This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Novel neurotechnologies: intervening in the brain* between 1 March 2012 and 23 April 2012. The views expressed are solely those of the respondent(s) and not those of the Council.

European Medicines Agency (EMA)

Comments on Brain-Computer Interfaces and Neurostimulation

We share the observations and associated risks of techniques like BCI and Neurostimulation as described in the document. We support further investigations on their long term effects and associated risks. In this respect we would like to highlight our current activities on nanotechnologies and nanomedicines having the potential to replace or reduce certain risks of these techniques e.g. by avoiding invasive surgery.

Special physical chemical characteristics (PCC), pharmacokinetics, organ distribution and release rate of nanoapplications result in properties that allow targeted accumulation and persistence in selected areas with the potential for controlled release upon specific stimulation. A number of these applications fall under the remits of the European Medicines Agency (EMA) under the scope of the pharmaceutical framework. The EMA explores and evaluates the benefits and risks of novel techniques including nanoapplications and ensures that only medicines whose benefits outweigh their risks are being authorised. Evaluating novel techniques including nanoapplications and nanomedicines we consider it of utmost importance to follow Good Clinical Practices (GCP), respecting Ethic Conventions including patient education and informed consent.

Comments on Neural Stem Cell Therapy

With regards to Neural Stem Cell Therapy we consider that bioethical implications of stem cell use in brain disorders include the risks associated with the origin of the cell to be administered. Further the implantation procedure which, depending on the disease to be treated, may itself be the cause of severe impairment or could pose a potential life threat to the patient. A further aspect to be considered is how the implantation of stem cells (autologous and allogenic) in a human brain will impact the patients' neurological functions and eventually behavior. Specific considerations arise from the target organ in which these cells will be administered (i.e. brain) and the lacking knowledge and understanding of neurological diseases. For these reasons the regulatory approach to be followed is still judged mainly on a case-by-case basis which will be carefully put into a Benefit-Risk balance perspective for the patient. With respect to the ethical concerns in the field of stem cell treatment we would like to draw your attention to the following documents published by the European Medicines Agency:

- CAT Reflection Paper on Stem Cell based medicinal products: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/02/WC500101692.pdf
- EMA Public Statement on 'Concerns over unregulated medicinal products containing stem cells': http://www.ema.europa.eu/docs/en_GB/document_library/Public_statement/2010/04/WC500089472.pdf
- EMA weblink to Stem Cells: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000471.jsp&mid=WC0b01ac058050f348
- CAT Lancet article: Use of unregulated stem-cell based medicinal products http://www.lancet.com/journals/lancet/article/PIIS0140-6736(10)61249-4/fulltext