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**House of Lords Science and Technology Committee  
Genomic Medicine**

**Response of the Royal Pharmaceutical Society of GB  
21<sup>st</sup> April 2008**

**Introduction**

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the regulatory and professional body for pharmacists in Great Britain. It has responsibilities in relation to the education, registration, conduct and practice of pharmacists, and it registers and inspects pharmacies. The Society is also a Chartered body with functions concerning the advancement of science and practice and the application of pharmaceutical knowledge.

The RPSGB submitted detailed responses to the Human Genetics Commission's consultations on the uses of genetic information (2001) and genetic tests supplied direct to the public (2002). We have also submitted responses to the Nuffield Council on Bioethics consultation entitled Pharmacogenetics: ethical issues (2003) and to the Genetics White Paper: Three year review '(2006). These responses are available on request from the RPSGB.

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## **Policy framework**

**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?**

The RPSGB Council sets all the Society's policies. Scientific advice is primarily provided by the Chief Scientific Advisor and the Science Advisor of the RPSGB. The Society's staff work closely with the Society's Science Committee, an implementation committee of the Council, to implement and monitor policy. Any policy development issues are considered in conjunction with the Society's Policy Development Unit. The Society's responses have, in the past, influenced external policy development in governmental and other organisations; examples include complementary therapies, cannabinoids, genetic testing and genetic information.

The Society endeavours to influence and add value to pharmaceutical policy development in a number of ways. At the central Government level, the Society looks to influence policy development through: the provision of briefings to members of parliament and to the All Party Parliamentary Group on pharmacy issues and policy; responses to formal government consultations on pharmacy issues; and its relationships with key central government health agencies including the Department of Health, the NHS, the Medicines and Healthcare products Regulatory Agency.

At the national level, through its national boards and group committees (covering academic pharmacy, veterinary pharmacy, community pharmacy, hospital pharmacy and industrial pharmacy) the Society is able to canvas opinion and test policy perspectives from across the pharmacy family. The Society also participates in a number of pharmacy forums including but not limited to; the Health Policy Forum, (established by the RPSGB and run jointly by representatives from the Medicines and Healthcare products Regulatory Agency), the Academy of Pharmaceutical Sciences and the Joint Pharmaceutical Analysis Groups (jointly sponsored by the RPSGB and the Royal Society of Chemistry). The Society also convenes the annual British Pharmaceutical Conference, which combines a forum on developments in the professional practice of pharmacy with a major international platform for new work in the pharmaceutical sciences. The Society also runs a Public Liaison Group, which engages the public in its work, and advises Council and comments on policy proposals.

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

**What impact will genomic information have on the classification of disease?**

**How will it affect disease aetiology and diagnostic labels?**

It is expected that the exponential growth in genetic information generated through research will continue to contribute to the identification and classification of genes responsible for more known diseases and disabilities (see for example 'Breakthrough of the year - Human Genetic Variation', *Science* 21 December 2007: Vol. 318. no. 5858, pp. 1842 - 1843). Whilst some of these genes, such as those responsible for

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single gene disorders will inevitably be directly associated to disease aetiology (spinocerebellar ataxias, early onset Alzheimer's), others will be only one of several genes contributing to the susceptibility of developing the disease. As most common and complex genetic diseases are dependent on environmental as well as genetic effects, the use of diagnostic labelling will depend on the strength of the genetic component as well as a range of environmental components.

### **How useful will genomic information be as part of individualised medical advice?**

From the information that is available to us today, individualised medical advice can work well for certain diseases such as the spinocerebellar ataxias and Huntington's disease, however for other diseases, such as diabetes and hypertension where a genetic history is clearly important but where the number of genetic and environmental components involved in the predisposition to the disease is not, a diagnosis of elevated risk of disease may only be possible. This may lead to realistic health advice, but may also make significant ethical demands.

Individualised medical advice can also exist with relation to predicting response to specific drugs. In the case of the drug Herceptin, a biomarker can be used to predict whether an individual will respond to the drug, this clearly has huge benefits in terms of patient outcome and economics. However, pharmacogenetic testing, may only work for certain drugs and for certain genetic profiles. In cases when pharmacogenetics is used, cautious medical advice would be necessary to counter situations where there may be perceived 'winners' and 'losers'; e.g. a loser being an individual who would today receive a particular drug but would not receive it in the future if pharmacogenetic testing showed they had a low probability of responding to the drug. Any advice would need to be presented with careful consideration and in probabilistic measures and should be executed in favour of the patient. Such information could make significant contributions to health economic considerations.

### **What provisions are there for ensuring that the individual will be able to understand and manage genomic information, uncertainty and risk?**

We are aware that physicians are currently trained in genomic medicine and in dealing with and delivering sensitive and difficult information to patients as well as with providing counselling. Some of the challenging decisions that physicians are having to face include justifying who should have the test, the need to consider patient choice, consent of the test and the results, dealing with sensitive data, impact on the patient and their family, knowledge of alternative treatments that are available and having an understanding of when and how to refer to a specialist practitioner for treatment.

It is important that genetic data is deciphered correctly and that the public receive information only from trained persons and other trustworthy, accredited sources. As more genomic information becomes available, a wider range of health professionals will have an important role in translating genomics expertise for the public. Pharmacists receive substantial education in genetics which provides a sound grounding for their contribution to patient support (see further details below). From

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preliminary work that we have undertaken at the Society relating to genomics and pharmacy practice, we see a clear role for pharmacists in genomic medicine. The ready access of pharmacists in the community can ensure good patient information at both generic and specific levels.

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

We are not aware of a regulatory code existing relating to this. However it would seem important that a mandatory regulatory code existed. This would be useful at several levels namely protecting the public, safety issues, and standardisation of tests. A regulatory code would also provide advice and guidance, which has been based on expert opinion, to give confidence to the health care professional. Ethical considerations will have a major bearing on codes of professional practice.

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

Technological developments are likely to translate into greater output with the evolution of more diagnostic and predictive tests. This will have significant implications on specialist and health professional in the understanding of the subject, interpretation of tests and more importantly care and support of patients.

The RPSGB together with the NHS National Genetics Education and Development Centre recently undertook a scoping exercise to understand how pharmacogenetics could impact on pharmacy practice (report in press). The participants represented a range of pharmacy stakeholders including representatives from community pharmacy, hospital pharmacy, education and industry. The outcome from this meeting concluded that there was a role for the pharmacist in advising patients about pharmacogenetics and testing. It was suggested that pharmacists working in specialist areas could also be involved in interpreting pharmacogenetic test results, although they may require additional specialist training to do so. A range of activities was identified that might form the basis of the pharmacist's role in offering pharmacogenetics services, including critical appraisal of evidence, decision-making, sample handling, interpreting test-results and providing counselling to patients. These activities may however require some additional training to ensure that any new knowledge is applied to existing clinical skills.

We see a clear role for pharmacists in genetic testing. Pharmacy education has a strong scientific base as acknowledged in the recent white paper entitled 'Pharmacy in England: building on strengths-delivering the future'. The RPSGB foresees a role for pharmacists in supplying and advising on pharmacogenetic tests. The unique expertise of pharmacists lies in their in-depth knowledge of the properties, actions and uses of medicines. Acquiring expertise in pharmacogenetic testing is in our view an appropriate extension of the core role of a pharmacist for those wishing to take this on.