Pan UK Pharmacy ATMP Working Group Terms of reference (January 2019)

The Pharmacy Working Group (PWG) was established in 2018 to support the activities of the three Advanced Therapy Treatment Centres (ATTC). It has since evolved to include other Pharmacy Advanced Therapeutic Medicinal Product (ATMP) Groups and includes representation described under membership.

Purpose / role of the group:

The PWG will:

- Act as an expert and informed body on the use of ATMPs within the National Health Service (NHS); promote good practice, to identify and resolve problems, to maximise the effectiveness and development of services, and to address all pharmacy issues pertaining to this objective.
- Clarify the complete scope of Pharmacy Services in the implementation of ATMPs in the NHS clinical setting in relation to licensed medicines, unlicensed medicines and investigational medicinal products.
- Agree and define the role of Pharmacy in the reconstitution, preparation and dispensing of ATMPs, including supervision where responsibilities are delegated in a collaboration with expert colleagues e.g. stem cell laboratory teams.
- Identify ATMP training needs for the future and existing Pharmacy workforce (including primary and secondary care, clinical and technical workforce) and to aid in developing and disseminating suitable educational materials.
- Engage with academia and industry to develop consistent practice in the development of ATMPs with regards to pharmacy activities.
- Maintain effective links between the key Pharmacy stakeholder groups in order to disseminate information both to and from these national and local groups. In particular, this will enable awareness to be raised nationally about ATMP issues and projects under development.
- Evaluate, endorse and disseminate appropriate standards of best practice, and to promote the efficient use of resources.
- Compile resource and management documents as necessary to promote best practice.
- Identify needs in Pharmacy infrastructure and organisational governance for regular use of ATMPs in the clinical setting.
- Monitor, interpret and contribute to the development of relevant guidance or legislation, and to disseminate such information to interested parties.
- Enable and encourage cooperative working with non-Pharmacy key stakeholders in order to optimise delivery operations for patient benefit.
- Act as a consultative resource for all pharmacy matters relating to the ATMPs

Membership:

- Membership of the group is open to pharmacists and representatives of organisations dealing with the implementation of ATMPs into standard clinical practice.
- Representatives will be invited from:
    - Northern Alliance ATTC
    - iMATCH ATTC
    - Midlands/Wales ATTC
    - Cell and Gene Therapy Catapult
    - The devolved regions to ensure standard practice is spread across the United Kingdom.
    - London Advanced Therapies Network
    - Professional bodies involved with Advanced Therapies
        - ATMP Working Party (subgroup of NHS Pharmaceutical QA Committee)
        - National Health Service England CAR-T commissioned centre operational group
        - National Pharmacy Clinical Trials Advisory Group
        - National Institute for Health Research ATMP Working Group
        - Royal Pharmaceutical Society
- Membership of the PWG will be held through the lifespan of the Advanced Therapy Treatment Centres.
- Members of Subgroups that are not of the PWG may leave when their topics have been addressed

Accountability:

- A nominated Chairman and Secretary shall be appointed from within the membership of the Group. Individual group members will report back to the PWG on their individual activities and from activities of the Subgroups.
- Each Advanced Therapy Treatment Centre will report on progress made within their Centre.

Review:

- The terms of reference will be reviewed on a minimum yearly cycle.

Working methods / ways of working:

- Meetings of the PWG will establish topics to be investigated by smaller Subgroups.
- Subgroups will be convened to address topics set by the PWG.
- The Subgroup may invite individuals from outside the PWG to provide technical support where appropriate.

- Information and recommendations from the Subgroups will be reported to the PWG in its normal meeting structure.
- Information and documentation generated by the PWG will be disseminated across pharmacies in the UK to promote consistent practice with Advanced Therapies

Meetings:

- Meetings of the PWG will be held on a bi-monthly basis.
- The meetings will be organised by the Chair with support from Cell and Gene Therapy Catapult.
- Meeting agendas will be set by the Chair with input from Cell and Gene Therapy Catapult and members.
- Meeting papers will be sent via e-mail to members one week prior to the meeting when possible.
- Meetings of the Subgroups will be organized by their leaders to reflect time and staff requirements needed to fulfil the brief set by the PWG
- Meetings of the PWG will be mainly conducted via teleconference with occasional “face to face” meetings when agreed by the members.
- Non-members will be invited to PWG meetings to provide technical support where required.
- Secretariat support will be provided by Cell and Gene Therapy Catapult.

Sharing of information and resources (including confidential materials)

- Meeting minutes and reports of the PWG and associated Subgroups will be held on a shared access point hosted by Cell and Gene Therapy Catapult
- All information shared by bodies with the PWG will be considered as being in the public domain. Once recommendations for best practices and procedures are finalised and disseminated, they will be considered to be in the public domain.
- Recommendations from the PWG may be published on the ATTC website, maintained by the Cell and Gene Therapy Catapult, when appropriate to the scope of the site.

Definition of terms

ATMP: Advanced Therapy Medicinal Product is a biological medicinal product that can be classified as either

- **Gene Therapy Medicinal Product:** biological medicinal product which has the following characteristics:
  (a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence;
  (b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.

- **Somatic Cell Therapy Medicinal Product:** biological medicinal product which has the following characteristics
  (a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;
  (b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues

- '**Tissue engineered product':** biological medicinal product which has the following characteristics
  (a) contains or consists of engineered cells or tissues, and
  (b) is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue

- **Combined Device-ATMP**
  — it must incorporate, as an integral part of the product, one or more medical devices, and
  — its cellular or tissue part must contain viable cells or tissues, or
  — its cellular or tissue part containing non-viable cells or tissues must be liable to act upon the human body with action that can be considered as primary to that of the devices referred to.