Department of Health & Social Care

NICE's technology appraisal and highly specialised technology work programmes (Charging and Appeal Panels) - Consultation response

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Introduction

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Executive summary

The National Institute for Health and Care Excellence (NICE) makes recommendations on whether medicines and other treatments should be routinely funded by the NHS in England through its technology appraisal ("TA") and highly specialised technology ("HST") programmes. These programmes are currently funded by Government.

NICE's TA and HST programmes, together with the associated requirement for NHS commissioners and local authorities as appropriate to fund recommended treatments, play a vital role in ensuring access for NHS patients to new and cost-effective treatments. As such, it is important that NICE's technology appraisal and highly specialised technology programmes operate in a sustainable and efficient way that allows it be more responsive to developments in the life sciences sector. The Triennial Review of NICE, published in 2015, recognised this and recommended that consideration should be given to the introduction of charges for technology appraisal and highly specialised technology recommendations as one of a set of possible measures to enable NICE to operate more efficiently.

The Department of Health and Social Care (DHSC) carried out a public consultation to seek views on proposed amendments to the National Institute for Heath and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 ("the Regulations") that would enable NICE to charge for making technology appraisal and highly specialised technology recommendations, and recruit Appeal Panel members engaged in the provision of health care in the health services across the UK instead of just England. The public consultation was launched on 10th August 2018 and was open for submission of responses until 14th September 2018.

This report provides information about the consultation responses and the analysis undertaken. The Impact Assessment (IA) has also been updated to incorporate evidence submitted in response to the consultation and is published alongside this report.

The consultation sought views on transferring the cost of NICE making a technology appraisal or highly specialised technology recommendation to the private life sciences sector and allowing NICE to charge small companies less and permit small companies to pay in instalments. The charging model in the consultation document proposed a 25% discount for small companies.

There were 78 responses to the consultation, of which 41 respondents represented views from the life sciences industry, including pharmaceutical companies, industry representatives, consultancies and Medtech companies. The next largest group of responses came from patient groups (15%, 12/78) with other responses from NHS organisations and individuals.

The majority of respondents (62%, 48/78) disagreed with the main proposal that NICE may charge companies for making TA and HST recommendations. However, an analysis of key themes from the responses shows that just over half (51%) of respondents agreed that life sciences companies should contribute to the cost of developing NICE recommendations. Respondents supported (59%, 24/41) a mechanism for reducing the impact on small companies, but felt that the proposed 25% discount did not go far enough and that a more complex system than a discounted cost would be more appropriate. Specific concerns were raised in response to the consultation about the potential impact on patient access to new treatments, in particular rare diseases, and about the analysis contained in the IA .

The majority (85%, 66/78) of respondents agreed that it was appropriate to extend the pool of potential NICE appeal panel members engaged in the provision of health care in the health services across the UK rather than limit it to England.

The Government has considered the consultation responses with NICE and has carried out additional work on the Impact Assessment that is published alongside this document to consider further specific concerns that were raised by respondents. The Impact Assessment now includes further consideration of: the value to companies of a NICE recommendation, the impact on small companies, NICE's processes to mitigate conflicts of interest and the impact of additional costs to companies.

Following consideration of the consultation responses and the additional analysis, the Government proposes two main changes to the proposed policy:

- A number of respondents expressed concern about the potential impact on small companies. NICE will now offer a larger discount of 75% to small companies to minimise barriers to the participation of small companies and in line with the Government's commitment support small companies in the Industrial Strategy. The increased discount for small companies is intended to minimise barriers to small companies bringing forward new products.

- The Government is keen to create flexibility for changes to the charging model should issues arise in its first years of operation and the addition of a new provision in the amending Regulations will enable the Secretary of State to direct NICE in specific cases to calculate charges on the basis NICE considers to be the appropriate commercial basis. This would provide more flexibility for amending charges should this be required in future, and subject to consultation with stakeholders.

The Government is satisfied that the introduction of charging for NICE TA and HST recommendations will create a sustainable model for NICE, and that the proposed changes to the charging model will mitigate the risk of any unintended and undesirable consequences. We will monitor the impact of the charges.

The Government will also introduce the proposed changes to enable appeal panel members to be appointed from across the UK

1. Introduction

1.1. The Department of Health and Social Care (DHSC) carried out a public consultation to seek views on proposed amendments to the Regulations that would enable NICE to charge life science companies for the cost of making technology appraisal and highly specialised technology appraisal programmes and recruit Appeal Panel members engaged in the provision of health care in the health services across the UK, not just England.

Technology appraisal and highly specialised technology appraisals

1.2. NICE operates two separate programmes through which it makes recommendations that require relevant health bodies (NHS England, CCGs, local authorities) to provide funding to ensure the recommended medicines and other treatments are made available to treat patients:

- Technology Appraisals (TA) - a thorough analysis of the available evidence on clinical and cost effectiveness. Most new medicines and significant licence extensions for existing medicines are appraised by NICE.
- Highly Specialised Technology (HST) evaluations - a thorough analysis of the costs and benefits of a technology for rare or very rare conditions. A small number of very high cost medicines for very small patient populations are evaluated through the highly specialised technology programme.

1.3. The funding requirement that applies to NICE's technology appraisal and highly specialised technology recommendations is reflected in the NHS Constitution as a right to NICE approved treatments: "You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are appropriate for you."

Charging proposal

1.4. NICE’s technology appraisal and highly specialised technology programmes play a vital role in ensuring access for NHS patients to new and cost-effective treatments. It is therefore essential that these programmes operate in a sustainable and efficient way. The Triennial Review of NICE, published in 2015, recognised this and recommended that consideration be given to the introduction of charges for both programmes in order to enable NICE to operate more efficiently.

1.5. Charging will provide a more sustainable model that enables NICE to flex its capacity in response to the pipeline of technologies that require assessment by NICE, adapt its charging policies and procedures and methods and processes to different types of technology, and allow it to be more responsive to developments in the life sciences sector.

1.6. Charging will also enable NICE to continue the full breadth of its important work, while at the same time reducing its reliance on central government funding.

1.7. The consultation sought views on transferring the cost of NICE making a technology appraisal or highly specialised technology recommendation to the private life sciences sector and allowing NICE to impose a charge on small companies calculated on an appropriate commercial basis (i.e. at a reduced rate). It also sought views on proposals

to enable small companies to pay in instalments. The consultation document proposed a 25% discount for small companies.

NICE appeals panels

1.8. The Regulations require NICE to have processes in place to hear appeals against its technology appraisal and highly specialised technology recommendations. Appeals against NICE's recommendations are heard by appeal panels that must include a member who has experience in the life sciences industry, a member who is a patient or carer or member of an organisation that represents patients or carers and a member who is engaged in the provision of health care in the health services.

1.9. The appeal process is an important part of the assessment process and can lead to topics being returned to NICE's independent Appraisal Committees for further consideration. It is therefore important that NICE is able to recruit appeal panel members of a high enough calibre to provide sufficient challenge to its decision-making.

1.10. To widen the pool of people eligible to be Appeal Panel Members, the consultation proposed enabling people engaged in the provision of health care across the UK health services to apply.

2. Awareness and Engagement Activities

2.1. The Department decided to consult on the proposals to charge for technology appraisal and highly specialised technology recommendations and miscellaneous amendments to NICE legislation given the potential impact on NICE, the life sciences industry and patients.

2.2. The consultation was run on the GOV.UK digital platform[1] and the NICE charging page had 1782 hits during the live consultation period. Policy officials shared a link to the NICE charging page with the Association of the British Pharmaceutical Industry (ABPI).

2.3. NICE promoted the consultation by e-mail to its own networks and stakeholders, which included the life sciences industry and patient groups.

2.4. Correspondence was received from one Member of Parliament acting in her capacity as Chair of the All Party Parliamentary Group (APPG) on Access to Medicines and Medical Devices.

2.5. Officials also met with the ABPI.

2.6. The Department's consultation followed NICE's 2016 targeted stakeholder awareness and engagement exercise with pharmaceutical industry associations. NICE's 2016 stakeholder engagement exercise was circulated by e-mail by NICE to the Chief Executives of each of the pharmaceutical industry associations. Although there was no formal engagement meeting, NICE invited the industry associations to submit comments either in writing or through a telephone conversation. All of the respondents submitted comments in writing.

[1] https://www.gov.uk/government/consultations/nice-recommendations-charging-and-appeal-panels

3. Summary of Responses

3.1. A total of 78 responses were received, of which 63 were submitted on-line and 15 via e-mail to a dedicated NICE consultation inbox.

Table 1 - Respondent Type and Numbers

Organisation type	Responding on behalf of an organisation	Responding as an individual
Pharmaceutical company	29	-
Patient group	12	-
Industry representative	8	-
Professional body	6	-
NHS	1	4
Research organisation	3	-
Consultancy	1	1
Medtech company	2	-
Non-UK healthcare organisation	-	2
NICE	-	1
All Parliamentary Group	1	-
Individual view	-	7

3.2. The Department sought views from a wide range of interested parties. It was not a straight forward "vote" based upon numbers answering "agree" or "disagree" to the consultation questions. The response form was designed to allow respondents to state an "agree" or "disagree" answer and give an explanation for their response. Respondents could also suggest alternative proposals. The following tables show in detail the number of responses for each question, and a full evaluation follows in Chapter 4. A breakdown of replies to questions, by respondent type, is contained in Annex A. Please note not all respondents answered every question.

Table 2 - Question 1 Responses to "Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?"

	Yes	No	Not Answered	Total
Number	26	48	4	78
Percentage	33%	62%	5%	100%

Table 3 - Question 2 Responses to "Do you agree or disagree that such charges should be calculated on a cost recovery basis?"

	Yes	No	Not Answered	Total
Number	18	49	11	78
Percentage	23%	63%	14%	100%

Table 4 - Question 3 "Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?"

	Yes	No	Not Answered	Total
Number	29	34	15	78
Percentage	37%	44%	19%	100%

Table 5: Question 4 " Do you agree or disagree that small companies should be able to pay in instalments as proposed"

	Yes	No	Not Answered	Total
Number	37	24	17	78
Percentage	47%	31%	22%	100%

Table 6: Question 5 "Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?"

	Yes	No	Not Answered	Total
Number	13	47	18	78
Percentage	17%	60%	23%	100%

Table 7: Question 6 " Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England"

	Yes	No	Not Answered	Total
Number	66	5	7	78
Percentage	85%	6%	9%	100%

4. Evaluation of Responses

Key Stakeholder Responses

4.1. In response to the consultation many organisations submitted completed questionnaires or letters setting out their views and those of their members. These have also been considered and evaluated below and we have summarised the main points of their consultation responses.

Responses from industry representatives and life science companies

4.2. There were eight responses from industry representatives. These were received from British In Vitro Diagnostics Association, Association of the British Pharmaceutical Industry (ABPI), Association of the British Healthtech Industries (ABHI), Japanese Pharmaceutical Group (JPG), British Generic Manufacturers Association (BGMA), European Medicines Group, Ethical Medicines Industry Group and Health Tech Alliance.

4.3. There were thirty-one responses from pharmaceutical and medical technology companies. These were received from NuVasive UK Ltd, Synsana EEIG, MSD, Sarepta Therapeutics, Alexion Pharmaceuticals UK , Roche Products Limited, Decideum , Norgine Pharmaceuticals Limited, Bayer, Amgen Ltd., AbbVie , MAP Biopharma, Aspire Pharma Ltd, Janssen UK, GlaxoSmithKline, UCB Pharma Ltd, Pfizer, Chiesi UK , Gilead Sciences, Grünenthal Ltd, Bluebird bio, Novartis Pharmaceuticals UK Ltd, Eli Lilly and Company Limited, AKCEA Therapeutics UK LTD, PTC Therapeutics Limited, Astellas Pharma Ltd., Santen Pharmaceuticals, Merck Serono Limited , AstraZeneca, Roche Diagnostics Limited and Sirtex Medical.

4.4. Most industry responses (78%) disagreed with the proposal to charge companies the full cost of developing TA and HST recommendations. However, an analysis of the comments reveals greater levels of support for companies to contribute to the cost of making recommendations; including from the ABPI (the main industry body), and a number of other life sciences organisations, who recognised the importance of NICE being placed on a more sustainable financial footing.

4.5. Around half (51%) of industry responses disagreed with a 25% discount for small companies, with 27% supporting the proposal. However, comments received showed that there was support for the principle of minimising the impact on smaller companies for whom a charge may present a significant barrier to the introduction of innovative new products. There was broad disagreement (83%) with the analysis presented in the Impact Assessment, with specific concerns raised about DHSC's standard approach to valuing health benefits from NHS savings at £15,000 per Quality Adjusted Life Year (QALY) and the way in which companies make investment decisions.

4.6. The key elements of the responses are summarised below:

- Most respondents disagreed with the main proposal, although an analysis of the narrative accompanying the responses shows recognition that it was appropriate for life sciences companies to contribute to the cost of NICE. recommendations; the disagreement was around the proposed charging model.
- Importance of NICE being placed on a more sustainable footing by having adequate funding to continue its important work.
- NICE needs the resources to allow it to rapidly evolve its processes and methods to keep up with the new technologies coming to market and in the pipeline.

- NHS patients would lose out if sustainable funding of NICE's work does not happen and so Government and industry have a shared interest in finding a workable solution.
- The UK gains significant reputational benefit from having a health technology assessment (HTA) body that is seen as competent, impartial and truly independent. Concerns were raised that charging industry could compromise NICE's reputation and impartiality.
- Given the impending EU exit the need to ensure that the UK is an attractive market for investment gains greater importance.
- Alternative costing models were suggested including phasing-in the introduction of charges to ease the transition for industry.
- Charging should be considered as part of the ongoing voluntary medicines' pricing scheme negotiations rather than in a standalone consultation.
- There was support for reducing the impact on small companies including reduced charges and phased payment rather than all payment upfront. But in general industry preferred the ABPI alternative costing model (see para 6.1.1).
- Concerns about the impact of charging on not just small companies but medium sized companies too i.e. small and medium sized enterprises ("SMEs")
- Concerns about reduced technology uptake and patients being denied access to innovative technologies
- Suggestions that performance metrics should be developed to monitor these aspects of NICE's performance.
- The ABPI proposed an alternative costing model through which companies' voluntary and statutory scheme payment percentages would be uplifted to take into account the expected cost of NICE TA and HST recommendations. The uplift would be ring-fenced and passed to NICE by the Department to fund NICE's TA and HST programmes.
- Concern that companies have little say in whether drugs are evaluated under either the TA or HST process.
- The charging model does not address the challenges in bringing new medicines to market for ultra-rare conditions.
- Lack of clarity over how the proposed fees have been calculated.
- The proposed introduction of charging in April 2019 does not give companies sufficient time to prepare as companies operate on a financial year which runs from January to December and the business planning cycle for 2019 is already underway or complete for next year.
- Companies should be able to pay charges on a yearly or quarterly basis.
- Companies that choose to invest in the UK are already likely to experience additional costs during and after Brexit, with additional regulatory processes and burdens.
- Additional charges for a HTA could impact on the UK's attractiveness and delay access to new innovative therapies for NHS patients compared with patients in other European countries.
- Most respondents agreed that NICE's appeal panel NHS membership should be drawn from the whole of the UK

NHS responses

4.7. Responses were received from NHS England Specialised Commissioning and four individual NHS commissioners/providers.

4.8. 60% of responses disagreed with the proposal to charge companies for the cost of making TA and HST recommendations.

4.9. The key themes are summarised below:

- NICE recommendations should continue to be funded by Government as they have had a net effect of significant price reductions for numerous medications allowing the NHS to treat patients at significantly lower cost owing to the robust cost-utility analysis.
- Similar concerns as industry about affordability of pricing on small and medium sized companies
- Reputational risk to NICE as a result of perceived or actual conflicts of interest
- Long term impacts of industry expecting and seeking further influence over process
- Most respondents agreed that drawing appeals panel members from across the UK would bring diverse views on the impact of new technologies.

Academic group responses

4.10. There were three responses from academic groups. These were received from the Amyloidosis Research Consortium UK, the York Health Economics Consortium and the All Wales Therapeutics and Toxicology Centre. Of the three respondents, two agreed with the proposal to charge companies for making TA and HST recommendations. However, one proposed a tariff approach based on the complexity of the appraisal instead of straightforward cost recovery. There was a mixed response to whether a 25% discount for small companies was appropriate. The key themes are summarised below:

- Charges should be made on a tariff basis as there is variation in the cost of individual appraisals depending on complexity.
- 25% discount appears to be arbitrary and unsupported by any scientific market research.
- A change in the number of TAs could have substantial implications for population health and should be considered analytically.
- Academic groups agreed that NICE appeal panel members should be drawn from the whole of the UK and not just England.

Patient group responses

4.11. There were twelve responses received from eighteen patient groups (some were joint responses). These were received from Birdshot Uveitis Society, Vasculitis UK, Gaucher Disease Association, British Cardiovascular Intervention Society (BCIS), Batten Disease Family Association, UK Lysosomal Storage Disorder (LSD) Patient Collaborative, Fight for Sight, Action Duchenne, Genetic Alliance UK, Cancer Research UK; Alzheimer's Research UK; Breast Cancer Now; Diabetes UK; MS Society; Prostate Cancer UK, The Brain Tumour Charity, Society for Mucopolysaccharide Diseases.

4.12. Most patient groups (67%) that responded disagreed with the proposal to charge companies for making TA and HST recommendations, and 60% of respondents in this category that answered the question disagreed that a cost-recovery model was appropriate. There was more agreement (58%) among patient groups with a proposed 25% discount for small companies as an appropriate measure to help ensure that

innovations introduced by small companies were not hindered. Some commented that a 25% discount was not sufficient.

4.13. The key themes are summarised below:

- Most respondents disagreed with TA charging. There was particular concern about patients' access to new medicines, especially for groups affected by rare long-term conditions.
- Concern that charging could reduce incentives for companies to develop drugs for rare diseases.
- Companies will need to undertake extra work to get drugs approved in the UK after UK's exit from the EU.
- Uncertainty on the analysis behind introducing flat fees.
- Agreement with introducing instalment payments for smaller companies which might aid small companies bringing products to market, although some respondents felt that larger companies should also have the option to pay by instalments.
- Respondents agreed that NICE's appeal panel NHS membership should be drawn from the whole of the UK.

Professional bodies

4.14. There were six responses from professional bodies. These were received from the Royal College of Ophthalmologists, the British Association of Dermatologists, British Society for Rheumatology, Royal College of Radiologists and Royal College of Physicians and the British Society for Allergy and Clinical Immunology.

4.15. All professional bodies that responded agreed with the proposal to charge companies for making TA and HST recommendations, though some respondents expressed reservations about the impact of charges on companies' ability to bring products to market and on patient access. Views on whether a cost recovery model was appropriate were also mixed. There was general agreement (67%) that a 25% discount for small companies was appropriate, and that small companies should have the opportunity to pay in instalments.

4.16. The key themes are summarised below:

- Respondents agreed that charging companies for NICE's TA and HST recommendations was appropriate
- Charging seemed sensible given the increased demand for appraisals, austerity in the NHS, and the need to get innovative products to NHS patients.
- Concern that a cost recovery model could result in additional downstream costs for the NHS as companies would increase prices accordingly.
- Most of the respondents agreed that it is good practice to recruit Appeal Panel members from across the health services in the UK
- One respondent commented that appeals panel membership should only be drawn from countries in which NICE decisions are valid and where they are routinely implemented.

Responses from Members of Parliament

4.17. There was one response from a Member of Parliament and that was the Chair of the All Party Parliamentary Group (APPG) on Access to Medicines and Medical Devices. The key points from the response are summarised below:

- The response disagreed with the introduction of charging companies for NICE TA and HST recommendations. The APPG expressed concern that the introduction of charging would stifle the life sciences industry in the UK by providing a significant barrier given the proposed costings and therefore restrict patients' access to innovative and effective new medicines.
- Companies have little say in which process drugs are evaluated under either the TA or HST processes, which could disincentivise the launch of products for rarer diseases in the UK market.
- Expressed concern that the dis-benefit of charging would accrue to the system through disinvestment and loss of access to new medical technology, and through the reputational risk to NICE itself and this outweighs the gain to the taxpayer from the extra resource.

Other responses

4.18. There were eleven other responses, seven received from individuals and four associated with respectively JPD Buckley PR Consultancy Services, Athena Market Access Solutions Ltd, Navarre Regional Health Service (Spain) and Navarre Health Service, Spain.

4.19. 64% of respondents in this category agreed with the proposal to charge companies for making TA and HST recommendations, with a similar proportion agreeing with a cost-recovery model and a 25% discount for small companies.

4.20. The key themes are summarised below:

- Most respondents agreed with charging for NICE's TA and HST programmes
- Companies would benefit from a NICE recommendation in the long term
- Charging was a good example of a public private partnership that ensured the credibility the companies received from NICE endorsement was monetarised
- Concerns were raised about charging on NICE's impartiality
- It would preclude small organisations from being able to start up or be competitive in the market
- Most respondents agreed that NICE's appeal panel NHS membership should be drawn from the whole of the UK. These individuals should be engaged with UK NHS services.

The Government's view on these issues is discussed in section 6.

5. Statutory requirements

Statutory duties under the NHS Act 2006, the Public Sector Equality Duty and the Family Test

5.1. In considering the proposed changes, Ministers must comply with the Public Sector Equality Duty (PSED) and consider the Family Test. Ministers must also comply with their general duties under the National Health Service Act 2006 (NHS Act 2006), where applicable. Some further information about these duties is given below.

5.2. The need to comply with the PSED and consider, and where sensible and proportionate, apply the Family Test arises on each occasion that Ministers perform their public functions. The general duties in the NHS Act 2006 require the Secretary of State to have regard to certain things (such as the need to reduce health inequalities) or to act with a view to certain things (such as improving the quality of health services) whenever he is exercising functions “in relation to the health service” in England.

5.3. Our analysis of these duties with respect to the proposals as amended following the public consultation is summarised below.

Public Sector Equality Duty (Section 149 Equality Act 2010)

5.4. This duty comprises three equality objectives, each of which needs to be considered separately. Ministers must have due regard to the need to:

- Eliminate unlawful discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

5.5. The protected characteristics covered by this duty are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.

5.6. We considered the implications for each of the three equality objectives in relation to the proposals for amending the Regulations to allow NICE to charge companies for making technology appraisal and highly specialised technology recommendations in relation to their products and for extending the eligibility criteria for appeal panel members:

- Eliminate discrimination - Although some respondents were concerned that charging may reduce incentives for companies to develop drugs for rare diseases which may impact disproportionately on people with protected characteristics (including those with disabilities), we do not foresee any negative impacts on access to medicines and there is no evidence to suggest that orphan drugs would be disadvantaged compared to other medicines (see paragraph 6.1.2). The charging model will put NICE on a more sustainable financial footing which will ensure that it can continue to play a vital role in providing access for all NHS patients to clinically and cost-effective drugs.

- Advance equality of opportunity - NICE's work helps to ensure that patients, including those with a protected characteristic, benefit from consistent access to the same level of treatment across the country. The proposals will allow NICE to continue the full breadth of its work at a lower cost to the taxpayer and in so doing should help achieve greater equality of opportunity. It will also give NICE greater access to potential appeal panel members thereby facilitating its work.

  The Government has considered in the associated IAwhether the introduction of charges will affect the availability of orphan products for the treatment of rare diseases, a concern that was raised by several consultation respondents and one that could potentially affect people with disabilities. The Government has found that there is insufficient evidence to conclude that such products would be disproportionately impacted by the introduction of charges. Manufacturers of orphan drugs are able to charge higher prices than for drugs for less rare conditions, and companies can make large revenues from such products.

- Foster good relations - we do not consider that the proposals will have any negative impact on good relations between those with a protected characteristic and those without.

To promote a comprehensive health service (section 1 NHS Act 2006)

5.7. The Secretary of State is required to continue the promotion in England of a comprehensive health service designed to secure improvement:

- in the physical and mental health of the people of England; and
- the prevention, diagnosis and treatment of physical and mental illness.

5.8. The proposed measures provide a more flexible model that better enables NICE to adapt its methods and processes to the future pipeline of technologies and will allow NICE to continue to make in a timely manner the full breadth of evidence-based recommendations that result in the funding of clinically and cost effective medicines and other treatments and technologies in England, thereby contributing to the continued promotion of a comprehensive health service designed to secure health improvements.

To act with a view to securing continuous improvement in the quality of services (section 1A NHS Act 2006)

5.9. The Secretary of State is required to exercise his NHS functions with a view to securing continuous improvement in the quality of services provided to individuals in connection with the prevention, diagnosis or treatment of illness, or public health.

5.10. NICE plays an important role in providing authoritative, evidence-based guidance for the health and care system that is intended to drive quality improvement. The introduction of charges for making technology appraisal and highly specialised technology recommendations will enable NICE to continue the full breadth of its important work and respond to future demand for recommendations in this area.

5.11. In addition, enabling NICE wider access to potential appeal panel members will further facilitate NICE to continue with the full breadth of its work.

5.12. We therefore believe the introduction of these charges and extended appeal panel membership will further enable NICE to contribute to Secretary of State meeting his duties to secure continuous improvement in the quality of services.

To have regard to the NHS Constitution (section 1B NHS Act 2006)

5.13. The Secretary of State must have regard to the values, principles, pledges and rights in the NHS Constitution.

5.14. The NHS Constitution reflects the right to drugs and treatments that have been recommended by NICE. The proposals, including the measures for small companies, are not expected to result in a decline in the number of products assessed or recommended by NICE. Moreover, the increased discount for small companies (see para 6.3), will minimise any risk that such companies will not participate in the process.

5.15. The changes to appeal panel membership, will not impact on NHS Constitution rights.

To have regard to the need to reduce health inequalities (section 1C NHS Act 2006)

5.16. When exercising his functions in relation to the NHS, the Secretary of State must have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS.

5.17. It is important to emphasise that this duty is separate from the PSED. Other socio-economic impacts need therefore to be considered such as income, social deprivation and rural isolation.

5.18. NICE's recommendations will continue to result in the funding of clinically and cost effective medicines and other treatments and consistent access to those treatments in England irrespective of income, social deprivation and rural isolation.

To promote autonomy (section 1D NHS Act 2006)

5.19. The Secretary of State must have regard to securing, so far as is consistent with the interests of the NHS:

- That any other person exercising NHS functions or providing services for its purposes is free to exercise those functions or provide those services in the manner that it considers most appropriate; and
- That unnecessary burden is not imposed on any such person.

5.20. The proposed changes do not impact on NICE's freedom to provide NHS services as they see fit. It will be the responsibility of NICE to ensure that the charges are calculated to enable NICE to recover the cost of making recommendations (with an appropriate subsidy for small companies), and to keep the policy, level of charges and associated guidance under review. It will also give NICE greater access to potential appeal panel members thereby facilitating its work.

To promote research (section 1E NHS Act 2006)

5.21. In exercising his functions in relation to the NHS, the Secretary of State must promote:

- Research on matters relevant to the NHS; and
- The use in the NHS of evidence obtained from research.

5.22. In addition, the Secretary of State is also required, under the NHS Act 2006, s266 (4) (b), to bear in mind the costs of research and development.

5.23. We do not consider that the proposed changes will have any bearing on NICE's use of research or evidence obtained from research.

To secure education and training (section 1F NHS Act 2006)

5.24. The Secretary of State must exercise his NHS (and other) functions so as to ensure that there is an effective system for the planning and delivery of education and training for the persons employed, or considering becoming employed, in the NHS or connected activities.

5.25. We have considered this duty in relation to the measures and none of the measures impact on the Secretary of State's functions to secure education and training.

To review treatment of providers (section 1G of the NHS Act 2006)

5.26. The Secretary of State is required to keep under review any matter, including taxation, which might affect the ability of health care providers to provide NHS services or the reward available to them for doing so.

5.27. We have considered this duty in relation to the changes being proposed and do not consider that the proposed changes will have any bearing on the ability of providers to provide NHS services.

The Family Test

5.28. The Secretary of State must consider and, where sensible and proportionate, apply the Family Test when making policy. The five family test questions are:

- What kinds of impact might the policy have on family formation?
- What kind of impact will the policy have on families going through key transitions such as becoming parent, getting married, fostering or adopting, bereavement, redundancy, new caring responsibilities or the onset of a long-term health condition?
- What impacts will the policy have on all family members' ability to play a full role in family life, including with respect to parenting and other caring responsibilities?
- How does the policy impact families before, during and after couple separation?
- How does the policy impact on those families most at risk of deterioration of relationship quality and breakdown?

5.29. We have considered the Family Test and concluded that it is not applicable to the proposed changes to the Regulations.

6. Consultation outcome and next steps

6.1. The Government has considered the consultation responses and has revised the Impact Assessment to reflect concerns that were raised in relation to the value to companies of a NICE recommendation, the impact on small companies, NICE's processes to mitigate conflicts of interest and the impact of additional costs to companies on UK industry. With regard to a number of the themes raised in the consultation:

6.1.1. An alternative funding model. We gave serious consideration to ABPI's proposed funding model which was favoured by many industry respondents. ABPI proposed a model through which companies' voluntary or statutory scheme payment percentages would be uplifted to take into account the expected costs associated with NICE's TA and HST recommendations. The proposed uplift would be ringfenced and passed to NICE by DHSC to fund NICE's TA and HST recommendations. Under the Health and Social Care Act 2012 the imposition by NICE of charges has to be "for or in connection with the….making of recommendations" (section 237(5) (c). Charging on the basis of a company's payment percentage under the voluntary or statutory scheme would break the required link between the charge and the cost of making of recommendations and would fall outside DHSC's statutory powers. Additionally, the pattern of appraisals suggests that most companies do not have appraisals done on a regular basis and only very few have appraisals in every year. It seems unlikely that companies with such an irregular pattern would find a pooling scheme attractive.

6.1.2. A number of responses suggested that appraisals for drugs for rare diseases (orphan drugs) should also benefit from a reduced fee. However, the Government was not convinced that this was necessary and notes that worldwide orphan drug sales are forecast to grow at 11.3% per year (Compound Annual Growth Rate) from 2018 to 2024[2], double the rate forecast for the non-orphan drug market and that the median cost per patient and per year is 19.1 times higher for an orphan drug than for a non-orphan drug[3]. Moreover, NHS spending on orphan drugs with a positive NICE recommendation can be very large; for example, the NHS spent around £67.5m on the orphan drug ibrutinib in 2016/17[4]. The charges for HSTs are the same for TAs (i.e. there is no premium rate for developing HSTs) and there is therefore no disadvantage for drugs for rarer diseases.

6.1.3. NICE's impartiality. Respondents raised concerns about the impact of being reliant on industry funding which would present a conflict of interest for NICE. NICE's recommendations, and decisions on the most appropriate programme (eg TA or HST) for individual products, are made transparently and in accordance with published methods and processes. NICE has long established arrangements for managing potential conflicts of interests to ensure guidance is produced by

[2] EvaluatePharma. Orphan Drug Report 2018. http://info.evaluategroup.com/rs/607-YGS-364/images/OD18.pdf

[3] OECD Health Working Paper, 2016, Pharmaceutical Expenditure and Policies: Past trends and future challenges. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DELSA/HEA/WD/HWP(2016)10&docLanguage=En

[4] NHS Digital. Prescribing costs in hospital and the community, England 2016/17. https://digital.nhs.uk/data-and-information/publications/statistical/prescribing-costs-in-hospitals-and-the-community/2016-17

independent advisory committees. NICE's policy on declaring and managing interests was substantively updated in 2018 following a public consultation, and is subject to regular review. Companies, with the exception of small companies, will also be charged at the outset of the appraisal, and irrespective of whether NICE makes a positive recommendation. We are confident that the introduction of charges will not impact on NICE's impartiality.

6.1.4. A number of respondents also wanted to see a discount for medium sized companies. A company qualifies as medium-sized in the Companies Act 2006 if it meets at least two of the following conditions in the relevant financial year: a turnover of not more than £36 million, a balance sheet total of not more than £18 million, not more than 250 employees (s.465). The Government is of the view that the proposed NICE charges are affordable for medium-sized companies. We will though keep this under review. For example, it may be that a company that does not qualify as a small company in the Regulations but has a turnover well below £36 million may have 3 or 4 TAs going through the system in the relevant financial year.

6.1.5. There were some comments about how the fees were derived. In advance of the consultation, NICE calculated the cost of developing different types of appraisal, including direct staffing costs, the costs of running appraisal committees, as well as support costs such as communications. These costs were then translated into the fee structure. Apart from small companies, the fees are therefore calculated on a cost recovery basis.

6.1.6. A number of respondents raised concerns about the impact of charging as the UK prepares to leave the EU. The Government has set out a clear proposal for the future relationship we want to build with the European Union. The Government's overall aim remains that patients in the UK and across the EU continue to be able to access the best and most innovative medicines and devices and be assured that their safety is protected through ongoing cooperation and the strongest regulatory frameworks. The key guiding principles are that we ensure patients are not disadvantaged; that the UK will continue to play a leading role promoting and ensuring public health; and that industry must be able to get their products into the UK and EU markets as quickly and simply as possible.

6.2. Following the consultation, the Government has decided to proceed with amending the Regulations to allow NICE to introduce charges for technology appraisal and highly specialised technology recommendations. As set out above, the Government considers such charges to be an appropriate funding model that will create a sustainable funding model for NICE that better positions it to adapt to future changes in the life sciences sector.

6.3. However, as a result of the consultation responses, we are making two changes:

- NICE will now offer a 75% discount to small companies (defined in accordance with the conditions specified in section 382 of the Companies Act 2006) instead of a 25% discount as proposed in the consultation document. As detailed in chapter 4, a number of respondents expressed concern about the impact of charges on smaller companies, and felt that - if charges were introduced - a measure to mitigate any potential impact would be necessary. The Government has therefore decided to increase the proposed 25% discount to 75% to ensure that small companies are still able to bring new and innovative products to market.

So, for example, instead of the charge to small enterprises for a single technology appraisal being £126,000, it will now be £31,500. Small companies will also be able to pay by instalments, as proposed in the consultation document. Given that historically, products manufactured or sponsored by small companies make up approximately 10% of NICE's technology appraisal and highly specialised technologies work, this will mean reduced income of approximately £750,000 per year on the assumption that there is no change in the volume or mix of recommendations. The cost of the discount will be made up from the Government grant that NICE receives. The Government wants to ensure that appropriate support is available to small companies and the increased discount will minimise barriers to the participation of small companies.

- The addition of a new provision in the amending Regulations that will enable the Secretary of State to direct NICE in a specific case or class of cases to charge companies on the basis that it considers to be the appropriate commercial basis should this be required in future and subject to consultation with stakeholders. Given the continuously evolving range of life sciences products, it may be that a few years down the line, the fee structure would need some amendments. The current model is very much based on the pharmaceutical model because historically, that is where the focus of NICE appraisals has been and where the immediate pipeline of activity lies. However, if in future, we are to see different types of innovations, including devices and digital products, going through a technology appraisal process, we need flexibility to allow NICE in future to charge at a level appropriate to that market (for example should there be a demand for TAs for products developed by new entrant digital micro businesses).

6.4. The Government and NICE remain committed to monitoring the impact of the charges, due to be introduced from April 2019, in the first year and reviewing the charging regime at the end of the second year following introduction and thereafter as required, as set out in the consultation document.

6.5. The Government is also proceeding with the proposals related to appeal panel membership.

Annex A - Breakdown by Respondent Type

There were 78 respondents to the consultation, 15 as individuals and 63 on behalf of an organisation.

Summary of responses from all respondents to consultation questions

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	26 (33%)	48 (62%)	4 (5%)
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	18 (23%)	49 (63%)	11 (14%)
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	29 (37%)	34 (44%)	15 (19%)
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	37 (47%)	24 (31%)	17 (22%)
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	13 (17%)	47 (60%)	18 (23%)
Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England?	66 (85%)	5 (6%)	7 (9%)

Life sciences company responses

41 respondents represented views from the Life Sciences industry, including pharmaceutical companies, industry representatives, consultancies and Medtech companies.

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	7 (17%)	32 (78%)	2 (5%)
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	4 (10%)	34 (83%)	3 (7%)
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	11 (27%)	21 (51%)	9 (22%)
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	15 (37%)	18 (44%)	8 (20%)
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	1 (2%)	34 (83%)	6 (15%)
Do you agree or disagree that NICE’s appeal panel NHS membership should be drawn from the whole of the UK and not just England?	35 (85%)	2 (5%)	4 (10%)

Industry representative responses

There were 8 responses from industry representatives

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	0	8	0
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	0	8	0
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	4	3	1
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	5	3	0
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	7	0	1
Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England?	7	0	1

Pharmaceutical and Medical Technology companies

There were 31 responses from Pharmaceutical and Medical Technology companies

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	6	24	1
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	3	26	2
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	6	18	7
Do you agree or disagree that small companies should be able to pay in instalments as proposed?	9	7	15
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	0	27	4
Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England?	27	2	2

NHS responses

Responses were received from NHS England Specialised Commissioning and four individual NHS commissioners/providers

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	1	3	1
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	2	2	1
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	1	3	1
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	1	3	1
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	2	3	0
Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England?	3	1	1

Academic group responses

There were three responses from academic groups received.

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	2	0	1
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	0	1	2
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	1	1	1
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	2	0	1
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	0	1	2
Do you agree or disagree that NICE’s appeal panel NHS membership should be drawn from the whole of the UK and not just England?	3	0	0

Individual/other responses

There were seven responses from received individuals and four associated with consultancy companies, foreign healthcare and NICE

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	7	4	0
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	7	3	1
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	6	4	1
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	9	1	1
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	7	1	3
Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England?	9	1	1

Patient groups

There were twelve responses submitted from eighteen patient groups (some were joint responses).

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	4	8	0
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	4	6	2
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	7	4	1
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	6	2	4
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	6	2	4
Do you agree or disagree that NICE’s appeal panel NHS membership should be drawn from the whole of the UK and not just England?	12	0	0

Professional bodies responses

There were six responses received from professional bodies

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	6	0	0
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	2	2	2
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	4	0	2
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	4	0	2
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	2	1	3
Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England?	4	1	1

Member of Parliament on behalf of APPG

One response was received from a Member of Parliament in her capacity as chair of the APPG

Consultation question	Consultation response		
	Agree	Disagree	Other
Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term?	0	1	0
Do you agree or disagree that such charges should be calculated on a cost recovery basis?	0	1	0
Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?	0	1	0
Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2?	1	0	0
Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?	0	1	0
Do you agree or disagree that NICE’s appeal panel NHS membership should be drawn from the whole of the UK and not just England?	1	0	0