

10 July, 2008

GENOMIC MEDICINE

I am responding to your e-mail of 23rd June to Neil Ebenezer requesting further information about the work of the MHRA. Your request can be split into three areas which I will deal with separately.

Firstly you request information on the remit of the Agency and whether we have any difficulties in deciding what falls in or out of this remit. Secondly you are interested in our authority in terms of genetic tests carried out in the NHS, in the private sector and in relation to direct-to-consumer genetic tests. Finally you ask our views on the regulation of new emerging tests.

Remit of MHRA

The MHRA is an Executive Agency of the Department of Health and its activities are governed by its Trading Fund Order 2003 (SI 2003No 1076, as amended). In terms of medical devices the Agency is the Competent Authority for medical devices in the UK which we regulate under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended). The Regulations transpose into UK law a number of European Medical Devices Directives one of which is the In Vitro Medical Devices (IVD) Directive which is the Directive your Committee is interested in in the context of this Enquiry.

In the Government's Memorandum to the Committee dated April 2008 Annex E covers MHRA and the IVD Directive so I will not repeat any of that evidence here. That said I will expand on that evidence to hopefully give the Committee a better understanding of the Agency's role in the regulation of IVD's especially genetic test kits. As stated the Regulations require manufacturers to meet certain relevant essential safety requirements in order to place their products on the EU market. There are four risk classification associated with the risk associated with relative dangers to public health and/or patient treatment by a kit not performing as intended. Genetic test kits fall within the lowest risk category and therefore the manufacturer self declares conformity with the requirements of the Directive. The manufacturer then registers with the Competent Authority where he has his registered place of business and places his device on the EU market. Unless the test kit is for self testing there is no third party Notified Body involvement in the assessment process. I should therefore clarify that the Agency is not involved in this pre market process. The role of the Competent Authority is in the main in the post market phase to ensure that only compliant devices are placed on the market.

As far as post market surveillance is concerned the Agency would investigate any complaints received about a genetic kit's compliance with the Regulations and also undertake proactive inspections where indicated on a risk assessment basis. Under the terms

of the IVD Directive manufacturers also have a legal obligation to report to the Competent Authority serious adverse incidents brought to their attention. The Agency investigates all such reported incidents and takes whatever corrective action is necessary. The Agency has only received two reported incidents of a genetic test. One not a device related issue and the second was a software issue which was resolved.

In conclusion therefore in terms of the regulation of IVD test kits the Agency's remit extends to the designation and auditing of UK Notified Bodies, the registration of IVD manufacturers, investigation of adverse incident reports and market surveillance. Such activities are determined by the requirements in the IVD Directive.

Genetic Tests Carried Out

I think it is important to stress at this point that the Agency has no authority in relation to the actual genetic tests themselves carried out in the NHS, or in the private sector. The Agency's competence is in ensuring that genetic test kit itself meets the requirements of the Regulations. The Agency's remit does not extend to regulation of the service provider in terms of competence, how and where the tests are carried out or how the results are transmitted to the patient.

The majority of genetic tests used are assays put together in the hospital laboratory and used in that healthcare establishment's premises on their own patients. This is considered to be in-house manufacturing and because there is no placing on the market is not covered by the provisions of the Directive. Such establishments are encouraged to manufacture their assays in accordance with the requirements in the Directive and to report any adverse incidents to the Agency.

In addition there are a number of commercial genetic testing service providers who provide a range of services on the basis of a supplied sample providing data for linkage analysis, carrier screening, prenatal diagnostic testing, newborn screening, forensic testing, conformational diagnostic testing i.e. for leukaemia, etc. The kits themselves would be subject to the Regulation but not the private sector laboratories themselves. Turning to direct-to-consumer genetic tests the Agency is not aware of any genetic kits being made available over the counter for use by the general public in the home environment. However if any became available they would have to be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and means available to users and the influence resulting from variation that can reasonably be anticipated in users technique and environment. The information and instructions provided by the manufacturer should also be easily understood and applied by the user taking into account their level of knowledge.

Regulations of New and Emerging Tests

Under the terms of the IVD Directive such kits have to meet the requirements of the IVD Directive. The Directive also requires that a manufacturer of a new kit informs his Competent Authority accordingly when he places a product on the market. The Directive defines “new” as if

- (a) there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter;
- (b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years”

I hope that this provides sufficient information for the Committee to better understand the work of MHRA.