

The European Statements of Hospital Pharmacy

The European Statements of Hospital Pharmacy were formulated following an 18-month review process, which included two rounds of online Delphi consultations with EAHP's member associations and an equal number of patient and other healthcare professional organisations. Final agreement on the wording of the statements was reached at a European Summit on Hospital Pharmacy, held in Brussels in May 2014. Only those Statements where there was a high level of agreement between patient groups, doctors, nurses, and pharmacists were accepted. The primary purpose of the statements is to provide safer and more effective care where medicines are used in European hospitals. The Statements can also be used as a guide for safer and more effective use of medical devices as well, with the responsibility for medical devices being with Hospital Pharmacies in several of our member countries. The European Statements reflect the importance of the hospital pharmacist as a key stakeholder within the hospital teams for providing optimal and safe patient care. Therefore, the European Statements reflect what we believe every European health system should be aiming for when delivering hospital pharmacy services.

The adoption of the European Statements was followed by the set-up of an implementation team that developed a strategy that included tools that enable a quantifiable measurement of progress. EAHP also sought further endorsement of the European Statements from organisations that were not involved in the original formulation.

In 2019 a review was conducted to assess the continued relevance of the Statements and that they effectively covered emerging issues. It was found that the document has remained remarkably resilient and a decision was made that the wording of the statements would not be changed, thereby staying true to the scientific principles used to develop and finalise them. What was agreed though, is that a small number of Statements would benefit from the addition of comments to further clarify their meaning.

A commented update to the European Statements of Hospital Pharmacy is presented here with a firm belief that EAHP will continue to have the support of patients, healthcare professional and a range of managerial organisations. We believe that we are all stronger by working together as we all have the ultimate goal of improving patient outcomes and putting the patient at the centre of their care.

While, in theory, the scientific community was aware of the risks and the possibilities of a worldwide pandemic, COVID-19 still found the world largely unprepared. Reflecting now

on whether the European Statements have supported the fight against COVID-19, it is clear that many of the Statements proved critical. Specifically, they proved particularly useful for managing shortages, using medicines outside of their marketing authorisations and conducting clinical trials. COVID-19 has also highlighted the importance of the hospital pharmacy profession in ensuring a rapid response to patient needs and evidence-based approach to medicinal therapy management.

EAHP believes that through the European Statements, the hospital pharmacy profession can achieve a higher level of preparedness for future challenges and crises in order to support society, while also improving the safety and efficacy whenever medicines and medical devices are used to help assure the best outcome for patients.

SECTION 1

Introductory Statements and Governance

- 1.1 The overarching goal of the hospital pharmacy service is to optimise patient outcomes through working collaboratively within multidisciplinary teams in order to achieve the responsible use of medicines across all settings.
- 1.2 At a European level, 'Good Hospital Pharmacy Practice' guidelines based on the best available evidence should be developed and implemented. These guidelines will include corresponding human resources and training requirements and assist national efforts to define recognised standards across the scope and levels of hospital pharmacy services.
- 1.3 Health systems have limited resources and these should be used responsibly to optimise outcomes for patients. Hospital pharmacists should develop, in collaboration with other stakeholders, criteria and measurements to enable the prioritisation of hospital pharmacy activities.
- 1.4 All hospitals should have access to a hospital pharmacist who has overall responsibility for the safe, effective and optimal use of medicines. Health authorities should ensure that each hospital pharmacy is supervised by a pharmacist with appropriate working experience in the hospital setting, and explicit demonstration of competence in hospital pharmacy.

1.5 Hospital pharmacists should work with all relevant stakeholders to develop hospital pharmacy human resource plans covering the breadth of hospital pharmacy practice. These should be aligned to engage hospital pharmacists as supervisors in all steps of all medicine use processes to meet health needs and priorities across public and private sectors that optimise medicines use and patient outcomes.

1.6 Hospital pharmacists should take the lead in coordinating the activities of multi-disciplinary, organisation-wide Drug & Therapeutics Committees or equivalent. They should have appropriate representation as full members of these Committees which should oversee and improve all medicines management policies.

COMMENT – *Hospital management, taking account of national guidelines, determines what structures are in place to assure the efficacy, safety and cost-effective use of medicines.*

1.7 Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes. This will ensure that pharmacy services are integrated within the general Information and Communication Technology (ICT) framework of the hospital including electronic health (eHealth) and mobile health (mHealth) procedures.

SECTION 2

Selection, Procurement and Distribution

2.1 Hospital pharmacists should be involved in the complex process of procurement of medicines. They should ensure transparent procurement processes are in place in line with best practice and national legislation, and based on the principles of safety, quality and efficacy of medicines.

2.2 Hospital pharmacists should take the lead in developing, monitoring, reviewing and improving medicine use processes and the use of medicine related technologies. Responsibility for using these processes may rest with other health care professionals and may vary according to the medicine, the medicine related technology, the health care setting and the multidisciplinary team delivering care.

COMMENT – *Hospital pharmacists have a key role, working with others, in ensuring continuous quality improvement for medicines use processes, including where information technology is utilised.*

2.3 Hospital pharmacists should coordinate the development, maintenance and use of a medicines formulary system, which may be local, regional and/or national. The medicine formulary system should be linked to

guidelines, protocols and treatment pathways based on the best available evidence including patient outcomes and pharmacoeconomic evaluations where these are available.

2.4 Procurement should be according to the medicine formulary and informed by the formulary selection process. A robust process should also be in place to appropriately procure medicines not included in the formulary where their use is indicated for the safe and effective care of individual patients.

2.5 Each hospital pharmacy should have contingency plans for shortages of medicines that it procures.

2.6 Hospital pharmacies should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, distribution and disposal conditions for all medicines, including investigational medicines.

2.7 Hospital pharmacists should be involved in the development of policies regarding the use of medicines brought into the hospital by patients.

SECTION 3

Production and Compounding

3.1 Before pharmacy manufacture or preparation of a medicine, the hospital pharmacist should ascertain whether there is a suitable commercially available pharmaceutical equivalent, and if necessary, discuss the rationale for this decision with the relevant stakeholders.

3.2 Medicines that require manufacture or compounding must be produced by a hospital pharmacy, or outsourced under the responsibility of the hospital pharmacist.

3.3 Before making a pharmacy preparation, the hospital pharmacist must undertake a risk assessment to determine the best practice quality requirements. These must consider premises, equipment, pharmaceutical knowledge and labelling.

3.4 Hospital pharmacists must ensure that an appropriate system for quality control, quality assurance and traceability is in place for pharmacy prepared and compounded medicines.

3.5 Hazardous medicines should be prepared under appropriate conditions to minimise the risk of contaminating the product and exposing hospital personnel, patients and the environment to harm.

COMMENT – *To achieve this there will need to be a multidisciplinary risk assessment of the hazardous medicines to determine where and how it is best prepared.*

- 3.6 When the reconstitution or mixing of medicines takes place in a patient care area, a hospital pharmacist should approve written procedures that ensure staff involved in these procedures are appropriately trained.

COMMENT – *Among healthcare professionals the hospital pharmacist is in the best position, because of their expertise in formulation, to advise on reconstitution or mixing of medicines. It is critical that any healthcare professional undertaking these tasks is competent.*

SECTION 4

Clinical Pharmacy Services

- 4.1 Hospital pharmacists should be involved in all patient care settings to prospectively influence collaborative, multidisciplinary therapeutic decision-making; they should play a full part in decision making including advising, implementing and monitoring medication changes in full partnership with patients, carers and other health care professionals.
- 4.2 All prescriptions should be reviewed and validated as soon as possible by a hospital pharmacist. Whenever the clinical situation allows, this review should take place prior to the supply and administration of medicines.
- 4.3 Hospital pharmacists should have access to the patients' health record. Their clinical interventions should be documented in the patients' health record and analysed to inform quality improvement interventions.
- 4.4 All the medicines used by patients should be entered on the patient's medical record and reconciled by the hospital pharmacist on admission. Hospital pharmacists should assess the appropriateness of all patients' medicines, including herbal and dietary supplements.
- 4.5 Hospital pharmacists should promote seamless care by contributing to transfer of information about medicines whenever patients move between and within healthcare settings.
- 4.6 Hospital pharmacists, as an integral part of all patient care teams, should ensure that patients and carers are offered information about their clinical management options, and especially about the use of their medicines, in terms they can understand.
- 4.7 Hospital pharmacists should inform, educate and advise patients, carers and other health care professionals when medicines are used outside of their marketing authorisation.
- 4.8 Clinical pharmacy services should continuously evolve to optimise patients' outcomes.

SECTION 5

Patient Safety and Quality Assurance

- 5.1 The "seven rights" (the right patient, right medicine, right dose, right route, right time, right information and right documentation) should be fulfilled in all medicines-related activities in the hospital.

COMMENT – *This is not an exhaustive list of 'rights' and with the increase in use of personalised medicines the 'right patient' has an additional meaning beyond just identification of the individual, it is also now whether the medicine is genetically appropriate for that individual patient*

- 5.2 Hospital pharmacists should ensure the development of appropriate quality assurance strategies for medicines use processes to detect errors and identify priorities for improvement.
- 5.3 Hospital pharmacists should ensure their hospitals seek review of their medicines use processes by an external quality assessment accreditation programme, and act on reports to improve the quality and safety of these processes.
- 5.4 Hospital pharmacists should ensure the reporting of adverse drug reactions and medication errors to regional or national pharmacovigilance programmes or patient safety programmes.
- 5.5 Hospital pharmacists should help to decrease the risk of medication errors by disseminating evidence-based approaches to error reduction including computerised decision support.
- 5.6 Hospital pharmacists should identify high-risk medicines and ensure appropriate procedures are implemented in procurement, prescribing, preparing, dispensing, administration and monitoring processes to minimise risk.
- 5.7 Hospital pharmacists should ensure that the medicines administration process is designed such that transcription steps between the original prescription and the medicines administration record are eliminated.
- 5.8 Hospital pharmacists should ensure accurate recording of all allergy and other relevant medicine-related information in the patient's health record. This information should be accessible and evaluated prior to prescription and administration of medicines.
- COMMENT** – *Ensuring there is comprehensive recording of allergies is a responsibility of all professionals within the multidisciplinary team. Hospital pharmacists should share this responsibility where there is no allergy record for a patient.*
- 5.9 Hospital pharmacists should ensure that the information needed for safe medicines use, including both

preparation and administration, is accessible at the point of care.

- 5.10 Hospital pharmacists should ensure that medicines stored throughout the hospital are packaged and labelled so to assure identification, maintain integrity until immediately prior to use and permit correct administration.
- 5.11 Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.

SECTION 6

Education and Research

- 6.1 Undergraduate pharmacy curricula should include experience of hospital pharmacy practice. The role of all hospital healthcare practitioners, including hospital pharmacists, should be integrated into the curricula of other health professionals.
- 6.2 All those involved in medicines use processes must be able to demonstrate their competency in their roles. Hospital pharmacists should participate in the development of European-wide competency frameworks to ensure standards of best practice are met.
- 6.3 A European-wide framework for initial post graduate education and training in hospital pharmacy with an assessment of individual competence is essential. In addition, hospital pharmacists should engage in relevant educational opportunities at all stages of their career.
- 6.4 Hospital pharmacists should actively engage in and publish research, particularly on hospital pharmacy practice. Research methods should be part of undergraduate and postgraduate training programmes for hospital pharmacists.
- 6.5 Hospital pharmacists should be actively involved in clinical trials of medicines.