Practical Guidance on Pharmacy Oversight and Pharmacist Supervision of licensed ATMPs requiring a preparation/reconstitution step

Pan UK Pharmacy Working Group for ATMPs

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Scope

The purpose of this guidance is to outline the responsibilities of pharmacists in the preparation of licensed advanced therapy medicinal products (ATMPs) for administration in hospitals. Full compliance with the summary of product characteristics (SmPC) requirements is always recommended, and this document proposes a risk-based approach, in line with the required legislation. This guidance clarifies where activities require the oversight of a pharmacist and distinguishes circumstances in which preparation under the supervision of a pharmacist would be a legal requirement, providing distinction between the use of these terms.

Background

ATMPs are newly authorised medicines within Europe, which have been commissioned for administration in some hospitals across the UK. ATMPs are sterile medicines. If they require a preparation step prior to administration (also known as a reconstitution step) then this must occur in line with the SmPC. The optimal location for preparation should be decided locally. Where the SmPC or local risk assessment supports preparation in a clinical area, or where lack of / short post preparation stability data mandates this – the role of the pharmacist requires clarification.

Many hospital pharmacies operate unlicensed aseptic units which undertake preparation of small molecule medicines e.g. cytotoxic injectables under the supervision of a pharmacist. The practice is undertaken under a Section 10 exemption from the Medicines Act 1968 in line with the Royal Pharmaceutical Society (RPS) Quality Assurance of Aseptic Preparation Services Standards Edition 5. Unlicensed aseptic units are able to deviate from the SmPC where there is evidence to support this, and the Accountable Pharmacist documents and approves the deviation. For example, a shelf life of a prepared injectable can be allocated up to a maximum of 7 days expiry where there is evidence to support this.

As ATMPs must only be prepared exactly as specified in the SmPC, preparation under the supervision of a pharmacist is **not** routinely required. However, it is important that that any preparation activity is undertaken by trained and competent staff. For example, stem cell laboratory staff may prepare the product as per their standard processes.

Where the preparation is performed according to the SmPC instruction outwith pharmacy, (e.g. by competent nurses/stem cell laboratory staff) then pharmacist oversight is required, as is the case for any medicine.

Where any aspects of receipt, storage or preparation are outsourced pharmacy oversight will be required. In addition it is recommended that in this circumstance a technical agreement is put in place to ensure that roles and responsibilities are clear and product quality is optimised.

Definitions
The use of the terms 'oversight' and 'supervision' in this guidance are to be considered in the context of this document and refer to the preparation of ATMPs only; not to other medicinal products. The following are not formal definitions of pharmacist oversight and supervision.

Oversight: Where the term **pharmacist oversight** is used; oversight of an activity or process is required, but the pharmacist's presence for the activity or process to be carried out each time by qualified members of staff is not necessarily required, providing the appropriate training has been provided and a pharmacy approved SOP is in place; e.g. if a stem cell staff member or nurse has been trained and is competent to carry out the activity, it may be good practice for the pharmacist to be present the first time the activity is performed, and to monitor the activity at future intervals to ensure continued compliance, but it is not necessary for the pharmacist to be present each time the staff member performs the activity.

Supervision: Where the term **pharmacist supervision** is used; the presence of a pharmacist is required* for an activity or process to be carried out, e.g. where a product is reconstituted outside of the requirements stated in the SmPC, this must be performed under the supervision of a pharmacist using the Section 10 exemption.

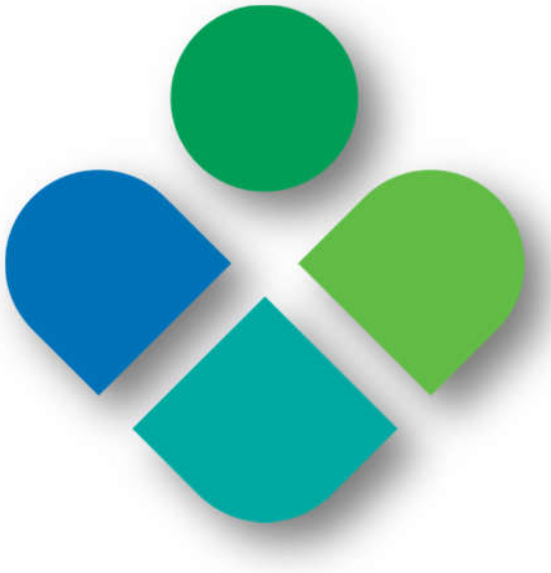
**NB. Other exemptions may also apply for medical and nursing staff in line with Section 9 and Section 11 of the Medicines Act 1968 as amended*.

Summary
Part IV EudraLex Volume 4 (Good Manufacturing Practice specific to ATMPs) specifies that activities required after batch release prior to administration of an ATMP, which are not considered to be a manufacturing step can be performed outside of an MHRA licensed GMP environment at the administration site (i.e. in aseptic preparation suites, clinical areas etc). This is in line with the requirements for all medicines.

ATMP reconstitution steps defined in Part IV EudraLex Volume 4 include thawing of cryopreserved products in a ready to administer presentation. Pharmacists should therefore be involved in the process of producing / approving the SOP and ensure that it is performed in line with the SmPC. Where thawing only is required, physical supervision is not a requirement.

For further information / clarification please contact the Pan UK Pharmacy Working Group for ATMPs (anne.black7@nhs.net).

The Regulatory/Governance subgroup of the Pan UK Pharmacy Working Group for ATMPs would like to thank the Royal Pharmaceutical Society for their review of this document.



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