

# How genetics could change pharmacy

It is 50 years this month since the structure of DNA was described. In a week that has seen a report about genetic testing on the high street being published, Clare Bellingham examines the potential of genetics to change pharmacy practice

MOST genetic tests should not be sold directly to the public. That is the conclusion of a report published by the Human Genetics Commission (HGC) this week. Although it advises that stricter controls on genetic testing are needed, the HGC does not go as far as suggesting a total ban.

Genetics has come a long way since the double helix structure of DNA was first described in April 1953 in *Nature* by James Watson and Francis Crick. Would the scientists working on deducing the structure then have predicted that in 2003 a report would be needed to examine control of genetic tests to the public?

As things stand now, there are no specific legal requirements in the United Kingdom concerning the supply of genetic tests to the public. That is why the HGC — the Government's independent advisory body on human genetics — was asked by ministers to review the provision of genetic tests to the public last year. The result of the consultation that followed is this week's publication of "Genes Direct: ensuring the effective oversight of genetic tests supplied directly to the public".

The HGC recommends:

- Stricter controls on direct genetic testing but not the statutory prohibition of some or all genetic tests
- Most genetic tests that provide productive health information should not be available for home-testing or home-sampling
- The setting up of a well-funded NHS genetics service in primary care that can manage and allow access to genetic tests
- A proposed regulatory framework for regulating both the tests themselves and the supply of tests

Philip Webb, chairman of the HGC working group that carried out the review, comments: "We are concerned that these tests could give misleading health information

that overstates the role of genetics in the onset of diseases. Predictive genetic tests performed without a medical consultation may provide false reassurance or cause unnecessary alarm to people. As a result they could either delay seeking proper medical advice, make unnecessary lifestyle changes or seek unnecessary medical treatment."

## NO TOTAL BAN

The problem with genetic tests, the HGC observes, is that because of the complex variety of tests, there can be no "one size fits all" answer.

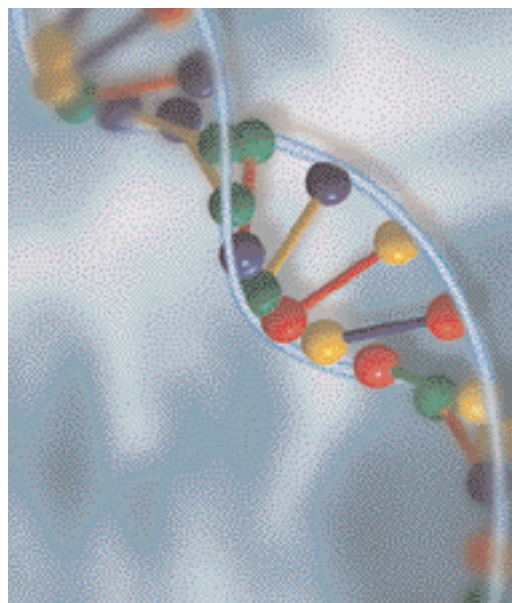
This is why it concludes that "most" genetic tests should not be sold directly to the public. "We think that it is a helpful analogy to consider the restrictions on medicines," the HGC says. "Medicines are often only available with a doctor's prescription. But some may be provided via pharmacies and others, if they are low risk, can be bought in any shop."

Under this proposed system, most tests would — at least initially — be "prescription-only". The HGC explains: "The presumption should be that a genetic test that is predictive of a medical condition is generally unsuitable for supply direct to the public".

The HGC also sees the possibility of "pharmacy-only" tests. It recommends that if a company wants to make a genetic test directly available to the public then it should be able to convince a regulator "that the test is sufficiently well validated and that anyone involved in providing the test has the right training and expertise to give good quality advice to the consumer". An example of this could be providing genetic tests that guide prescribing of medicines through pharmacies. In this instance, the HGC suggests: "A company would need to convince a regulator that a particular service was eligible to be offered over the counter via pharmacies. The pharmacist would have to meet necessary professional standards of competence in genetics and have suitable facilities."

The report expresses concern over tests that are either conducted at home or tests where the sample is taken at home and sent away for analysis with results sent directly to the patient. The concern lies mainly in "the problems of providing full information so that the implications of the test can be properly understood". Home testing kits may also be prone to inaccuracies, the report notes.

Baroness Helena Kennedy QC, chairwoman of the HGC, comments: "We do not see a need for an outright ban as people



DNA's double helix structure was first described in 1953

have the right to information about themselves. But we do want people to be properly protected. We believe the majority of genetic tests should be carried out under the supervision of a doctor within the NHS and that people need to think twice before paying money for something they may not need or understand."

Bodies that the HGC suggests should play a regulatory function in the area include the newly created Medicines and Healthcare Products Regulatory Agency for assessing the tests themselves and the new Council for the Regulation of Health Care Professionals for regulation of health professionals involved.

However, GeneWatch UK criticises the HGC report as "a triumph of spin over substance". Dr Helen Wallace, the deputy director, says: "The HGC's proposals are weak and ineffective. They simply hope that most genetic tests are sold through doctors and independently assessed but they recommend no real controls to make this happen."

## ROLE FOR PHARMACY

With its analogy to medicines, the HGC makes it clear that it wants nearly all genetic tests to be offered by doctors. Furthermore, it says that most genetic tests should be carried out at a primary care level by general practitioners. More complex conditions could be tested in specialist clinics. However, it is positive in its description of what pharmacists could offer, particularly in comparison with other groups.

In its response to the HGC consultation, the Royal Pharmaceutical Society proposed a middle ground where some genetic tests could be carried out by pharmacists. Professor Tony Moffat, the Royal Pharma-

## Genetics paper soon

The Government is expected to publish a green paper on genetics imminently. A Department of Health spokeswoman told *The Journal* this week that the date has yet to be fixed by it is likely to be within the next four weeks.

When Alan Milburn MP, Secretary of State for Health, announced the decision to produce the report last year, he said the report will "set out the Government's vision of how the genetics revolution could transform treatments and services available to NHS patients". He added: "It is intended to foster a more informed national debate about genetics."

ceutical Society's chief scientist, says: "The Society's standpoint on this is that some tests should be controlled through the relevant health professional. It doesn't necessarily have to be a GP. But it has to be someone who can give a consultation before the test so that when the test is performed, the individual knows what the result will mean to them and their family." How much intervention is needed depends on the nature of the test itself, he adds.

Professor Moffat also points out that it is difficult to stop tests being sold via the internet: "Pharmacists should be ready to respond to people who buy tests this way and want advice."

The report is complimentary towards the Society's work in considering issues surrounding genetics including quality assurance, training, practice guidance and patient counselling. It also highlights the changing role of pharmacists with greater consulting roles and better co-operation with GPs.

Meanwhile, the report finds that a wide range of alternative and complementary health practitioners who are interested in providing genetic testing are not suitable for

such roles. Lack of regulation of such groups is a problem. Criticism is levelled at nutritionists who were interested in supplying diet and lifestyle genetic tests. "We were concerned that the British Association of Nutritional Therapy and its members appeared to have no mechanism for making judgements on the usefulness or otherwise of such tests," the report says.

Pharmacists reading the report might think that little of it applies to them. First, there are not many genetic tests currently marketed. Second, if tests are to be primarily supplied through doctors then there is less of a role for pharmacy. This is not the case. Although the number of tests is limited now, it is likely to grow substantially over the next 10 years. As technology and understanding of genetics improves, so it is likely that the number and variety of tests will increase. The cost of tests could potentially drop simultaneously. Both of these factors mean that the likelihood of genetic tests being produced, and perhaps sold through pharmacies, will increase.

But even if the majority of genetic tests are supplied through GPs, pharmacists will

still have a role: just a different one. Professor Moffat comments that pharmacists might find themselves playing advisory roles while not actually carrying out the genetic test. This is particularly the case with the development of new drugs that will only be prescribable for people with particular genetic conditions or in the monitoring of response to therapy according to genotype (see Panel below).

"Pharmacists have the opportunity to provide testing for members of the public who need it. Our priority should be to ensure we have an understanding of pharmacogenomics so that we can prescribe or act as prescribing advisers to the benefit of patients so they get the right drug in the right dosage. It may be that we conduct diagnostic tests ourselves or that we refer patients for these tests," Professor Moffat comments.

This week's report suggests that genetic tests will not be sold on the high street. But the fast-developing field of genetics means that new opportunities for pharmacists will open up in this area. How quickly science has moved in 50 years.

## The potential of pharmacogenomics and how it will affect pharmacists

Pharmacogenomics is a relatively new science. It refers to how genes affect the way someone responds to a drug. This includes both the positive aspects of successful treatment and the negative adverse drug reactions.

Results from the Human Genome Project have helped to develop this field. The more genes that are identified, the more that can be understood about what genes do — including response to drugs. The project is nearing completion. A draft genome map was published in 2001 and, one by one, the exact detail of each chromosome is being sequenced.

The main benefit of pharmacogenomics is that it will offer better targeted medicines that are safer and more effective. It should offer a more accurate way of determining appropriate doses. In other words, it is about tailoring a medicine to an individual. Improved medicines management is certainly on the cards.

It is widely known that some people do not respond to medicines and that some suffer toxic effects at therapeutic doses. Furthermore, some suffer adverse effects while others do not. These differences can be a result of genetic variations.

The Royal Pharmaceutical Society's chief pharmacist Professor Tony Moffat says that 50 per cent of patients do not respond to tricyclic antidepressants and 25 per cent do not respond to selective serotonin re-uptake inhibitors. For antischizophrenia drugs, the proportion of non-responders is even higher. For statins, the figure could be anything between 30 and 70 per cent. "The question is, why aren't people responding? How do their receptors and metabolising enzymes differ?" he asks.

The use of pharmacogenomics is not limited to predicting treatment response. It can also be applied to preventing adverse reactions or to aid the production of specifically targeted medicines. After all, most diseases have a genetic component.

One drug on the market now demonstrates use of pharmacogenetic targeting: trastuzumab (Herceptin). Before taking it, patients have to be tested to ensure the drug is appropriate. Trastuzumab is only effective in cases of breast cancer where the tumour over-expresses human epidermal growth factor receptor 2 (HER2). In five years, Professor Moffat predicts, a whole raft of medicines that require these sorts of tests will be common place.

Such a prediction sounds fantastic but there might be problems if the pharmaceutical industry is not willing to invest in the production of pharmacogenomically targeted drugs. If new drugs are specific, how wide a population will take them? In other words, targeting drugs could cut profits.

Market analyst Datamonitor comments: "The emergence of new drug discovery and patient response technologies such as genomics, pharmacogenomics and proteomics is signalling new opportunities for the industry to generate products that can dominate certain indications. Consequently, market segmentation or fragmentation through the targeting of high responding patients is often seen as the end of blockbusters." However, Datamonitor does not see the developments as the end of blockbusters. "They change the current definition of these high earning drugs to that of multi-busters or a series of personalised therapies that are able to dominate a certain targeted disease area."

If new drugs requiring genetic testing are marketed, then it might be considered negligence if patients do not receive a test. Professor Moffat believes responsibility for deciding to carry out tests before using a particular drug will lie with the prescriber — whether that person is a doctor or, with the introduction of new prescribers, a pharmacist. Regardless of who prescribes, pharmacists need to ensure that they are supplying patients with the right medicine. In the future, Professor Moffat says that this could include ensuring genetic tests have been carried out and that drugs that are appropriate for the result have been prescribed.

Professor Moffat admits that pharmacists may not be completely prepared for the roles that could come from developments in pharmacogenomics. Education is something the Royal Pharmaceutical Society is looking at. It is involved with a working group that is examining training of all health professionals in genetics.

In addition, the Society has set up two projects in this area — one examines predisposition testing for diseases and the other pharmacogenetics. The projects will look at what role pharmacists should have in these areas, what standards are necessary, what guidance is needed and what educational requirements pharmacists will have. As a first step, the Society produced advice about pharmacogenomics last year that is available in the science section of its website ([www.rpsgb.org.uk](http://www.rpsgb.org.uk)).

How pharmacogenomics develops will be interesting. Will the pharmacy of the future contain many more drugs than today's pharmacy with each being appropriate for only a smaller population of people?