What is compounding and what is it used for in the hospital environment?

Compounding is the science of extemporaneously creating a pharmaceutical preparation that addresses the immediate and individual therapeutic needs of a specific patient (WHO Technical Report Series [1], No. 1010, 2018)[1]. It is a vital service of the modern healthcare system that aims at ensuring positive patient outcomes and safety, especially for those individual patients or patient groups whose medical requirements cannot be met by industrially manufactured medicines. In other words, it is the basis of personalised medicine.

The justifications for compounding range from the necessity to customise care interventions to patients’ special needs due to characteristics such as medicines dosage strength or formulations to the absence or the discontinuation of a manufactured drug on the market.

The types of situations that would require a compounded preparation inside a hospital pharmacy include, but are not limited to, the following:

1. Patients who are allergic to components present in the industrially manufactured drug;
2. Patients who require modified dosages, e.g. paediatric patients;
3. Elderly patients who have adherence or ingestion difficulties;
4. Patients who require a specific route of drug administration;
5. Immunocompromised patients;
6. Patients suffering from rare diseases;
7. Patients undergoing clinical trials;
8. Patients subject to customised therapies, such as pain management;
9. Preparation of medicines with specific stability requirements;
10. In case a certain medicine is in shortage inside the hospital.

The present European regulations on compounding

that falls under the exceptions to the rules governing medicinal products for human use at European level. Therefore, products that are created in accordance with the magistral formula and the officinal formula do not have to follow the same legal requirements that are imposed on medicinal products for human use which are prepared industrially or manufactured by a method involving an industrial process.

A European Court of Justice (ECJ) ruling (C-544/13 and C-545/13 Abcur AB v Apoteket, 2015 (4)) found that it is the Member States’ prerogative to establish regulations vis-à-vis pharmacy preparations, including the need to obtain a national authorisation. Although there is a high degree of variation in the compounding policies across Member States, allowing extemporaneous pharmacy preparations when there is no licensed medicinal product available on the market is a common practice in order to ensure patient care (Scheepers et al, Legislation on the preparation of medicinal products in European pharmacies and the Council of Europe Resolution, European Journal of Hospital Pharmacy, Vol. 24 (4), July 2017 [5]).

The Magistral Formula

?Any medicinal product prepared extemporaneously in a pharmacy (and dispensed immediately after preparation and not kept in stock) in accordance with a medical prescription for an individual patient.?

The Officinal Formula

?Any medical product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia. It is maintained in stock and it is intended to be supplied directly to the patients served by the pharmacy in question.?

The hospital pharmacist is a crucial actor in compounding

Hospital pharmacists are responsible for selecting, procuring and compounding medication in accordance with the medical intervention decided within the care team. It is their duty to ensure an appropriate quality control, assurance and traceability system for pharmacy compounded medicines inside the hospital. Also, their training allows them to provide specialised information and advice on clinical management options in terms of medicine use, their risks and benefits, not only to other healthcare professionals, but also to patients and their carers. Initiatives such as the 44 European Statements of Hospital Pharmacy [6] and the Common Training Framework [7] contributed to the continuous education of hospital pharmacists with the aim to harmonise educational standards and to further advance good compounding practice.

Depending on national regulations, extemporaneous preparations can be used in the hospital setting in case of an imminent shortage risk, emergencies or high prices. A recent practice example (November 2018) comes from the Amsterdam Medical Centre in the Netherlands. In this instance, the Dutch government approved [8] the legal possibility of large-scale production by hospital pharmacists, acknowledged as compounding experts, of medicines licensed nationally or by the European Medicines Agency (EMA) because of unreasonably high prices for a specific drug.

Compounding is one of the core activities occurring in the hospital setting and the hospital pharmacist, in his/her medication expert capacity, is a key actor who is best positioned to significantly contribute to optimising medicines use, as well as patient outcomes.
Compounding should not be confused with the practice of reconstitution which involves manipulation to enable the use or administration of a medicinal product for products with a marketing authorisation issued by any competent medicines regulatory authority [that] is carried out in accordance with the instructions given in the summary of product characteristics (SmPC) or the package leaflet? (Council of Europe Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use). Reconstitution can neither be seen as being industrially manufactured, nor as an extemporaneous pharmacy preparation because the starting material is a licensed, market authorised medicinal product, not a raw material described in a pharmacopoeia monograph. Additionally, preparation occurs more often in clinical areas inside healthcare establishments, rather than in hospital pharmacies. The process is subject to strict quality assurance requirements for the safe preparation of sterile products. A typical example includes parenteral nutrition, a type of licensed medicine that cannot be directly administered to patients since it needs to be reconstituted. Source: Scheepers et al., Aseptic preparation of parenteral medicinal products in healthcare establishments in Europe, European Journal of Hospital Pharmacy, Vol. 23 (1), January 2016 [9].

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Links
[5] https://ejhp.bmj.com/content/24/4/224
[9] https://ejhp.bmj.com/content/23/1/50.short