House of Commons

Science and Technology Committee

Direct-to-consumer genomic testing: Government Response to the Committee's First Report

First Special Report of Session 2021–22

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Science and Technology Committee

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First Special Report

On 22 June 2021 the Science and Technology Committee published its First Report of Session 2021–22, *Direct-to-consumer genomic testing* (HC 94). The Government Response was received on 15 October 2021. The Response is appended to this Report.

Appendix: Government Response

Government Response to the House of Commons Science and Technology Committee's Report on Direct-to-Consumer Genomic Testing

The Government welcomes this opportunity to respond to the House of Commons Science and Technology Committee report on Direct-to-Consumer (DTC) Genomic Testing, chaired by Rt Hon Greg Clark MP. Responses to each of the recommendations in the Committee's report can be found from page three onwards.

It is important to note that this response covers the structures in the health and social care system in England except for where an organisation, such as the MHRA, has a UK-wide remit. The report does not consider the separate healthcare structures of the devolved administrations; it will be the responsibility of the governments in each devolved administration to consider the recommendations for their respective area, taking into account differing NHS structures as appropriate. The National Genomics Board (NGB), represented by all the devolved administrations, will seek to bring together and provide oversight of the work of each of the devolved administrations in taking these recommendations forward.

This response largely focuses on health-related DTC genomic tests, but the Government Chief Scientific Adviser will shortly publish a report on potential future uses of genomics beyond health and their implications, including in the DTC market.

Introduction

In June 2021, the House of Commons Science and Technology Committee published their report on DTC Genomic Testing, following an inquiry on commercial genomics launched in 2019. The inquiry was prompted by the rapid rise in genomics-based tests sold directly to the public, usually for ancestry or health and fitness purposes. They are also offered by private clinics for reproductive and fertility purposes. The inquiry focused on genomic tests sold directly to consumers ('DTC genomic tests'), not those used in the NHS.

The Committee's report reviews a range of issues surrounding genomic tests sold directly to consumers, as well as the main regulatory changes suggested during the inquiry. There are seventeen recommendations for Government. Overall, the Committee has recommended improved regulation of DTC genomic tests and increased consumer protection, whilst recognising the potential positive impact the tests could have on the population's health.

The following response has been prepared by officials in the Office for Life Sciences (OLS), which is a joint unit between the Department for Business, Energy and Industrial Strategy

(BEIS) and the Department for Health and Social Care (DHSC). OLS have engaged closely with the Medicines and Healthcare products Regulatory Agency (MHRA) given that the central theme of the report's recommendations is to call for better regulation of DTC genomic tests, which is led by MHRA. OLS have also sought input from stakeholders across Government, the devolved administrations, and other relevant organisations, given the wide range of policies that the report's recommendations cover.

Overarching Government Response

Through years of investment in scientific research, landmark infrastructure projects and world-leading healthcare initiatives, the UK has become a clear front-runner in genomics. The Government has committed to sustaining that position by "*creating the most advanced genomic healthcare system in the world, underpinned by the latest scientific advances, to deliver better health outcomes at lower cost*." (Genome UK strategy, September 2020).[1]

We welcome the Committee's report and the body of evidence collected as part of this inquiry. We recognise many of the issues raised and in some cases our responses to the Committee's recommendations highlight activity already underway to tackle these concerns.

Many of the recommendations made by the Committee relate directly or indirectly to improving the way that DTC genomic tests are regulated. The Committee's report is therefore timely, given that the MHRA launched a public consultation on the regulation of in-vitro diagnostic devices (IVDs), the category in which DTC genomic tests fall under, on 16 September 2021.[2]

Post-EU Exit, the Government recognises that the MHRA will have a crucial role in supporting the effective development of innovative genomic tests, whilst maintaining the highest standard of safety. We are aware that the regulation of DTC genomic testing within the United Kingdom requires updating and will need further input from across the sector, including from consumers and manufacturers.

Part of MHRA's consultation explores the extent to which the issues related to the regulation of DTC genomic tests are specific to the genetic information analysed, or if they are applicable to DTC tests more broadly. The result of this will form a key part of future policy development regarding DTC genomic testing regulation.

To help realise the UK's ambitious vision for genomic medicine, the Government established the National Genomics Board (NGB). The Board is co-chaired by Lord Kamall, Parliamentary Under-Secretary of State for Health, with senior leaders in genomics on the board from across academia, the devolved administrations, the NHS, and industry. The NGB will ensure that the issues raised in the Committee's report are kept under review and, if appropriate, matters will be discussed and further actions agreed by the board.

1 https://www.gov.uk/government/publications/genome-uk-the-future-of-healthcare
2 https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom

Responses to the report's individual recommendations

Recommendation one: The Government should set out a specific timeframe in which it intends to review the case for introducing new regulations for genomic tests provided directly to consumers ('direct-to-consumer genomic tests'). (Paragraph 34)

The Government recognises both the opportunities and risks raised by direct-to-consumer genomic tests and is committed to ensuring effective and proportionate regulation. The MHRA is working to develop a robust, world-leading regulatory regime for medical devices that prioritises patient safety.

The MHRA launched a public consultation on the 16 September 2021 into the regulation of IVDs, which covers DTC genomic tests, and new regulations are planned to follow in summer 2022. The consultation explores several matters raised in the Committee's report and will be open for ten weeks. The Government is therefore unable to provide a detailed response to many of the report's recommendations until the consultation has completed and the results have been analysed.

Recommendation two: The Government should continue its support for genomic testing in the UK. (Paragraph 37)

The Government welcomes the Committee's recognition that the UK is world-leading in genomic testing. The Government will continue to support the UK's genomic testing industry and recognises that it plays an important role in the UK's thriving life sciences sector, bringing benefits for the population's health and the economy.

In July 2021, the Government launched its Life Sciences Vision,[3] which was commissioned by the Prime Minister to outline the Government's and the life sciences sector's ambitions over the next decade. This vision demonstrates the Government's commitment to growing the UK's life sciences sector, including the DTC genomic testing industry.

Furthermore, through its publication of *Genome UK* last year, and its subsequent Implementation Plan,[4] the Government demonstrated a commitment to supporting the development of genomic technologies in an environment that promotes responsible, equitable and ethical patient care.

Implementation of *Genome UK* is supported by a robust governance system. This includes the Minister-chaired National Genomics Board, providing strategic oversight, as well as an Implementation Coordination Group (ICG) which monitors the delivery of *Genome UK*'s commitments more closely. These groups bring delivery partners and stakeholders together, with UK-wide representation. Progress against the delivery of *Genome UK*'s commitments has been made possible thanks to consistent government investment in Genomics England, the NHS Genomic Medicine Service, and the UK's valuable research programmes, such as UK Biobank and Our Future Health.

As part of the first Implementation Plan for *Genome UK*, the Government announced the roll-out of a world-first whole genome sequencing (WGS) programme to patients with a suspected rare disease and certain cancers in the NHS Genomic Medicine Service, in partnership with Genomics England. More broadly, the NHS continues to develop

3 https://www.gov.uk/government/publications/life-sciences-vision

4 https://www.gov.uk/government/publications/genome-uk-2021-to-2022-implementation-plan/genome-uk-2021-to-2022-implementation-plan

innovative testing strategies for the early detection of cancer and hereditary diabetes and high cholesterol, such as through the commercial agreement with the diagnostic company GRAIL announced in November 2020.

Furthermore, Our Future Health (formerly known as the Accelerating Detection of Disease challenge) is helping to drive developments in the next generation of diagnostics and clinical tools, including the evaluation of polygenic risk scores (PRS). This ground-breaking research programme, supported by Government investment, will further enhance the genomic testing industry in the UK, whilst of course bringing health benefits to the UK's population.

We would like to thank the Committee for supporting the policies that have enabled the UK to become a world leader in genomics and life sciences.

Recommendation three: The Government should require manufacturers of direct-to-consumer genomic tests to have the performance of their tests assessed by an external body prior to placing their products on the UK market. (Paragraph 41)

The outcome of MHRA's public consultation will help to inform future policy on how DTC genomic tests are regulated and in turn, how they are assessed prior to being placed on the UK market.

Recommendation four: The Government should work with Genomics England and the NHS to define clear technical standards for direct-to-consumer genomic testing that, if met, would enable the genomic data generated by the test to be used and trusted by Genomics England and the NHS. The Government should also establish a mechanism by which providers of direct-to-consumer genomic tests could validate that their tests met these standards. (Paragraph 44)

The Government acknowledges the critical importance of genomic test results meeting appropriate standards and requirements should they have the potential for use in the NHS. We acknowledge that there are a series of practical challenges relating to data standards and clinical validity of DTC genomic tests but believe this is predicated on having more effective scientific and clinical regulation of the devices themselves, before integrating their data into NHS and/or Genomics England (GEL) records.

All NHS laboratories, including the seven NHS Genomic Laboratory Hubs (GLHs) are accredited and assured through the United Kingdom Accreditation Service (UKAS) under the ISO:15189 standard, which ensures quality and competency for all testing delivered in medical laboratories. The scientific and clinical specification of DTC genomic tests do not currently adhere to the same clinical standards as those used in the NHS. Until they do, for example through more effective regulation, bringing those results directly into health records may lead to undue confidence in those results, even if the technical data standards to integrate them had been reached.

In time, NHS England and NHS Improvement will work with NHS laboratories, the NHS Genomics Clinical Reference Group, GEL, and others to agree a position on how comparable technical and reporting standards for DTC genomic testing should be developed and implemented.

This will utilise the technical standards on how to describe and share human genetics and genomics data, developed by the international organisation the Global Alliance for Genomics and Health (GA4GH), which is supported by the UK's National Institute for Health Research (NIHR) and Medical Research Council (MRC), along with other international funders. Both GEL and other key research datasets, such as UK BioBank, have commitments to implement GA4GH standards which will minimise harms and maximise research outcomes.

There are also secondary data standards to consider, for instance that standardise the causal link between genetic information and specific diseases. This involves international collaboration between organisations such as the European Bioinformatics Institute (EMBL-EBI), National Centre for Biotechnology Information (NCBI), GEL, US National Institute for Health (NIH) and other clinical research institutes world-wide. Here the support from the UK Government to key institutions, including the support of EMBL-EBI (via UK Research and Innovation, ultimately via BEIS) and GEL (via the Office for Life Sciences) is key to an open, standard understanding of human health and disease which is kept up to date as knowledge progresses.

The Government have established a Data Working Group under the Genome UK Implementation Coordination Group to consider the steps needed to implement the commitments under the "Data" theme in the *Genome UK* strategy. Part of this work will bring together key delivery organisations (such as GEL, NHS England and Improvement, and UK Biobank) to work through the practical challenges of implementing GA4GH standards into their systems. This expert group will keep the Committee's recommendation in mind as we continue the implementation of *Genome UK*.

Recommendation five: The Government should extend the scope of the performance requirements on direct-to-consumer genomic tests to explicitly cover clinical performance as well as analytical performance. (Paragraph 47)

Performance requirements for IVDs, including DTC genomic tests, are explored as part of MHRA's public consultation and will help to inform future policy related to this recommendation.

The National Institute for Health Care Excellence (NICE) are also exploring the development of rapid, straightforward, trusted advice on important diagnostic, and digital technologies, such as at-home diagnostic tests which are directly accessible to patients/consumers.

The Government encourages other well-placed partners, such as the independent UK National Screening Committee (UKNSC), to share their expertise with the MHRA on the validity and utility of DTC genomic tests, given that they have experience working with academic experts on the assessment of the validity and utility of other types of medical tests.

Government will keep this recommendation under review following the outcome of MHRA's consultation and will facilitate discussions between MHRA, NICE and the UKNSC, where appropriate.

Recommendation six: In addition to pre-market validation of direct-to-consumer tests, the Government should consider requiring companies offering such tests to regularly update the evidence submitted to the external validation body, and for that body to review this, for example on an annual basis. (Paragraph 53)

MHRA's public consultation explores the pre-market requirements for devices placed on the UK market.

Recommendation seven: The Government should consider the case for amending the regulation of genomic tests provided directly to consumers, to require medical supervision or the provision of genetic counselling for at least some types of genomic testing offered directly to consumers. Criteria used to determine which tests should require medical supervision could include the severity of the conditions being tested for, as well as the predictive power of the test. Requirements for supervision and genetic counselling should cover the qualifications of the medical intermediary required and minimum requirements on the content and format of the support or oversight provided. (Paragraph 64)

MHRA's public consultation explores requirements around the information provided to users of DTC genomic tests and the outcome of this will help to inform future policy on how the tests are regulated.

Recommendation eight: The Government should consider the case for including reviews of the information provided to consumers prior to and after taking a direct-to-consumer test within any external validation required to place such tests on the market. This could, for example, include assessment of studies of consumer understanding of the information provided. (Paragraph 71)

Several areas being explored as part of MHRA's public consultation, including the potential to introduce new classification rules for IVDs, will help to inform future policy on this recommendation.

Recommendation nine: Building on its review of advertising for non-invasive prenatal testing, the Advertising Standards Authority should review, within the next year, the marketing materials used by companies offering other genomic tests directly to consumers, focusing in particular on the clinical performance implied by the tests compared with their actual performance. (Paragraph 72)

The Government has sought information from the Advertising Standards Authority (ASA), the UK's independent advertising regulator who ensure that advertising is legal, decent, and truthful. The ASA respond to concerns and complaints raised by the public, assessing them against relevant UK advertising codes and taking action to ban advertisements which are found to be misleading, harmful, offensive, or irresponsible. The ASA also monitor advertisements across different sectors to ensure they are compliant with relevant advertising codes and conduct research to assess public opinion and identify where action is necessary to protect consumers.

As referenced in the Committee's report, in November 2019 the ASA published a series of rulings against advertisements for non-invasive prenatal testing (NIPT) for genetic conditions because the presentation of 'detection rates' was misleading. The ASA subsequently published an Enforcement Notice directed at the advertising of NIPT

services, setting out the guidance and telling companies to take immediate action to ensure their advertising complied. Companies were encouraged to avoid quoting "detection rate" figures. If advertisers still chose to use "detection rate" figures then they had to be accompanied by a robust Positive Predictive Value figure and an explanation of both terms. Advertisers were also told not to use the claim "diagnostic" to describe NIPT. The Enforcement Notice made clear that if issues continued, targeted enforcement action would be taken which can include referral to the relevant professional regulatory body or Trading Standards who can consider legal sanctions. The full Enforcement Notice can be found here: https://www.asa.org.uk/resource/enforcement-notice-nipt.html

The ASA ensures the outcome of upheld rulings—such as for NIPT testing – are complied with. They have not yet received any further complaints regarding NIPT advertising but have reassured Government that they will carry out swift action if made aware of any non-compliance. They are considering carrying out a 'compliance sweep' of NIPT advertising within the next year, which involves actively monitoring advertising to ensure companies are compliant with UK advertising codes. If advertising is found to break the relevant advertising codes, the ASA will ask advertisers to withdraw or amend their adverts.

The ASA have also informed Government that they will continue to carefully consider any evidence of non-compliance of advertising for DTC genomic tests and take action where necessary.

The Government will keep this recommendation under review and is supportive of the ASA's work in this area.

Recommendation ten: As the Government considers the requirements that should be introduced on the information provided to consumers using direct-to-consumers genomic tests, it should consider specific requirements for prenatal genomic testing to ensure that the information provided is balanced and non-directive, with accurate information on what might be expected from life for a child or adult with the condition being tested for. (Paragraph 76)

This issue is addressed in MHRA's consultation, as the information provided alongside such tests is a crucial part of their regulation.

There may be a role for the UK National Screening Committee (UKNSC) in providing advice on regulation of prenatal genetic testing, given that they have experience exploring the use of prenatal genetic testing for Down's Syndrome, Edwards' Syndrome and Patau's Syndrome, and appreciate the highly charged and contested debate in the public domain.

The wider landscape of prenatal genetic testing is also changing rapidly, for example in recent years there has been a marked increase in the number of private clinics offering non-invasive prenatal testing (NIPT) to expectant mothers. As part of its inspection programme of baby scanning services, the Care Quality Commission (CQC) inspects NIPT services where they are offered in relation to Down's Syndrome. In such services, CQC expect providers of NIPT to ensure that women using the service fully understand the procedure, understand that it is not a diagnostic test, are informed of the possible outcomes, and have appropriate support available when the test results are delivered. This includes facilitating access to counselling and other relevant services, as well as medical follow-up when needed.

The Government will work with the UKNSC and MHRA to establish what actions are required to meet the recommendation, and with the CQC to understand if best practise can be transferred from private clinics to DTC genomic tests.

Recommendation eleven: The Government should gather evidence on the current impact of direct-to-consumer genomic testing on the NHS, as well as the effectiveness of guidance and other support offered to NHS professionals encountering patients who have used such tests. If necessary, the Government should support the Royal Colleges and other relevant organisations to publish guidance for NHS professionals, as well as for consumers consulting the NHS following a direct-to-consumer genomic test, explaining the capabilities and limitations of those tests, how the NHS will act on results obtained from such tests and the reasons for the actions that the NHS will and will not take. (Paragraph 79)

The Government agrees that it is important to gather more information on the impact of DTC genomic testing in the NHS. An NHS Genomics Workforce Survey, aimed at doctors initially, was launched on the 23 August 2021 across the NHS in England. It includes a question to quantify the proportion of doctors who have encountered patients seeking advice after taking a DTC genomic test, and whether doctors believe this will impact their future practice. This question will also be included in other versions of the survey that will be aimed at other healthcare professionals, for example, a survey aimed at pharmacists will be launched early next year.

The Government also agrees that it is important that NHS professionals are well supported with guidance on DTC genomic testing. The British Society for Genetic Medicine (BSGM) and Royal College of General Practitioners (RCGP) have published a position and guidance statement on DTC genomic testing, issued in 2019 (https://www.rcgp.org.uk/policy/rcgp-policy-areas/genomic-position-statement.aspx). The NHS England and NHS Improvement Genomics Clinical Reference Group, which advises on clinical policy and strategy for genomics in the NHS, have considered and endorsed this guidance and continue to consider implications of DTC genomic testing on the NHS.

This guidance notes that NHS patients may present to their GP or other NHS professionals requesting help with the interpretation of DTC genomic results and sets out recommendations on how NHS professionals should approach the management of these patients. It explains that the analytical validity, sensitivity, and clinical utility of DTC genomic testing may be lower than NHS standards and, for certain types of DTC genomic test results, there is a high chance of false positive or false negative results. This means that patients should be offered the NHS care which would otherwise have been offered (for example, family history and risk assessment, healthy lifestyle advice, or referral to specialist care) regardless of their DTC result.

Furthermore, the Health Education England Genomics Education Programme (HEE GEP) will work with the Academy of Medical Royal Colleges, NHS England and NHS Improvement, and Government to build on this existing guidance. The HEE GEP is already working with the Royal College of GPs to develop resources to support GPs in understanding DTC genomic test results, managing conversations with patients who have taken such tests and managing required NHS care as appropriate, whilst adhering to the 2019 RCGP guidance outlined above. The HEE GEP will also explore the resources required to support other NHS professionals, such as nurses and midwives, encountering

patients who have used DTC genomic tests. Resources and learning interventions will be evaluated by the HEE GEP to provide evidence of usage and impact.

Recommendation twelve: The Government should continue to explore, with NHS England and NHS Health Education England, the opportunity for companies selling genomic tests directly to consumers to contribute to the costs of training genetic counsellors in the NHS. (Paragraph 82)

Genomic counsellors play a key role in the genomic pathway and are an important but limited resource whose roles are first and foremost focused on activity commissioned by the NHS, covering referrals from NHS clinicians. As noted above, patients presenting to GPs after taking a DTC genomic test should be offered the NHS care which would otherwise have been offered (including referrals to genomic counselling services) regardless of their DTC result. NHS patients cannot access genomic counselling services in the NHS without a referral from an NHS clinician and a referral would not be made based solely on DTC genomic test results. Referrals to NHS genomic counselling services would only be made following the relevant NHS testing and/or assessment by an NHS clinician. Given this, DTC genomic tests are unlikely to be directly increasing demand for NHS genomic counselling services and therefore the NHS does not currently wish to seek contributions from DTC testing companies for the cost of training NHS genomic counsellors.

Furthermore, if this recommendation were to be implemented, it would imply that NHS genomic counsellors could advise and support patients presenting with DTC genomic test results. There are several complex issues which would need to be addressed within the wider clinical pathway before this could be possible. This means that, at this stage, the NHS would not be able to implement this recommendation without additional funding and resource. For example:

- Data and results generated from DTC genomic testing would need to be validated and accredited appropriately so that they can be used by the NHS (see recommendation 4). This may involve re-validation within the NHS and additional laboratory work, including interpretation and confirmatory testing in line with NHS clinical and scientific standards. This would incur additional costs for the NHS;

- Allowing patients who have used DTC genomic tests to access NHS genomic counsellors would result in increased referrals to relevant services for patient management, including clinical genetics and oncology services, resulting in increased demand and pressure for these services;

- Appropriate data and information infrastructure would need to be developed to support the incorporation of DTC genomic test results into the NHS, including the development of an appropriate laboratory information management system (LIMS). As it stands, the DTC genomic test results would not be compatible with the NHS' data infrastructure.

Despite the difficulties in implementing this recommendation immediately, the Health Education England National School of Healthcare Science (NSHCS) does have prior experience of enabling private sector companies to fund the cost of training staff providing NHS services, for example in fertility services. Therefore, the Health Education England Genomics Education Programme will work with NHS England, the NSHCS, the

professions (Association of Genetic Nurses and Counsellors) and Government to explore the feasibility of implementing this recommendation in the longer term.

Recommendation thirteen: The Government should aim for the data protection framework governing genomic data in the UK to be world-leading. It should review the adequacy of the UK's data protection framework for direct-to-consumer genomic testing, including the risks and opportunities presented by technological developments and growing numbers of consumers using direct-to-consumer genomic tests. The Government should also consider the case for requiring companies providing direct-to-consumer genomic tests to inform consumers, at the point of sale, of the potential consequences of genomic test results for their relatives. (Paragraph 88)

The Government agrees that it is important to have a strong data protection framework governing genomic data in the UK. The Information Commissioner's Office (ICO) is the regulator for the UK's data protection law and it must be adhered to by DTC genomic testing companies. The law is based on high-level principles which are designed to be technology neutral. This means that new technologies, or existing technologies used in new and different ways, will still be subject to these principles. The principles can be applied successfully across any sector, including the DTC genomic testing sector. Therefore, data protection law in the UK can be applied in a proportionate manner to ensure that personal data generated by DTC genomic testing is in a lawful and fair manner, is kept securely, and is protected in line with the principles. There are a number of different guidance documents about the Data Protection and the UK General Data Protection Regulation on the ICO website here.

For DTC genomic testing, the data being created is genetic data about the individual which is considered 'special category data'. Special category data gets extra protections applied to it. This includes a requirement for 'explicit consent' from the individual for their personal data to be used. Although 'explicit consent' is a term used in data protection law, it has not been specifically defined. However, any explicit consent given by the individual for their personal data should be in line with the definition given to 'consent' as a minimum. In practice, the extra requirements for consent to be 'explicit' when processing special category data, such as genomic data, are likely to be:

- That explicit consent must be confirmed in a clear statement (whether oral or written), rather than by any other type of affirmative action;
- That it must specify the nature of the special category data that will be used; and
- That it should be separate from any other consents you are seeking – i.e. consent received for other types of personal data cannot be considered to apply to the special category data. A separate 'explicit' consent will need to be given by the individual for their special category data to be stored and used.

For more detailed information on what constitutes a valid consent the ICO has published guidance here.

In terms of DTC genomic testing, consideration needs to be given to the transparency information that must be provided. Individuals have the right to be informed about the collection and use of their personal data. Furthermore, the personal data must be used in a way that is fair to the individual and their situation. With regards to the potential

consequences and inferences that can be made to and about others (such as relatives), when an individual gives explicit consent to their own personal genetic data being used/created through a DTC genomic testing firm, there is currently no specific requirement to inform individuals involved about these potential consequences.

MHRA's public consultation includes a question on whether the UK should introduce requirements for companies to inform consumers of the nature, significance, and implication of genomic tests. The results of this will help to inform future policy regarding this issue.

In respect of the complexity and uncertainty around the future uses of genomic data, it should be noted that UK law requires that the purposes of processing personal data must be clear from the start. This requirement aims to ensure that the reasons for obtaining personal data, and any intended processing of that data are clear from the point of collection and remain in line with the reasonable expectations of the individuals concerned and goes some way to protecting potential scope creep around the use of collected genomic data.

If an organisation intends to transfer an individual's personal data, specifically in this instance their genomic samples, outside of the UK, UK law would restrict that, unless the rights of the individuals in respect of their personal data are protected in another way, or one of a limited number of exceptions applies.

The Government will keep this recommendation under review and explore with the ICO whether further guidance in this area is necessary.

Recommendation fourteen: The Government should consider which, if any, genomic tests for asymptomatic children should be able to be provided directly to consumers, including whether there should be a ban on the provision of genomic tests for use on children that do not meet the criteria of the UK National Screening Committee. (Paragraph 95)

and

Recommendation fifteen: The Government should consider if any restrictions should be placed on the conditions that prenatal genomic tests provided directly to consumers are able to test for. (Paragraph 99)

Under the UK Medical Device Regulations 2002, the MHRA could only take action against the use of certain genomic tests if a compliance or safety issue associated with the device had arisen. The MHRA proactively investigate and review adverse incident reports for all medical devices placed onto the UK market and take necessary regulatory action where needed.

The UKNSC is keen to be involved in any future discussions with MHRA to advise on policy relating to recommendation 14. The Government will encourage and facilitate these discussions where appropriate.

Recommendation sixteen: The Government should consider requiring any manufacturer making genomic tests available to consumers in the UK to register a legal representative in the UK, with responsibility for ensuring that products supplied to consumers in the UK meet all relevant UK regulatory requirements. (Paragraph 101)

MHRA's public consultation explores the registration of medical devices in the UK and the outcome of this will help to inform future policy on this recommendation.

Recommendation seventeen: The Government should consider extending the definition of products covered by the regulation of genomic tests to include software and other services offering analysis and interpretation of genomic test results obtained from third parties. (Paragraph 104)

MHRA's public consultation explores the scope of medical device regulations in the UK and the outcome of this will help to inform future policy on this recommendation.