PUBLIC CONSULTATION PAPER ON THE REGULATION ON ADVANCED THERAPY MEDICINAL PRODUCTS

Response on behalf of the NHS Pharmaceutical Quality Assurance Committee (UK)

27/3/2013

Responses

2.1. MA

Although we recognise the need for Marketing Authorisations to protect patient and public safety, we are concerned that the requirement for MAs for ATMPs could restrict innovation. Training for academic institutions in obtaining MAs and education on the need for them would be required.

2.2 Requirements for combined ATMP

The Committee's view is that all 'devices' that are used for medicinal purposes should be regulated as medicines with consequently more stringent standards than for devices.

2.3 Hospital exemption

We appreciate the need for a Hospital Exemption is required to allow flexibility for novel therapies. However, in order to protect patients, minimum manufacturing standards should be defined for example the MHRA Manufacturers Specials (MS) licence in the UK Preparation of ATMPs in hospital clinical areas or academic laboratories also need to have a defined set of uniform GMP standards to prevent quality risk and subsequent patient safety.

2.4 Incentives

No comment

2.5 Scope

The scope appears appropriate.