland's equivalent of NICE, excludes the assessment of vaccines.

As noted in section 1, the JCVI (which pre-dates NICE) is responsible for providing advice on vaccines in England and Wales. Its terms of reference explicitly require it to take cost-effectiveness into account (italics added):

> "The Committee must advise the Secretary of State for Health and Welsh Ministers on matters relating to vaccination and immunisation as the Committee considers appropriate and on any questions referred to it by the Secretary of State or Welsh Ministers. In particular, upon request of the Secretary of State, the JCVI must make recommendations relating to new provision for vaccination (other than vaccination relating to travel or occupational health) under a national vaccination programme or to changes to existing provision under such a programme, *that are based on an assessment which demonstrates cost-effectiveness*.
>
> In formulating any advice and recommendations, the Committee should take into account the need for impact of vaccines, the safety, efficacy and quality of vaccines and the strategies to ensure that their greatest benefit to the public health can be obtained from their most appropriate use."
>
> (source: http://www.dh.gov.uk/ab/JCVI/DH_094787, accessed 9 February 2010)

The JVCI is the only UK body that makes immunisation recommendations. The separation of responsibilities between the JCVI and NICE exists for historical reasons but our interviewees identified several benefits from the continued existence of this arrangement.

First, the epidemiological modelling methods used for vaccines are fundamentally different from those used for curative or palliative health care technologies in that they involve different timescales and modelling complexities, such as the need to account for herd immunity benefits. Also, one of our manufacturer interviewees stated that the degree of specialist expertise and international reputation of the JCVI is significantly greater than that of NICE's Appraisal Committees, which typically comprise individuals who are not necessarily specialists in the particular technology that they are appraising. The JCVI's scientific expertise is particularly important, given that evidence about vaccines is based to a large extent on the science and measurement of immunogenicity rather than on observed efficacy in trials, given the long time period over which effects emerge and the very large numbers of individuals who need to be vaccinated to observe the effects.

Second, NICE deals with technologies aimed at individuals who are ill, and will therefore accept some amount of risk for the chance of achieving improved health outcomes. The JCVI, on the other hand, deals with technologies aimed predominantly at the healthy; and they (or their parents, in the case of children) may be less willing to accept such risks. Given this, a different attitude towards risk is required and it is arguably even more crucial than for NICE that the JCVI maintains trust and public confidence that its recommendations have been arrived at independently.

Finally, although like NICE the JCVI is statutorily responsible only for England and Wales, in practice it provides advice to all four of the UK's nations. According to our Scottish Government interviewee, Scotland could not practically establish alternative sources of advice on vaccination that replicate the depth of expertise that exists on the JCVI without going beyond Scotland's borders for members, so there is no advantage in doing so. Scottish representatives sit on the JCVI, and Scotland-specific epidemiological data have been used by the JCVI in the past. There is

no suggestion that the JCVI cannot or does not adequately reflect the Scottish situation (source: interview with Gareth Brown, Scottish Government).

Cost-effectiveness analysis has played an increasingly important role in vaccine decision making over the past 10 years (source: interview with John Edmunds, HPA). In order for a new vaccine or major change to the vaccination programme to be approved by the DH, a cost-effectiveness analysis would normally have to be considered by the JVCI. These studies have to date almost always been commissioned from the HPA's National Vaccine Evaluation Consortium, which is responsible for undertaking economic modelling and evaluations of new immunisation programmes. The models are peer reviewed extensively before being presented for consideration by the JCVI. Going forward, the DH is looking to conduct more in-house analyses and to widen the sources of economic advice to include academic units (source: interview with DH).

The JCVI requires that cost-effectiveness analyses of vaccines use the same approach and perspective as NICE (that is, the perspective of the NHS and PSS [Personal Social Services] rather than a wider public sector or societal perspective). This is a matter of practice, rather than a statutory obligation. Both of our industry interviewees expressed reservations about the use of the narrow NHS/PSS perspective, arguing that the societal impacts of vaccination, in particular productivity benefits such as those arising from parents not having to take time off work to care for sick children, should also be taken into account but they are currently ignored.

The JCVI also adopts NICE's ICER threshold range of £20,000 to £30,000 per QALY gained in order to determine whether or not a programme is cost-effective. This ensures compatibility with other health care technology evaluations. The evaluation may compare non-identical vaccines (e.g. Jit et al. 2008) or simply compare a vaccinated cohort with an unvaccinated cohort (e.g. Melegaro and Edmunds 2004).

Owing to the typically long time lag between vaccination and benefit (avoidance of later illness), the discount rate used in the economic evaluation is particularly important. The HPA's analyses use a 3.5% real annual discount rate – as required by the UK Treasury (the finance and economics ministry) – but the HPA also presents sensitivity analyses using 1.5% and 0% real discount rates (source: interview with DH).

The HPA is not made aware of the actual price that the DH pays for the vaccine, as this information is commercially confidential (source: interview with John Edmunds, HPA). The price assumption used in cost-effectiveness analyses is the UK list price if there is one; if not then a sensitivity analysis is conducted using a range of price estimates, with the price in another major market (e.g. US federal government contract price) often used to inform the estimates.

In principle, it is possible that a separate Scottish cost-effectiveness analysis for any given change to the vaccine programme might reach different conclusions from an analysis which considers the situation in England and Wales – just as NICE and the SMC occasionally reach different conclusions when appraising the same medicine – but our Scottish Government interviewee indicated that this has not been an issue in practice.

In addition to the JCVI assessment, whenever a major change is made to the national vaccination programme, the DH is also required to undertake a Policy Impact Assessment, which includes a cost benefit analysis. Policy Impact Assessments are designed to ensure that best policy-making practice is adopted, and they take a wider societal perspective (in line with the guidance of the UK Treasury) than the NHS/PSS perspective adopted by the JCVI. In principle the DH can reject a JCVI recommendation on the basis of the Impact Assessment, or for any other reason, but our interviewees were not aware that this has happened.

The main process improvements suggested by our interviewees relate to the speed and transparency of the JCVI's working. Although there is no indication that manufacturers wish to see responsibility for appraising the cost-effectiveness of vaccines handed over to NICE (indeed, in general they appear to respect highly the expertise and reputation of the JCVI), our industry interviewees said that they would like the JCVI to be as willing to engage, and be as transparent in its processes, as NICE. Currently there are few opportunities for dialogue between the JCVI and manufacturers, who are kept at arm's length and are not permitted to attend JCVI meetings.

JCVI process can also be slow on occasion. For example, the pneumococcal vaccine was licensed in Europe in 2001 but the vaccination programme for it in the UK only commenced in 2007. The pandemic swine flu vaccination, on the other hand, was introduced much more rapidly – perhaps indicating what is possible.

Finally, one of our manufacturer interviewees noted that the JCVI's membership does not include an expert health economist and recommended rectifying this. To this end, the JCVI was, in early 2010, seeking to recruit new members with specific health economics expertise.

3. How the Outcomes of Cost Benefit Analysis Affect Pricing and Reimbursement

If the JCVI recommends, based on evidence including cost-effectiveness analysis, the use of a vaccine, then the DH is now required by the NHS Constitution to procure it. The arrangements for the procurement of routinely provided vaccines are described later in this report. However, the DH may also procure vaccines that are not yet supported by cost-effectiveness evidence. The NAO report indicates that costs are in general considered secondary to public health and national priority issues, particularly for vaccines purchased for emergencies (NAO 2003). Welte et al. report that the relevant cost-effectiveness analyses of the meningococcal group C conjugate vaccine programme were conducted after (rather than prior to) the procurement and introduction of the vaccine due to the attractiveness of the programme from a public health perspective. Although the results of the cost-effectiveness analyses did eventually confirm the economic attractiveness of the programme, and may have supported its expansion to target those aged between 20 and 24 years, the overall role of economic considerations in the making of key decisions was in this case minor as public health considerations took precedence (Welte et al. 2005).

As noted in section 2, the vaccine price used in the economic evaluation is the UK list price if there is one, or the price in another major market if not – for example, in the economic evaluation of routine HPV vaccination, the price assumption was varied between the price in the US and the price available privately in the UK (Jit et al. 2008). The list price is generally higher than the price bid in competitive tendering procurements but the HPA (or whoever else is responsible for conducting the economic evaluation) is not made aware of the likely magnitude of the discount. The economic evaluation then indicates whether it is worth conducting a procurement exercise by producing an estimate of the cost-effectiveness of the vaccine programme, given the list price (or proxy for it). The fact that the economic model is publicly available should in principle enable manufacturers to identify the price threshold below which the vaccine is likely to be considered cost-effective, and therefore to offer a bid price that does not exceed this threshold. If the procurement proceeds, then it is the bid price that ultimately determines whether or not the vaccine will be purchased.

In practice, the information made available as part of the economic evaluation process is not always sufficient to lead to the successful procuring of a vaccine. A good example of this is that of rotavirus. The JCVI commissioned a cost-effectiveness analysis of two rotavirus vaccines, RotaReq® and Rotarix®. The study, which was published in a prominent peer-reviewed journal, concluded that, based on their list prices, the two vaccines would cost £79,900 or £61,000 per QALY gained, respectively – well above the range normally considered acceptable for the NHS (Jit and Edmunds 2007). The study noted that the vaccines would have to be competitively priced in order to render them cost-effective, a point that was echoed in the JCVI's subsequent statement on rotavirus vaccines:

> "Using the cost-effective analysis and assumptions, the cost of both the vaccines would need to be much less than their current list prices before either could be considered to be cost-effective using currently accepted thresholds in the majority of scenarios considered."
>
> (JCVI 2008; available at: http://www.dh.gov.uk/ab/JCVI/DH_094744)

The DH nevertheless invited the submission of tenders. At least one manufacturer offered a price below the list price that it thought would be accepted, but this was also rejected on cost-effectiveness grounds (source: interview with manufacturer). Ultimately the DH did not buy the rotavirus vaccine from anyone, so the NHS does not currently provide it.

Thus, although in the majority of cases the outcomes of cost-effectiveness analyses do affect the bid prices of vaccines, the example of rotavirus shows that it is not always the case that the manufacturer is able to correctly determine the price at which the vaccine becomes cost-effective. If the bid price is not low enough to render the vaccine cost-effective, it will not be reimbursed by the NHS.

4. Strengths and Weaknesses of the UK Approach to Cost Benefit Analysis of Vaccines

- The use of economic evaluation to determine whether a vaccine is included in the national immunisation programme should encourage allocative efficiency.

- Maximising QALYs versus maximising cost-effectiveness: the DH method gets the most QALYs from the Immunisation Unit's budget, but it is not necessarily the most efficient method when considering the budget of the DH or the public sector as a whole. However, where there is competition on the supply side the price should be driven down such that the option that maximises QALYs is also the one that maximises cost-effectiveness.

- The way in which the outcomes of cost-effectiveness analysis are used for pricing and reimbursement might in effect create a target price for manufacturers. This might weaken the competition between manufacturers, particularly in view of the small numbers of companies active in most vaccine markets.

- Taking a societal perspective in economic evaluation, rather than the current narrow NHS perspective, could have a greater impact on the view of vaccines' cost effectiveness.

- There seems to be widespread agreement that having the JCVI separate from NICE is a strength – primarily because of the peculiarly specialised nature of vaccines compared with other health care technologies.

5. Pricing and Reimbursement of Vaccines in the UK

If the JCVI recommends, based on evidence including cost-effectiveness analysis, the use of a vaccine, then the DH is now required by the NHS Constitution to procure it. This procurement follows EU rules and until recently would have been managed for the DH by PASA but (since autumn 2009) we understand would now be managed by the PICD, which is part of the DH itself.

In essence, and with few exceptions, the prices of vaccines currently offered to patients by the NHS are determined via centralised procurement based on competitive tender. The only large scale exception to this is seasonal flu vaccine, for which purchasing is decentralised. The following paragraphs discuss first the majority of NHS vaccines and secondly seasonal flu vaccine. Small scale examples of vaccines that are not procured centrally, such as pneumococcal vaccine for adults and other targeted vaccines such as those against chicken pox and hepatitis B, are not discussed further here.

As in the rest of the report of the UK case study, we focus on the arrangements for routinely procured and provided vaccines. We discuss the supply only of routine vaccines available on the NHS, which excludes travel vaccines, and seasonal flu vaccine for people not in high risk groups of the population. Special one-off procurements, such as that in 2002 of smallpox vaccine in response to biological terrorism fears post-'9/11', and more recently the 2009 procurement of pandemic H1N1 flu vaccine in response to the worldwide swine flu scare, are not explicitly discussed other than to note that they also are purchased via central procurement for the whole UK in a comparable approach to that for most other vaccines available on the NHS. A detailed description of the 2002 smallpox vaccine procurement is available in a report by the National Audit Office (2003), which is summarised in a report of the House of Commons Committee of Public Accounts (2004).

5.1. Routine vaccines excluding seasonal flu

The Immunisation Branch of the DH in London has the responsibility to identify the supply requirements, including the quantities required, and then to invite manufacturers to bid. The PICD part of the DH (previously PASA) manages the procurement exercise and the contract for all vaccines that are centrally purchased by DH. Procurement follows the requirements of the EU Procurement Directive, including an advertisement in the Official Journal of the European Union (OJEU). Vaccine manufacturers respond to that advertisement and undertake a pre-authorisation exercise. When that has been satisfactorily completed they receive the tender documents from DH and submit their bids within a fixed timescale.

For new vaccines, manufacturers are free to choose the price they will bid, subject to the pressure of any competition and as long as they remain within the overall rate of profit permitted by the Pharmaceutical Price Regulation Scheme (explained below). But if they have

sold the same vaccine previously they will not generally be permitted to charge a higher price subsequently.

When it has received the bids, the DH adjudicates between them at a meeting with its Northern Irish, Scottish and Welsh equivalents. In the words of the Director of the DH Immunisation Branch:

> "Criteria for successful bidding are safety, efficacy, availability, price, and record of the company against previous contracts. Wherever possible, more than one supplier is chosen." (Salisbury 2005)

Trading off quality (in terms of QALYs produced by the vaccine) versus price is explicitly allowed for in the DH tendering exercises. It is inevitable where non-identical vaccines are available, for example in the recent HPV vaccine procurement. The principle explained to us by DH interviewees is that the price paid for a vaccine must fall below the cost/QALY threshold level (as described above) in order to be purchased at all; and once that condition is satisfied the DH's aim is to maximise the QALYs obtained for their budget. A scoring system is now used in assessing tenders that also takes account of vaccine availability, the probability of programme failure and aspects of innovation (e.g. innovations to save staff time such as pre-loaded syringes), alongside price.

Having adjudicated, DH then buys sufficient quantities of vaccine from the chosen supplier or suppliers for the whole UK NHS, and is paid by the Northern Irish, Scottish and Welsh health departments for any vaccine they require. This means that the same vaccines are available and used throughout the UK. The vaccines are then held in cold storage facilities and distributed from there free of charge to GPs, NHS clinics etc. as required.

Some companies bid a single unit price, others price in bands with larger volumes triggering lower prices. In the latter case the DH may choose to purchase just enough from one supplier to trigger a lower price but buy the remainder from another supplier(s). Buying from more than one supplier is desirable for the NHS for security of supply reasons, as is discussed further below. It also reduces the risk to bidding manufacturers, relative to an 'all or nothing' competition, as they have a greater probability of winning at least a share of the market – at the cost that they know they will not be able to win 100% of the market.

Contract periods are usually one year plus the option to extend for a further year. This provides flexibility if there is a change to the national immunisation programme but also secures the same price for the vaccine in the second year if the contract is extended. Where there is more than one potential supplier, a tender exercise is usually undertaken every year to keep the market competitive.

There are a limited number of potential suppliers of vaccines, and sometimes only a single supplier. The UK Vaccine Industry Group (UVIG), which represents the main vaccine manufacturers supplying the NHS, currently has seven members:

- AstraZeneca
- Baxter Healthcare

- GlaxoSmithKline
- Novartis Vaccines and Diagnostics
- Sanofi Pasteur MSD
- Solvay Healthcare
- Wyeth Vaccines

Where there is a monopoly supplier, having a single purchaser for the UK NHS at least maximises its bargaining power. The UK is a small part of the global market for vaccines, although the NHS does deliver quite high uptake rates out of the eligible population for vaccination, which improves the attractiveness of the UK market to global manufacturers. The high international reputation of the JCVI also adds a cachet to being a supplier to the UK market, as it may signal to other markets internationally the quality of that manufacturer's product.

The most recent published summary of the number of actual vaccine suppliers contracted with by DH (rather than the, presumably larger, number of suppliers who bid) is in the National Audit Office (NAO) 2003 report and gives the position in that year. The NAO noted that the DH was contracting with two or three manufacturers for most of the most widely used vaccines: diphtheria and tetanus vaccine for children; measles, mumps and rubella, and meningitis C; and also for smallpox vaccine. But at that time all other vaccines were being supplied to the NHS by a single supplier in each case.

DH and manufacturer interviewees all confirmed that typically the prices bid for vaccines in tender exercises are well below the notional published list prices. Both the DH and the manufacturers were unwilling to reveal the magnitude, even approximately, of those discounts. This information is considered by all parties to by highly commercially confidential: manufacturers do not want to reveal the information to their competitors and that suits the DH equally well.

However, our search for websites related to vaccine sales in the UK found that for seasonal flu vaccine, which is considered in more detail below as it is not obtained via the centralised DH process, a consortium of GP practices in south west England was purchasing the vaccine for its members at 55% off the list price for its chosen brand (Enzira – manufactured in by Wyeth). The seasonal flu vaccine was available to consortium members at £2.84 per dose, compared with the list price of £6.33 (source GPCare, URL: http://www.gpcare.org.uk/site/members/flu_vaccine.html accessed 23 December 2009). The size of the discount may reflect that the main flu vaccination period for winter 2009/10 was, by December, past. But it is at least indicative of the potential magnitude of discounting relative to list price.

Vaccines are included within the Pharmaceutical Price Regulation Scheme (PPRS), along with all branded medicines. The PPRS is complex and contains many arcane details (Association of the British Pharmaceutical Industry and Department of Health 2008). In essence it is a form of profit regulation. It limits the rate of return that an individual manufacturer may earn from its total sales of branded medicines and vaccines to the NHS. The key features of the current (2009) PPRS to note are that:

- companies are free to set the launch prices of new vaccines and medicines sold to the NHS in all four countries of the UK;

- the rate of return (i.e. profit) earned by a company from sales of all its branded medicines and vaccines to the NHS may not exceed the higher of 29.4% on capital or 8.4% on sales. Revenues in excess of those levels must be refunded to the NHS;

- once set, prices of medicines or vaccines may not be increased without the permission of the Medicines, Pharmacy and Industry (MPI) Group of the DH, and that can only be given when the company's rate of return on NHS sales of branded medicines and vaccines in total has fallen below 8.4% on capital or 2.4% on sales.

Thus the PPRS provides 'back-stop' regulation, preventing vaccines (and medicines) manufacturers from earning excessive profits from the NHS even if they have significant monopoly power due to the absence of close competitors for one or more of their vaccines or medicines.

Our interviewees at DH, including the head of the Immunisation Branch, expressed satisfaction that their approach to determining the prices of vaccines is delivering good value for money to the NHS and the taxpayers who fund it. The vaccine manufacturers we interviewed had no complaints about the conduct of procurements and were broadly content with a centralised approach, which obviated the expense of maintaining sales forces to visit GPs and others responsible for administering vaccines.

5.2. Seasonal flu vaccine

As already mentioned, the arrangements for purchasing seasonal flu vaccine are different from those for most other vaccines. Seasonal flu vaccination is offered each year on the NHS to all aged 65+ and all registered by their GPs as suffering from respiratory illnesses (asthma, chronic obstructive pulmonary disease, etc.). The demand for seasonal flu vaccine is by its nature less predictable and more irregular through the year than for the vaccines that are procured centrally, and consequently implies greater warehousing and logistics costs. There are also several manufacturers of seasonal flu vaccine, which means that any one manufacturer as little or no monopoly power; even a relatively small customer, such as a GP practice, has some market power as it is easy to take their business elsewhere.

The DH does not buy seasonal flu vaccine centrally. Instead, in England and Wales, GPs buy seasonal flu vaccine directly from manufacturers, of whom there are several, or wholesalers and are free to choose whichever supplier(s) they wish. The GPs then pay for the vaccine themselves and are reimbursed for that within a fixed payment from the DH (or equivalent in Wales) per eligible patient vaccinated. Companies use sales forces who visit GPs to try and boost sales of their own vaccines, in much the same way as they do for medicines.

In Scotland, purchasing of seasonal flu vaccine is also decentralised but it is community pharmacists who buy the vaccine from the manufacturers, or wholesalers. The pharmacists pass flu vaccine doses on to GPs under 'transfer orders' for them to administer to patients, and are then reimbursed a fixed fee per dose by the health department of the Scottish Government. Our interviewee at the Scottish Government Health Protection Team (part of the health department in Scotland) advised us that his team is due to review in 2010 the pros and cons of other options, including looking at centralised procurement and distribution of seasonal flu vaccine

Procurement and distribution of seasonal flu vaccine is centralised at the country level in Northern Ireland (population 1.8 million). Purchasing is via competitive tender.

The existence of different arrangements for procuring seasonal flu vaccines in different countries, and the fact that they differ from the UK centralised approach for other NHS vaccines, is interesting. The reasons for seasonal flu vaccine being different seem partly historical, partly due to the less predictable pattern of demand and partly due to the existence of strong competition on the supply side making decentralised procurement practical. It is unclear whether, and how long, the distinction will last. The general tenet of our interviews, with all parties, was that centralised procurement works well in the UK. If there were to be any change in arrangements in future in the UK we conclude, therefore, that it is more likely to be in the direction of centralising the procurement and distribution of seasonal flu vaccine than of decentralising procurement and distribution of any other vaccines.

6. Approach to Achieving Economic and High Quality Vaccines Supply

The approach to determining the national immunisation programme, limiting that to vaccines deemed cost-effective, and then procuring those vaccines for NHS patients, has already been described. In this section we discuss the UK approach to trying to ensure security of vaccines supply, to avoiding waste of vaccines, to the distribution of vaccines, and to encouraging the maintenance of a pipeline of new vaccines in future.

6.1. Security of supply and avoidance of waste

A major consideration in running the national immunisation programme is to ensure that the desired vaccines are available in sufficient quantities as and when required, while avoiding wasteful over-purchasing resulting in unnecessary levels of cold storage costs and eventual destruction of out-of-date stock.

Ensuring security of supply is adversely affected by two factors:

- vaccines are biological products, not chemicals, and they must in effect be grown, rather than manufactured. Thus if a manufacturer encounters a problem at a vaccine production plant – e.g. contamination – it takes time for alternative sources to expand production to meet the shortfall: months rather than days (House of Commons Committee of Public Accounts 2004, page 12, paragraph 21);

- small numbers of manufacturers of most vaccines.

Where different companies' vaccines are interchangeable the DH commonly prefers to contract with two or more manufacturers at a time in the interests of greater security of supply: typically giving the larger share of the contract to the lower cost bidder but giving a substantial minority of the market to another supplier. This policy is pursued "even if the consequence is higher prices than could be obtained from a single supplier" (Salisbury 2005; page 753).

DH forecasts stockholdings up to a year in advance (Salisbury 2005) and tries to ensure that a 'strategic reserve' of all vaccines is held in storage, available for distribution to NHS users: approximately three months' supplies worth if there are two or more suppliers of the vaccine; but approximately six months' worth if there is only a single supplier. Not only do these stockholdings allow time for a new supplier to be found if there is an unexpected interruption to any existing supplies, but they also help to cope with the uneven incidence of demand through the year while avoiding the need to seek additional vaccine supplies at short notice and consequently at less advantageous commercial terms.

Normally GPs are allowed to order supplies of vaccines from the central distributor as and when they wish. The average order is for delivery every two weeks (Salisbury 2005). Normally the doctor is also allowed to choose which manufacturer's vaccine they want, if more than one supplier has been contracted by the DH. However, on occasions, in order to avoid waste, DH will direct which manufacturer's vaccine will be delivered to the doctor. This may happen if purchased stocks of one manufacturer's vaccine are running low, or if a batch of vaccine is approaching its 'use by' date, or in the run-down of a vaccine that is being discontinued.

Only when a shortage is anticipated does DH impose allocation to control the quantity of vaccine being distributed, i.e. DH then determines how much is distributed, when, to whom. Allocation happens only rarely: the last time was in 2008 for the combined diphtheria, tetanus, pertussis, polio and Hib (DTaP/IPV/HiB) vaccine (source: DH interviews).

Overall, the DH seems to be achieving a secure supply of vaccines. The Parliamentary Office of Science and Technology (2008) noted that "DH's policy of central purchase and distribution has resulted in a continuous supply of vaccines (with no shortages) for at least the last eight years for the childhood immunisation programme."

The centrally purchased and monitored supply of vaccines enables DH to trace where any batch of any vaccine has been delivered. That is important if ever any safety issues were to be raised about particular batches, but it also, more mundanely, enables DH to monitor the use of vaccines in each location.

There are no explicit mechanisms to prevent GPs over-ordering and wasting vaccines or fraudulently selling them on (e.g. overseas or to the private market), but the DH monitors use of vaccines (PCTs/Health Boards etc. monitor seasonal flu vaccine use) through reports from the DH ImmForm website and from the vaccine distributor (Gates et al. 2009). Unusual changes in quantities of vaccines ordered would be spotted. There is no incentive for GPs to order products other than those supplied by the DH, since these are free of charge to the GP.

Supplies of vaccines to be administered to children at school – such as HPV – are restricted to the size of the (known) school roll of children of the relevant age and sex, to ensure that wastage and the scope for fraud is kept to a minimum.

We have not been able to find, and our interviewees were also unaware of, any evidence about the scale of vaccine wastage or over-ordering in practice – i.e. the percentage of doses purchased that are not delivered to patients.

6.2. Distribution

Storage and distribution of vaccines other than seasonal flu vaccine is contracted out by DH, via competitive tender and in accordance with EU requirements, for the whole UK in a single contract every 3-5 years. The current contractor, Movianto UK Ltd, was awarded the contract in March 2006 (under the company's then name: Healthcare Logistics). There is no publicly

available evidence of the cost of this contract. Just as with the procurement of the vaccines themselves, the procurement of storage and distribution services, i.e. logistics, was until recently managed by PASA but has now been moved into the PICD, part of the DH. Our DH interviewees all considered that centralised contracting for distribution delivers a highly cost-effective solution.

Movianto take in stocks of vaccines from manufacturers, store them appropriately and securely, pick and pack them, and deliver them to the point of end use (GP practice, clinic) weekly or fortnightly. DH knows within 2-3 hours of delivery where every batch of every vaccine has gone in the UK. This contributes to safety – e.g. permitting recalls if faulty batches are suspected.

GPs and other end users order the vaccines they require from Movianto. GP ordering using the DH's ImmForm website is growing but is not yet universal and orders can still be placed by email or telephone. Movianto deliver free of charge to the recipient: DH pays Movianto rather than the GP or NHS Trust etc. The counterpart health departments in Northern Ireland, Scotland and Wales pay the DH for their respective shares of Movianto's services.

As with procurement of the vaccine itself, distribution of seasonal flu vaccine is the major exception to the centralised model just described. Each manufacturer has its own distribution arrangements: either arranging distribution itself with its chosen distribution company or by selling through wholesalers who arrange the distribution; it is a purely commercial decision. For seasonal flu vaccine the end user (GP practice) pays for each dose directly and is then reimbursed at a standard rate by DH or its counterparts in the other countries of the UK. Movianto is amongst the companies that deliver seasonal flu vaccines on behalf of manufacturers, but it does this through separate contracts, not through the DH contract for the centrally procured vaccines described above.

All of our interviewees were content with the current, largely centralised, distribution and storage arrangements.

6.3. Dynamic efficiency: maintaining the flow of new vaccines

The problems of maintaining, globally, a research pipeline producing new and improved vaccines are well documented in the economic literature and apply across all countries (see for example: Danzon et al. 2005; Offit 2005; and Stephenne and Danzon 2008). In essence they arise from the fact that research development and testing of vaccines, and the manufacture of them, involved high fixed and sunk costs relative to the scale of the potential market; and that the demand for vaccines tends to be concentrated in the hands of a small number of (public) organisations.

With respect to the particular impact of centralised purchasing, one of our manufacturer interviewees expressed it as follows. They observed that there are understandable reasons why the UK operates a centralised (single national purchaser) approach for most vaccines procurement. But they added that centralised contracts can nevertheless act as a disincentive for innovation and new technology when (low) pricing is seen to be the dominant criterion for

tender award, as there is then little encouragement for developing higher quality vaccines if they are going to cost more.

A specific set of points of concern related to the processes of the JCVI and the DH were made by our industry interviewees. The first concerned the speed, or rather the lack of it, with which vaccines are adopted into the UK national immunisation programme. Delays in deciding to introduce vaccines onto the market are frustrating to manufacturers and deter investment in R&D for vaccines. An extreme and recent case was the six-year delay between the licensing of pneumococcal vaccine in 2001 and its eventual introduction in the UK in 2007.

Another concern expressed by manufacturers was related to what they saw as too narrow a perspective being taken by the JCVI of the potential benefits of vaccines, which was a further discouragement, though a lesser issue than delays in putting new vaccines into the national immunisation programme. The manufacturer interviewees argued that the perspective taken in economic evaluations should, but fails to, take full account of 'herd immunity' benefits and other societal impacts, in particular productivity gains from parents not having to be off work to care for sick children. The JCVI's narrow health care perspective on benefits is however consistent with that taken by NICE, whose approach to economic evaluation they follow.

Finally, manufacturers would be more encouraged if they could have earlier and more engagement with the JCVI, in particular to help them 'scan the horizon' in a way that was informed by companies' knowledge of likely future developments of new and improved vaccines.

7. Strengths and Weaknesses of UK Approach to Pricing and Supply of Vaccines

With the exception of arrangements for seasonal flu vaccine, the UK approach to pricing and supply of vaccines is characterised by centralised purchasing by the DH for the NHS of all four countries. Distribution and logistics arrangements are similarly centralised, again with the exception of distribution/logistics for seasonal flu vaccines.

We found no pressure from any quarter to change these arrangements, but we consider here the strengths and weaknesses of that centralised approach that were expressed by our interviewees. The broad alternatives against which the current arrangements were compared, either explicitly or implicitly, are:

- decentralisation to the four countries individually; or

- decentralisation to the level of individual GP practices and clinics, as is currently the case in England, Scotland and Wales for seasonal flu vaccine.

It may be no surprise that the interviewees at the DH Immunisation Branch considered the current, centralised, arrangements to be the most appropriate for the UK: after all they not only have the leading role they have also, de facto, designed the current model. The main advantages of centralisation that were reported by some or all of the DH interviewees are:

- economies of scale. A centralised buyer has the greatest possible market power. This is further enhanced by the fact that the DH is also responsible for immunisation policy in the UK, and for designing policies to encourage high rates of uptake of vaccines. Thus the DH is able to deliver not only the whole UK market for a vaccine, but also to demonstrate that it has policies in place to help maximise that market. Centralisation should therefore enable the greatest scope for volume-related economies and related price discounts to be realised. The potential downside is that manufacturers may exit the market if they fear a significant risk of winning none of it because there is a single 'all or nothing' tender. DH mitigates this by sometimes splitting the UK market between two, or even three, manufacturers rather than awarding the whole UK contract to a single manufacturer;

- greater influence over manufacturers. The influence is derived as described in the preceding bullet point. This influence can be used not only to improve the terms under which vaccines are obtained, but also to encourage manufacturers to, for example, conduct clinical trials of their vaccines and other products in the UK, and to launch them in the UK earlier rather than later, which helps to improve access to new vaccines (and other products) for the UK;

- greater security of supply, reducing the risk of shortages within each country.

We tested the DH's perspective in our interviews with the Scottish Government Immunisation Team and with vaccine manufacturers. If anyone would prefer decentralisation to the level of individual countries within the UK, it could be expected to be the devolved administrations. We were able to interview a senior official of the Scottish Government Health Protection Team. He expressed satisfaction with the centralised DH-led, UK-wide approach to purchasing vaccines and to purchasing the associated distribution and logistics services. The absence of any move by the Scottish Government to diverge from the centralised UK approach is perhaps the strongest evidence that centralisation is generally preferred to decentralisation, because it is entirely within the power of the Scottish Government and the NHS in Scotland to go their own way in obtaining vaccines and/or distribution and logistics for vaccines.

Our interviewee at the Scottish Government Health Protection Team described the following significant benefits from being part of a single UK approach:

- DH has much greater contracting experience and expertise with vaccines procurement;
- the much greater purchasing and negotiating power yields better value for money – not simply lower prices but better terms – due to a stronger position when dealing with manufacturers than Scotland could have alone as Scotland is only one twelfth of the total UK market;
- greater security of supply;
- infectious disease does not respect national boundaries so a common approach throughout the UK is desirable and has historically been the practice;
- Scotland could not practically replicate the depth of expertise that exists on the JCVI without going beyond Scotland's borders for members, so there is no advantage in doing so. Scottish representatives sit on the JCVI, Scottish specific epidemiological data have been used by JCVI, and Scottish Ministers can ask the JCVI for advice – there is no suggestion that the JCVI cannot or does not adequately reflect the Scottish situation.

He described the relationship between the health department in Scotland and the DH (as well as with counterparts in Northern Ireland and Wales), and with the JCVI, as long having been one of openness and pragmatism. It works well. There is no desire to move away from it.

What is true for Scotland might reasonably be expected to apply also to the somewhat smaller countries: Wales and Northern Ireland. We note that there has also been no move by either of those countries' devolved governments to move away from the DH-led centralised approach, despite being free to do so.

The interviews with two vaccine manufacturers and with the UK Vaccines Industry Group (UVIG) did not reveal any fundamental unease with the centralised purchasing and distribution of vaccines in the UK. No desire was expressed to spread the decentralised approach adopted for seasonal flu vaccine to other vaccines. But equally, no strong case was put for moving to centralised purchasing of seasonal flu vaccine, so this might be seen as indifference between the two approaches rather than a strong preference for one or the other.

On the plus side, centralisation was seen as obviating the commercial need for sales forces to go out to individual GP practices and NHS clinics. The downside was noted that centralised purchasing potentially increases the market risk – i.e. the greater risk of winning no part of the UK market as compared with a decentralised approach with multiple buyers. But this is tempered by DH's approach of sometimes awarding contracts to two or three suppliers rather than one, and because of the size of the market that DH is able to deliver to the successful bidder.

The greater problem that might be posed by centralisation is in the longer term if manufacturers fear that R&D into new and improved vaccines will not be rewarded adequately, i.e. if they fear short-sighted opportunistic behaviour by a centralised purchaser unwilling to recognise and pay for the sunk costs of producing vaccines. Overcoming this problem depends on the centralised purchaser making credible undertakings to pay prices that reflect the total costs of cost-effective (at such prices) new vaccines.

The main concern of UVIG and manufacturers in the UK are to improve some aspects of the work of the JCVI and the DH. To do so would not only yield, in their view, immediate benefits but would also increase manufacturers' confidence in the DH as customer and should thereby reduce the dynamic inefficiency problem described in the previous paragraph. Specifically the manufacturers want to see in the UK:

- a reduced time lag between a vaccine obtaining a licence for the UK and its entering the national vaccination programme. An extreme case, the pneumococcal vaccine, was only added to the national programme in 2007, six years after it was licensed in 2001. HPV vaccine was licensed in Europe in September 2006 but the vaccination programme for it in the UK commenced in September 2008. Pandemic swine flu (H1N1) vaccination was introduced much more rapidly than that in 2009 – indicating what is possible;

- horizon scanning by the DH. There is no clear, formal locus currently for vaccine manufacturers to be able to share information with DH or JCVI about the companies' pipelines of upcoming products, so as to pave the way for their speedy introduction once licensed. Companies share information on an informal basis with the DH, and this may then be conveyed to the JCVI, but without any further company input to check accuracy and content. The most recently published DH strategy on vaccines was in "Getting Ahead of the Curve" in 2002, but this failed to foresee the introduction of HPV vaccine and, conversely, foresaw the introduction of rotavirus vaccine which was in the event deemed not cost-effective by the JCVI. The House of Commons Committee of Public Accounts (2004) concluded that: "Greater opportunity for suppliers to influence the development of the Department's immunisation policies, perhaps through the Joint Committee on Vaccination and Immunisation, might enable them to plan more strategically to meet the Department's medium and longer term vaccine requirements." (page 4);

- greater transparency in JCVI's processes. NICE is responsible for advising on the cost-effectiveness of all health technologies apart from vaccines. NICE was seen by manufacturers as having some weaknesses of its own, and was felt not to embody in its

appraisal committees the same depth of specialist expertise that the JCVI brings to its considerations of vaccines. The manufacturer interviewees did not want responsibility for appraising the cost-effectiveness of vaccines to be given to NICE, but would like the JCVI to be as willing to engage, and as transparent in its processes, as NICE.

The overall conclusion from the UK case study appears to be broad willingness by all parties to continue with the current, mostly centralised, UK-wide arrangements. The existence of alternative, decentralised, arrangements for seasonal flu vaccines may be due to the existence of several, rather than one or two, suppliers and to the less predictable level of demand in any area. But these differences are matters of degree, rather than fundamental. The NHS in Northern Ireland has centralised purchasing of seasonal flu vaccine, and we understand that the possibility of doing the same in Scotland will be reviewed this year (2010) by the Immunisation Team of the Scottish Government's health department. So, if anything, the pressure seems to be towards more centralisation for seasonal flu vaccine, at least in parts of the UK, and no pressure for decentralisation for any other vaccine(s).

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