Accelerated Access Review

Key themes in responses to engagement exercise

Independent analysis by The Evidence Centre

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Prepared by The Evidence Centre, an independent organisation

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Executive summary

Between July and September 2015, the Accelerating Access Review asked people and organisations to share their views about speeding up access to new medicines and health technologies. This document summarises the main trends in responses to the Review.

Background

The Accelerated Access Review is considering how to speed up access to innovative drugs, devices and diagnostics for people using NHS services. The Review asked people and organisations for ideas about:

- developing a transparent framework for early dialogue and collaboration which drives transformative innovation and supports partnerships from end to end
- streamlining regulatory processes and articulating a clear accelerated process for innovative products
- integrating or accelerating national reimbursement processes and funding clinically and cost-effective innovation across the pathway
- accelerating the speed at which clinically and cost effective innovative products are commissioned
- ensuring that patient and user engagement is key throughout

The first phase of open engagement ran between July and September 2015. The Review team ran discussion groups, attended meetings and invited feedback via an online portal and by email / post. Eighteen questions were posed. The Review paused to take stock of feedback in September 2015. This document sets out an independent analysis of key themes in the responses.

Responses

Individuals and organisations provided a total of 392 comments via the online portal and 54 responses by email / post or as part of notes from meetings. Some people and organisations provided more than one response so these were grouped together, making a total of 108 responses from unique respondents. Half of these responses (52%) were submitted through the online portal, 39% were submitted via email, post or meetings and 9% combined online and other submissions.

Three quarters of responses were from organisations (78%) and one quarter were from individuals (22%). Most responses from organisations were from the pharmaceutical industry, voluntary sector and medical device industry. Most responses from individuals were from academics / researchers, NHS personnel and service users.

Key messages

Table 1 lists the questions posed during phase 1 of the Review and the main trends in responses.

It is important to remember that each response could represent many different people. For example, some responses were from meetings with many participants and other responses were from large organisations.

Table 1: Summary of key trends in responses to the Accelerated Access Review

Question	Responses	Key themes
Early dialogue and communication		
How can we develop a systematic way to share patient and NHS needs with innovators?	45	Having clear priorities at a national and regional level, with clear communication channels, promotional activities and forums to build shared understanding of these priorities across stakeholders; Strengthening the role of existing organisations and forums rather than creating new structures. The role of Academic Health Science Networks was particularly emphasised; Having a publicly accessible horizon scanning function with broad scope, with an online portal where stakeholders of all types can review and add information.
Would a single point of access for advice to innovators be helpful?	34	There were mixed views about the value and feasibility of a single point of access. Whilst a single point of access to advice may have been welcomed in theory, responses were concerned that this would not be feasible in practice. Some thought this would mean setting up a new organisation.
How can we give innovators more clarity on data requirements throughout the whole pathway?	30	Need for clear information up front, including information about appropriate research designs; Access to anonymised large datasets; Ensuring consistency of requirements across regulatory and commissioning components of the pathway.

Question	Responses	Key themes
Regulatory processes		
How can we build on existing regulatory flexibilities for innovative products?	33	Reviewing and refining the Early Access to Medicines Scheme, including reimbursement; Aligning regulatory and reimbursement requirements and the data requirements between agencies internationally and nationally; Increasing focus on real world and easily accessible / feasible data collection strategies, with patient-centred outcomes at the core.
Do any parts of the existing development and regulatory pathways need to be redesigned to help accelerate access to new transformative health technology?	42	As above
What data is needed to generate sufficient evidence of safety, efficacy and value throughout the product lifecycle?	33	Using real world data rather than relying solely on clinical trials, especially given NHS access to a national dataset of patient records; Ensuring that data continue to be collected after innovations have been approved; Ensuring clear definitions and templates from the outset, including defining value in terms of outcomes that are important to service users and commissioners.
What data is needed to generate sufficient evidence of safety, efficacy and value throughout the product lifecycle specifically for the pharmaceutical industry?	21	Using real world longitudinal datasets to explore usage, safety and efficacy.

Question	Responses	Key themes
Reimbursement processes		
How can we make the current funding system more flexible?	48	Implementing conditional reimbursement alongside risk sharing models; Supporting multi-year contracts and less siloed budgets; Enhancing Pharmaceutical Pricing Regulation Scheme (PPRS) approaches; Having a single assessor of value, such as NICE, to reduce local and national duplication.
What are the options for a long-term strategy for reimbursing new health technology in the NHS?	42	As above
How should NICE evolve to keep pace with advances in technology?	48	Assessing value based on factors other than cost-effectiveness; Having a more flexible and speedy appraisals process that allows for different types of evidence, conditional approvals and varying criteria for different categories of products; Extending the remit to include horizon scanning and implementation of guidance and being the single source of cost-effectiveness appraisal in England.
How can patients and the public be involved in funding decisions?	31	Providing good quality, easily accessible data in a format that people not working in the health system can use, to enable well-informed public discussion and decision-making; Seeking input from service user organisations routinely. Note that suggestions focused on public involvement, not necessarily specific to funding decisions.
How should the health and care system address the affordability question?	39	Setting out longer-term strategies spanning multi-year budgets; Considering the cost of medicines in the context of the wider pathway; Building on the PPRS approach to create a new medicines fund; Proactive decommissioning of older technologies.

Question	Responses	Key themes
Adoption		
How can we reduce or remove barriers to using transformative health technology?	51	Removing duplication of approvals processes at national and local levels; Monitoring adoption to ensure uptake; Ensuring budgets, tariffs and incentives are aligned to support uptake.
How can we strengthen incentives to use transformative health technology?	32	Tracking uptake of innovation; Using current incentive structures to increase adoption.
How can the system support uptake of transformative health technology?	39	Solutions related to research and development; appraisals; financing and personnel.
Could patients help unblock some of the barriers to the adoption of innovation in the NHS?	22	Responses thought that patients could help to unblock barriers. Suggestions included increasing patient advocacy and information regarding both treatment options and the roles that service users can play in funding decisions.
User engagement		
How do we better engage all patients in new health technology?	40	Working closely with existing groups, including the voluntary sector and patient groups associated with regulators and commissioners; Consulting with service users about the outcomes that are most important to them; Providing a variety of different approaches to engagement, including information for both service users and clinicians.
How can we increase patient and public involvement in the development of innovations?	32	As above

Chapter 1: Responses to the Review

Background

The Accelerated Access Review aims to speed up access to innovative drugs, devices and diagnostics for people using NHS services. The independent Review will make recommendations about pathways for the development, assessment and adoption of innovative medicines and medical products within the NHS. The Review is focusing on medicines, medical technologies and digital health (hereafter jointly referred to as 'technologies' or 'innovations').

The Review has five key areas of investigation:

- developing a transparent framework for early dialogue and collaboration which drives transformative innovation and supports partnerships from end to end
- streamlining regulatory processes and articulating a clear accelerated process for innovative products
- integrating or accelerating national reimbursement processes and funding clinically and cost-effective innovation across the pathway
- accelerating the speed at which clinically and cost effective innovative products are commissioned
- ensuring that patient and user engagement is a key component of development

The Review is progressing in phases. Between July and September 2015, the Review team asked for feedback related to collaboration, regulation, reimbursement, adoption and the involvement of people using services. In September 2015, the Review team paused to reflect on feedback and incorporate suggestions for the future. The second phase of the Review will seek feedback about specific suggestions.

This document summarises key themes from responses to the first phase of engagement, based on analysis by an independent team. The document lists feedback about each of the 18 questions posed by the Review.

This chapter describes how trends from the responses were analysed and provides an overview of the number and type of responses received. The following chapters describe feedback about each of the Review questions, grouped into five sections as listed in the bullet points above.

Compiling responses

Receiving responses

The Accelerated Access Review team disseminated information to organisations and stakeholder groups, took part in events to promote the Review and publicised the Review online and using social media and blogs. There were 18 key questions of interest.

Individuals and organisations were invited to submit comments via an online portal or via email, post or by taking part in meetings.

Identifying trends

An independent organisation, The Evidence Centre, drew together the main themes from all of the responses, focusing on practical suggestions for change. The analysis team was not involved in any other aspect of the Review and had no vested interest in the outcome.

The purpose of the analysis was to provide a summary of key themes in responses. The analysis was not designed to substitute for reading each response to the Review or to provide a great deal of detail.

The Accelerated Access Review team received all responses and provided copies to the independent analysis team. The analysis team read every response and collated the feedback about each question into in an electronic spreadsheet, along with background details about the respondent, where available. Where responses did not explicitly answer specific questions, material relevant to questions was extracted. All of the verbatim feedback for each question was then categorised to identify trends.

The analysis team drew out recurring feedback and examined whether there were any trends depending on whether responses were from organisations or individuals or based on the type of organisation or individual responding.

Reporting on trends

This report lists the number of responses that commented about a particular question, the main trends in feedback related to the question and a summary of whether some types of stakeholders were more likely to provide certain feedback. The feedback is arranged according to the five key topics of the review, as listed previously. Responses could provide multiple comments about each question.

Feedback from responses is reported without assessing the feasibility of the suggestions made, or weighing the relative pros and cons of various suggestions. The purpose of the document is to provide an overview of what individuals and organisations said. The Accelerated Access Review team is responsible for considering all of the trends and the more detailed comments from the responses, and deciding how to use feedback.

Quotes are used throughout the report to illustrate key points made. These quotes were chosen to provide a flavour of what many other responses said and to show the variety of different types of respondents.

It is important to recognise that one response does not equate to one person. Some responses were from organisations or groups representing many hundreds or thousands of people or comprised notes from discussion events with many participants. For this reason, the number of responses that made a certain point should not be used to judge the scale of agreement.

Characteristics of responses

Number of responses

Individuals and organisations provided 392 comments via the online portal and 54 responses by email, post or as part of notes from meetings. Some of the emailed responses contained multiple documents.

Some people and organisations provided more than one response containing different points. Responses from the same person or organisation were grouped together to avoid double counting, making the total number of unique responses analysed 108.

In addition, the Accelerated Access Review team also received feedback in draft form from stakeholders and as part of iterative discussions. This developmental feedback was not provided to the independent team for analysis. The themes summary is based on formal responses to the Review.

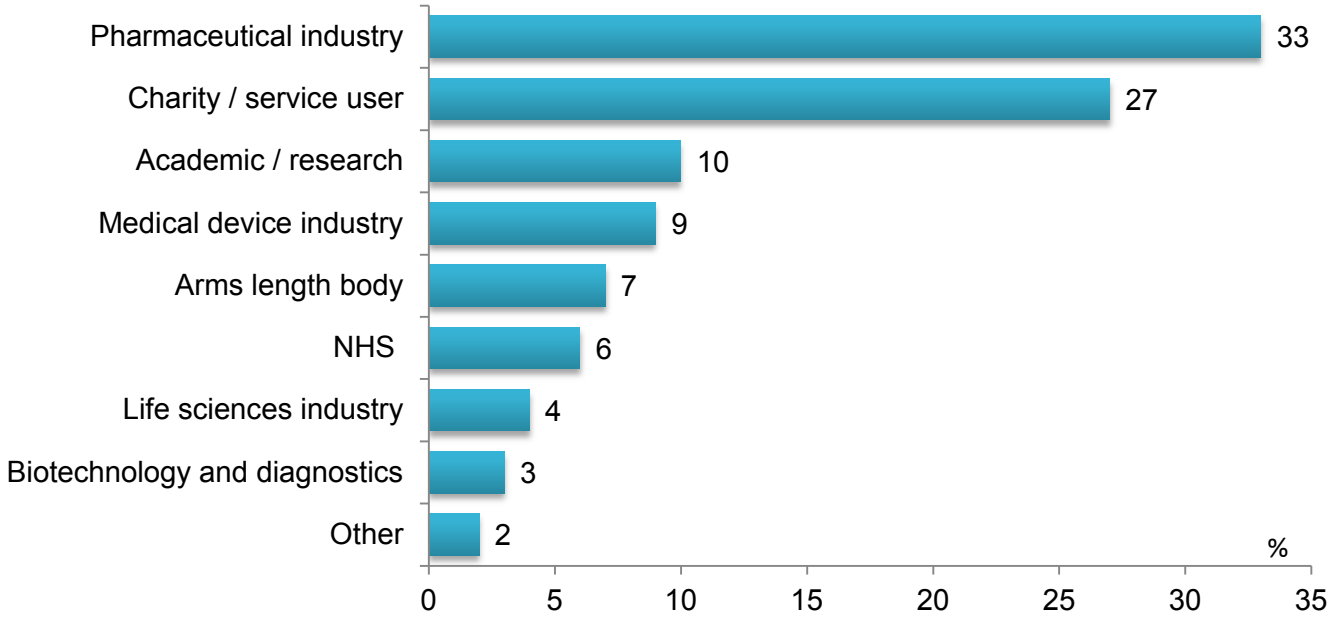
Types of responses

Half of the responses were submitted using the Review's online portal for comments (56 out of 108 responses; 52%), 39% were submitted via email, post or meetings (42 responses) and 9% combined online and other submissions (10 responses).

Types of respondents

Figure 1 shows the sectors from which responses were gained. This includes responses from organisations and from individuals responding from a specific sector. The most common sectors were the pharmaceutical industry, the voluntary sector and academic / research organisations.

Figure 1: Sectors represented in responses to the Accelerated Access Review



Note: Percentages are based on all 108 responses

Individuals and organisations

Overall, three quarters of responses appeared to come from organisations (84 responses; 78%) and one quarter appeared to come from individuals or were not clearly an organisational response (24 responses; 22%). Where responses did not state that they represented the views of an organisation or where there was uncertainty about whether the response reflected an organisational view, they were classified as a response from an individual. The breakdown of 'individual' versus 'organisation' is provided to show that most responses were from organisations. This was not used to weight the responses in any way.

All responses from the pharmaceutical industry, biotechnology and diagnostics sectors represented organisations, whereas it was less clear whether responses from the NHS and academic / research sectors were submitted by individuals or teams as opposed to representing the official views of the organisation.

Two fifths of organisational responses came from the pharmaceutical industry (41%), one quarter came from the voluntary sector / charities (26%) and one in ten came from the medical device industry (10%). Other organisational responses came from arms length bodies (6%), academic / research organisations (4%), the life sciences industry (4%), biotechnology and diagnostics organisations (3%) and other groups, such as the NHS (4%).

One third of responses that were from individuals (or not clearly from organisations) were from those in academic / research posts (32%), one quarter were from NHS staff (26%) and one fifth were from service users (21%). Staff from arms length bodies, the life sciences industry and other industries also responded as individuals.

Demographic details such as age, gender and geographic location were not collected as part of the Review.

Questions addressed

Figure 2 shows how many responses addressed each of the 18 Review questions. The exact wording of the questions is provided in Table 1 (in the Executive Summary) and referred to throughout the document. The purpose of this figure is to show 'at a glance' which questions were most commonly responded to.

This chapter has outlined how themes from responses were compiled and the characteristics of the responses. The rest of this document explores what responses said about each of the Review questions in turn.

Figure 2: Number of responses providing feedback about each of the Review questions

Chapter 2: Early dialogue and collaboration

This chapter summarises feedback about questions related to developing a transparent framework for early dialogue and collaboration which drives innovation and supports partnerships. The Review questions were:

- How can we develop a systematic way to share patient and NHS needs with innovators?
- Would a single point of access for advice to innovators be helpful?
- How can we give innovators more clarity on data requirements throughout the whole pathway?

Feedback about each question is listed in turn.

How can we develop a systematic way to share patient and NHS needs with innovators?

In total, 45 responses provided feedback about this question. Three quarters of these responses were from organisations (35 responses; 78%).

There was a good mix of feedback from different types of organisations, including the voluntary sector, pharmaceutical industry, medical device industry and academic / research organisations.

There was recognition of the importance of sharing needs with innovators to unpin the development process.

> ***"The importance of sharing patient and NHS needs with innovators and the broader research community is vital and should not be underestimated as it ensures research aligns to both clinical relevance and patient needs and acceptability."*** **(Academic / research organisation)**

The main suggestions regarding how to do this focused on priority setting, data and engagement with service users, clinicians and innovators. Some of the potential 'solutions' described broad principles, such as the desire for a joined up and strategic approach. Other suggestions were more operational, such as providing a toolkit or funding to release clinicians. This mix of high-level and more practical solutions is reflected in the answers to all questions posed by the Review.

Solutions related to setting and sharing priorities

- Having a formal horizon scanning function such as a national information hub, with a publicly accessible online portal to maintain and update information. A number of organisations, including the National Institute for Health Research (NIHR) Horizon Scanning Horizon Scanning Centre, already provide horizon scanning for new medicines so to add value the new approach would need to consider whole pathways, disease areas and interdependencies. Rather than developing a new organisation or function, it was suggested that existing mechanisms could be strengthened and widened, with participation being mandatory if organisations want NHS funding (12 responses)

"NHS England could set up an information hub where treatment needs can be recorded for various conditions. Innovators could use the hub to inform their work and understand what treatments, medical devices and digital products are required to enhance the lives of patients and NHS staff. Patient groups could upload their research findings about patients' unmet treatment needs … This hub could also record provider needs." **(Voluntary sector)**

"One idea could be to set up a new horizon scanning organisation which could be developed out of one of the existing organisations performing this role. This would need to be integrated with MHRA [Medicines and Healthcare products Regulatory Agency], NHS England and NICE processes. This organisation could partner with the NHS (in England and the devolved nations) to review all forthcoming interventions (treatments, technologies and services) to review potential impact and assess required service configuration and anticipated resource requirements." **(Pharmaceutical industry)**

- Taking a more strategic and joined up approach to communicating needs, including prioritising the most important needs (6 responses)
- Publishing an updated information strategy which includes processes to establish a secure collaborative network of centralised patient data in order to match patients to innovative treatments (1 response)
- Aligning with international organisations such as the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) (3 responses)

- Setting longer-term research priorities, particularly around basic research rather than research about specific clinical applications (3 responses)

"Understandably there is a focus on short term / immediate priorities, but the absence of a clear longer term vision makes it challenging for funders of basic research to align to national needs. If a relevant body such as NIHR was able to take a more active interest in basic research rather than focusing on later stage development; emerging technologies could be better informed by clinical need and 'pulled' towards the NHS. This would drive faster translation of scientific discoveries into tangible benefits for patients." **(Academic / research organisation)**

- Having clear definitions of metrics and outcomes and using robust tools to measure these outcomes in a standardised manner (5 responses)

"It is important that NHS England's prioritisation decisions are made in a transparent way, with outcomes documented at every stage of the process and clear to the public. A robust set of evaluation criteria should be communicated to innovators at the earliest opportunity, in order to ensure that the correct data is collected during the development process. At present, horizon scanning within specialised commissioning is poorly understood and more work could be done to ensure that all stakeholders are clear on how NHS England, alongside NICE, identifies and prioritises innovation to assess." **(Patient umbrella organisation)**

- Using real world data and evaluation as a tool for early and continuous assessment of new products. Some responses suggested that access to NHS data would help identify patterns and test hypotheses (3 responses)
- Placing greater emphasis within value assessments on the potential benefits of new treatments and technologies for service users and carers. This may include funders asking how needs have been identified (4 responses)

Solutions related to engaging service users

- Engaging service users regularly for input, including in the design of research and outcomes that are important to them (7 responses)
- Using existing forums such as the NICE Citizen's Council, National Voices and the James Lind Alliance which brings together patients, carers and clinicians to identify and prioritise the top 10 uncertainties or 'unanswered questions' about treatments or conditions (4 responses)
- Setting up dedicated forums for priority disease areas with significant unmet need (2 responses)
- Having an online database listing organisations with which to engage (1 response)
- Issuing a toolkit with strategies and tools to help organisations engage effectively with stakeholders (1 response)
- Drawing on international learning and case studies about how to engage with service users (2 responses)

Solutions related to engaging with clinicians and the NHS

- Using structures such as Academic Health Science Networks (AHSNs), Healthcare Technology Cooperatives and Diagnostic Evidence Cooperatives. This may include central direction about effective industry collaboration and clarification about what authority such organisations have to request NHS adoption once innovative approaches have been successfully tested (7 responses)

> ***"AHSNs are the realistic platform where innovators, patients, commissioners and providers can come together under a common agenda and work cohesively, ensuring that the patient and NHS Needs are aligned, ultimately informing innovators, in a non-biased way."*** **(Individual response from NHS staff member)**

- Developing an 'agreed ways of working' manual to ensure transparency about joint working, covering the Association of the British Pharmaceutical Industry (ABPI) code (2 responses)
- Engaging clinicians regularly for input (2 responses)
- Providing support to identify appropriate clinicians within the NHS with which to engage (1 response)
- Providing training so NHS staff can work jointly effectively (1 response)
- Running a promotional campaign in partnership with industry to showcase the benefits of commercial partnerships (1 response)
- Providing funding to allow NHS clinicians to be released from routine duties in order to have a role in development and research (1 response)
- Seconding NHS staff to work in industry and staff from industry to work in the NHS (1 response)
- Helping the NHS understand that some changes are incremental, so longer-term support and development is needed, whereas other changes may be revolutionary and need to be well managed (2 responses)
- Encouraging the NHS to innovate itself, rather than waiting for industry to provide new ideas (3 responses)

> ***"Innovation is not just for manufacturers. The NHS needs to stop waiting for medical innovation to land on their desks and invest more resource in thinking and articulating the improvement and innovations it needs to improve clinical outcomes or reduce spend, and then work with a range of stakeholder, including industry and patients, to develop and implement it."*** **(Pharmaceutical industry)**

Solutions related to communicating with innovators

- Enhancing communication and engagement with innovators so their work aligns with important outcomes at a national, regional and local level. This may involve collaboration between regulatory bodies, professionals, industry, universities and people with specific conditions through dedicated forums (7 responses)

> ***"Dedicated forums for interaction between health professionals, patients and industry are a vital means of exchanging information and ensuring that the debate is properly informed."*** **(Individual response)**

- Streamlining communication routes, rather than having separate NICE and NHS England processes (1 response)
- Clarifying the needs of reimbursing agencies, not just regulatory agencies (1 response)
- Using language that can draw in innovation from diverse disciplines (2 responses)
- Exploiting the expertise available in the pharmaceutical sector to help transform patient pathways to accommodate new innovations and train staff (1 response)
- Making further funding available specifically for collaboration and addressing unmet needs (2 responses)
- Providing more dedicated funding and routes for smaller businesses (3 responses)
- Appointing innovators to committees and as non-executive members of NHS boards (1 response)

Overall, the three most commonly suggested solutions were:

1. Having clear priorities at a national and regional level, with clear communication channels, promotional activities and forums to build shared understanding of these priorities across stakeholders;
2. Strengthening the role of existing organisations and forums rather than creating new structures. The role of Academic Health Science Networks was particularly emphasised;
3. Having a publicly accessible horizon scanning function with broad scope, with an online portal where stakeholders of all types can review and add information.

In general, there was no difference between the views of organisations versus individuals. Organisations from the voluntary sector were more likely than those from industry to provide suggestions for engaging with service users (as opposed to clinicians, the NHS or informatics). Industry responses were more likely to focus on suggestions relating to access to data via horizon scanning and engaging with NHS partners.

Would a single point of access for advice to innovators be helpful?

In total, 34 responses provided feedback about this question. Seven out of ten of these responses were from organisations (24 responses; 71%).

It appears that many read this question as meaning that a new body may be set up rather than having a single point of access that might sit with an existing body or set of bodies.

There were mixed views about the value of a single point of access for innovators, perhaps because responses interpreted this in different ways. Six out of ten responses indicated that having a single point of access would be helpful (20 responses; 59%).

> ***"A single point of access for advice to innovators would definitely be helpful and allow for greater transparency and accountability in the system. It would also reduce duplication and inefficiencies across the NHS, which often see assessor and commissioner lines blurred. It is important that this single point of access joins up the MHRA, NICE and commissioners including NHS England and CCG bodies, as where advice can also be coordinated across decision-making bodies, it becomes even more impactful. At present, often innovators have to broker both the risk of following advice as well as the potential for conflicting advice."*** **(Pharmaceutical industry)**
>
> ***"Coordinating advice across a number of decision-making bodies would be valuable for innovators, and we would welcome early joint dialogue and scientific advice with MHRA and NICE on trial endpoints and outcomes. Early joint dialogue could enhance our ability to resolve any conflicting advice that different agencies may provide. Whilst the two agencies should continue to operate separately, as their remits are and should remain quite separate, collaboration on research requirements at an early stage would be helpful."*** **(Pharmaceutical industry)**

Some responses provided suggestions for how a single point of access could work in practice. These included:

- Incorporating the NICE Office of Market Access and the Medicines and Healthcare products Regulatory Agency (MHRA) Office for Innovations functions to ensure consistency (2 responses)
- Helping to streamline and simplify research governance processes across all four countries of the UK (2 responses)
- Having a joint EU-level advisory organisation, incorporating regulators and Health Technology Assessment (HTA) bodies (1 response)

Two fifths of responses to this question did not think a single point of access for advice would be feasible (14 responses; 41%). This was largely due to the practicalities of managing the variety of advice that an organisation would need throughout the lifetime of development. Another reported barrier was different processes in different countries of the UK.

> ***"A single point of access implies a single adoption pathway whereas these are different for each innovation."*** **(Medical device industry)**
>
> ***"It is … a complex world to deliver innovations into healthcare and single points of access may be unable to address the needs of all stakeholders. It would be unfortunate to create a new body when there are many existing organisations that do important parts (including NOCRI, NHS England Innovation team, AHSNs, etc) so more effort to join up what is there with up to date and consistent messaging is a better approach."*** **(Individual response)**

Some thought there were already organisations fulfilling some of the functions of a single point of access (2 responses).

Views about the value of a single point of access were thus mixed. Whilst a single point of access to advice may have been welcomed in theory, responses were concerned that this would not be feasible in practice and many appeared to view the proposal as setting up a new organisation for this purpose, which was not necessarily what was intended.

There were no strong trends according to the type of respondent. For example, some pharmaceutical companies were in favour of this approach and others were not. The same was true of medical device companies, umbrella organisations and other stakeholders.

How can we give innovators more clarity on data requirements throughout the whole pathway?

In total, 30 responses provided feedback about this question. Three quarters of these responses were from organisations (22 responses; 73%).

The main suggestions focused on the types of information that could usefully be provided and the processes for accessing information, including existing databases. A small number of responses stated that the term 'data requirements' may be interpreted in various ways.

There was no difference between the views of organisations versus individuals or between various types of organisations or individuals. Many of the responses to this question came from the pharmaceutical industry.

Solutions related to the type of information required

- Providing information about evidence requirements needed for national reimbursement, including research designs and specific outcomes of interest, particularly where multiple outcomes could be measured (8 responses)
- Providing feedback about where there is duplication in effort during the early development phase (1 response)
- Providing information about NHS staff and capacity available for research (1 response)
- Helping researchers and innovators to understand the regulatory process (1 response)
- Ensuring transparency about why data are required and how data will be used (2 responses)

> ***"For innovators, evidence requirements for a new molecular entity or new active substance begin at the earliest stages of discovery; these are the data that support decisions to proceed with development or not. Innovators are constantly seeking better and additional data to better understand molecular biology and better address human health and disease progression. If the UK galvanises its current efforts to provide a multi-dimensional health data platform for research and healthcare, this could support global drug discovery and development."*** **(Pharmaceutical industry)**

Solutions related to processes for providing or accessing data

- Providing access to existing databases such as large real world datasets about the safety and efficacy of products in use for many years. There was a call for a multidimensional health data platform which would enable NHS data to be accessed by third parties in an anonymised manner (11 responses)
- Aligning data requirements for regulatory and reimbursement bodies, especially around comparative effectiveness (7 responses)
- Providing clear templates or an 'evidence map' in advance about data requirements (4 responses)
- Creating a database, website, open access source or point of contact where innovators can gain contact details, information and examples about patient-relevant data and clinical pathways (2 responses)
- Clarifying who should pay for the collection of data, such as data collected via the NHS (1 response)
- Eliminating re-evaluation of technologies at local level by NHS organisations and moving towards a single approval for the entire NHS (1 response)
- Incorporating standards on the provision of information about clinical trials in NHS service specifications to increase the number of people from the UK enrolled in clinical trials and setting goals for the proportion of international clinical trials enrolling people from the UK (1 response)
- Being mindful of difficulties in generating evidence in relatively smaller patient populations or for highly specialised services / conditions (2 responses)

> ***"Access to large, real-world patient datasets allows researchers the unique opportunity to identify patterns, predict outcomes and test hypotheses. This information can help improve the design of clinical trials and speed up the drug development process, affording faster patient access to innovative new treatments. It can also enable real-time analysis to better understand how a medicine is performing; improving its overall safety and efficacy profile as well as increasing the wider knowledge base to improve the potential of further scientific breakthroughs. The UK is in a unique position to harness the potential of 'big data', with NHS patient records offering a full lifetime of information for more than 60 million people."*** **(Pharmaceutical industry)**
>
> ***"Government should encourage better data collection across the NHS and create a single point of entry for organisations wanting to access clinical data for R&D; continue to build on the work of Genomics England to link clinical data with genetic information; work more closely with global and European partners to set standards for data interoperability."*** **(Pharmaceutical industry)**

Thus the three most common comments about this question were the need for clear information up front, access to anonymised large datasets and ensuring consistency of requirements across regulatory and commissioning components of the pathway.

Chapter 3: Regulatory process

This chapter summarises feedback about questions related to streamlining regulatory processes and articulating an accelerated process for innovative products. The Review questions were:

- How can we build on existing regulatory flexibilities for innovative products?
- Do any parts of the existing development and regulatory pathways need to be redesigned to help accelerate access to new transformative health technology?
- What data is needed to generate sufficient evidence of safety, efficacy and value throughout the product lifecycle?
- What data is needed to generate sufficient evidence of safety, efficacy and value throughout the product lifecycle specifically for the pharmaceutical industry?

There were overlaps in the feedback about the first two questions listed above, so comments about these are combined below.

How can we build on existing regulatory flexibilities and do any development and regulatory pathways need to be redesigned?

In total, 33 responses provided feedback about building on existing regulatory flexibilities and 42 responses provided feedback about redesigning development and regulatory pathways. Much of the content covered in these questions was similar, so trends have been combined.

Nine out of ten responses that addressed these questions were from organisations (90%), particularly from the pharmaceutical industry.

Responses agreed that streamlining existing processes was a priority.

The main suggestions related to communication and working relationships, streamlining regulation processes and improving reimbursement processes.

Solutions relating to working relationships and communication

- Setting up ways for the NHS and industry to work together to identify and address blockages. There was a request for the Review to set out how pragmatic partnership could be embedded as a core operating principle for the NHS and industry, with associated funding (5 responses)
- Ensuring that NICE, MHRA Industry and others work together and communicate across the pathway (5 responses)
- Accounting for the global market in which industry operates (4 responses)
- Being clear about the levels of investment required from industry and from the NHS (3 responses)

> ***"Steps should be taken to improve communication between the MHRA, Industry and NICE, linking the regulatory, pricing and reimbursement phases of the medicines development pathway."*** **(Pharmaceutical industry)**
>
> ***"It is essential that NHS England works with NICE, MHRA and local commissioners and clinicians to embed a culture where all parts of the healthcare system are working together to accelerate patient access to new EAMS treatments - both during the EAMS period itself and immediately after NICE guidance is issued."*** **(Pharmaceutical industry)**

Solutions relating to streamlining the regulatory process

- Aligning EU and FDA regulatory and NICE data requirements, widening EU conditional approvals and making increasing use of EU processes for post-approval efficacy studies (12 responses)
- Building in flexibility for innovative products, such as tailoring NICE criteria when evaluating innovative technologies or orphan products (11 responses)
- Aligning data requirements between regulatory and HTA bodies (5 responses)
- Streamlining the regulatory process particularly for combinational interventions and allowing a fast track process (6 responses)
- Developing a flexible iterative decision-making process (3 responses)
- Widening the applicability of European Medicines Agency (EMA) adaptive pathways to a range of approaches beyond initial approval (3 responses)
- Widening the use of digital platforms and automated systems for collecting real time data about outcomes (10 responses)
- Tailoring clinical trial design to consider smaller patient populations (4 responses)
- Strengthening the collection of patient-centred data and the role of tools such as the Medicines Optimisation Dashboard and the Innovation Scorecard (2 responses)
- Fostering academic investment in the regulatory sciences and incentivising research collaborations that respond to service user and NHS needs (6 responses)
- Incentivising research in the NHS such as by aligning it to continuing professional development (CPD) for clinicians, provider governance frameworks and specific funding streams (3 responses)
- Considering cross sector / industry peer review of trial funding applications to prioritise innovative approaches (1 response)
- Fast tracking research and development and ethics processes (1 response)

"Decisions around how to design the regulatory package of evidence for medicines are made within the framework of a global regulatory review process. Across the globe, leading regulatory authorities are looking to expedite reviews where possible for new innovative medicines to better address unmet need for patients and to explore the "adaptive" paradigm – iterative phases of evidence gathering to reduce uncertainties about a medicine and advancing its value in use over time and the lifecycle of the medicine." **(Pharmaceutical industry)**

"Greater alignment between the data requirements of licensing authorities and NICE. It is often a source of contention and frustration that NICE queries the value of data collected by pharmaceutical companies in proving safety and efficacy of products, when these data have themselves been collected by virtue of the requirements of licensing bodies." **(Pharmaceutical industry)**

Solutions relating to adoption and reimbursement

- Improving the Early Access to Medicines Scheme (EAMS) such as making the scheme more simple, encompassing a wider range of medicines and using a common system for data capture (24 responses)
- Ensuring appropriate follow-up data are required as part of the EAMS (3 responses)
- Educating the NHS about what technology is available and how it can be used (2 responses)
- Requiring NICE to recommend appropriate commissioning processes to speed up decision-making (1 response)
- Revising financial incentives such as the Pharmaceutical Price Regulation Scheme (PPRS), setting up a special medicines fund or similar supporting small businesses (6 responses)
- Implementing commercially confidential pricing agreements and overall cost caps (3 responses)
- Increasing service user involvement in trials and in funding allocation decisions for innovative products (5 responses)

"Conditional approval and other existing options are very important innovations in the regulatory routes to patient access, but in terms of reimbursement, the subsequent and corresponding mechanism for adoption and diffusion is not there. For example, payers are often reluctant to pay for a medicine that has been granted Conditional Approval by the EMA as it is addressing an unmet need, however as the evidence base may be relatively limited." **(Life sciences consultancy)**

"There are still areas in which EAMS could be strengthened. In particular, we believe it would be helpful for the Government to provide pharmaceutical companies with support to apply and deliver their drug via EAMS. Currently, companies must meet these costs themselves which could be a barrier to an application, or even beyond the financial means of some smaller companies." (Voluntary sector)

Overall, the three most commonly proposed solutions involved:

1. Reviewing and refining the Early Access to Medicines Scheme, including reimbursement;
2. Aligning regulatory and reimbursement requirements and the data requirements between agencies internationally and nationally;
3. Increasing focus on real world and easily accessible / feasible data collection strategies, with patient-centred outcomes at the core.

There was no difference between the overall views of organisations versus individuals or between various types of organisations or individuals.

What data is needed to generate sufficient evidence of safety, efficacy and value throughout the product lifecycle?

In total, 33 responses provided feedback about this question. All but one of these responses were from organisations.

The main suggestions about data needed to generate evidence of safety, efficacy and value related to types of data, when data should be collected and processes for data collection.

Solutions regarding types of data

- Using real world data to support regulatory submissions and onward testing. This may require leadership and promotion of the value of existing datasets (11 responses)

> ***"It is important that our data collection goes beyond patients entering clinical trials as trial data excludes patients that did not fit trials' criteria. We need rich and inclusive real life quality data that will capture patients' journeys and major outcome measures. Real world data will also inform strategy and policy in situations where there are no trial data."*** **(Voluntary sector)**
>
> ***"Real world data could … enable the NHS to make progress toward becoming an outcomes-focused healthcare system. By better tracking patient progress following a specific intervention, or set of interventions, the NHS could move to a situation where suppliers could be paid on delivery of a promised health improvement, rather than on the input. This would drive the development of effective treatments and technologies, as those that improve patient outcomes the most would be reimbursed, whilst also reducing the risk of the investment to the NHS."*** **(Pharmaceutical industry)**

- Ensuring the data collected are meaningful for service users and commissioners (6 responses)
- Requiring evidence of clinical and cost-effectiveness (3 responses)
- Increasing the quality and quantity of clinical trials with a UK focus or involvement (2 responses)
- Enhancing use of the NHS Innovation Scorecard (2 responses)
- Setting a target product profile that must be met (1 response)

Solutions related to the data collection timeframe

- Focusing on ongoing testing of impacts, including comparative matrix trials after approval (9 responses)
- Seeing the data provision process as a continuum, with different requirements at different stages (2 responses)

> ***"Data collection throughout a product lifecycle is a continuum. Continual evidence collection once outside the remit of clinical trials and post-authorisation safety studies can take the form of databases for formal collection of efficacy and safety data."*** **(Pharmaceutical industry)**
>
> ***"Increasingly we are seeing drugs go through the technology appraisal system earlier in the drug development process and therefore the data that NICE needs to be able to make a decision is lacking. Products often go through technology appraisal without overall survival data, making it difficult for NICE to make a judgment on the clinical effectiveness of the product. While we appreciate the need for drugs to be appraised as quickly as possible to allow for earlier access for patients, it does not benefit patients if the drugs are appraised but uncertainty in the data means that NICE is forced to issue negative guidance. If drugs going through technology appraisal are lacking survival data, the drug should then be made available on an interim basis and survival data should be collected using real world evidence."*** **(Voluntary sector)**

Solutions related to data collection processes

- Rewarding and incentivising data collection (4 responses)
- Standardising data collection and compiling datasets in a central resource unit rather than NICE and NHS England requiring different data (3 responses)
- Considering innovative approaches to data collection, such as using social media and smart phone applications (4 responses)
- Recognising issues with collecting data about relatively small patient populations / those with rare conditions (5 responses)
- Tailoring evaluation processes for data to specific innovations, such as diagnostics (1 response)
- Working in partnership with the voluntary sector, patient groups and regulators to define and collate data (3 responses)

> ***"Regarding medical technologies, innovators need to know upfront how value will be defined and measured by those procuring devices. If we wish to move away from incremental changes based on pricing, we need to be taking a wider, more joined up and longer term view of value that includes savings, patient acceptability of product, benefits to social care."*** **(Arms length body)**
>
> ***"Registries and data collection are often talked about as being a way of collecting real life data once a product is on the market to be sure it really delivers the value promised, especially when the evidence base might be relatively low for innovative medicines in rare diseases/ small populations. However, insufficient support and investment is made by the NHS to make this happen, and it is cited as a ˜burden' for the NHS to collect this data."*** **(Life sciences consultancy)**

Some responses suggested that it was not the specific data requirements that were of issue but rather the process of appraisal which can be long and complex (4 responses).

Thus the key points related to data focused on:

1. Using real world data rather than relying solely on clinical trials, especially given NHS access to a national dataset of patient records;
2. Ensuring that data continue to be collected after innovations have been approved;
3. Ensuring clear definitions and templates from the outset, including defining value in terms of outcomes that are important to service users and commissioners.

This third point was most likely to be championed by the voluntary sector and patient organisations.

What data is needed to generate sufficient evidence of safety, efficacy and value throughout the product lifecycle specifically for the pharmaceutical industry?

Out of all of the questions posed by the Review, this question was the least commented on. In total, 21 responses provided feedback about this question. All but one of these responses were from organisations.

The key themes were the same as for the more general question about data described overleaf. In brief, responses suggested:

- Using real world longitudinal datasets to explore usage, safety and efficacy (13 responses)
- Collecting ongoing data after approval (2 responses)
- Defining 'value' clearly and consistently between partners and stakeholders, including cost-effectiveness (3 responses)
- Standardising data collection (1 response)
- Recognising issues collecting data for small or specialised populations (3 responses)
- Building processes to collect and analyse data robustly and flexibly (3 responses)

There was no difference in views based on the type of respondent.

> ***"Data has the potential to revolutionise the way we deliver healthcare, however we need a mind-set change in the NHS supported by appropriate resources and national leadership to realise its potential. Real world data could provide valuable insights into the efficacy and value of medicines, particularly for those treatments with smaller patient populations which struggle to recruit the required numbers for large scale clinical trials. Real world data also has the added advantage of reflecting outcomes based on a representative patient population as opposed to being limited by the boundaries set in clinical trials."*** **(Pharmaceutical industry)**
>
> ***"The bigger challenge is more around who collects the data and how, rather than what data is collected. As medicines become more stratified, and regulatory and HTA systems develop flexible models, the widespread availability of linked, quality data will become essential. It will be necessary to embed data collection systems into the NHS, training staff and patients, and establishing robust, interoperable systems for collecting and curating data."*** **(Pharmaceutical industry)**

Chapter 4: Reimbursement processes

This chapter summarises feedback about questions related to integrating or accelerating national reimbursement processes and funding clinically and cost-effective innovation across the pathway. The Review questions were:

- How can we make the current funding system more flexible?
- What are the options for a long-term strategy for reimbursing new health technology in the NHS?
- How should NICE evolve to keep pace with advances in technology?
- How can patients and the public be involved in funding decisions?
- How should the health and care system address the affordability question?

Feedback about the first two bullet points listed above overlapped significantly so trends from those questions are combined for reporting purposes.

How can we make the current funding system more flexible and what are the options for a long-term reimbursement strategy?

In total, 48 responses provided feedback about making the current funding system more flexible and 42 responses commented about a long-term strategy for reimbursing new health technology. There was considerable overlap in the trends, so the themes are combined.

Most responses suggested that changes to the funding systems and reimbursement system would be useful. The main proposed solutions focused on assessing value, pricing strategies and financial issues related to adoption.

> ***"Short term cost savings predominate and system-wide benefits are often not considered. Develop a funding system than rewards overall NHS/patient benefits rather than a continuing a siloed approach."*** **(Arms length body)**

Solutions related to assessing value nationally or regionally

- Aligning the decisions and processes of key national stakeholders (10 responses)

> ***"A coherent framework that aligns all relevant bodies including DH, PASLU, NICE, NHSE etc, that would support more flexible and innovative patient access schemes (PASs) and managed entry agreements (MEAs) would be helpful. We would welcome the introduction of pricing by indication to provide a more flexible reimbursement system."*** **(Pharmaceutical industry)**

- Having NICE or similar as the sole assessor of value thus reducing national and local duplication and divergent methodologies across organisations (12 responses)

> ***"Currently, in England we have a system in which we have two bodies which evaluate new technologies for funding – NICE and NHS England. We believe NHS England should continue to commission services but we are concerned that their process to evaluate medicines is not yet fit for purpose. As a result, we believe that NICE should be the single assessor of medicines."*** **(Pharmaceutical industry)**

- Assessing value based on outcomes rather than price alone (5 responses)

> ***"A long-term strategy for reimbursing new health technology in the NHS needs to ensure that decisions about providing products to patients are not based simply on the basis of the unit cost paid per product, but following an assessment of the overall value provided by the product."*** **(Individual response)**

- Using NICE to set new tariffs (1 response)
- Convening a centralised 'pricing board' or similar to broker financial deals based on factors such as volume and patent life (2 responses)
- Reducing siloed budgeting arrangements, for example by regionally aggregating medicines budgets for improved decision-making (5 responses)
- Linking technology assessment and reimbursement systems with NHS local and national procurement (3 responses)
- Ensuring that the NHS is represented in price negotiations rather than solely the Department of Health (1 response)

Solutions related to pricing strategies

- Implementing flexible pricing models and conditional reimbursement more closely linked to the collection of real world data. This may involve incentivising via 'cost-sharing' or risk sharing models whereby the NHS only pays for products if they are shown to be effective (25 responses)

> ***"We recommend in particular a formal process of conditional reimbursement is introduced, allowing for technologies to be funded for a fixed period of time within specific perimeters while real-life usage data is collected… This system increases flexibility and incentive for innovators and will facilitate quicker access for patients. It also resolves one of the most pressing issues relating to innovative medicines by giving the scope for conditional reimbursement."*** **(Biotechnology industry)**

> ***"Some companies have been exploring innovative ways to price treatments to make them more affordable for the NHS. Some drugs are already priced based on their effectiveness and there are schemes where the NHS is reimbursed for any treatment costs after a set number of months also help to get expensive new drugs to patients."*** **(Academic / research organisation)**

- Ensuring that future Pharmaceutical Pricing Regulation Scheme (PPRS)-type initiates address affordability concerns at a local level, support the uptake of innovation and deliver rebates to the NHS as planned (16 responses)
- Supporting multi-year contracts to account for incremental change (16 responses)
- Better utilising best price tariffs, high cost device lists and capitation and developing a technology tariff (5 responses)
- Considering increasing service user co-payment (2 responses)
- Considering a 'new medicines fund' (1 response)
- Keeping negotiations about price confidential to protect the UK as a reference market for other markets (2 responses)

Solutions related to adoption issues

- Ensuring appropriate incentives to the NHS for innovation (7 responses)
- Decommissioning outdated treatments and services (6 responses)
- Providing advice about how to set up complex financing schemes that are workable in the NHS (2 responses)
- Utilising outcomes-based commissioning (5 responses)
- Ensuring that NICE recommendations are implemented by holding organisations to account for adoption (8 responses)

Solutions related to specific conditions or devices

- Working flexibly to appraise and fund treatments for rare conditions or first types of technology (10 responses)
- Adopting a whole life cycle asset management service for capital medical equipment and new medications (2 responses)
- Amending reimbursement processes so they do not penalise medical devices and diagnostics (2 responses)
- Consulting about ways to manage and reform the Cancer Drugs Fund (7 responses)
- Ensuring that primary care is a focus (3 responses)
- Considering the distribution of funding to smaller organisations (2 responses)

To summarise, the four most commonly mentioned suggestions were:

1. Implementing conditional reimbursement alongside risk sharing models;
2. Supporting multi-year contracts and less siloed budgets;
3. Enhancing Pharmaceutical Pricing Regulation Scheme approaches;
4. Having a single assessor of value, such as NICE, to reduce local and national duplication.

There was no difference between the overall views of organisations versus individuals or between various types of organisations or individuals.

How should NICE evolve to keep pace with advances in technology?

In total, 48 responses provided feedback about this question. Nine out of ten of these responses were from organisations (45 responses; 94%).

Some responses believed that NICE was internationally recognised for its approach. The main suggestions for development related to the functions and processes of NICE.

> ***"NICE has a worldwide excellent reputation and does what it does very well, such as Single Technology Appraisals for drugs where randomised data exist. However methodologies do not always suit innovative technologies, particular where endpoints are not so easily assessed. We would advise keeping as much assessment of novel technologies within the NICE umbrella, but in general processes need to be faster."*** **(Pharmaceutical industry)**

Solutions related to NICE functions

- Removing multiple assessments of products, such that NICE is the sole body responsible for cost-effectiveness assessments (10 responses)
- Giving NICE an innovation mandate and ensuring NICE is better aligned with the goals of the NHS (5 responses)
- Horizon scanning the sector to better understand how to match the technology under development to areas of growing patient need (4 responses)
- Playing a greater role in the adoption of guidance, considering strategies to ensure uptake of guidance and measuring uptake (10 responses)
- Establishing a formal role for NICE to comment on tariffs and take part in discussions about EU-level processes (2 responses)
- Evolving the development of guidelines towards whole disease pathways and combination treatments, focusing less on individual treatments (2 responses)
- Having a more collaborative approach between charities, industry and the NHS in early stages of development pathway, with NICE being involved early (1 response)
- Externally reviewing the objectives and functions of NICE every three to five years (2 responses)

> ***"In order for NICE to keep pace with advances in technology, we feel its processes should be subject to regular review and stakeholder comment, perhaps on a three-to-five year cycle, to confirm that they remain fit for purpose and can be reformed if necessary. Ongoing review and stakeholder input will ensure broader public ownership in, support for and adherence to processes and procedures, which is beneficial to all parties."*** **(Pharmaceutical industry)**

Solutions related to NICE processes

- Assessing value based on factors other than finance / quality-adjusted life years gained (17 responses)
- Allowing for a wider range of evidence and uncertainty, including real world data (10 responses)

"In order to become fit for the future, the NICE technology appraisal process needs to be realigned with the goals of the NHS, which include helping the most vulnerable members of society, those with the greatest medical need and recognising differences in willingness to pay more for medicines at the end of life and for rare conditions. The NICE process must also be realigned with the changing pace of science, with increasing numbers of personalised and targeted medicines and with regulatory approval granted to promising medicines, based upon immature data." **(Pharmaceutical industry)**

- Increasing the speed at which appraisals are made (10 responses)
- Providing interim approvals whilst awaiting full review or having other processes in place to allow people to benefit earlier from new medicines, perhaps through conditional approvals (7 responses)
- Having differing levels of assessment, such as compact appraisal for products that are second or third to the market within an existing class of medicines (7 responses)
- Having different criteria for rare conditions / smaller populations (9 responses)

"The most innovative technologies benefit a smaller number of patients. Ensuring this is reflected when assessing the cost-effectiveness of new medicines is essential if innovation is to be truly encouraged and rewarded. An enhanced role will help in this regard, by ensuring that NICE not only assesses the clinical and cost-effectiveness of new technologies, but also recommends the appropriate commissioning pathway." **(Biotechnology industry)**

- Reforming the medical technology appraisal process (6 responses)
- Adopting Complex Patient Access Schemes (PAS), not only simple discount schemes (3 responses)
- Taking into account whether a product was developed or researched in the UK as part of the appraisal process (1 response)
- Applying greater relative weighting to service users' input into appraisal and involving service users in the appeals process (5 responses)

Responses noted that developing the functions and processes of NICE would require greater funding of NICE.

> ***"NICE should … rapidly assess every new medicine using different grades of assessment to avoid over-burdening the system. However, it is essential that NICE's mandate is modernised, to reflect new scientific, societal and NHS paradigms and maintain its global influence and leadership. NICE needs to also be tasked with driving patient benefit and encouraged to ensure that its recommendations meet societal expectations, balancing cost with patient benefit. It needs appropriate resources to be able to deliver this increased role."*** **(Pharmaceutical industry)**

To summarise, the three most commonly mentioned suggestions for developing NICE were:

1. Assessing value based on factors other than cost-effectiveness;
2. Having a more flexible and speedy appraisals process that allows for different types of evidence, conditional approvals and varying criteria for different categories of products;
3. Extending the remit to include horizon scanning and adoption of guidance and being the single source of cost-effectiveness appraisal in England.

There was no difference between the main trends in views from various types of organisations and individuals. Pharmaceutical companies were more likely to comment on this question than other respondents.

How can patients and the public be involved in funding decisions?

A total of 31 responses provided feedback about this question. Eight out of ten of these responses were from organisations (26 responses; 84%). The main suggestions related to providing information and enhancing engagement. Most were not specific to funding decisions.

Solutions related to information provision

- Providing good quality, easily accessible data in a format that people not working in the health system can use to enable well-informed public discussion and decision-making (4 responses)
- Having good links with patient organisations (1 response)
- Having a dedicated website and making use of social media (2 responses)
- Using the Innovation Scorecard and simplifying it into a more accessible format (1 response)
- Ensuring that NHS commissioners and providers have a duty to demonstrate how they are making sure that service users are aware of their rights and have access to NICE-approved medicines (2 responses)
- Making commissioning and reimbursement processes transparent (1 response)

Solutions related to engagement

- Mandating service user engagement in development (2 responses)
- Engaging service users via NICE (8 responses)
- Seeking input from service user organisations routinely (6 responses)
- Giving additional resources to Clinical Reference Groups (1 response)
- Polling members of the public or service users for their views (3 responses)
- Making sure service users are seen as key members of the team (3 responses)
- Reflecting how service users were involved in guidance documents (2 responses)
- Training service users to take a more active role (2 responses)

> ***"Greater emphasis should be placed on engaging and consulting with patient and industry groups to ensure that their voices are given primacy. In conjunction efforts should be made to empower such organisations and also to offer them the relevant training and support needed to understand and galvanise their member's views."*** **(Individual response)**

There was no difference between the overall views of different types of organisations. The voluntary sector was more likely than the pharmaceutical sector to provide suggestions.

How should the health and care system address the affordability question?

Overall, 39 responses provided feedback about this question. Nine out of ten of these responses were from organisations (36 responses; 90%).

The main suggestions were:

- Setting out longer term strategies spanning multi-year budgets (8 responses)
- Developing an understanding of the whole system costs of procuring, maintaining and managing the NHS asset base and its effect on healthcare delivery (3 responses)
- Considering the cost of medicines in the context of the wider pathway so as to recognise the full value (i.e. cost of medicine compared to reduction in healthcare and social care costs) (7 responses)
- Proactive decommissioning of older technologies and medicines (5 responses)
- Building on the PPRS approach to ensure local reimbursement and use proceeds to set up an innovations fund (8 responses)
- Taking steps to ensure adoption, such as monitoring compliance with guidance, training clinicians in how to apply new products and auditing patient records to identify people who might benefit (3 responses)
- Medicines optimisation to reduce medicines dispersed but not taken, perhaps through enhancing medicines use reviews (4 responses)
- Using robust horizon scanning when making decisions about affordability (1 response)
- Reducing duplication by implementing a single cost-effectiveness assessment and setting up regional bodies to oversee adoption (2 responses)
- Developing a single electronic catalogue to be used across NHS organisations (1 response)
- Increasing access to differentiated generic drugs and biosimilars (3 responses)
- Not separating cancer as a special case for funding (1 response)

There was no difference between the overall views of organisations versus individuals or between various types of organisations or individuals.

> ***"There is a need to consider and develop new finance models, systems that effectively determine the appropriate ROI period and recognize savings in other parts of the Health and care system as well as actively discarding incentive based systems which are counterproductive to the adoption of new and beneficial technologies and services."*** **(Arms length body)**

Chapter 5: Adoption

This chapter summarises feedback about questions related to accelerating the speed at which clinically and cost effective innovative products are commissioned and get to service users. The Review questions were:

- How can we reduce or remove barriers to using transformative health technology?
- How can we strengthen incentives to use transformative health technology?
- How can the system support uptake of transformative health technology?
- Could patients help unblock some of the barriers to the adoption of innovation in the NHS?

Feedback about each question is listed in turn.

How can we reduce or remove barriers to using transformative health technology?

Out of all of the questions posed by the Review, this was the question that the most responses chose to provide feedback about. In total, 51 responses commented about this question. Nine out of ten of these responses were from organisations (47 responses; 92%).

The main suggestions related to the approvals process, commissioning and adoption.

Solutions related to approvals

- Adopting a consistent and robust methodology for evaluating new technologies (5 responses)
- Including a wider definition of value (5 responses)
- Having one source of approvals (6 responses)
- Removing local duplication of review when NICE has deemed a technology cost-effective. Local groups could focus on ensuring adoption rather than re-evaluating value (15 responses)

> ***"At the point of a national level recommendation, all other regional and local groups across the NHS which currently undertake parallel and often duplicative evaluations should be re-purposed to focus on implementation."*** **(Pharmaceutical industry)**

- Resourcing NICE or similar appropriately to undertake more rapid appraisals and greater numbers of appraisals (3 responses)
- Reducing the number of steps in the approvals process (4 responses)
- Ensuring that the system is streamlined for repurposing drugs (2 responses)
- Reducing the time between approval and availability of technologies to the NHS (3 responses)
- Recognising that PPRS can act as a disincentive (5 responses)
- Reducing administrative and financial burden in the approvals process (3 responses)

> ***"The regulatory system for clinical trials puts an enormous administrative and financial burden on academic clinical trialists, and has damaged the ability of academic organisations to lead international studies."*** **(Academic / research organisation)**

> ***"There is unfortunately in the UK no consistent route to local markets for many medical devices and diagnostic products, with access highly dependent on clinical advocacy and stakeholder relationships. This has resulted in vast variations in uptake across the country as well as significant inefficiencies and costs for manufacturers. This is exacerbated by the lack of funding direction for medical devices and diagnostics, which limits local commissioners' willingness to invest in innovative technologies as compared to pharmaceutical products. Central coordination and standardisation of the evidence requirements will be useful in reducing some of the variation and duplication of effort across local health economies."*** **(Medical device company)**

Solutions related to commissioning

- Ensuring local accountability for uptake of NICE approved technologies. This may involve greater use of the Innovation Scorecard or mandating adoption (19 responses)

"Addressing poor uptake and adoption of new medicines should be a priority for the Government and the NHS. However, a fundamental contradiction prevents many innovative medicines reaching patients at the right time. On the one hand, NICE appraises medicines to ensure that they are clinically and cost effective. The purpose of NICE is to highlight which medicines should be available for use in a healthcare system constrained by limited budgets. On the other hand, prescribers are limited by budgets that cannot keep pace with the demand for healthcare in their local areas." **(Pharmaceutical industry)**

"Even after innovative new treatments are accepted by NICE, it can be challenging to ensure they are widely adopted by the NHS. The fragmented arrangements for commissioning, and the NHS's ˜payments by results' scheme for reimbursing hospitals for the procedures they have conducted, can both act as financial barriers to adoption, even where treatments should save the NHS money." **(Academic / research organisation)**

- Ensuring local budgets and tariffs allow the purchase of new technologies, perhaps with support from NICE regarding tariffs (12 responses)
- Addressing siloed budgets and allowing multi-year budgets (4 responses)
- Horizon-scanning to allow timely budget planning, with budget-holders open to early dialogue with manufacturers about potential budget or service impacts (2 responses)
- Having a robust decommissioning strategy (2 responses)

Solutions related to adoption

- Providing commissioners and clinicians with guidance and education about how to adopt proven technologies (7 responses)

> ***"Education – both for patients and for healthcare professionals – remains one of the biggest barriers to local commissioning of, and patient access to, innovative healthcare solutions…Ongoing education for healthcare professionals in the use of new technologies is not only vital to ensure effective local commissioning, but also to help patients maximise benefit from treatment options."*** **(Voluntary sector)**

- Developing local champions within the NHS (1 response)
- Supporting strategic clinical networks (SCNs) as drivers of innovation, underpinning the upskilling of primary care clinicians (1 response)
- Creating new incentive structures, including a NICE quality standard on innovation, innovation committees within NHS trusts and innovation champions at CCG level with a focus on identifying and supporting areas of best practice (2 responses)
- Considering financial incentives for changing physician behaviour (1 response)
- Strengthening the role of groups such as AHSNs and new models of care vanguards in testing and spreading new ideas and best practice (3 responses)
- Having a more streamlined process for logging devices and keeping records about their maintenance and use to ensure older devices are replaced as new technologies become available (1 response)
- Enabling organisations across the NHS to communicate and share information between healthcare professionals and with patients (1 response)

In summary, the three most common suggestions were:

1. Removing perceived duplication of approvals processes at national and local levels;
2. Monitoring adoption of guidance to ensure uptake;
3. Ensuring budgets, tariffs and incentives are aligned to support uptake.

There was little difference in views depending on what type of organisation or individual was responding, although responses from the pharmaceutical industry were more likely than others to mention barriers related to the approvals process.

How can we strengthen incentives to use transformative health technology?

A total of 32 responses provided feedback about this question. All but two of these responses were from organisations (94%).

The main suggestions related to enhancing measurement, targeting end users and building on existing incentives.

Solutions related to monitoring and measurement

- Focusing on measuring outcomes and tracking changes over time. This may involve improvements in IT systems and greater use of the Innovation Scorecard and Medicines Optimisation Dashboard (13 responses)
- Reducing the focus on cost and increasing the focus on patient outcomes, including long-term outcomes. This may include rewarding commissioners and providers for investment in innovation (5 responses)
- Setting up systems whereby organisations must justify if they choose not to adopt an innovation with proven effectiveness / recommended by NICE. This may involve sanctions (5 responses)
- Focusing on commissioning providers that demonstrate good performance (2 responses)
- Supporting an increased role for AHSNs in measurement and uptake (3 responses)
- Increased data sharing across organisations (1 response)

> ***"Commissioners and providers need to be rewarded or incentivised to focus on investment in innovation rather than cost cutting alone. There needs to be alignment between NICE guidance and incentives. Tools such as the Medicines Optimisation dashboard and Scorecard must be better understood and used to monitor progress against best practice, and need to be linked to local NHS planning and form part of the review process."*** **(Pharmaceutical industry)**

Solutions related to targeting end users

- Formally reviewing what the adopters (finance and operations) and users (clinicians and patients) say would incentivise them (1 response)
- Educating commissioners and clinicians about innovations (3 responses)
- Appointing innovation champions at senior level, for example as part of NHS boards (1 response)
- Recognising the potential for informed service users to be drivers of change (1 response)
- Incentivising key personnel required for effective translational delivery including leaders of R&D departments, clinical trials units and individual clinical academics and research nurses (1 response)

"Cultural and operational change will be needed across the NHS to support the choice of innovative products. Commissioners and other decision makers should feel empowered and equipped to adopt new technologies and adapt services as needed to realise value. Industry is a key partner to better inform decision makers." **(Pharmaceutical industry)**

"Give guidance and support to those trying to adopt so that they feel they can overcome barriers and then reward by acknowledging achievement. Make adopting transformative products and innovation key performance indicators." **(Voluntary sector)**

Solutions about building on existing incentives

- Aligning existing incentives such as the Quality and Outcomes Framework and ensuring these do not have unintended consequences. Commissioners and providers could be rewarded for adopting innovation (5 responses)
- Using financial incentives such as CQUIN, quality premiums or local incentive schemes to reduce unnecessary prescribing and over-cautious prescribing and reward acceleration of uptake (3 responses)
- Strengthening the national tariff for elective surgery to support medical technologies (1 response)
- Developing a single tariff office and having a fast track tariff process (2 responses)
- Enabling commissioners to make decisions based on potential long-term savings to the system (1 response)
- Changing the criteria for acceptance on the high cost device list (1 response)
- Reviewing the incentive system every five years (1 response)
- Ensuring the PPRS rebate is used to fund innovation, perhaps by setting up a new medicines fund (1 response)
- Offering an extension to the current R&D Enhanced Credit regime for companies that partner with academia or small biotechnology companies (3 responses)

> ***"The Government should enable development of local incentive schemes in the short term to accelerate adoption of innovation and implementation of medicines optimisation plans, together with capturing/sharing details on those schemes which are deemed to be most effective."*** **(Pharmaceutical industry)**
>
> ***"Once the technology has become embedded in best practice, through the incentive system, it should then seamlessly transfer to the tariff system (or other appropriate funding stream), with an appropriate figure for that tariff to cover the use of the technology. This would allow for continuation of use of the technology, freeing up the financial incentive system for further innovative technologies."*** **(Biotechnology industry)**

Thus, overall the most commonly mentioned suggestions related to tracking uptake of innovation and using current incentive structures to increase adoption.

There was no difference between broad trends in the views of organisations versus individuals or between various types of organisations or individuals. Relatively more responses to this question came from the pharmaceutical industry.

How can the system support uptake of transformative health technology?

Overall, 39 responses provided feedback about this question. Nine out of ten of these responses were from organisations (36 organisations; 92%).

The main suggestions related to research and development, personnel and financing. These suggestions largely repeated answers to other questions.

Solutions related to research and development and appraisals

- Considering new expedited development pathways, linked to adoption (2 responses)
- Creating a strong research environment (1 response)
- Developing the mandate of AHSNs (4 responses)
- Providing test beds and large scale demonstrator sites (2 responses)
- Disseminating evidence-based information on new technologies to NHS R&D departments, boards and clinical leads (2 responses)
- Having a single national value assessment system, with multiple types of assessment available (2 responses)
- Implementing a system to track the uptake of innovations (5 responses)

"More effective use of innovation for patients locally can be achieved through the removal of local barriers to the uptake of medicines, with simpler pathways by which medicines are adopted. Replication should be removed through moving to single assessments that are mutually recognised across the system. Incentives and metrics should be aligned to support the adoption of transformative new medicines. There should be a clinician-led, patient-centric approach to medicines choice which considers the patient experience." **(Pharmaceutical industry)**

"The uptake of innovation does not happen just by 'diffusion and adoption' but in our view requires active support across the entire spectrum of translation from basic science through to healthcare delivery." **(Voluntary sector)**

Solutions related to financing

- Incorporating incentives for uptake of innovative products into the national tariff (3 responses)
- Introducing marginal tariffs for selected outdated interventions (1 response)
- Using multi-year health budgets (2 responses)
- Allowing NICE to negotiate on the pricing of new medicines through creative Patient Access Schemes (PAS) (1 response)
- Considering 'Pay per procedure' or 'Equipment Financing Agreements' (EFAs) (1 response)
- Funding new healthcare technologies with PPRS industry rebates (2 responses)
- Creating a new medicines fund (4 responses)
- Focusing on decommissioning (3 responses)
- Ensuring that technology assessment and reimbursement systems are aligned with NHS procurement (8 responses)

Solutions related to personnel

- Creating board level positions responsible for innovation in NHS organisations, including in NHS England (2 responses)
- Working with service users from the outset (4 responses)
- Empowering and educating clinicians and commissioners (4 responses)
- Resourcing NICE appropriately to undertake a greater quantity and more rapid technology appraisals and to have a larger role in dissemination and uptake (5 responses)

> ***"The lack of demand for innovation in the NHS is also a product of the lack of consumer power in the NHS. Patients are often not demanding best practice because they lack access to the right information. Unleashing the power of patients – as a disruptive force in the service - promises to lead to a radical increase in innovation."*** **(NHS organisation)**

There was no difference between the overall views of organisations versus individuals or between various types of organisations or individuals.

Could patients help unblock some of the barriers to the adoption of innovation in the NHS?

Out of all of the questions posed by the Review, this question was one of the least commented on. Overall, 22 responses provided feedback about this question. Nine out of ten of these responses were from organisations (19 responses; 86%). Voluntary sector organisations were highly represented in answers to this question. Pharmaceutical organisations were relatively less likely to answer this question compared to others.

All responses to this question suggested that service users could help to unblock barriers to the adoption of innovation.

The main suggestions about this were:

- Increasing patient advocacy and information regarding treatment options and the roles that service users can play in funding decisions (8 responses)
- Emphasising the NHS Constitution (4 responses)
- Supporting the role of service user organisations (4 responses)
- Undertaking a service user education campaign, perhaps in association with organisations such as Healthwatch (2 responses)
- Using social media, focus groups and other tools to involve service users in development and assessment decisions (3 responses)
- Supporting registries so service users can be involved in trials (1 response)
- Tracking and publicising metrics. This may include improving the Innovation Scorecard to make it more meaningful to service users and carers (3 responses)

"Patients could be invited to be involved in the decision making process on the adoption of innovation in the NHS through focus groups/support group networks, primary care, outpatient appointments, dedicated website, social media." **(Academic / research organisation)**

"Empowered patients are the foundation of a strong and responsive healthcare system. Through greater awareness and understanding of their rights and responsibilities, patients are more likely to access and benefit from interventions that have a positive impact on their lives." **(Pharmaceutical industry)**

Chapter 6: User engagement

This chapter summarises feedback about service user engagement, in addition to the specific questions asked about this in previous chapters. The additional Review questions were:

- How do we better engage all patients in new health technology?
- How can we increase patient and public involvement in the development of innovations?

As responses often provided combined feedback about these questions or repeated feedback to each question, the themes are combined below.

How do we better engage patients and the public in new health technology and the development of innovations?

In total, 45 responses provided feedback about one or both questions. 80% of these responses were from organisations.

There was wide agreement that engaging service users was important, though the voluntary sector, patient organisations and individuals were more likely than industry or research organisations to provide feedback about these issues.

> ***"Participants stressed the importance of "patient pull" as a driver of diffusion and adoption… It was noted that research and drug development are too often focussed on what industry professionals believe are the desired outcomes, rather than what patients actually want. Patient participation early in the R&D process offers pharmaceutical companies a better understanding of patients' needs, in order to develop medicines tailored towards maximising outcomes and confronting unmet need."*** **(Academic / research organisation)**

> ***"There is a particular opportunity to improve the way in which patient input informs the HTA decision making process. Patients and clinicians can offer important perspectives on the value of a treatment that cannot be captured in traditional economic analysis and add credibility and legitimacy to the HTA process. Their views could help to balance the current dominance of the QALY and provide valuable insight in discussions on areas such as unmet need, experience of having the disease, impact of treatment and what constitutes a good patient outcome."*** **(Pharmaceutical industry)**

The main solutions suggested for involving service users related to information provision, methods for engagement and underpinning policy.

Solutions related to providing information

- Providing clear guidance about how to engage service users, developed in partnership with patient organisations (1 response)
- Providing guidance to service users to help them engage in the development of new technologies (2 responses)
- Making sure information for service users is provided in a jargon free and accessible format (4 responses)
- Providing information about the UK Clinical Trials Gateway and Early Access to Medicines mechanisms (2 responses)
- Improving the information available through the Innovation Scorecard (1 response)

> ***"Make it easier and more accessible for them to be involved by providing different and flexible routes; this should include patient leaders to lead wider patient involvement. Make use of patient-directed dissemination (i.e. lay summaries with clear language and no jargon), use the media better as well as the more typical research dissemination."*** **(Arms length body)**

Solutions related to engagement approaches

- Working with patient organisations, patient participation groups and the voluntary sector (18 responses)
- Strengthening the role of NHS England's Clinical Reference Groups, NICE's Citizens Councils and other similar regulatory and commissioning groups (7 responses)
- Supporting independent focus groups, advisory boards, interviews and workshops / training sessions with service users (7 responses)
- Developing a network of expert patient support groups (1 response)
- Providing information leaflets and posters at supermarkets, community groups, care homes, clubs and other community venues (1 response)
- Using digital media and online surveys and hubs (3 responses)
- Using multiple engagement channels and media (2 responses)
- Undertaking formal consultations with the public (2 responses)
- Ensuring that clinicians are engaged so that they can promote involvement to service users (3 responses)
- Inviting members of the public to attend NHS England meetings about new technologies (1 response)
- Including lay representatives on NICE appraisal committees (1 response)
- Setting up a portal to support service user involvement in clinical trials (2 responses)
- Having a system or hub where people can provide ideas for new technologies (2 responses)
- Drawing on international examples of good practice for engaging service users (4 responses)

"Clinicians and researchers need to be aware of the importance of patient involvement from trial design stage onwards through the whole process. Patient organisations should be at the forefront of helping to match patients willing to help and share their experiences with innovators/researchers." **(Voluntary sector)**

"In order to productively increase the participation of the public/ patients there is a need to communicate using multiple channels (press, digital and social media, etc) using language that is simple (and translated) and presenting the target audience with a very clear call to action." **(Life sciences consultancy)**

Solutions related to policy and adoption

- Consulting with service users about the outcomes they value (9 responses)

> ***"It is essential to identify the most relevant and appropriate outcomes on a patient-by-patient basis and to keep their needs at the forefront of decision making. Similarly, patient choice and guaranteeing access to those products that ensure comfort and usability, regardless of how novel they may be, should be central when drawing up access plans."*** **(Individual response)**

- Embedding engagement within research and development processes and policies, including as part of reimbursement processes (5 responses)
- Encouraging the NHS to facilitate access to service users on behalf of researchers (2 responses)
- Putting in place an appeals process for service users regarding NHS England decisions about new medications (1 response)
- Increasing awareness about the importance of clinical trials (5 responses)
- Increasing the proportion of clinical trials conducted in the UK (1 response)
- Extending the remit of the Trials Acceleration Programme (1 response)

> ***"While the UK has a good reputation for high quality clinical trials, set up times are slow and there are changes required to streamline the approval and patient recruitment processes to improve the UK's competitiveness. The National Institute for Health Research (NIHR) has developed a set of framework tools to speed up the clinical trial set up process in the NHS, but many trusts have not fully implemented them. We believe that the NIHR framework and tools should be simplified and mandated across the NHS."*** **(Pharmaceutical industry)**

To summarise, the three most commonly mentioned suggestions for strengthening service user engagement were:

1. Working closely with existing groups, including the voluntary sector and patient groups associated with regulators and commissioners;
2. Consulting with service users about the outcomes that are most important to them;
3. Providing a variety of different approaches to engagement, including information for both service users and clinicians.

Chapter 7: Summary

Key messages

The key messages from responses to the Review to date are summarised here.

Early dialogue and collaboration

Around half of the responses provided feedback about one or more questions asked about early dialogue and collaboration. Responses stated priorities should include:

- Having consistent priorities at a national and regional level, with clear communication channels, promotional activities and forums to build shared understanding of these priorities across stakeholders;
- Strengthening the role of existing organisations and forums rather than creating new structures. The role of Academic Health Science Networks was particularly emphasised;
- Having a publicly accessible horizon scanning function with broad scope, with an online portal where stakeholders of all types can review and add information;
- Needing clear information up front about the regulatory process;
- Ensuring consistency of requirements across regulatory and commissioning components of the pathway.

There was mixed feedback about the value of a single point of advice for innovators, with 59% of responses supporting this and 41% not in favour, including some large umbrella organisations. Whilst a single point of access to advice may have been welcomed in theory, responses were concerned that this would not be feasible in practice.

Regulatory processes

About two fifths of responses provided feedback about one or more questions asked about regulatory processes. Responses stated priorities should include:

- Reviewing and refining the Early Access to Medicines Scheme, including reimbursement;
- Aligning regulatory and reimbursement requirements and the data requirements between agencies internationally and nationally;
- Increasing the focus on real world data and easily accessible / feasible data collection strategies, with patient-centred outcomes at the core;
- Ensuring that data continue to be collected after innovations have been approved;
- Ensuring clear definitions and templates from the outset, including defining value in terms of outcomes that are important to service users and commissioners.

Reimbursement processes

About six out ten responses provided feedback about one or more questions asked about reimbursement processes. Responses thought that priorities should include:

- Supporting multi-year contracts and less siloed budgets;
- Having a single assessor of value, such as NICE, to reduce local and national duplication;
- Assessing value based on factors other than cost-effectiveness;
- Having a more flexible and speedy appraisals process that allows for different types of evidence, conditional approvals and varying criteria for different categories of products;
- Extending NICE's remit to include horizon scanning and adoption of guidance and being the single source of cost-effectiveness appraisal in England;
- Enhancing Pharmaceutical Pricing Regulation Scheme approaches;
- Providing good quality, easily accessible data in a format that people not working in the health system can use to enable well-informed public discussion and decision-making about funding;
- Proactive decommissioning of older technologies and medicines.

Adoption

About six out of ten responses provided feedback about one or more questions asked about barriers and facilitators for adoption. Responses thought that priorities should include:

- Removing duplication of approvals processes at national and local levels;
- Monitoring implementation of uptake;
- Ensuring budgets, tariffs and incentives are organised to support uptake;
- Using current incentive structures to increase adoption;
- Increasing uptake through solutions related to research and development, appraisals, financing and personnel.

User engagement

About two fifths of responses provided feedback about one or more questions asked about engaging service users. Responses thought that priorities should include:

- Working closely with existing groups, including the voluntary sector and patient groups associated with regulators and commissioners;
- Consulting with service users about the outcomes that are most important to them;
- Providing a variety of different approaches to engagement, including information for both service users and clinicians.

Next steps

The Accelerated Access Review team will consider all of the feedback to phase 1 of the Review when developing suggestions about practical solutions. It is planned that phase 2 of the Review will take place in the final quarter of 2015, whereby organisations and individuals will be invited to comment further on the proposals developed based on initial feedback.