



## **BiIndustry Association response to the House of Lords Science and Technology Committee inquiry into genomic medicine**

### **EXECUTIVE SUMMARY**

The BIA is the trade association for innovative enterprises in the UK bioscience sector, representing over 300 members, the majority of which are involved in realising the human health benefits that bioscience promises. The BIA seeks to represent the interests of these innovative companies to all stakeholders and present positive evidence based suggestions for policy change that assists the development and uptake of innovation for the benefit of the UK patient population.

The key points of this response may be summarised as follows:

1. To ensure that policy activity keeps pace with the technological advances in genomic medicine, sufficient horizon-scanning activity by or on behalf of government is essential. Adequate funding should also be provided to support this activity.
2. Such horizon-scanning activity should then feed into the development of regulation to ensure that the UK remains a competitive environment to translate scientific advances into therapies for the benefit of patients. Regulators and the bioscience and pharmaceutical industries will need to continue to work together to ensure development of a robust regulatory framework that is conducive to the development and authorisation of a medicine and, where appropriate, co-development and co-authorisation of a pharmacogenetic test.
3. With the development of personalised medicines will come challenges and potentially higher costs in the short term. Indeed, barriers to the uptake of innovative therapies into the NHS remain a serious challenge for the UK<sup>1</sup>. The BIA hopes that under Lord Darzi's leadership the recently established Health Innovation Council<sup>2</sup> (HIC) will begin to address this issue.

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<sup>1</sup> PICTF Competitiveness and Performance Indicators 2005

<sup>2</sup> [http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Worldclasscommissioning/DH\\_083661](http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Worldclasscommissioning/DH_083661), the HIC will advise ministers on issues relating to improving patients' access to cost-effective new medicines, medical technologies, procedures and processes through the NHS and social care system

4. The bioscience and pharmaceutical industries play a vital role in the discovery and use of genetic information to further disease understanding, select compounds for development and thereby develop safer and more effective medicines.
5. The BIA believes that initiatives such as the Office for Strategic Coordination of Health Research (OSCHR)<sup>3</sup> and the Translational Medicine Board (TMB) offer unique opportunities to capitalise on advances in genomic medicine and translate research into clinical practice and patient benefit.
6. Encouraging up-take of innovative medicines will in turn encourage industry to invest in research that will translate science from the bench to the bedside. Initiatives such as reforming the Small Business Research Initiative (SBRI) and implementing a national Proof of Concept Scheme as recently announced in the Department for Innovation Universities and Skills (DIUS) White Paper “Innovation Nation”<sup>4</sup> are urgently needed to reaffirm the UK as an attractive place for investment in research and development of bioscience-based therapies.

## **1 Policy Framework**

1.1 Who is in charge of setting and reviewing policy in this area? Who provides scientific advice on policy development? Who monitors and anticipates potential scientific developments and their relevance to future policy? How effective are these mechanisms?

1.1.1 Within UK government, the Department of Health (DH) is taking the lead on policy activity for genomic medicine and published a White Paper on Genetics in 2003<sup>5</sup>. The DH's Chief Scientist and Director General for Health Improvement and Protection, Professor David Harper, has very recently published a progress review on the implementation of the 2003 genetics White Paper<sup>6</sup> which gives the most recent assessment from key stakeholders regarding the accomplishments of genetic science, its potential within healthcare, and what future priorities might be – both for government and in other sectors. Furthermore, within the DH several advisory bodies provide assistance; the Gene Therapy Advisory Committee (GTAC) advises on

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<sup>3</sup> Office for Strategic Coordination of Health Research (OSCHR) [http://www.nihr.ac.uk/about\\_oschr.aspx](http://www.nihr.ac.uk/about_oschr.aspx)

<sup>4</sup> <http://www.dius.gov.uk/publications/ScienceInnovation.pdf>

<sup>5</sup> Our inheritance, our future: realising the potential of genetics in the NHS (2003)

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4006538](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006538)

<sup>6</sup> *Our inheritance, our future*, Realising the potential of genetics in the NHS, Progress Review, [http://www.dh.gov.uk/en/PublicHealth/Scientificdevelopmentgeneticsandbioethics/Genetics/DH\\_084147#\\_1](http://www.dh.gov.uk/en/PublicHealth/Scientificdevelopmentgeneticsandbioethics/Genetics/DH_084147#_1)

developments in gene therapy research and their implications and the Genetics and Insurance Committee (GAIC) evaluates genetic tests and their relevance to insurance. The Human Genetics Commission advises the Government on the social, ethical and legal issues around human genetics.

1.1.2 The industry provides input under the auspices of the Bioscience Futures Forum<sup>7</sup> (BFF) which was set up as a recommendation from the Bioscience Innovation and Growth Team (BIGT) report<sup>8</sup> to horizon-scan across bioscience advances and considers the ethical, social and regulatory questions, which they raise. The purpose of BFF is to monitor and assess emerging issues and to anticipate areas where regulation may be needed and to feed this into government where applicable. The BIA has also played a role in attempting to alert government of the need to look at potential contentious issues by inputting evidence to the House of Commons Scientific and Technology Committee enquiry on Human Embryology and Fertilisation for example. At a European level, the BIA provides strategic input to policy development through partnership working the UK Clinical Research Collaboration (UKCRC)<sup>9</sup> and the European Bioscience Intelligence Committee (EBIC) which in itself was bourn out of the BFF. However, BIA considers that more should be done by government to horizon scan to ensure that policy keeps pace with scientific advances in genomics that may translate to medicines and therapies and it is vital that there is sufficient funding to support such activity.

1.1.3 Finally it is important that regulators and government base decisions on future regulation on the scientific evidence rather than being drawn by the headlines in the lay press.

1.2 Does the existing regulatory and advisory framework provide for optimal development and translation of new technologies? Are there any regulatory gaps?

1.2.1 Pharmacogenomics is a term used to describe the study of variations of DNA and RNA characteristics as related to drug response<sup>10</sup>. Pharmacogenetics describes the analysis of ways that genetic variation affects drug responses and provides the potential for more informative prescribing by health care professionals, generating a positive impact on healthcare systems and

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<sup>7</sup> [http://www.bioindustry.org/cgi-bin/contents\\_view.pl?SITE\\_ID=34&ID=380](http://www.bioindustry.org/cgi-bin/contents_view.pl?SITE_ID=34&ID=380)

<sup>8</sup> BIGT, 'Bioscience 2015: Improving National Health, Increasing National Wealth' <http://www.bioindustry.org/bigtreport/>

<sup>9</sup> [www.ukcrc.org](http://www.ukcrc.org), The main aim of the UKCRC is to re-engineer the environment in which clinical research is conducted in the UK, to benefit the public and patients by improving national health and increasing national wealth

<sup>10</sup> <http://www.ich.org/LOB/media/MEDIA3383.pdf>

most importantly improved patient outcomes. The use of pharmacogenetic information to improve the risk/benefit profile during drug development is actively encouraged by the regulatory authorities. However, to translate the potential of genomics to patient benefit, regulators and the industry will need to continue to work together to ensure development of a robust regulatory framework that is conducive to the development and authorisation of a medicine and, where appropriate, co-development and co-authorisation of a pharmacogenetic test. Working with regulators to bring about satisfactory guidelines on first in man clinical trials is also an essential part of helping translate research into therapy. Furthermore, timescales for the approval of genetic tests should not exceed those for drug approval, and medicines which employ pharmacogenetic information during prescribing must be assessed in a timely and appropriate manner during reimbursement decisions by NICE. Failure to address these issues will further undermine the UK's competitiveness as a global research leader.

### 1.3 How does the framework compare internationally?

1.3.1 Frameworks related to Good Clinical Practice and the Clinical Trials Directive apply globally. In addition, the regulatory agencies have actively sought to include innovative genetic approaches to the development of safer and more effective medicines. For example, the Federal Drug Administration (FDA) in the US, the European Medicines Agency (EMA) in the EU (which includes the MHRA) and the PDMA in Japan have all developed guidelines and procedures to evaluate the use of pharmacogenetic information during the development and prescribing of medicinal products. These three regions have also collectively produced guidelines on pharmacogenetic terminology in order to facilitate research by the adoption of a common set of definitions and terms<sup>11</sup>.

## **2. Research and Scientific Development**

2.1 What is the state of the science? What new developments are there? What is the rate of change?

2.1.1 Genomic science developments will continue to impact on the delivery of healthcare through improved diagnostics, patient safety, targeted therapeutics and regenerative medicine. Like most areas of science and research, genomic science is an actively evolving field and so the applications of genetics to medicine and healthcare will evolve over time rather than there being a

sudden revolution. In terms of research and development, key parameters requiring continued exploration include platform technology, bioinformatics/analytical techniques and clinical trial design.

2.1.2 In the area of targeted, so called 'personalised medicine' - aiming to better match patients with therapies on the basis of genetic information, the largest achievements have been in oncology. Over the past decade, therapies for patients with cancer have changed moving away from the administration of broadly acting cytotoxic drugs towards the use of targeted therapies<sup>12</sup>. This ongoing shift has been enabled by the development of diagnostic biomarkers (biological indicators) to identify the patients to treat and of predictive biomarkers to identify the patients most likely to benefit from specific therapies or to predict the clinical outcome of a specific therapy for a specific patient.

2.1.3 Advancements in pharmacogenetics are clearly reflected by the increasing number of drug labels that now include validated genomic biomarkers markers as an integral component of prescribing information for a range of indications including HIV, cancer, psychiatry, cardiovascular and hypertension<sup>13</sup>. Because it is now scientifically and economically possible to develop the clinical biomarkers necessary for clinical development, this approach is being widely applied in the industry in many therapeutic areas including virology, neurodegenerative diseases, diabetes, psychiatric disorders and many others.

2.1.4 However there are some limitations to a strategic approach with biomarkers applied being universally to all areas drug development. The potential of present technologies is almost limitless, and there are few difficulties in discovering biomarkers. However, in some instances, scientific knowledge is not sufficiently advanced or the genomic information can not be translated into clinically applicable solutions for targeted therapies. A further limit is the difficulty in obtaining informative human material collected in the appropriate patient population, at the right time and with the right methods to address the specific issues for biomarker validation in clinical setting. Projects such as the UK Biobank<sup>14</sup> will provide invaluable resources for future research to help tackle these issues.

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<sup>11</sup> <http://www.ich.org/cache/compo/276-254-1.html>

<sup>12</sup> Herceptin® is one of the most recent examples where a therapy is effective only for a subset of the patient population, in this case related to genetic differences in the expression of the HER2 receptor

<sup>13</sup> [http://www.fda.gov/cder/genomics/genomic\\_biomarkers\\_table.htm](http://www.fda.gov/cder/genomics/genomic_biomarkers_table.htm) and Kivexa (abacavir) and other abacavir-containing products – risk of abacavir hypersensitivity reaction <http://emc.medicines.org.uk/>

<sup>14</sup> [www.ukbiobank.ac.uk/](http://www.ukbiobank.ac.uk/)

2.1.5 Furthermore, with the development of personalised medicines will come challenges (and potentially higher costs in the short term) in clinical development – for example, tailored clinical trials will require different and effective recruitment for smaller more specific patient populations and additional analyses. Ultimately, personalised medicines will need to be adopted by the NHS for patients to benefit from scientific advances however, barriers to the uptake of innovative therapies into the NHS remain a serious challenge for the UK- new medicines launched in the UK have lower rates of uptake relative to other countries <sup>15</sup>. The BIA hopes that under Lord Darzi's leadership the recently established Health Innovation Council<sup>16</sup> (HIC) will indeed begin to address these issues and hold the Department of Health and the NHS to account for helping to overcome barriers and taking up innovation.

2.2 Who is taking the lead in the consideration and co-ordination of research and the development of new technologies?

2.2.1 Whether it is providing cutting edge services in bioinformatics, pharmacogenomics, proteomics, target molecule identification the development of diagnostics, gene therapy or regenerative medicine, the bioscience industry is a leading contributor to the understanding and application of genomic medicine.

2.2.2 The BIA believes that initiatives such as the Office for Strategic Coordination of Health Research (OSCHR)<sup>17</sup> and the Translational Medicine Board (TMB) offer unique opportunities to capitalise on advances in genomic medicine and translate research into clinical practice and patient benefit. The BIA is keen to see continuous dialogue with industry, in order to ensure that their experience can be used to encourage uptake of innovation in the fast paced field of genomics.

2.3 How effective is the policy and investment framework in supporting research in this area?

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<sup>15</sup> PICTF Competitiveness and Performance Indicators 2005

<sup>16</sup> [http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Worldclasscommissioning/DH\\_083661](http://www.dh.gov.uk/en/Managingyourorganisation/Commissioning/Worldclasscommissioning/DH_083661), the HIC will advise ministers on issues relating to improving patients' access to cost-effective new medicines, medical technologies, procedures and processes through the NHS and social care system

<sup>17</sup> Office for Strategic Coordination of Health Research (OSCHR) [http://www.nihr.ac.uk/about\\_oschr.aspx](http://www.nihr.ac.uk/about_oschr.aspx)

2.3.1 Substantial investment has been made in the private sector to explore and apply genetic information to the understanding of disease, the discovery and development of innovative medicines and diagnostic procedures.

2.3.2 Within the UK, the Department of Health has allocated initial investment to evaluate the application of pharmacogenetics to the use of some generic medicines e.g. azathioprine<sup>18</sup>. Whilst these are extremely important initiatives they require continued support and development if they are to provide meaningful research data and evaluate the translation of research findings into clinical application in the setting of the NHS.

2.3.4 Continued government support for gene therapy development will be necessary to provide more experience in treating very rare genetic conditions and to get the technology right. It may also be important to support innovation in treatments for these very rare diseases ('orphan diseases') where the market forces are so weak, and research challenges so great, that it is harder to state the case for pharmaceutical or biotechnology industries to invest. Currently there is insufficient government funding to translate the outputs of academic research into investment ready propositions to maximise the opportunities for new therapy development (see para 4.1.4).

## 2.4 What are the current research priorities?

2.4.1 The genomic research community is addressing three broad areas – disease (risk factors, prevention, biomarkers of diagnosis, progression or prognosis), efficacy of therapeutics and safety of therapeutics. The bioscience industry is active in all three areas as they relate to improving drug discovery and development as well as delivering safer and more effective treatments.

## 2.5 What is the role of industry? How much cross-sector collaboration takes place?

2.5.1 Between the public and private sectors, research is undertaken on a cross-sector collaborative basis both nationally and internationally. This research includes pharmacogenetic research with physicians during clinical trials, disease gene understanding studies with clinical geneticists and epidemiologists, and technological or statistical development with universities. Industry plays a vital role in the discovery and use of genetic information to further disease

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<sup>18</sup> [www.genres.org.uk](http://www.genres.org.uk)

understanding, select compounds for development and thereby develop safer and more effective medicines.

2.5.2 In addition the pharmaceutical and bioscience industries participate in public-private partnerships to pursue genomic medicine including with the FDA's 'Serious Adverse Event Consortium' and 'Critical Path Initiative' and the EU Innovative Medicines Initiative<sup>19</sup>.

2.5.3 However, in the UK there are barriers to collaboration with academia and the NHS. To redress these, the DH and the Association of the British Pharmaceutical Industry (ABPI) have worked closely to develop the concept of 'joint working' between the NHS and the pharmaceutical industry and have recently issued best practice guidelines for NHS staff<sup>20</sup> and a supporting best practice 'toolkit'<sup>21</sup>. The Royal College of Physicians will shortly publish an evidence-based report that focuses on solutions to overcome the perceived barriers to collaborative working between industry, academia and the NHS.

### **3 Data Use and Interpretation**

3.1 Is genomic information published, annotated and presented in a useful way? Should there be a common, public database? If so, who should fund, and have responsibility for, such an initiative?

3.1.1 Databases which provide access to both researchers and healthcare professionals in order to address specific health-related questions are of considerable value in advancing the understanding of genetics.

3.1.2 Since the initiation of the Human Genome Project in the early 1990s, public databases containing genomic information have been developed to store genomic data and to allow access to biomedical researcher communities from around the world. The National Centre for Biotechnology Information (NCBI) has been instrumental in providing such an integrated infrastructure (databases and software) for the reference human genome sequence, maps and annotation in addition to smaller satellite projects on other mammals, non-mammalian vertebrates and invertebrates, plants, fungi, bacteria and archaeobacteria sequence. However, the future challenge will be the integration of the plethora of genomic, biomedical and clinical data and tools that have been developed globally.

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<sup>19</sup> [http://imi.europa.eu/index\\_en.html](http://imi.europa.eu/index_en.html)

<sup>20</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_082370](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082370)

3.1.3 To maintain the open access nature of such resources, government or public-private-partnership (PPP) approaches should be adopted to fund their development.

3.2 Is other medical information recorded in a suitable format to allow optimal interpretation of genomic data? How should genomic data be brought together with other health information?

3.2.1 Interpretation of any genetic data is dependent upon access to accompanying relevant medical data that has been collected in an accurate and consistent manner. Electronic medical/health records (EHRs) are integral to research, prescribing practice, pharmacovigilance and public health. Within the NHS, electronic medical databases and EHRs offer direct benefits to patients and healthcare professional through improved completeness, accuracy and timely sharing of medical information amongst members of the healthcare team. Technological advances can also be embedded to aid in clinical diagnosis, disease understanding and management, more effective preventative care, identification of drug interactions and early identification of potential drug side effects. The enhanced analytical capability of electronic database management over historic paper records means that such systems offer the potential for augmenting health research within the NHS. This would have a positive impact on patient safety through drug surveillance and pharmacovigilance, the identification of disease patterns for allocation of resources, health outcomes research and the identification and design of clinical research programmes.

3.2.2 The growth of computerisation and integration of EHRs through the current National Programme for Information Technology (NPfIT) and Connecting for Health (CfH<sup>22</sup>) will open up many opportunities to improve medical and scientific research.

3.3 What are the implications of the generation and storage of genome data on personal data security and privacy, and on its potential use or abuse in employment and insurance? How should these be addressed?

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<sup>21</sup> <http://www.hsconsultants.co.uk/Joint%20Working%20Toolkit%20v5.3a>

<sup>22</sup> <http://www.connectingforhealth.nhs.uk/>

3.3.1 Conceptually, all genetic data are part of the overall spectrum of confidential medical information and cannot be categorised separately. The information content of any medical data is highly contextual and genetic exceptionalism should be avoided. Within the industry, mechanisms to ensure patient confidentiality during pharmaceutical research are well-established. For example, only coded data is supplied to the company researcher who has no direct access to the patient or identifying details such as name, address etc. Additionally, the ABPI has recently developed comprehensive guidelines for the secondary use of data for medical research purposes<sup>23</sup>.

## **4 Translation**

4.1 Given the pace of technological advance, how 'future-proof' is healthcare investment in this area?

4.1.1 OSCHR and TMB have been tasked with the development of strategy to ensure translation of clinical research into improved healthcare provision and treatments and have assigned budgets to that end. However, the bioscience sector by its nature has long timeframes associated with drug development and validation thus attracting investment will always be a challenge not least in the current economic climate. Currently the UK is one of the lowest adopters of innovative medicines in the EU<sup>24</sup>. The UK government could further 'future-proof' healthcare investment by ensuring that innovative safe medicines are adopted for use in the NHS in a speedy manner. This would provide a clear demonstration to the private sector that the products they are developing have a route to market in the UK and would encourage further investment to the sector. It is anticipated that the long-term investment issue will also be focus of the review and refresh of Sir David Cooksey's recommendations made in his report "Bioscience 2015"<sup>25</sup>.

4.1.2 Encouraging up-take of innovative medicines will in turn encourage industry to invest in research that will translate science from the bench to the bedside. Initiatives such as reforming the Small Business Research Initiative (SBRI) and implementing a national Proof of Concept Scheme as recently announced in the Department for Innovation Universities and Skills (DIUS) White Paper "Innovation Nation"<sup>26</sup> are urgently needed to reaffirm the UK as an attractive place for investment in research and development of bioscience-based therapies. It is essential that these schemes are implemented as soon as possible, especially given the current economic

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<sup>23</sup> [http://www.abpi.org.uk/publications/pdfs/Guidelines\\_SecondaryUseData.pdf](http://www.abpi.org.uk/publications/pdfs/Guidelines_SecondaryUseData.pdf)

<sup>24</sup> PICTF Competitiveness and Performance Indicators 2005

<sup>25</sup> <http://www.bioindustry.org/bigtreport/>

<sup>26</sup> <http://www.dius.gov.uk/publications/ScienceInnovation.pdf>

climate and the recent implementation of tax reforms that are a disincentive to investment in the bioscience sector in general.

4.3 How meaningful are genetic tests which use genome variation data? What progress has been made in the regulation of such tests?

4.3.1 The analytic validity, clinical validity or clinical utility of genetic data will be influenced by what marker(s) are being measured and what purpose the test result will serve. In the hands of a healthcare professional, genetic tests used for example to determine if a patient is a carrier of a specific mutation are highly reliable. When this genetic mutation is the causative defect of the disease, the results of genetic tests are meaningful and contribute to the classification of disease<sup>27</sup>. If the test is to predict the likelihood of a serious adverse event, the test specification requirements will be very different than a test used to select patients likely to respond efficaciously to a medicine. Since 1998 all diagnostic tests in the UK have been governed by the European Directive on In Vitro Diagnostic Medical Devices (98/79/EC).

## **5 Biomarkers and Epidemiology**

5.1 In what way do genome-wide association studies contribute to the identification of biomarkers? How is the study of genetic factors and biomarkers integrated for translational purposes?

5.1.1 Genome-wide association (GWA) studies, not conceivable few years ago, are now performed with highly parallel leading-edge technologies<sup>28</sup>. These studies contribute to realise personalised medicine in different ways along the drug development process as indicated below:

- In pre-clinical stages:
  - To facilitate/support the discovery of new targets and to understand target pathways, especially in complex diseases,
  
- In the clinical stages:
  - to identify clinical biomarkers of disease susceptibility, initiation, severity or progression: disease clinical biomarkers

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<sup>27</sup> (example LDL receptor mutations and Familial Hypercholesterolemia)

<sup>28</sup> For example Illumina and Affymetrix systems

- to identify response biomarkers in patient subpopulations by a better understanding of efficacy and/or safety profiles and clinical outcomes: response clinical biomarkers.

5.1.2 GWA studies are the initial step – the biomarker discovery stage - allowing the confirmatory and validation studies to be performed in clinical trials. It is widely accepted by drug developers that, as long as the disease and response biomarkers are known, the earlier they are integrated and analysed in the clinical development program, the better. Integration of biomarkers as early as in Phase I studies gives the opportunity to build the necessary knowledge to allow personalised medicine to be implemented at a later stage in clinical practice.

5.1.3 However, as with all fields of innovation, the accumulation of knowledge will be constrained if genetic research is focussed purely on areas with existing data and *a priori* assumptions. Basic research should therefore not focus on a specific technology, nor merely on known biological pathways but in some instances involve genome-wide exploration to identify novel markers associated with disease or drug response. Furthermore, the application of markers e.g. SNP profiles, to drug development and ultimately prescribing, should not be contingent upon a complete understanding of the biological pathways involved. Any requirement of this nature would be in excess of that required for other therapeutic interventions and would therefore pose an unwarranted hurdle to the implementation of genetics in healthcare.

5.1.4 It should also be recognised that technologies and approaches used during the research and development process will not necessarily be those that are translated to clinical practice. Whilst a genome wide scan may be used in research to determine the full range of potential marker associations, once identified and validated only the informative genetic marker sets would be incorporated into a clinical test.

## **6 Use of genomic information in a healthcare setting**

6.1 Should there be a regulatory code (mandatory or voluntary) covering the provision of this advice?

6.1.1 The use of genetic information in prescribing for common diseases is expected to fall within the normal interactions between physicians, clinical analysis and patients, and not within the framework currently used for genetic service provision i.e. genetic specialists and counsellors.

6.1.2 It is recognised that knowledge to relay pharmacogenetic information to a patient needs to be acquired by a great many practicing physicians, however any assumption that such information will be overly complex, is not supported by examples such as Herceptin® (trastuzumab) or abacavir. Moreover, physicians routinely interpret other risk factor data e.g. blood pressure, cholesterol levels and family history during prescribing selection. Whilst advice to, and training of, healthcare professionals is vital, it is impractical to have any regulatory code mandating the way in which all genetic advice is given to patients. In the context of healthcare, genetic testing should be accompanied by the provision of relevant information. In some instances i.e. in the case of highly predictive tests for serious disorders, the offer of specific counselling advice should be made. However a policy requiring a similar level of support for tests designed to predict a therapeutic response would be inappropriate and create an unnecessary hurdle to healthcare provision.

6.2 What are the implications of developments in genomic technologies for the training of medical specialists and other health professionals? Are there any gaps that need addressing? What is the assessment and planning for future needs in capacity?

6.2.1 Increased education on genetics will need to become an integral part of the standard curriculum in medical, nursing and pharmacy training programmes if healthcare professionals are to make the potential of genetics fully available to their patients. The National Genetics Education and Development Centre (NGEDC) was established in Birmingham to look at the genetics educational needs of health professionals who are not genetics specialists and to work with the relevant professional and regulatory bodies to get genetics incorporated into curricula and continuing professional development to meet those needs. Although DH has confirmed the extension of the current contract with the NGEDC to August 2009, longer term provision of this type of service will need to be assessed to keep pace with the ever evolving field of genomic medicine.