

Preparation of Medicines in Clinical Areas by Pharmacy Staff: The Legal and Regulatory Framework



Purpose: this document has been prepared to inform the professional judgment which a Chief Pharmacist needs to make if asked to advise their Trust's senior management about the value-added services which pharmacy staff working in clinical areas can contribute to patient care. It neither encourages nor discourages any specific course of action. The final decision about the course of action most appropriate for a particular organisation rests with the Chief Pharmacist and their organisation's clinical governance committee.

Executive Summary

- A review of all regulation relating to the preparation of medicines was carried out by a representative of the NHS Pharmaceutical Quality Assurance Committee in consultation with the MHRA. The relevant legislation relating to preparation in clinical areas is:
 - Regulation 3, 20, 214 of the Human Medicines Regulations 2012 and
 - Section 10 of the Medicines Act 1968.
- The Human Medicines Regulations 2012 allow pharmacists to prepare medicines. Under section 10 of the 1968 Medicines Act, which remains in force, pharmacists can also supervise the preparation of medicines by others
- Regulation 3 of the Human Medicines Regulations 2012 permits nurses and doctors to prepare doses but it is silent about supervision of others to do so. The regulatory provisions under which it is common practice for Operating Department Assistants to prepare doses of medicines are unclear.
- Regulation 20 of the Human Medicines Regulations 2012 allows doctors, dentists and nurses, or pharmacist independent prescribers, to mix medicines. It also allows anyone to mix medicines as long as this is in accordance with the written directions of these prescribers. However, "mixing" in this context means **combining two or more medicines where one is not a vehicle for the administration of the other**. Although there is an expectation that the person mixing would usually be professionally competent, it was recognised at the time the legislation was put in place that there would be certain circumstances in which a carer or family member might have to do the mixing. This is why the exemption is broadly worded^{1,2,3} The MHRA have clarified that Regulation 20 does not cover diluting, reconstitution etc. and so this Regulation does not permit preparation of medicines by anyone under the supervision of nurses or doctors.
- Regulation 214 of the Human Medicines Regulations 2012 allows for a person acting in accordance with the directions of an appropriate practitioner (a prescriber) to administer doses of parenteral medicines to patients. It provides the legal basis under which the administration of parenteral medicines can occur. Regulation 214 is silent about assembly or preparation of such doses.
- Pharmacy staff have a key role to play in reducing the risk of medication error and microbiological contamination associated with the preparation of doses of injectable medicines in clinical areas including:
 - Identifying high risk products (as defined by NPSA Patient Safety Alert 20⁴)
 - Supplying products in a ready-to-administer form, wherever possible

- Training of clinical staff in good preparation practices, including aseptic non-touch aseptic technique (ANTT)
- Supporting development and implementation of safe systems of work in clinical areas

Introduction

Queries on the legality of the preparation of medicines in clinical areas by pharmacy personnel have recently been received from hospitals in a number of areas of the country.

The purpose of this document is to summarise the current legal frameworks relating to the practice of preparation of medicines in clinical areas and to describe what activities may or may not be considered as viable options when considering the development of the ward based roles of various categories of pharmacy staff.

It is important to remember that the philosophy behind NPSA Patient Safety Alert 20⁴ remains fundamental and that the preferred option is always to remove the preparation of high-risk injectable medicines from clinical areas or to use ready-to-use or ready-to-administer products.

The preparation of products in clinical areas, whatever group of staff undertakes this and however they have been trained, will always remain a higher risk option in terms of patient safety.

Historical Legal Position

Prior to 2012, this area was covered solely by the Medicines Act 1968. The Medicines Act regarded the preparation of medicines as an assembly activity and thus subject to licensing requirements unless an exemption applied. The Medicines Act 1968 contained three professional exemptions to allow doctors, pharmacists and nurses to carry out these activities as part of their professional role without the need for a licence. These professional exemptions were contained in Sections 9 (Doctors), 10 (Pharmacists) and 11 (Nurses) of the Medicines Act 1968.

The wording of Sections 9 and 11 only allowed the professionals to carry out the activity themselves, but Section 10 exemption for pharmacists allowed the activity to be “by or under the supervision of a pharmacist”.

Thus, prior to 2012 a pharmacist could prepare medicines on a ward and pharmacy support staff could have prepared medicines under the direct supervision of a pharmacist, thus requiring the presence of both on the ward whilst preparation was taking place. No mechanism existed for pharmacy support staff to undertake this activity under the supervision of a doctor or nurse as the professional exemptions in Sections 9 and 11 did not contain the provision of “by or under the supervision of”.

The NHS Pharmaceutical QA Committee has published standards which clarify the QA arrangements that need to be in place for aseptic preparation under the supervision of a pharmacist (the Quality Assurance of Aseptic Preparation Services⁵). This standard describes the comprehensive QA measures required for safe preparation of injectable medicines including risk management, preparation processes, documentation and facilities amongst other aspects and assumes that preparation takes place in a pharmacy.

All of these principles could be extrapolated to a clinical environment with the exception of facilities, designed specifically to control the risks of contamination. In a clinical area the risk of contamination is mitigated, however, as products should be administered immediately after preparation⁴.

The NHS Pharmaceutical QA Committee supports the principle that appropriately trained pharmacy staff should have an extended role to improve patient safety in relation to preparation and administration of injectable medicines in clinical areas by helping to design and implement effective systems to minimise risk. Concurrently, clinical pharmacists can help to further mitigate risks associated with IV preparation in their clinical area by facilitating the transfer of preparation of high risk products to pharmacy aseptic units or by encouraging rationalisation of the range of commonly used preparations to aid the procurement of products prepared as batches in licensed facilities.

Current Legal Position

In 2012, large parts (but not all) of the Medicines Act 1968 were replaced by the Human Medicines Regulations 2012 (HMR 2012). The key issue in relation to the current topic is that Section 10 of the Medicines Act 1968 remained in place. Thus the position with regards to what is possible under the Section 10 exemption remains unchanged from that described above. However, Section 9 and 11 exemptions were removed and replaced by new provisions in the Human Medicines Regulations 2012.

With regards to the potential for pharmacy support staff (non-pharmacists) to prepare products in clinical areas, recently proposed scenarios have supposed a potential mechanism for them to work under the instructions or supervision of a nurse. A scenario for them to work under the supervision of a doctor could in theory also be proposed, but it is unlikely this would be accepted as realistic or effective use of clinical resources.

The next section of this document will therefore consider the actual wording of the HMR 2012 with regards to the activities of nurses, but it must be remembered that the exact equivalent wording also exists with regards to doctors should this alternative scenario ever be considered.

Regulation 3, Section 1 of the HMR 2012 is relevant to the preparation of injectable medicines by nurses.

Regulation 3 states:

3.—(1) Regulation 17(1) (manufacturing of medicinal products: requirement for licence) shall not apply in circumstances where paragraph (4) applies.

This states in paragraph 4:

(4) This paragraph applies where a medicinal product is assembled by a registered nurse or a registered midwife if—

- (a) the nurse or midwife is acting in the course of his or her profession; and
- (b) the conditions in paragraphs (8) and (9) are met.

Paragraphs 8 and 9 then go on to say:

(8) This condition is that the medicinal product is supplied—

- (a) to a patient in the course of the treatment of that patient; or
- (b) to a patient of another doctor or dentist who is a member of the same medical or dental practice.

(9) This condition is that the medicinal product is not manufactured or, as the case may be, assembled—

- (a) on a large scale; or
- (b) by an industrial process.

This wording therefore still contains no provision allowing medicine preparation activities to be carried out by another person acting under the supervision of a nurse.

Mixing of Medicines

Reference has been made to interpretation of Regulation 20 of the HMR 2012 dealing with mixing of medicines and whether this includes another exemption to allow non-pharmacist pharmacy staff to prepare medicines in clinical areas.. The HMR 2012 states in Part 3 Section 20, that the requirement for a manufacturer's licence does not apply to the mixing of medicines in certain situations.

20.—(1) Regulation 17(1) (manufacturing of medicinal products) does not apply to the mixing of medicines by—

- (a) a nurse independent prescriber;
- (b) a pharmacist independent prescriber;
- (c) a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient;
- (ca) physiotherapist independent prescriber;
- (cb) podiatrist independent prescriber;
- (cc) a therapeutic radiographer independent prescriber;
- (d) a person acting in accordance with the written directions of a—
 - (i) doctor,
 - (ii) dentist,
 - (iii) nurse independent prescriber,
 - (iv) pharmacist independent prescriber,
 - (v) physiotherapist independent prescriber,
 - (vi) podiatrist independent prescriber; or
 - (vii) therapeutic radiographer independent prescriber; or
- (e) a person acting in accordance with the written directions of a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient.

However, to understand the context of this, it is important to understand the history of this regulation which was added in the HMR 2012 and was not covered by the Medicines Act 1968. The context in which this issue was first raised in 2008 was that potentially the existing Medicines Act professional exemptions at the time did not cover activities such as mixing of several drugs into syringe drivers in palliative care and other similar activities in other spheres of practice.

A working group was set up to look at this issue, and an interim interpretation was produced to allow this practice to continue. This has subsequently been embedded in legislation in the HMR 2012 in the above section.

To fully understand the context of this new regulation in HMR 2012 covering the mixing of medicines as part of routine practice, one must refer to the introduction to the guidance issued initially by the MHRA on Mixing of Medicines in 2009^{1, 2, 3}.

This clearly stated that mixing of medicines, as referred to in this context, related to the mixing together of drugs where one is not a vehicle for the administration of the other.

Therefore, this legislation does not apply to the majority of ward-based reconstitution activities, where the activity will clearly be using a vehicle to prepare the medicine for administration.

Administration of doses

The question has also been raised as to why certain groups of staff (e.g. Operating Department Assistants) can apparently prepare and administer parenteral doses to patients and whether this provides a mechanism for pharmacy support staff to develop this role in clinical areas.

Regulation 214 of the HMR 2012 provides that if not self-administered, parenteral medicines may only be administered by an appropriate practitioner or a person acting in accordance with their directions. In this context, an appropriate practitioner is a:

doctor,

dentist;

supplementary prescriber;

nurse independent prescriber; pharmacist independent prescriber.

community practitioner nurse prescriber (in relation to specified medicines)

podiatrist independent prescriber (in relation to any prescription only medicine which are not controlled drugs and a specified list of the latter).

physiotherapist independent prescriber (in relation to any prescription only medicine which are not controlled drugs and a specified list of the latter) and

therapeutic radiographer independent prescriber in relation to any prescription only medicine which is not a controlled drug.

The regulation provides a legal basis under which the administration of parenteral medicines can occur, but interestingly does not mention assembly or preparation of such doses. Whether this would be an attractive option for pharmacy support staff given that no legal provision exists to allow them to carry out the preparation stage requires careful consideration by individual organisations and an appropriate risk assessment which takes into account the current legal framework which is outlined in this paper.

Other roles for Pharmacy staff in the Clinical Environment

Whilst the legal and regulatory framework described above does not specifically address the issue of pharmacy staff working in clinical areas, consideration must be given to what value-added services such staff may be able to provide.

Higher risks will always exist with preparation in uncontrolled environments but enhanced training on aseptic technique for staff working in clinical areas would undoubtedly lead to a lower risk of microbiological contamination and preparation errors. The NHS Pharmaceutical QA Committee supports the principle that appropriately trained pharmacy staff should have an extended role to improve patient safety in relation to preparation and administration of injectable medicines in clinical areas by helping to design and implement effective systems to minimise risk. Concurrently, clinical pharmacists can help to further mitigate risks associated with IV preparation in their clinical area by facilitating the transfer of preparation of high risk products to pharmacy aseptic units or by encouraging rationalisation of the range of commonly used preparations to aid the procurement of products prepared as batches in licensed facilities.

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