Department of Health

Consultation on UK Implementation of Directive 2011/24/EU (on the application of patients' rights in cross-border healthcare)

Government Response to Consultation

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UK Government's Response to Consultation

Prepared by the EU and International Cross-border Healthcare Policy Team

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Introduction

This is the Government's response to the 2013 public consultation on the implementation in England of the main requirements of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011on the application of patients' rights in cross-border healthcare ("the Directive").

The main objectives of the Directive are to clarify and simplify the rules and procedures applicable to patients' access to cross-border healthcare; provide EU citizens with better information on their rights, ensure that cross-border healthcare is safe and of high-quality and to promote cooperation between Member States.

The Directive must be implemented into the laws and systems of each Member State by 25 October 2013. However, it is for each Member State to decide how the Directive is implemented at national level and there is considerable scope to decide how best to implement the Directive's requirements into the domestic system. The purpose of the consultation was to help inform the Government's overall approach to implementation. This response seeks to address how the Directive's requirements will be implemented in England, taking into account the feedback received during the course of the consultation. Scotland, Wales and Northern Ireland conducted their own consultations.

The purpose of the Directive is not to foster or promote cross-border healthcare but to facilitate the exercise of patient choice to access healthcare services in another Member State and to ensure that they are safe and of high quality when citizens decide to use the Directive's provisions to access necessary healthcare. The Directive also aims to help patients benefit from improved information and better clarity on the rules that apply to reimbursement of expenditure on a healthcare service which a patient obtains in another Member State.

The consultation asked respondents to consider:

- Steps that could be taken to ensure that all patients/citizens are fully informed of their rights in cross-border healthcare and that their needs are considered;
- The impact the Directive could have on future uptake of cross-border healthcare by NHS patients and the impacts this could have on the NHS;
- The definition of 'health professional' and the list of health professions to which the provisions of the Directive will apply when treatment is supplied in the UK;
- The requirement of Member States to provide clarity on entitlements to its patients/citizens;
- The role of the National Contact Point (NCP) and the nature and extent of the information it should provide – to both incoming and outgoing patients, as well as to NCPs in other Member States;
- Whether NHS England should have the discretion to make payments directly to overseas providers (where this would be of benefit to patients with limited financial means);
- The option to continue operating a system of prior authorisation and the choices that operating such a system generates - respondents were asked to consider the services that should be subject to prior authorisation and the conditions with which a patient can be refused prior-authorisation, including the option to refuse authorisation where treatment can be provided within a medically justified period of time (the 'undue delay' derogation at Article 8(6)(d));

- Administrative procedures resulting from the Directive including the decision-making timescales;
- Whether to operate a system of voluntary prior notification;
- The information on treating practitioners that should be shared between competent authorities;
- The provisions for EU-level co-operation in voluntary networks on European Reference Networks, eHealth and Health Technology Assessment Networks.

Respondents were also asked to provide feedback on the consultation-stage impact assessment, equality impact assessment and implementing regulations.

The Department of Health ran a parallel consultation on the indemnity requirements stemming from Article 4 of this Directive. The work to meet these requirements is being taken forward separately. The Medicines and Healthcare products Regulatory Agency (MHRA) is leading on the work needed to meet the requirements set out in Article 11 of the Directive.

The Government previously held a public consultation in 2008 on the European Commission's original proposal for a Directive. The purpose of that consultation was to help inform the Government's negotiating position on the then draft Directive and to aid assessment of the impacts that the proposed Directive could have on the UK.

The Consultation Process

The Government undertook an 8-week public consultation from 28 March to 24 May 2013 as part of its on-going work to transpose the Directive. The consultation covered England – separate consultations have taken place in Wales, Scotland and Northern Ireland.

As part of the consultation process, a consultation document on proposals for implementation in England was placed on the Department of Health website (the Department of Health has responsibility for leading negotiations in Europe on the Directive on behalf of the UK). Alongside the consultation document, the consultation-stage impact assessment, equality impact assessment and transposition regulations were also placed on the website. Further details can be found at:

https://www.gov.uk/government/consultations/eu-directive-on-patients-rights-to-healthcare-in-other-european-countries

A letter was sent to key stakeholders informing them of the consultation, asking for their views and directing them to the public consultation webpage. We also notified the NHS through the *Bulletin for CCGs*, published by NHS England, and an NHS Confederation bulletin.

In addition to this, a consultation event was held on 2 May in London, attended by a variety of stakeholders. This allowed the Department of Health to set out what the Directive means for patients and the NHS and to seek views from stakeholders on the proposed implementation approach. Further details are provided at Annex B.

The Department of Health, leading this exercise received a total of 31 responses to the consultation. A full list of respondents is provided at Annex A.

Key Themes in Responses to the Consultation

There was no substantial disagreement with Government's overall approach to implementing the Directive and the majority of respondents expressed positive views on the scope and effect of this new European health legislation.

Key themes for stakeholders that emerged from the consultation were:

- The content and format of the information provided to patients on their rights under the Directive and the role of the National Contact Point in providing this information;
- The exchanging of information between Member States on the competence of healthcare professionals and their registration status;
- Clarity on patient entitlements and the provision of clear and consistent information to patients on the NHS services they are entitled to receive;
- Operating a system of prior-authorisation and the services that would come under such a system – respondents also commented on the option to refuse authorisation where the NHS can provide the patient with the treatment within a medically justified period of time;
- Concerns about equity under the Directive, in particular any unfairness caused by patients being required to pay up front for treatment before seeking reimbursement – respondents were asked whether they were supportive of NHS England having the option to make direct payments to providers in certain circumstances;
- The need to ensure there is clear information on pricing and tariffs in addition to there being procedures in place for when no tariff/pricing mechanism exists;
- Concerns about ensuring there is continuity of care for patients who have accessed services in another Member State under the Directive, including operating a system of voluntary prior-notification for services not subject to prior-authorisation;
- Benefits from the UK joining voluntary co-operation schemes, including European Reference Networks and Health Technology Assessment Networks.

Responses to Consultation Questions

In order to provide further background, the responses to each of the consultation questions are addressed in turn below.

General

1. What proportionate measures can we take so that all patients/citizens, regardless of age, race or ethnicity, disability, religion or belief, gender, sexual orientation or socio-economic status feel a) reassured they will be treated with respect and their specific needs considered b) they are fully informed to make the right choice for them?

Respondents approached this question from a number of angles but the key theme was the provision of information to patients and patients being able to access the information required in order for them to make an informed decision regarding their healthcare. Respondents felt that being able to access information, be it on other countries' healthcare systems, including the quality and safety of foreign providers, complaints procedures, information on pricing (for both incoming and outgoing patients) and on the roles of NHS England, Clinical Commissioning Groups, practitioners and the National Contact Point, was essential to this decision-making process. Respondents also suggested working with patient groups on the provision of information to citizens.

2. To what extent do you think that these proposals will have a positive or an adverse impact on equity? What can be done to manage any adverse impact?

Some respondents suggested that, while they had initially been concerned about the negative impacts the Directive could have on equity, they have been reassured by NHS England's ability, as outlined in the consultation document, to make payments directly to the overseas provider on behalf of the patient.

Another point raised in response to this question was that patients who could not afford the cost of cross-border healthcare could get better access to NHS care, through NHS beds or capacity being freed up due to some patients choosing to receive their healthcare in another Member State.

3. Please provide any evidence you may have on the reasons for which patients travel abroad to receive healthcare, the likely uptake (current and future) of cross-border healthcare by NHS patients as well as the impacts this has on the NHS (budget, administrative costs, commissioning etc).

Respondents to this question gave a number of reasons why patients may choose to receive healthcare abroad. Many focussed on their relevant sector, highlighting that availability of treatment locally on the NHS, or waiting times for certain treatments, may be a factor in patients choosing to receive treatment abroad. Respondents also commented that knowing that they will be able to access treatment can be a deciding factor for people looking to travel or work abroad.

With regard to incoming patients, respondents stated that EU citizens visiting family members in the UK or the status as centres of excellence of some UK providers could in theory lead to patients from the EU seeking to access healthcare in the UK through the Directive route.

However, the situation will need to be monitored in order to assess any potential impact on NHS systems.

Responsibilities of Member State of treatment

4. Are there any other "health professions" in the UK to which the provisions of the Directive will apply when treatment is supplied in the UK?

While some respondents felt that the list of health professions set out in the consultation document was comprehensive, a number of respondents made suggestions regarding which professions should be included on the list. Despite this not being a requirement of the Directive, concern was expressed about limiting the definition of health professional to those who are regulated in statute as this may exclude some groups.

Some respondents stated that the list should include all professional groups used by the NHS, including counsellors, psychotherapists and acupuncturists. Surgical care practitioners were also highlighted as missing from the list.

Responsibilities of Member State of affiliation

5. Do you agree that this broad requirement would ensure that the NHS is able to deliver the required clarity on entitlements and thereby respond appropriately to patient requests?

The majority of respondents supported the need for greater clarity in the NHS on what patients are and are not entitled to with regard to NHS services and were supportive of the Department's proposed approach to place a legal requirement (through regulations) on Clinical Commissioning Groups and NHS England to make clear what those entitlements are. In addition, a few respondents stated that they did not think that the language proposed for the regulations went far enough.

Respondents who commented on the proposal to support the legal requirement with directions were supportive of this approach. However, respondents recognised that delivering greater clarity could prove challenging for the NHS, especially taking into account that the NHS recently underwent a restructuring. One concern expressed was that greater clarity on patient entitlements at a local level could result in the NHS facing criticism if issues arise as a result of the 'postcode lottery'.

Several respondents pointed to the right in the NHS Constitution of patients to drugs and treatments recommended by the National Institute for Health and Clinical Excellence (NICE) where deemed clinically appropriate, stating that this right should be reflected in any communication made on patient entitlements.

Rather than replying directly to this question, a few respondents made a general statement on the issue of patient entitlements. They agreed that there must be clear information to patients on what NHS services they are entitled to. In their statements, they put forward the suggestion that greater clarity on entitlements could be achieved through CCGs outlining a local list of services of what is not generally provided as NHS treatment. They argued that a negative list of that kind would also cover treatments excluded nationally. Such a list should also allow CCGs to set out the rationale for any thresholds for treatments used when commissioning locally.

National Contact Points

6. Do you agree that the Commissioning Board is best placed to deliver the NCP function for England?

The overwhelming majority of responses to this question supported placing the NCP function for England within NHS England. There was one dissenting argument, which stated that the NCP function should be independent of NHS England as NHS England holds the decision-making function regarding cross-border healthcare and any advice should be independent of that function.

7. What information, and presented in what format(s), do you think patients need to make an informed decision on receiving treatment in another EU Member State?

Overwhelmingly, respondents agreed that in order for patients to exercise their rights under the Directive, they would need to be able to access clear, accessible and comprehensive information on a wide range of issues. As suggested by the respondents, this includes information on:

- Different healthcare systems in other Member States
- The cultural context of the state where treatment is received
- Professional standards and guidelines
- Treatment options and prices, including likely cost of treatment
- Healthcare provider registration status
- The regulatory framework for providers and health professionals, including, for example, that a professional group may be regulated in one Member State but not another
- Assurance about professional indemnity
- Information on complaints and redress
- Information on training and education requirements within the Member State of treatment
- How reimbursement will work
- Clear signposting to further information, where needed

The point was also made that the information should not seek to promote cross-border healthcare but rather the information should be factual and focus on how the systems work.

With regard to how the information should be presented and in what formats, respondents emphasised that the information will need to accessible for people with disabilities. The suggestions included:

- The information should be made directly available to patients via electronic and online means
- The Department should work in partnership with patient organisations to help inform patients of their rights in cross-border healthcare
- Providing the information in other UK languages should be considered
- The information should be provided online and in a variety of formats on request for partially sighted or blind people – this included braille, large print or audio

In addition to providing information to patients, respondents also stated the need to provide information to NHS staff in a range of settings. They emphasised that NHS England or the

National Contact Point will not necessarily be the first place patients will look for information on cross-border healthcare and that NHS staff, whether they work in CCGs, GP practices or in secondary care, will need to be made aware that patients have the choice to seek treatment in another Member State. They will also need to know how to advise patients on how to find information on cross-border healthcare, for example through the NCP. It was also suggested that guidance should be issued to GP practices about charging rules for EEA patients seeking GP services under the Directive.

Further to that, respondents said that would like to see engagement with CCGs so that staff are informed of their responsibilities, especially around entitlement setting and the provision of clear and consistent information to patients on the NHS services they are entitled to receive

8. What will be the impact of providing clear and transparent information on the volume of patients who may wish to access cross-border healthcare and the treatments they may wish to obtain? Please provide evidence where possible.

Few respondents addressed this question, and the answers that were provided differed in opinion. One perspective, based on the respondent's experience in its sector, was that the volume of information provided would not greatly influence the decision of a person considering accessing healthcare in another MS. However, another view was that that volume of patients considering receiving healthcare under the Directive would undoubtedly increase.

One common theme in the responses was the need for monitoring and review, on the volume and quality of the information provided and on the impact of the Directive.

General principles for reimbursement of costs

9. Do you agree that the NHS Commissioning Board should have discretion to make payments direct to overseas providers, where this would be beneficial for patients with limited financial means?

The vast majority of respondents supported the proposal that NHS England should have the discretion to make payments directly to overseas providers, where appropriate and necessary. The reasons why the proposal was supported included that:

- It would help with equity issues
- It could help to diminish the risk of fraud or falsification of claims
- Patients who can afford to pay upfront are more able to access treatment based on ability to pay, not need
- It would be beneficial for people seeking treatment for addiction disease as they would not have to handle potentially large sums of money and to have to go through the process of reclaiming treatment costs

However, several respondents did not agree with the proposal that NHS England should have the discretion to make direct payments. One reason for this was that it would be too difficult to draw the line on who is helped in this way or to explain the reason for making such a payment. The other reason was that NHS England making direct payments is considered a high-risk strategy which could result in NHS England being seen to be commissioning the treatment, thus invoking NHS duty of care.

10. If so, what safeguards would you like to see put in place?

Respondents listed a number of possible safeguards that could be put in place should a system allowing the discretion to make direct payments be implemented. These included:

- A transparent means testing system
- Evidence of limited means and a reason why the NHS alternative is not appropriate
- A requirement to submit all relevant documentation after treatment, including proof from the provider that treatment has been provided
- Confirmation with the patient's GP or NHS consultant, based on any follow-up care or examinations

Several respondents also highlighted the role of the National Contact Point in checking the status of the overseas provider.

11. How might any adverse impact be managed?

There were only a few responses to this question. These suggestions included sending warning out through NCPs should any bad practice, including fraud, occur.

The point was also made that patients should be advised on who would be responsible for making a direct payment to the provider on their behalf, the process that is involved and who would be responsible for covering the costs of further treatment should anything harmful occur during the initial course of treatment.

Healthcare that may be subject to prior authorisation

12. Do you agree that the UK should continue to operate a system of prior authorisation for patients requiring certain types of treatment?

Of those who replied to this question, the vast majority of respondents were supportive of the proposal to continue operating a system of prior-authorisation for patients requiring certain types of treatment.

Several respondents highlighted the bureaucracy or the additional administrative burden that operating such a system could create, however, views differed on the overall impact this could have. One view was that operating a system of prior-authorisation would create a level of bureaucracy that would outweigh any potential savings. However, the other view was that despite any additional administrative burden, a system of prior-authorisation should exist as it could help to combat the risk of fraud.

Several respondents set out the potential positive impacts, both for patients and on the system, that operating a system of prior-authorisation would have. These included patients gaining clarity on whether the NHS would reimburse them or not, an issue particularly relevant for high-cost treatments, and protecting the investment put into the NHS for high-cost or specialised services.

13. In addition to specialist services and services such as diagnostics requiring considerable planning and financing what other services might come within the scope of treatments / services that should be subject to prior authorisation?

Only a few respondents chose to address this question. One comment was that other services, such as homeopathic or other alternative therapies, should be included on a list of services subject to prior-authorisation. In addition, the point was made that a list of services subject to prior-authorisation may alter over time.

14. What is the evidence to support this inclusion?

There were no responses to this question.

15. Do you have a view on whether or how the Government should adopt the Art.8(6)(d) derogation?

A limited number of respondents addressed this question and views differed on whether to adopt the Article 8(6)(d) discretion to refuse authorisation where the NHS can provide treatment in a medically justified period of time ('undue delay'). The consultation document presented three options:

- Option [i] - adopt Article 8(6)(d) without limit
- Option [ii] - adopt Article 8(6)(d) but apply it to the limited list of those services requiring prior authorisation and apply certain additional caveats on the system
- Option [iii] - do not adopt Article 8(6)(d)

One respondent specifically commented favouring option ii, but that there needs to be a definition of what would be a medically justified period of time to ensure such a system would not be overly bureaucratic as proving evidence of undue delay on a case by case basis would not be practical. Another view in support of the use of undue delay was that the NHS should retain powers that are available to it to turn down requests where treatment is available on the NHS within reasonable timeframes.

From the other perspective, one response commented that the three reasons outlined in Directive for refusing prior-authorisation cover the most important considerations, therefore, at most, a limited uptake of the discretion would be required. Another comment was that the discretion, in principle, seemed to undermine the purpose of the legislation.

16. Should the derogation (if taken) be limited to the list of highly specialised services only?

There were no responses to this question.

17. Do you believe this Article can be made to work in practice without being unduly burdensome?

There were no responses to this question.

Administrative procedures

18. Is the current decision making timescale reasonable, or should it be amended?

The vast majority of respondent felt that 20 working is a reasonable timescale for the decision-making process. However, one response stated that while 20 days would suffice for most

cases, it does not allow much room for flexibility should the volume of applications be higher than expected and called for a 28 working day response period.

One respondent stated that if a system of prior-authorisation was not used, then a 20 working-day decision period would not be necessary.

19. Would a system of voluntary prior notification for some services not subject to mandatory authorisation be helpful in creating dialogue where cross-border healthcare is being considered?

The overwhelming majority of respondents to this question were supportive of a system of voluntary prior notification being put in place in England. The reasons for this included:

- Any steps that can help staff in the system with the smooth running of healthcare should be encouraged
- A system of voluntary prior-notification would help to provide clarity on potential reimbursement amounts and about any aftercare which may be needed
- It would allow time for proper consideration and dialogue
- Greater clarity on potential reimbursement amounts could help patients with the decision-making process
- A system of voluntary prior-notification could be helpful in the early stages following transposition when patients and the system are still learning about the rights created by the Directive

The reasons given as to why such a system would not be necessary were if points of contact within the system hold the appropriate information on cross-border treatment and if it was common practice for direct payments to be made directly to providers.

20. What would such a system look like and how could it work in practice?

Suggestions on ways such a system should operate include:

- A web-based questionnaire on the DH or NHS website: using this process, patients would be able to check whether the treatment they would like to receive requires prior-authorisation or not and could receive an estimate on the level of reimbursement they would be likely to receive
- A telephone conversation between the patient, the patient's clinician and NHS England
- Initially contacting the patient's local service provider to look into treatment options and any aftercare requirements, followed by a discussion with NHS England to determine potential reimbursement levels
- A system within the National Contact Point where patients can discuss their plans with an adviser

Mutual assistance and cooperation

21. What information should be shared between competent authorities on treating practitioners, and in what circumstances?

Respondents were very supportive of the requirement to make information on a healthcare professional's right to practice available to other Member States and generally they agreed on the nature of information that should be provided. This included information on:

- The status of registered healthcare professionals
- Education and practice history
- Regulatory processes and procedures
- Standards to which registrants must practice
- Notifications of disciplinary hearings and findings, including interim orders, conditions on a licence or limitations

Respondents commented that competent authorities across Europe should proactively and reactively share relevant information. With regard to the circumstances in which this information should be shared, respondents made the following suggestions:

- When a healthcare professional's right to practise has been restricted or removed. This could be because of serious matters relating to conduct, health, performance or matters of a criminal nature
- Where a competent authority has reasons to believe that identity or document fraud has been used to avoid restrictions on practice or to falsely obtain registration in another Member State

However, a few respondents argued that competent authorities must wait for the outcome of an investigation into a practitioner's fitness to practice before sharing any relevant information, unless an interim order has been imposed. The point was made that it was not necessary to exchange information on registrants with complaints made against them, prior to the complaint being upheld.

A number of respondents also referred to the Directive on the Mutual Recognition of Professional Qualifications (MRPQ), which is currently being reviewed, and a proposal for an alert mechanism which is being considered. They said they would like to see the same proposal adopted as part of the requirement in this Directive to share information on healthcare professionals.

22. & 23. How do you think the European reference networks and proposed ehealth and health technology assessment networks might best add value to the UK? What impact might these have on current UK systems?

Of those who replied to this question, the overwhelming majority agreed that cooperation at this level between Member States was a positive step. Comments on the positive impact that this cooperation could have were that:

- European reference networks could have a role in helping to advance the agenda on rare disease through information and knowledge sharing, cooperation on specialised healthcare and improving diagnosis and treatment for patients
- With regard to the treatment of rare disease, the UK stands to benefit as it already has the infrastructure and expertise to treat many rare conditions - UK providers could gain more patients thus ensuring that standards and experience are kept at high levels
- There could be potential cost savings from preventing the unnecessary duplication of research

- Member States, including the UK, could be supported in the provision of highly specialised services where there is a lack (including any services not provided, or not well-developed)
- The content of patient summaries should be an important focus for e-health cooperation

However, respondents also put forward some caveats to there being cooperation across Member States. These include that:

- Vigorous scrutiny and peer review must remain mandatory
- With regard to health technology assessments (HTAs), any action should recognise that Member States may use HTAs in different ways
- There should be no extension to the timeline for EU licensing and regulatory processes

Other Comments on the Consultation Package:

In addition to answering the specific consultation questions, a number of respondents made general statements on certain key issues.

Charging/Reimbursement:

Several respondents commented on charging patients under the Directive, focussing on incoming patients accessing NHS services under the Directive and what this means for providers. Respondents raised the following concerns:

- There is currently a lack of guidance on what happens when EU patients come to the UK to seek healthcare treatment from NHS providers
- For NHS providers, there is a need for greater clarity on how costs and tariffs will be calculated, including how charges will reflect any additional costs arising from the treatment being cross-border – examples included translation fees, the transfer of records, other administrative costs
- Do not think that current national tariff/pricing mechanisms always represent the actual cost to the NHS of providing treatment and are, therefore, concerned about the proposed approach to calculating prices under the Directive – concerned that as the tariff may not represent the actual cost of the treatment for the NHS that providers will be subsidising the cost of treatment for EU patients
- What happens when an NHS treatment does not have a tariff
- It is important that costs are recouped from patients who are chargeable, so there is work to be done on how NHS providers will identify those EEA patients receiving treatment under the Directive and charge them accordingly

From the perspective of outgoing patients seeking reimbursement from the NHS, a few respondents sought clarification on the flow of money between NHS England and CCGs and how costs are agreed, in particular what happens when a CCG does not agree with the reimbursement amount reached by NHS England.

Aftercare/continuity of care:

A few respondents touched on the issue of aftercare, each raising similar concerns:

- The on-going care needs of patients who receive cross-border healthcare is important and it was not clear in the consultation document how clinical liaison will work across EU Member States – would like to see communication occur between clinicians and health systems in both sending and receiving countries, in order to ensure continuity of care
- Clarification is needed on how aftercare arrangements will ensure continuity of care and where responsibility for a patient's safety and recovery resides

Language and translation:

Several respondents asked for clarification on language and translation services, in particular:

- Whether responsibility for providing language and translation services sits with the provider in the country of treatment
- Who is responsible for ensuring that a patient's medical records can be understood in their country of residence, if a patient has received cross-border healthcare

Liability:

A few respondents sought further information on the liability of NHS providers with regard to cross-border healthcare. There was concern about the liability that providers could face and on that basis, asked for clarification on the grounds NHS providers have to refuse treatment for EEA nationals. In addition, information was sought on whether NHS providers will be held legally liable should an error occur as a result of, for example, mistranslation, improper diagnosis or incorrect records from a patient's home Member State.

Department of Health Reply

Generally, respondents were supportive of the proposed approach to transposition as set out in the consultation document. There was no substantial disagreement with Government's overall plan and in fact the majority of respondents expressed positive views on the scope and effect of this new European health legislation.

The Government and Department of Health have considered consultation comments carefully and, since there were no strong objections, the Government's final approach to transposition is as set out in the consultation-stage documentation. Accordingly, the implementing legislation will be taken forward reflecting the following:

Patient entitlements

The Regulations will place a broad legal requirement on both NHS England and CCGs to provide clear and accessible information to patients on their rights entitlements in relation to receiving cross-border healthcare. It is a condition of reimbursement that the healthcare service for which the patient seeks reimbursement is medically necessary and that the same or equivalent treatment would be made available to the patient by the NHS. Therefore it will be important for patients to be able to obtain information about the treatment that would be made available to them by the NHS.

As set out at consultation stage, this requirement will be supported by directions to NHS England and CCGs. The intention is for these directions to set out further detail to the NHS on meeting this requirement, including:

- The information to be provided (this would need to include published information on services that are or are not generally available to NHS patients, including clinical and other access thresholds)
- The form in which the information is to be provided
- The time limits by which the information should be made available (by the relevant commissioner)

Prior authorisation

A system of prior-authorisation will be maintained as a condition of reimbursement that will be required for patients seeking to purchase expensive, highly specialised services in other EEA countries. Additionally, because it makes sense to seek to protect the NHS' investment in these areas by not allowing unrestricted reimbursement for such services obtained in other EEA countries, an available derogation enabling NHS England to refuse prior authorisation where the requested specialised treatment can be provided to the patient by the NHS within a medically justifiable period of time will be taken.

Therefore, with regard to the specific options presented in the consultation document, **option ii** will be reflected as follows: adopt Article 8(6)(d) but the condition of prior authorisation will be applied to a limited list of those specially commissioned services where the highly specialised nature of the service or the expense and the need for planning justify imposing this condition. The list of services will remain as set out at consultation-stage, however, the list will be kept under review by NHS England. From October, the list of services subject to prior-authorisation can be accessed through the National Contact Point.

Centralisation of functions

Overall, there was strong support for the decision to centralise the administrative functions relating to the reimbursement of patient costs and the consideration of prior-authorisation for cross-border healthcare within NHS England. Respondents were also supportive of the new role of the National Contact Point, including in the provision of information to patients on a range of subjects relating to cross-border healthcare. Accordingly, there will a National Contact Point in England, which will act as the UK lead, as well as territorial NCPs in Scotland, Wales and Northern Ireland respectively. The NCP for England will sit within NHS England.

The Department of Health has been and will continue to work closely with NHS England on setting up the NCP in time for the transposition deadline, including on the level of information provided and the formats it is provided in, taking into account the feedback that has been received throughout this process.

Other measures

Views were also sought on a number of discretionary measures in the Directive. These include:

- Operating a system of voluntary prior notification for services not subject to prior authorisation
- NHS England having the ability to make payments directly to overseas providers in order to create more equity in the system

Numerous consultation respondents were supportive of these measures.

Additionally, the Department of Health acknowledges the call in some consultation responses for additional guidance for NHS staff on other aspects of the Directive, including application, prior authorisation and reimbursement processes, patient charging, translation services and liability issues.

These are all areas where the Department of Health and NHS England will share responsibility and the two organisations will continue to work closely to ensure the necessary measures are put in place and that the system is ready to respond to the Directive's requirements by the transposition deadline.

Other voluntary measures included in the Directive were around facilitating participation by Member States in voluntary networks on ehealth, European Reference Network and health technology assessment work that is being taken forward in European committees and expert groups. The Department of Health has been fully involved in the setting up of these networks and will continue to be involved as this work is taken forward.

The Department of Health and NHS England will jointly monitor the operation of the Directive and of the domestic implementing legislation, including how the changes work in practice for patients and for the health service as a whole. In addition, NHS England will be collecting data on outbound cross-border healthcare activity.

The Government and Department of Health would like to thank all respondents to the consultation for their very helpful comments and insights.

Annex A

Public Consultation on UK Implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare – List of Respondents

National AIDS Trust

NHS Protect

British Medical Association

Royal College of Nursing

Royal College of Midwives

British Dental Association

Foundation Trust Network

Association of British Pharmaceutical Industry

Professional Standards Authority

British Standards Institution

Pharmacy Voice

Optical Confederation

Royal National Institute of Blind People

Royal College of Surgeons of England

Dental Law Partnership

Royal College of Anaesthetists

Royal College of Obstetricians and Gynaecologists

Genetic Alliance UK

Royal College of Surgeons of Edinburgh

Castle Craig Hospital Ltd

International Council on Alcohol and Addiction

General Medical Council

Primary Immunodeficiency UK

Independent Healthcare Advisory Service

QHA Trent Accreditation UK

Alliance of UK Health Regulators on Europe

Association of British Insurers

UK Ophthalmology Group

NHS Clinical Commissioners

General Pharmaceutical Council

NHS Confederation

Annex B

Details of the Consultation Event

As part of the consultation process, on 2 May the Department of Health held a consultation event. This was a two-way event which we used as an information sharing session between the Department and stakeholders.

The Department began the event with a slide presentation on the Directive to help attendees gain a better understanding of the Directive and its requirements. This was followed by a Q&A session. This helped to ensure that stakeholders were able to respond to the consultation in a constructive and informed manner.

Following the presentation and Q&A session, we held group discussions based on a number of scenarios which could arise as a result of the Directive. This gave stakeholders a chance to look at the Directive's implications from a number of different angles.

A full list of organisations that attended the event is given below:

Association of British Insurers

NHS Confederation

Association of British Pharmaceutical Industry

Rohde Public Policy

King's College Hospital NHS Foundation Trust

Royal College of Nursing

Royal College of Surgeons of England

Project: London - Doctors of the World UK

Optical Confederation

NHS Clinical Commissioners

Royal College of Midwives

Department for Work and Pensions

Royal College of Anaesthetists

Rare Disease UK

NHS Confederation

NHS Confederation Hospital Forum

Foundation Trust Network

NHS Partners Network

Sapient

Treatment Abroad

UK Trade & Industry

BMA

NHS England