Annex 2

The function and purpose of MHRA advisory committees

The Commission on Human Medicines (CHM)

The functions of the CHM are set out in regulation 10 of the Human Medicines Regulations 2012 (as amended):

- to advise Ministers and the Licensing Authority on matters relating to human medicinal products including giving advice in relation to the safety, quality and efficacy of human medicinal products where either the Commission thinks it appropriate or where it is asked to do so;
- to consider those applications that lead to Licensing Authority action as appropriate (i.e., where the Licensing Authority has a statutory duty to refer or chooses to do so);
- to consider representations made (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder in certain circumstances; and
- to promote the collection and investigation of information relating to adverse reactions to human medicines for the purposes of enabling such advice to be given.

The CHM has 18 Commissioners, 11 EAGs, 5 EWGs with over 200 members in total involved in the Commission's work. EWGs are set up, as required, by the CHM to address specific topic areas. These are normally set up for a relatively short period.

- Infection Expert Advisory Group
- Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group
- Chemistry, Pharmacy and Standards Expert Advisory Group
- Clinical Trials, Biologicals and Vaccines Expert Advisory Group
- Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group
- Medicines for Women's' health Expert Advisory Group
- Neurology, Pain and Psychiatry Expert Advisory Group
- Oncology and Haematology Expert Advisory Group
- Paediatric Medicines Expert Advisory Group
- Pharmacovigilance Expert Advisory Group
- Sodium Valproate Expert Working Group
- Isotretinoin Expert Working Group
- Covid-19 Therapeutics Expert Working Group
- Covid-19 Vaccines Benefit Risk Expert Working Group
- Real World Data Expert Working Group
- Reclassification Stakeholder Group – high strength toothpaste

Herbal Medicines Advisory Committee (HMAC)

The HMAC and its functions were established by the Herbal Medicines Advisory Committee Order 2005 (SI 2005/2791) pursuant to the powers contained in section 4 of the Medicines Act 1968. HMAC advises on the safety, quality and efficacy in relation to human use, of:

- herbal medicinal products eligible for registration under the simplified traditional use registration procedure established under European Directive 2004/24/EC, and
- unlicensed herbal medicinal products (unless it is subject to an application for a marketing authorisation, product licence or a homeopathic certificate of registration).

The primary role of the Committee will be issues relating to safety and quality, since there is not a requirement for efficacy to be separately demonstrated in relation to registered traditional herbal

medicines or unlicensed products sold under section 241 of the Human Medicines Regulations 2012. However, efficacy is still relevant - under the traditional herbal registration scheme, the pharmacological effects or efficacy of the medicinal product must be plausible on the basis of long-standing use and experience.

Committee changed on the 1st November 2012 from being an Advisory Non-Departmental Public Body (ANDPB) to an MHRA Expert Committee.

There are currently 13 members appointed by the MHRA.

Advisory Board for Registration of Homeopathic Products (ABRHP)

ABRHP was established in 1994 by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 1994 (as Amended) pursuant to the powers contained in section 4 of the Medicines Act 1968 (as amended) to:

- give advice on safety and quality in relation to any homeopathic medicinal product for human use, in respect of which a certificate of registration has been granted or applied for.
- give advice on safety, quality and indications for use within the UK homeopathic tradition in relation to any homeopathic medicinal product for human use,
    - in respect of which a marketing authorisation has been granted or has been applied for, or
    - in respect of which a licence of right has been granted.

The Board changed on the 1st November 2012 from being an Advisory Non-Department Public Body (ANDPB) to an MHRA expert Committee

The ABRHP has 9 members appointed by the MHRA.

The British Pharmacopoeia Commission (BPC)

The functions of the BPC are set out in Regulation 11 of the Human Medicines Regulations 2012 (as amended):

- preparing new editions of the British Pharmacopoeia (BP) and British Pharmacopoeia (Veterinary) (BP (Vet))
- providing advice to the United Kingdom delegation to the European Pharmacopoeia Commission
- the selection and publication of British Approved Names (BAN)

The BPC has 11 members appointed by Ministers. The BPC EAGs and Panels of Experts are generally focussed on the production of monographs for medicines and are split into specific areas. Working parties are established for specialised areas and may be for a specified time period. These include

Expert Advisory Groups

- Antibiotics
- Biological and Biotechnological Products
- Herbal and Complementary Medicines
- Medicinal Chemicals 1
- Medicinal Chemicals 2
- Medicinal Chemicals 3
- Pharmacy and Nomenclature
- Unlicensed Medicines

Panel of Experts

- Blood Products
- Excipients
- Inorganic and General Chemicals
- Microbiology
- Radioactive Materials
- Veterinary Medicines
- Veterinary Immunological Products

Working Parties
- Advanced Therapy Medicinal Products
- Analytical Quality by Design
- Alternative Approaches for Documentary and Physical Standards for Biotechnological Products

The Committee on Medical Devices (CMD)

CMD has replaced the Devices Expert Advisory Committee (DEAC). DEAC was formed following an independent review on the Medicines and Healthcare products Regulatory Agency's (MHRA) access to clinical advice and engagement with the clinical community. DEAC is responsible for providing MHRA with independent, external, expert clinical and scientific input and advice on a wide range of aspects relating to the introduction and safe use of medical devices.

The Medicines and Medical Devices Act 2021 introduces a power to allow the government to establish a statutory expert advisory committee on medical devices.

UK Stem Cell Bank Steering Committee (UKSCBSC)

UKSCBSC was established in December 2002 as an independent national committee overseeing the activities of the UK Stem Cell Bank and UK research involving established human embryonic stem cell (hESC) lines, whether obtained from the bank or from elsewhere.

The role of the steering committee is to support stem cell research and to ensure that this is conducted within an ethical framework that is transparent to the public.

The Review Panel

The Review Panel is a departmental expert committee which carries out statutory and non-statutory reviews of proposals, decisions and provisional decisions taken by Medicines and Healthcare Products Regulatory Agency.

The terms of reference for the Review Panel (MHRA) are to:

- review the provisional determinations made by the Medicines and Healthcare Products Regulatory Agency (MHRA) concerning the classification of a product as a medicine
- perform the role of the 'reviewers' in relation to decisions or proposals made by the MHRA related to the grant, renewal, revocation, suspension, refusal or variation of manufacturer's or wholesale dealing licences, and UK marketing authorisations (the 'persons appointed' role)
- consider representations about decisions made in relation to advertising