

## Medical Device Technology Forum

### Topic Selection Panel

10 March 2010

14.00 – 16.00

MHRA, The Boardroom, Market Towers, 1 Nine Elms Lane,  
London, SW8 5NQ

### Minutes

#### Attendees

Sir Alasdair Breckenridge (Chairman)  
Dr Christopher Brittain  
Professor Bruce Campbell  
David Brickwood  
Malcolm Carlisle  
Dr Neil Ebenezer  
Mrs Christine Glover  
Dr Haydar Jaafar  
Professor Julie Kent  
Dr Susanne Ludgate  
Robin Martin  
Dr John Perrins  
John Williams  
Professor David Williams  
Alison Wilson  
Laura Murray

#### **1. Welcome**

The Chairman welcomed all members to the meeting and introductions were made.

#### **2. Apologies**

Apologies received from Mr Clive Bray and Professor Ian Kimber

#### **3. Minutes of last Topic Selection Panel**

The minutes of the last Topic Selection Panel meeting (22 October 2009) were agreed.

### Action points

- Christopher Brittain updated the Panel on the proposal of establishing an Office of Regenerative Medicine within the MHRA. As the creation of an actual office was not deemed practical, a webpage has been created on the MHRA website which addresses common questions and identifies key contacts for enquiries regarding Advanced Therapy Medicinal Products (ATMPs).
- Neil Ebenezer updated the Panel on the topic of synthetic biology as a possible future forum. He felt it may be a little early to hold a Forum on this topic. The Panel agreed, although it is an area which needs watching as once it becomes more established, clarification from MHRA may be required.

#### **4. Review of Forum on Registers**

Bruce Campbell highlighted the main outcomes of the Forum held on medical device registers, and noted the general consensus on the usefulness of registers. The discussions and presentations at the Forum exposed the difficulties in setting up registers, and highlighted issues regarding funding. The main action agreed at the conclusion of the Forum was to investigate the economic case for registers, in terms of the costs of establishing and running them *versus* the potential financial savings that their findings could produce. Professor Campbell said that he was pursuing discussions at NICE about setting up such an investigation. He also described collaboration between NICE and Connecting for Health aimed at improving the availability of codes for new procedures, which might in future allow better collection of data about new interventions involving devices.

The Chairman suggested a report be written summarising the key points/outcomes of the Forum which could be placed on the MHRA website; and for discussions with the Communications division in MHRA on how to publicise the Forum externally. **(Action Point – Chris Brittain/Bruce Campbell)**

#### **5. Review of previous Fora**

Neil Ebenezer updated the Panel on the previous fora regarding tissue engineered products. A webpage for new technologies is under construction which will act as a contact point for those with enquiries. Neil Ebenezer also commented on a recent meeting he attended with Christopher Brittain to the European Medicines Agency (EMA) where the Innovation Task Force deals with new technology ATMPs, including medicine-device combination products, and it is hoped that MHRA and EMA can work together in dealing with manufacturer's queries on guidance and regulation.

The Panel discussed the area of regenerative medicine and tissue engineered products and comments from manufacturers are that they are not able to find the information they require and if this is not forthcoming there is a concern they will go elsewhere to develop their products.

The Chairman felt reports should be made for each of the previous Fora, again highlighting the main key points and for discussions to be held with the Communications division on how to advertise the outcomes.

**(Action Point – Chris Brittain/Neil Ebenezer)**

## **6. Update on upcoming Forum on Software as a Medical Device**

Neil Ebenezer updated the Panel on the upcoming Forum on the topic of software as a medical device to be held on 12 May.

The Forum will be chaired by John Williams. An issue raised by the Chairman and Panel was the need for “software” to be defined at the beginning of the forum. The Panel discussed the differences between firmware which is generally static and does not interact with the user, and software. It was also suggested that the topic of “firmware” may be a subject for a future Forum. David Williams suggested having a computer scientist attend the software Forum. Malcolm Carlisle raised the issue of design management technique and the need to include design consultancies. The Chairman felt the proposed programme for the Forum may need some further modifications, reducing the number of speakers, and ensuring the introduction clearly defines what software is and what is likely to be discussed. **(Action point – Neil Ebenezer/John Williams to provide panel with updated agenda once formalised)**

## **7. Discussion on future topics**

- Risk management and early access to medical devices

The Panel felt this would be an interesting and useful topic to cover, looking at the issues of how new devices become available to patients without having a reasonable amount of data and how manufacturers can look at putting together a risk assessment and engage at an earlier stage with MHRA. Those from industry felt manufacturers, particularly SME's, would be interested in a Forum on this subject. It was also suggested that as an output of the workshop MHRA could provide a guidance document. It was felt this topic might be more suitable for a workshop, initially within MHRA. **(Action point – initial discussions within MHRA, assistance from Malcolm Carlisle (Neil Ebenezer)).**

- Health Technology Assessment

Having had discussions with Tom Walley, Director of the HTA Programme, the Chairman suggested a Forum on health technology assessments covering both pharmaceuticals and devices. The Panel felt a Forum on HTA would be of great interest to manufacturers who are looking for a more simplified means

of submitting clinical trials. The Panel raised the concern of whether, if the Forum were to cover both pharmaceuticals and devices, keeping to a minimum figure of 35 attendees may prove difficult. **(Action point - internal discussions between Neil Ebenezer & Ian Hudson)**

**8. Any other business**

The Chairman reiterated the importance of suggestions of topics for further Forums from the Panel.

9. Dates of the next Topic Selection Panel meeting to be circulated. The next Medical Device Technology Forum is to be held on 12 May 2010 at Park Plaza, 200 Westminster Bridge Road, London, SE1 7UT.