Innovation Pass Pilot

A consultation on proposals for an Innovation Pass pilot

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Contact Details	Innovation Pass Pilot Consultation Medicines Pharmacy and Industry Group Skipton House London SE1 6LH	
For Recipient's Use		

Innovation Pass Pilot

A consultation on proposals for an Innovation Pass pilot

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Contents

The Consultation Process

Purpose

This consultation seeks views from the NHS, industry and other stakeholders on the Government's proposals for an Innovation Pass pilot, a Government commitment published in the Office for Life Sciences Blueprint. These proposals will be revised in light of comments received as part of this consultation and will be used to inform the first set of decisions for the pilot in 2010/11. The Innovation Pass will also need to be reviewed over the first 12 months of the pilot in order to inform the future Innovation Pass process. The proposals set out in this consultation apply to National Health Services operating in England.

Timetable

The consultation will start on 28th November 2009 and run until 8th February 2010. Any views submitted after this date may not be considered or reflected in our analysis. This ten week consultation will enable the pilot to become operational in April 2010[1], in line with the commitment set out in the Office for Life Sciences Blueprint.

Responses

Following this consultation we will continue to refine the proposals in light of the responses to this consultation and other emerging information from our discussions both within and outside Government.

If you would like to respond please use the response proforma published alongside this document. Please send responses to:

By email	innovationpass@dh.gsi.gov.uk
By Post	Innovation Pass Consultation Mr Cris Sowden Room 456D Skipton House London SE1 6LH

We will consider requests for accessible formats that may be required. Please send your requests to the above.

[1] The reduced consultation period of 10 weeks has received Ministerial approval

Information Handling

We manage the information you provide in response to this consultation in accordance with the Department of Health's **Information Charter.** The information you provide to us may also be passed to colleagues in the National Institute for Health and Clinical Excellence (NICE) and may be published in a Government response to this consultation.

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes. The relevant legislation in this context is the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

Code of Practice on Consultation

This consultation follows the 'Government Code of Practice'. In particular we aim to:

1. consult at a stage when there is scope to influence the policy outcome
2. consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible. This ten-week consultation will allow the pilot to become operational in April 2010.[2]
3. ensure the consultation documents are clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals
4. ensure the consultation exercise is accessible to, and clearly targeted at, those people the exercise is intended to reach
5. keep the burden of consultation to a minimum so that consultations are effective and consultees' buy-in is obtained
6. carefully analyse responses and give clear feedback to participants following the consultation
7. provide guidance to officials in how to run an effective consultation and share what they have learned from the experience

The full text of the code of practice can be found on the Better Regulation website at:

http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

[2] The reduced consultation period of 10 weeks has received Ministerial approval

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Contact: Consultations Co-ordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE

e-mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Executive Summary

Aim

There will be drugs for small patient populations which have the potential to deliver improved patient outcomes but where data to demonstrate cost-effectiveness is so far limited. This may limit the medicine's market access, denying NHS patients access to certain innovative and effective medicines, and limiting companies' abilities to bring valuable medicines to the UK market.

The Innovation Pass will make selected innovative medicines available on the NHS for a time-limited period, prior to a NICE appraisal. It is anticipated that the scope of the Pass could be extended to other medical technologies and diagnostics thereafter. Funding will be drawn from a new ring-fenced £25m budget, set aside exclusively for the Innovation Pass. The Pass gives earlier access to innovative drugs for patients with the greatest need, and at the same time it will facilitate the collection of further information to support a subsequent NICE appraisal.

The Innovation Pass – An Overview

The proposals set out in this consultation have been developed with input from the Department of Health, the National Institute for Health and Clinical Excellence (NICE), the NHS and industry. Underpinning this work are a number of general principles which have been set out in chapter four.

Chapter five then sets out our process proposals for applying and assessing applications for an Innovation Pass. There are five key stages in the process, these are:

- An initial review of suitability, to ensure the application is complete and appropriate, validation of the uptake calculations by the NICE Innovation Pass team, and verification that the price or cost of the bid is acceptable by the Department of Health.
- An overview of the application is produced for the advisory committee
- The overview is checked for factual errors by the sponsor company
- The Innovation Pass advisory committee consider the application and make recommendations to the Department of Health
- The Department of Health use the recommendations to inform the allocation of funding for the Innovation Pass

The Innovation Pass advisory committee will assess applications against the proposed set of criteria in chapter six. These ask the committee to assess if the product:

- is a significant medical innovation
- addresses an unmet clinical need
- has a substantial impact
- can demonstrate a relative immaturity of data for appropriate reasons
- has additional studies planned to gain further data
- is within the proposed Innovation Pass budget impact
- will not result in substantial additional service and monitoring costs on the NHS
- has other considerations that need to be made

Chapter seven of this consultation document sets out a number of options for dealing with the mechanisms for pricing and funding.

In chapter eight we set out the proposals for data collection and monitoring requirements during the application for an Innovation Pass, and for the monitoring mechanisms for those drugs that are successful in receiving a Pass.

Next Steps

Following the close of the consultation, a summary of responses will be published, and the views expressed in the responses will be analysed. Responses will be used to inform the first set of decisions for the pilot in 2010/11. The Pass will then need to be reviewed over the 12 months of the pilot to inform the future Innovation Pass process.

1. Introduction

1.1 In January 2009 the Prime Minister announced the creation of the Office for Life Sciences (OLS), which is led by Lord Drayson, Minister for Science and Innovation at Department for Business Innovation and Skills. The OLS co-ordinates national policy, and is undertaking work to build a sustainable and integrated life sciences industry for the future.

1.2 In July the OLS published the 'Life Sciences Blueprint' which announced a package of measures to help maintain a competitive life science sector. One of the initiatives announced in the blueprint was the introduction of an 'Innovation Pass'.

1.3 The aim of the Pass is to make selected innovative medicines available on the NHS for a time limited period, from a new ring fenced budget, without going through a NICE appraisal. This will give earlier access to innovative drugs for patients with the greatest need and facilitate the collection of further information to support a subsequent NICE appraisal. The Pass will enable more research and data collection to take place to inform future NICE appraisals, meaning that in the longer term the relevant NICE appraisals can be based on stronger evidence.

1.4 The Government has worked with the National Institute for Health and Clinical Excellence (NICE), industry and NHS commissioners to develop proposals for the pilot. These proposals are the subject of this consultation. The Pass will be a three year initiative for selected medicines with a budget of £25 million in 2010/11, with funding for future years determined in the context of the next spending review.

1.5 This consultation seeks views on the Government's proposals for the Innovation Pass pilot in 2010/11. These proposals will be revised in light of comments received as part of this consultation and will be used to inform the first set of decisions for the pilot in 2010/11. The Innovation Pass will also need to be reviewed over the first 12 months of the pilot in order to inform the future Innovation Pass process. The proposals set out in this consultation apply to National Health Services operating in England.

1.6 In particular this consultation seeks your views on proposals for :

- the Innovation Pass process
- the criteria for selecting technologies appropriate for an Innovation Pass
- the mechanisms of data collection
- funding arrangements
- the potential impact of these proposals on equality

2. Progress to date

2.1 Government and industry agree that it is vital to promote clinically and cost effective innovative products in the NHS. The National Institute for Health and Clinical Excellence (NICE) has played a key role in promoting the uptake of cost-effective innovative products since its creation in 1999. NICE is a world leader in appraising health technologies and it has been commended by the World Health Organisation. Progress has been made on creating greater flexibility in the NICE appraisal process through recent announcements by NICE on end of life drugs, the PPRS commitments on pricing flexibilities and uptake of innovation, and through Lord Darzi's review: *High Quality Care for All*.

2.2 The NHS Constitution makes it explicit that all patients have the right to access drugs and other health technologies that have been recommended in NICE appraisals, and underlines commitments to making the topic selection and NICE appraisal process more timely. In 2009, draft or final guidance will be available within six months of licensing for about half of the drugs appraised through the Single Technology Appraisal process. In 2010, draft or final guidance for all new cancer drugs will be available within an average of six months of a drug being licensed, and by 2011 NICE will be in a position to produce timely guidance on the great majority of significant new drugs.

2.3 Flexible pricing and the systematisation of the approach to patient access schemes are two key parts of the new Pharmaceutical Price Regulation Scheme (PPRS) agreement. These developments mean that companies have more flexibility to implement pricing solutions that will promote cost-effective use of new drugs. NICE has also announced adjustments to its appraisal methodology to introduce more explicit flexibility into the appraisal of drugs for less common end-of-life conditions, which will support increased patient access to specific innovative products.

2.4 The combination of these new measures means that patients should benefit from both earlier and increased access to innovative products that are recommended by NICE. The recent NICE appraisals of sunitinib for renal cell carcinoma and lenalidomide for multiple myeloma included both a patient access scheme and the use of NICE's end of life flexibilities, illustrating how recent changes are already making a difference.

3. Innovation Pass

3.1 The Innovation Pass is part of a package of measures to promote innovation in the NHS and should be viewed in the context of other work by the Department of Health and NICE. In particular:

- Work is also being taken forward with NICE and industry on creating a new evaluation pathway for medical technologies. This work is being progressed under the auspices of the Ministerial Medical Technology Strategy Group (MMTSG) and follows recommendations in *High Quality Care for all.* Industry are represented on all working groups on the creation of the pathway and are working in collaboration with NICE.

- A very small number of drugs and other specific technologies are currently considered as part of the specialised commissioning system, where they meet the relevant criteria. The Department of Health is considering whether there is a need to develop further the processes for evaluating relevant interventions as part of national specialised commissioning arrangements, and will consult separately on any proposed changes. The Innovation Pass is not likely to constitute an appropriate means of dealing with drugs for extremely small patient populations where the economics of an intervention are unlikely to improve over time – e.g. where there is little or no prospect of significantly better evidence, the patient population is so small and the nature of the clinical indication so specific that the drug is priced at a level that could never achieve a positive NICE appraisal.

Office for Life Sciences Blueprint

3.2 Good progress has been made in improving NHS uptake of, and patient access to, clinically and cost-effective new technologies. However, it has become clear that further progress needs to be made in promoting research into innovative products in the future, particularly in areas of unmet clinical need. It is also important for the NHS to receive value for money in order to ensure the most effective use of healthcare resources and improve patient outcomes. This must be balanced with the need to drive and reward innovation.

3.3 The Office for Life Sciences published its Blueprint in July 2009. The blueprint committed the Government to take action on a number of issues to develop the NHS as an innovation champion and promote research into innovative products. The Blueprint stated:

*"**Issue**: Whilst most significant new medicines should continue to go through NICE's existing processes, there will be drugs for small patient populations which have the potential to deliver improved patient outcomes but where data to demonstrate cost-effectiveness is so far limited, and market access may be inhibited, mainly because of the small number of patients, and other clinical factors"*

3.4 To address this the Government made the following commitment:

*"**OLS Solution:** The Government, with NICE will introduce an 'Innovation Pass'. This will be a three-year initiative for selected medicines, which will be funded for time-limited use across the NHS, from a new ring fenced budget, without going through a NICE appraisal. NICE will play a key role in developing and applying the eligibility criteria for the Pass. This will give earlier*

access to innovative drugs for patients with the greatest need. The Pass will be piloted with a budget of £25 million in 2010/11. The pilot will be developed with input from industry, NICE and the NHS and will the subject of a consultation by November 2009. Funding for future years will also be discussed through the consultation and will then be determined in the context of the next spending review."

3.5 As outlined in the Office for Life Sciences blueprint in July the Innovation Pass will be a three year initiative for selected medicines. However, it is anticipated that the scope of the Pass could be extended to other medical technologies and diagnostics thereafter. The presumption would be that, as for drugs funded through the Pass, non-drug technologies would then need published NICE guidance at the end of the Pass. It is our intention to consider the issue further in the light of experience from the pilot and replies to this consultation.

Patient Benefit

3.6 The Innovation Pass has the potential to bring great benefit to patients and ensures that further data can be collected to inform a future NICE appraisal. The Innovation Pass will be focused on small patient populations where the limited population pool means that patient data can be extremely limited. Industry have also highlighted that the success of other medicines, particularly in oncology, in receiving a licence at a relatively early stage because of a positive benefit-risk ratio has also meant that companies may have to finish clinical trials at an earlier stage, meaning that less data has been collected.

3.7 The criteria proposed later in this consultation document will ensure that patients will benefit from innovative products which employ a novel approach or pathway, and at the same time will ensure that further data is collected to support a future NICE appraisal. The Pass will be vitally important for patients, particularly in areas of unmet need, as it will provide access to a medicine that may not otherwise have been found cost-effective if a NICE appraisal had been undertaken at launch. However, when further data is collected, the medicine may be found to be cost-effective in a NICE appraisal following a period of funding through the Pass.

3.8 The issue of late stage disease has also been raised, where it may be challenging to demonstrate cost-effectiveness in an initial licensed indication but later indications, earlier in the disease process, may subsequently prove cost effective. The Innovation Pass may be relevant to these medicines if they meet the criteria proposed later in this document. However, it should also be noted that a number of other recent developments such as patient access schemes, flexible pricing and NICE's "end of life" flexibilities have been designed in part to address the challenges faced by medicines of this kind.

Links to NICE and Pricing

3.9 It is important to ensure that the creation of the Innovation Pass does not in any way undermine the vital role of NICE in providing authoritative advice to the NHS on clinical and cost-effectiveness. This is why medicines covered by the Innovation Pass will still go through a NICE appraisal after a maximum of 3 years and as outlined earlier, most significant new medicines will continue to go through a NICE appraisal close to the time of their launch. NICE will also play a key part in running the process for the Pass and will contribute valuable expertise to ensure that a professional service is provided for companies applying for the Innovation Pass.

3.10 The Pass should not incentivise higher pricing on the part of companies. This is why the Department of Health will have a role in determining that the cost of a medicine is reasonable,

therefore ensuring that the taxpayer's interests are protected in the development of the Pass, whilst recognising the commercial freedom of pricing for a company for new active substances. Chapter seven looks at this issue in greater detail.

3.11 In summary, the Pass is aimed at rewarding and promoting innovation in life sciences. A successful pilot has the potential to bring benefits to patients and the NHS, as well as to industry and the wider economy. This consultation seeks your help in developing a pilot which is best placed to secure these benefits.

1. Should medical technologies be considered for inclusion in the Innovation Pass in future? Please include your reasons.

2. Is the Innovation Pass relevant to drugs for late stage disease given other recent developments? Recent developments include patient access schemes, flexible pricing and NICE's end of life flexibilities (para 3.8).

4. General Principles

4.1 The proposals set out in this consultation document have been underpinned by a number of principles.

- The budget for the Innovation Pass is a physical ring-fenced budget which cannot be exceeded.
- An Innovation Pass will last for a maximum of three years for each selected medicine and will not be renewable.
- Application for a Pass is voluntary and can only be made by the sponsor or manufacturer. Applications should normally be made around the time the sponsor submits a regulatory dossier to the relevant competent authority for regulatory review.
- Medicines applying for a Pass will normally have been reviewed and selected by the relevant technology appraisal topic selection consideration panel as meeting the criteria for referral to NICE for consideration for appraisal.
- The funding for products selected for an Innovation Pass will be applied once the medicine receives regulatory approval and is available to the NHS.
- Technology appraisal guidance publication will be timed to coincide, as far as is practicable, with the end of the Innovation Pass period. Arrangements will need to be agreed with sponsors or manufacturers for the interim period between the end of the Pass and final published NICE Guidance.
- The sponsor provides the principal information for consideration for an Innovation Pass.
- The independent Innovation Pass advisory committee will review applications and provide advice to the Department of Health.
- NHS bodies retain their existing competences to procure drugs which have not been selected for an Innovation Pass.
- The Department of Health retains the ability to withdraw an Innovation Pass and funding in the event of regulatory changes.

3. Do you agree that these are the right principles to underpin the Innovation Pass initiative? If not please state your reasons why.

4. What other principles should be developed? Please state your reasons why these are important.

5. Innovation Pass Process

5.1 The general principles outlined in chapter four have also been used to develop a process which will be applied to all technologies that apply for an Innovation Pass. Each proposed stage is set out below:

Stage 1. Initial review of suitability of the application

5.2 An information proforma will be developed which will enable sponsor companies to provide the required information for an Innovation Pass application. When an application is submitted, the NICE Innovation Pass team will ensure that the submission is complete by screening the submission. If a submission is incomplete NICE will contact the manufacturer or sponsor and seek clarification. If substantial clarification is required, the submission may be returned to the sponsor without a further review.

5.3 There will be no communication in public as to which technologies have applied for an Innovation Pass. Information provided by the sponsor company for an Innovation Pass will be treated as 'commercial in confidence' as its public disclosure could have an impact on the commercial interests of the company.

5.4 During this screening stage, the Department of Health will verify if the price or cost of the bid is acceptable. The NICE Innovation Pass team will also validate the calculations of the likely uptake of the technology to ensure they are plausible. The arrangements for assessing these proposals, and what information is provided to the Innovation Pass advisory committee are set out in chapters six (criteria) and eight (data collection and monitoring).

Stage 2. Preparation for Panel Meeting

5.5 The Innovation Pass team will produce an overview of the application in preparation for the advisory committee review. This overview will highlight issues relating to the submission that the Innovation Pass advisory committee may want to consider. The overview will not make recommendations on the submission or evidence.

5.6 Information will also be requested from topic specific clinical and patient advisors with expertise in and experience of the therapeutic area under consideration. Two clinical and two patient advisors will be asked to submit a short, written personal view on what they think constitutes therapeutic innovation in the topic area under consideration. These personal views will be reviewed by the advisory committee to inform their discussions.

Stage 3. Sponsor/Manufacturer Factual Clarifications

5.7 The sponsor will then have five working days to check that the overview and commentary does not contain factual errors, such as errors in the figures, incorrect quotes from the application or text that does not describe the facts accurately. The response of the sponsor to this fact checking stage will be included in the papers for the advisory committee.

Stage 4. Innovation Pass Advisory Committee Review

5.8 The Innovation Pass advisory committee will be an independent panel which will meet once a year. The panel will not meet in public due to the commercially confidential nature of the discussions taking place. The panel will consist of the following membership:

- 5 members who are active NHS clinicians
- 3 members with expertise in healthcare industry research and development
- 1 member with expertise in NHS research and development commissioning
- 1 member with expertise in Primary Care Trust Commissioning
- 1 member with a public health background
- 2 lay members

5.9 The remit of the advisory committee is to review the application and form a view on whether the technology meets the Innovation Pass selection criteria. The committee will rank applications according to their view of the overall merit of the application based on the proposed criteria set out in chapter six (criteria).

5.10 Two representatives from the sponsor applying for the Pass will be invited to attend the advisory committee discussions for their topic. The Chair will ask the representatives to respond to questions from the committee and comment on any matters of factual accuracy and clarification before concluding discussions.

Stage 5. Recommendations to the Department of Health and granting of the Innovation Pass

5.11 The recommendations of the committee will be passed to the Department of Health to inform their decision on the allocation of an Innovation Pass to individual technologies. The Department will then make arrangements to distribute the funds to the successful applicants which is likely to be made through an appropriate body. The Department will then announce the successful technologies once the Department has allocated the funding as proposed in chapter seven (pricing).

5.12 There is no appeal stage.

5.13 NICE will invite the manufacturer or sponsor of the technology considered for an Innovation Pass to attend a debriefing meeting. The aim of the meeting is to examine information in the context of the decision taken regarding the Innovation Pass.

5.14 Further applications for unsuccessful topics may be made subsequently.

Process Overview

5.15 A process overview is presented below. The timings below are estimates which are dependent on the number of clarifications needed for each application and the nature of the allocation of funds required in granting the Innovation Pass.

Step	Action	Maximum Time taken (weeks)	Elapsed time from initiation (weeks)	Regulatory timeline
1 ⇩	**Application** In parallel with regulatory submission. Sponsor applies for Innovation Pass by sending completed proforma to NICE.		0	Pre-regulatory approval
2 ⇩	**Screening** NICE Innovation Pass team ensure the bid is complete and appropriate. DH verify whether the price/cost of the bid is acceptable. Review plausibility of the uptake curve. Clarification stage if required.	3 - 4	3 - 4	Pre-regulatory approval
3 ⇩	**Preparation for Panel meeting** NICE reviews application and develops overview. Personal views requested from clinical and patient advisors.	3 - 4	6 - 8	Pre-regulatory approval
4 ⇩	**Fact check** Manufacturer or sponsor asked to fact check the overview produced by NICE.	1	7 - 9	Pre-regulatory approval
5 ⇩	**Innovation Pass Review Panel** Applications assessed by the panel against criteria.	2	9 - 11	Pre-regulatory approval

6 ⇩	**Recommendations to DH** Innovation Pass review panel recommendations, with prioritisation, sent to DH	2	11 - 13	At regulatory approval
7 ⇩	**Innovation Pass granted** Funding agreed. Technology is planned into Innovation Pass spending plan.	4 - 7	15- 20	At regulatory approval
8	Debrief meeting with NICE			At regulatory approval
9	Innovation Pass for the technology announced		N.A.	Post Regulatory approval

5. Is the proposed process for applying and granting an Innovation Pass an appropriate one? How might this be improved? Please provide your justifications/reasons.

6. What further steps should the process include? Please include reasons for your suggestions.

7. Do you agree with the membership and remit of the advisory committee? What additional considerations should be made, and why?

6. Innovation Pass Criteria

6.1 The Innovation Pass advisory committee will consider applications that are successful at the screening stage.

Consideration of the criteria by the NICE advisory committee

6.2 The advisory committee will be asked to assess each candidate medicine/indication, answering the questions set out against each criterion. It will use its response to each question to form a judgement, firstly, on the suitability of the technology/indication for funding through the Innovation Pass and secondly, for those which meet all of the criteria, on the relative priority for funding.

6.3 The advisory committee will need to be convinced that the candidate product meets each of the criteria to a minimum level to proceed any further. Once it has identified those technologies that meet the criteria in that way, it will proceed to score each candidate against the first four evenly weighted criteria to devise an overall prioritised ranking.

6.4 As outlined earlier in this document, the Innovation Pass will only be implemented for products that have received their marketing authorisation and are available to the NHS.

6.5 Once the committee has made its recommendations, advice will be signed off by the NICE guidance executive to check that the recommendations have been made in line with the Innovation Pass processes and criteria which are the subject of this consultation, before being referred to the Department of Health.

6.6 Each application considered by the advisory committee will be assessed on the selection criteria proposed in the following table:

Criterion	Detail
Significant medical innovation	Does the technology employ a novel approach e.g. a novel pathway, receptor or other chemical or biological target? A modification to an existing technology with no clear promise of patient benefit in terms of efficacy or safety would not meet this criterion.
Unmet clinical need	Does the technology address a disease or condition which substantially reduces health-related quality of life and/or is seriously debilitating or life-threatening and *for* which there is an unmet medical need?
Substantial impact	Does the technology demonstrate, through its clinical data, substantial promise of delivering valuable, additional therapeutic benefits to length or quality of life?
Relative immaturity of data	Is there data immaturity to such an extent that a reliable cost/utility analysis could not be done at this time and it would be difficult to achieve a positive NICE appraisal? Is there a plausible reason why the data is immature such that there are insufficient data for a reliable cost utility analysis to be undertaken at this time? Factors to take into account include: - Is the patient population for which the product is indicated so small that the innovator cannot reasonably be expected to provide robust evidence? - Has evidence for benefit been solely derived from endpoints of uncertain validity/specificity?
Additional studies planned	Are relevant and credible studies already planned or in progress that address the immaturity in the clinical data as identified by the company and allow a formal appraisal to be undertaken at the end of the Innovation Pass? Are the results of the studies likely to be generalisable to a UK setting, for example, by recruitment of patients from the UK?

Innovation Pass Budget impact	Is the estimated peak budget impact likely to be less than £8 million per year for the treatment costs for patients in England for whom the product is indicated? Is it indicated for a small population or for a subgroup of a larger population?
Service Impact	Is use of the technology not likely to result in additional service and monitoring costs to the NHS substantially beyond those incurred with the use of current standard treatments?
Other considerations	Has the sponsor proposed a viable strategy to manage and support patients in the event of a negative NICE Technology Appraisal at the conclusion of the Innovation Pass period? These strategies will vary by product, however the sponsor will be expected to fund the product acquisition costs for existing patients and if necessary include a transition process to an alternative product. Transition arrangements will also need to be agreed for the short period between the end of the Innovation Pass and final NICE guidance being published (every effort will be made by all parties to keep any gap to a minimum).

8. Do you agree with how the advisory committee will consider the criteria? How might this be improved? Please state your reasons.

9. Are these the right criteria for consideration of an Innovation Pass? What additional criteria or amendments should be included? Please state your reasons.

7. Innovation Pass and Pricing

7.1 This section proposes how the Innovation Pass pilot will operate with regard to pricing and funding. These proposals also outline how the cost to Department of Health/NHS would be agreed between the company and the Department for each application for an Innovation Pass.

Links with the Pharmaceutical Price Regulation Scheme (PPRS)

7.2 Medicines which apply for the Innovation Pass will be branded new active substance and will fall within the scope of the Pharmaceutical Price Regulation Scheme (PPRS). Therefore a company will have freedom to set a list price for the relevant drug. The list price of the drug could be different from the cost to the Department/NHS. Profit made by companies through the Innovation Pass would be included as part of annual financial returns. However, price modulation under the PPRS would not be allowed during the three year period of the Innovation Pass.

7.3 The confidentiality of commercially sensitive information submitted to the Department will be assured.

Innovation Pass Pricing Principles

7.4 The Department and industry have agreed that certain principles need to be established with regard to pricing. We propose to use the following principles in the case of Innovation Pass candidate products:

i. It is for individual companies to propose prices for new active substances (as is the case in the PPRS). The 'cost' of an Innovation Pass medicine to the Department/NHS can be different to the list price.
ii. There must be safeguards in place to ensure that the cost to the Department/NHS of the medicine is fair and reasonable.
iii. The NHS will ensure that centrally funded Innovation Pass medicines are only used for a specific indication/population and not for uses other than that specified when the product's inclusion in the Pass is agreed.
iv. An exit strategy is required for patients post the three year period of the Pass in the event of a negative or restrictive NICE appraisal.
v. The £25m budget for the first year of the pilot cannot be exceeded as this is a single, physical budget not a notional sum.

Issue 1: Pricing mechanism

7.5 When submitting an application for an Innovation Pass companies would need to submit two main pieces of information:

a. An estimated uptake curve which will be provided to the NICE Innovation Pass team for the Pass, and
b. A proposed cost of an Innovation Pass drug to the Department of Health.

7.6 As outlined in chapter five (process), during the screening stage the NICE Innovation Pass team would validate the uptake curve and respond to the company with any queries/concerns. If agreed, this uptake curve will then be sent to the Department of Health and advisory committee so they know that it fits the criteria for a small patient population.

7.7 The Department of Health will then separately assess the cost to the Department/NHS mechanism. This exercise will not be a value-based assessment as this will be for NICE after the three years of the Pass. However, it will offer some limited protection for the NHS and patients against any unreasonable pricing. During the development of the Innovation Pass a number of potential pricing mechanisms have been considered. These include:

Option 1: The Department of Health would pay a company a total amount of money for supply of a drug for a specific population rather than paying for each cycle/dose of treatment dispensed. This would be in the form of a price volume agreement. Companies would propose the cost of a medicine through a simple calculation of: *Likely patient population (based on an uptake curve for the three years of the Pass) x Proposed cost per patient per year*. Under this option, there would also need to be a safety valve if the medicine was under-used so that money could be paid back to the Department in the event that usage were to be under a certain percentage of the expected uptake. Similarly, if usage was significantly over that estimated this would need to be managed. Auditing would need to be allowed if off-label use were suspected and would be dealt with outside Pass funding.

Option 2: Industry would propose a cost per unit price and the Department/NHS would pay that cost until a cap is reached. (This cap would be associated with the estimated uptake curve – see below). Once the cap was reached, the drug would then be provided free of charge for any eligible patients above the agreed uptake curve.

Option 3: The NHS pays list price for the relevant drug and no separate system is introduced for drugs under the Innovation Pass.

Option 4: A price is negotiated between the Department and Industry.

Assessment of Pricing Options

7.8 These options have been considered in line with the general principles of the Innovation Pass outlined in chapter four. Options three and four were immediately discounted. Option three was ruled out as it would provide no mechanism for keeping the cost of the Pass pilot under £25m for 2010/11. Option four was also ruled out as it is not consistent with the established principle of freedom of pricing and would require additional time and resource which could delay patients receiving drugs under the Pass.

7.9 Option two would allow expenditure to be contained within the overall cost cap, but would mean a time lag whilst the relevant data is collected and processed and would likely be bureaucratic to implement and monitor. Option one is the preferred option of the Department as it is simpler to administer than option two, which would require detailed monitoring and auditing of uptake of the relevant drug. Option one also ensures a financial return for the company and access to the drug for all qualifying patients.

How to ensure a 'reasonable price'

7.10 As outlined above, the proposed cost to the Department/NHS per unit/patient may be different to the NHS list price and may also be amended after the period of the Pass and at the time of the NICE appraisal. The proposed cost of an Innovation Pass medicine to the

Department/NHS will need to be reasonable. This will be assessed by a group drawn from the Department of Health and/or the NHS. There are several ways a reasonable price could be determined:

Option 1: An obvious option is to apply a maximum cost to the Department/NHS per patient to a drug. This would be calculated from the total budget for the specific drug, and the number of patients each Pass would be expected to cover. This proposal has the benefit that it is simple to calculate whether a drug's cost to the Department/NHS is below any agreed maximum. It could also disincentivise high pricing. However, it raises the question of how one would agree the appropriate level for the maximum cost to the Department/NHS. It could also incentivise companies to price to the maximum level.

Option 2: It would be possible to use the maximum cost per patient as a first stage of assessing a reasonable price. Companies whose drugs are below a particular cost per patient would have their drug referred to the advisory committee automatically. However, companies could justify a price above that level by providing other evidence. The group outlined at paragraph 7.10 would assess this against a range of factors. The onus would be on the company to make a compelling case in these circumstances.

7.11 Possible evidence of reasonable costs could include:

a. The cost of therapeutically similar medicines
b. The actual cost of the medicine in other European countries
c. The cost of manufacture and research into the medicine

7.12 Each of the above have their benefits and limitations; stakeholders may wish to suggest alternative or additional factors which could be taken into account.

Option 3: Another option would be to include an assessment along the lines of the proposals outlined at 7.11 but without any form of maximum cost per patient. It could be argued that the budget cap in the proposed criteria already sufficiently limits the potential cost (otherwise a company would have to withdraw their application). However, in assuring the reasonableness of cost, the budget cap criterion may not ensure a reasonable cost if companies price up to it and if their drug is for a very limited number of patients. It is questionable how robust this option would be.

Option 4: An indicative Incremental Cost-Effective Ratio (ICER) or indeed an ICER placed within a range, could be used in assessing cost. This would ensure that value is represented. However, it is questionable how this could be practically implemented without the full involvement of NICE and this relates to the issues raised in the next section. This option also fails to recognise that the Pass is for drugs where data is limited and a cost/QALY may not be a right way to measure a drug's potential at this early stage.

7.13 Views would be welcomed on these options as would suggestions of possible ways to assess whether the cost is reasonable.

7.14 If a product is subsequently not successful in securing Innovation Pass funding, the relevant company will not be bound by the pricing proposal it has submitted in the context of the Pass.

Issue 2: Role of Advisory committee

7.15 We are considering two options in relation to the committee's role and the cost of the drug. These options are:

> *Option 1*: The Department would inform the panel that the cost per patient was acceptable and the drug costs less than £8 million per annum but no further information would be given to the panel with regard to pricing. The committee would then prioritise drugs according to the proposed criteria set out in chapter six and would then send a list of the prioritised drugs, ranked in priority order, to the Department – price/cost would not be part of this prioritisation process.

7.16 The Department would then allocate funding in order of the advisory committee's recommended priorities until the funding has been exhausted. For example the manufacturer of prioritised drug 1 will receive £8 million (or whatever has been agreed), the manufacturer of drug 2 will receive £7 million etc.

7.17 A potential issue for the Department is what to do when the amount of money requested by a company is greater than what remains in the fund. Here, the Department proposes to take two steps:

7.18 Firstly, the Department will offer the manufacturer of the relevant drug an opportunity to make it available at a cost not exceeding the remaining unallocated component of the Pass funding (as long as the drug is offered to the same patient population as originally proposed).

7.19 Secondly, if the company declines this opportunity, the Department will speak to the manufacturer of the next drug on the prioritised list and so on until the budget is completely allocated or all manufacturers of drugs placed on the list have been approached. If two proposals had been ranked equally by the committee, the Department would give priority to the lowest overall cost application.

> *Option 2:* Once the Department of Health has agreed/validated the cost of the drug, it would send the costing information to the advisory committee. The committee would then have the task of coming up with the best list of drugs. The cost would then add up to £25m or less. This would include taking the cost into account alongside the agreed criteria.
>
> It would also be possible for the committee to be aware of cost but not use it as a criterion for decision making

7.20 In each option, a medicine would need to be assessed against the criteria proposed in chapter six in order to qualify for the Pass and ensure appropriate use of public funds. The objective of the Pass is not simply to spend the full amount available regardless of the quality of applications.

7.21 Both options also raise several issues around transparency/commercial confidentiality. The confidentiality of commercially sensitive information submitted to the Department of Health will be assured. However the total expenditure on a product would need to be published in the event of a product being granted the Pass. The allocation of the Pass would also need to comply with EU procurement legislation.

7.22 Overall, if the group drawn from the Department of Health and/or the NHS is able to endorse the proposed cost of the drug, it would not seem necessary or desirable to have any

further process to determine the value of the drug. This could only be done through a full NICE appraisal and the lack of data available means that this should not be done prior to entry into the Innovation Pass. In addition, there is particular concern from industry that the panel should make its judgments on the basis of the criteria proposed in chapter six and not on cost, whilst accepting that the Department must ensure that the cost of drugs is not excessive. It is therefore proposed that option one is the best way forward. However, this is dependent on having a robust system in place as outlined earlier in this chapter and we would welcome your views on the most appropriate role for the advisory committee with regard to cost.

Summary

7.23 We proposed the following arrangements for determining the price and cost of drugs put forward for the Pass, and allocating funding against the published criteria:

- A cost-volume proposal is put forward by industry.
- NICE will validate the associated uptake curve.
- DH/NHS group will assess the cost per patient of the drug and ensure that the total cost does not exceed the overall budget cap.
- Companies can propose to exceed this cost per patient and their applications will be assessed against criteria as outlined.
- The advisory committee will then prioritise the relevant drugs against the criteria outlined earlier in this document.
- DH will then allocate funds against this prioritised list.

10. Do you agree with the principles with regard to pricing? Please provide your reasons.

11. Is the Department's preferred option of a 'price-volume agreement' the right one? If not please state your preferred option and the reason why. Is there another proportionate option which has not yet been considered?

12. Which option is your preferred option to ensure a reasonable price to the NHS? Please state your reasons. Do you have further options or considerations which should be explored?

13. What additional information could companies submit to ensure that the NHS and patients do not pay unreasonable prices?

14. Which option is the most appropriate role for the advisory committee with regard to cost? Please state your reasons. Is there a further option which should be considered and why?

8. Data Collection and Monitoring

8.1 An important reason for the granting of an Innovation Pass is the collection of data that will inform the future NICE appraisal after the three years of the Pass. Although national data collection through the granting of the Innovation Pass cannot be mandated, NHS bodies will be strongly encouraged to participate in data collection exercises organised by companies under the terms of their data collection plans. Companies are encouraged to engage with the local NHS in order to maximise the impact of data collection exercises in the context of the Innovation Pass, and to consider carefully what support they need to offer to NHS bodies to help them to participate in these exercises. Any data collection needs to conform with good research practice for protection, patient consent and the appropriate use of data.

Information requirements during the application for an Innovation Pass.

8.2 The criteria for granting an Innovation Pass identify two aspects of data collection that are important for consideration of eligibility of products for the Pass; 'relative immaturity of data' and 'additional studies planned'.

8.3 An information proforma will be developed for the Innovation Pass in which companies can address both aspects of 'data collection'. Companies will be asked to specifically comment on whether 'there is a plausible reason why the data is immature such that there are insufficient data for a reliable cost utility analysis to be undertaken at the time of granting of the Pass'.

8.4 As part of their Pass application, companies will be asked to provide a plausible plan for data collection. It will be helpful for such plans to address, as far as is possible at the time the application is made, specific issues such as:

- patient group(s) [including inclusion and exclusion criteria plus expected numbers to be included];
- intervention(s) [including co-medication];
- comparisons;
- outcomes;
- study design [e.g. clinical trial, observational study, registry, database analysis];
- data sources;
- monitoring arrangements;
- statistical plans [including pre-specified analyses];
- number and names of centres to be involved;
- impact of the data collection on service and research arrangements in the NHS;
- time horizon of data collection;
- ethical approval.

8.5 Furthermore, companies will be asked to state whether 'relevant and credible studies [are] already planned or in progress that address the immaturity in the clinical data as identified by the company and allow a formal appraisal to be undertaken at the end of the Innovation Pass', and whether 'the results of the studies [are] likely to be generalisable to a UK setting, for example, by recruitment of patients from the UK'.

Monitoring

8.6 At the stage of granting of an Innovation Pass the topic of 'data collection' focuses on the planned work related to the existing immaturity of data.

8.7 Once an application for an Innovation Pass has been accepted, those involved in the granting of the Pass, and those that have applied for the Pass, will have an interest in monitoring whether the data collection is managing to address the evidence gaps identified in the application process.

8.8 We suggest that the sponsoring company should be primarily responsible for providing information to DH on:

(i) the progress of data collection work against their plan, in the form of a short annual report; and

(ii) the level of uptake of the individual technology, against the proposed "uptake curve". The nature and frequency of this information will be determined in part by the financial arrangements that are put in place following granting of the Pass (see chapter 7), but data is likely to be required more frequently – perhaps on a quarterly basis.

8.9 Once again, we would welcome consultees' views on these points.

15. Do you have any comments on the information requirements for data collection?

16. Do you have any views on the proposals on monitoring data collection?

ANNEX A
Equality Impact Assessment

The proposals for an Innovation Pass set out in this consultation document are underpinned by a number of principles. These principles affirm that an application for an Innovation Pass is voluntary and that it is for the pharmaceutical sponsor or manufacturer to decide to apply for an Innovation Pass.

Innovation Pass funded drugs will be prescribed and dispensed through existing clinical pathways. It will be a patient/clinical decision as to whether drugs selected for the Innovation Pass are prescribed to individual patients within the defined patient population set out in the Innovation Pass application. We expect patients from all groups to have the information and ability to inform decisions about whether a drug is prescribed to them. However individual clinical decisions are beyond the scope of the Innovation Pass.

The Innovation Pass will help to ensure that individuals and groups within a small patient population will benefit from truly innovative products which employ a novel approach or pathway. This is vitally important for patients, particularly in areas of unmet need, as it will provide access to drugs which have limited data available to demonstrate cost-effectiveness in a NICE appraisal. Whilst we do not know which drugs will be funded by the Pass we expect individuals and groups who may currently have relatively poor outcomes to benefit.

17. Please identify the impact the Innovation Pass pilot might have from the perspective of ethnicity, age, gender, gender reassignment, sexual orientation, religion or belief, socio-economic considerations? If there is a negative impact what proportionate measures could address those issues?

General Comments

18. Do have any additional comments on any aspect of the consultation?

Annex B
Summary of Consultation Questions

General Principles

1. Should medical technologies be considered for inclusion in the Innovation Pass in future? Please state your reasons. (Para 3.5)

2. Is the Innovation Pass relevant to drugs for late stage disease given other recent developments? (Recent developments include patient access schemes and NICE's end of life flexibilities) (Para 3.8)

3. Do you agree that these are the right principles to underpin the Innovation Pass initiative? If not please state your reasons why. (Section 4, page 14)

4. What other principles should be developed? Please state your reasons why these are important. (Section 4, page 14)

Innovation Pass Process

5. Is the proposed process for applying and granting an Innovation Pass an appropriate one? How might this be improved? Please provide your justifications/reasons (Paras 5.1 – 5.15)

6. What further steps should the process include? Please include your reasons for your suggestions. (Section 5)

7. Do you agree with the membership and remit of the advisory committee? What additional considerations should be made, and why? (Paras 5.8- 5.10)

Innovation Pass Criteria

8. Do you agree with how the advisory committee will consider the criteria? How might this be improved? Please state your reasons. (Paras 6.2- 6.5)

9. Are these the right criteria for consideration of an Innovation Pass? What additional criteria or amendments should be included? Please state your reasons. (Table, page 20-21)

Innovation Pass Pricing

10. Do you agree with the principles with regard to pricing? Please state your reasons.(Para 7.4)

11. Is the Department's preferred option of a 'price-volume agreement' the right one? If not please state your preferred option and the reason why. Is there another proportionate option which has not been yet been considered? (Paras 7.4 – 7.7)

12. Which option is your preferred option to ensure a reasonable price to the NHS? Please state your reasons. Do you have further options or considerations which should be explored? (Paras 7.10- 7.14)

13. What additional information could companies submit to ensure that the NHS and patients do not pay unreasonable prices? (Paras 7.10 – 7.14)

14. Which option is the most appropriate role for the advisory committee with regard to cost? Please state your reason. Is there a further option which should be considered and why? (Paras 7.15 – 7.19)

Data Collection and Monitoring

15. Do you have any comments on the information requirements for data collection? (paras 8.2-8.5)

16. Do you have any views on the proposals on monitoring data collection? (paras 8.6-8.9)

Equality Impact Assessment

17. Please identify the impact the Innovation Pass pilot might have from the perspective of ethnicity, age, gender, gender reassignment, sexual orientation, religion or belief or socio economic considerations? If there is a negative impact, what proportionate measures could address those issues?

General Comments

18. Do you have any additional comments on any aspect of this consultation?