

EAHP Statements on Hospital Pharmacy 2014 – Initial consultation version October 2013

Patients and healthcare professional's reflection on FIP Basel Statements

I. Introductory Statements and Governance			
Statement	Patients	Healthcare professionals	Hospital Pharmacists
1) The overarching goal of hospital pharmacists is to optimise patient outcomes through the judicious, safe, efficacious, appropriate, and cost effective use of medicines.	Pharmacists are trained in the use of medicines, and can advise that they are used effectively, safely and cost effectively. As a result of hospital pharmacist's professional judgement and contribution patients are provided with safe and effective treatment needed to achieve the best possible outcomes.	Doctors prescribe the therapeutic plan for their patients with the assurance that hospital pharmacists will assist in ensuring that the care provided is safe, effective, appropriate and cost effective. Nurses are provided with the prescribed medication for the patient in order for it to be administered in the appropriate and safest way.	All the work of hospital pharmacists should be conducted with the aim to ensure the optimisation of a patient's care by ensuring the safe, effective, appropriate and cost-effective use of his/her medication. Hospital pharmacists should provide the necessary information so that medicines are prescribed and administered safely and appropriately.
2) At a European level, 'Good Hospital Pharmacy Practice' guidelines based on evidence should be developed. These guidelines should assist national efforts to define recognised standards across the levels, coverage, and scope of hospital pharmacy services and should include corresponding human resource and training requirements.	Patients should be assured that for each individual patient pharmaceutical care that is provided in each hospital of any country is in accordance with European standards.	Healthcare professionals should be aware that hospital pharmacists approach their work and provide their support to all healthcare professionals is according to, defined and guided by European approved standards.	Hospital pharmacists will have clear goals and pathways to achieve excellence in their professional practice in the hospital. They are expected to contribute to and organise the work according to European guidelines concerning coverage and scope of the services provided and to assure adequate training of pharmacists with this aim.
3) Health authorities should ensure that each hospital pharmacy should be supervised by a pharmacist who has completed adequate training in hospital pharmacy. All Hospitals must have access to Hospital Pharmacy Services, including those	Without the presence and advice of hospital pharmacists medication processes may be ineffective and unsafe. Hospital pharmacists should be part of the medication processes in every hospital to ensure patient safety. The responsible pharmacist	Pharmacists help healthcare professionals to use medicines in the most effective way for the benefit of patients. Thus the expertise of hospital pharmacists should be available in every hospital. The important responsibility of advising healthcare professionals	To ensure the quality of medication processes all hospitals should have access to a hospital pharmacist's services, including hospitals without a pharmacy The head of a hospital pharmacy should be experienced due to the important responsibility and

<p>without a Pharmacy in the Hospital.</p>	<p>should be a senior professional to guarantee the quality of the counselling and practise.</p>	<p>doctors and nurses, and the requirement of high standards of practise requires a senior pharmacist supervising the hospital pharmacy.</p>	<p>therefore should have additional, specialised training in hospital pharmacy.</p>
<p>4) Health authorities and hospital administrators should bring together stakeholders to collaboratively develop and utilise evidence-based hospital pharmacy human resource plans. These should be aligned to engage hospital pharmacists in all steps of the hospital medicines-use process and to meet health needs and priorities across public and private sectors that optimise patient outcomes.</p>	<p>Current evidence based best practice for the treatment of patients is conducted through a multidisciplinary team. In order to ensure patients have the best possible outcomes whilst within the hospital, workforce planning must be conducted, in collaboration with health authorities. Hospital pharmacy staffing requirements should be agreed by all parties to avoid compromising the safety and treatment of patients.</p>	<p>There should be a structured national plan to ensure that the pharmacy services can be provided to patients and healthcare professionals. These services are proven through evidence based research to contribute to increase patient outcomes. Hospital administrations should ensure that healthcare professionals are able to refer to the expert knowledge of hospital pharmacists at all stages of the medicine-use-process. Staff shortages should be avoided by sustainable strategies.</p>	<p>Health authorities and hospital administrators should acknowledge that the role of hospital pharmacists is integral to all the medication management processes. At a national and European level there should be a structured approach to the delivery of pharmacy services. For hospital pharmacists this will mean that resources should be prioritised to areas where they are of proven benefit and deliver the optimal outcome for the patient. There should be a clear career pathway with opportunities for ongoing personal and professional development in each area of hospital pharmacy. This includes data collated at local and national level to improve human resource strategy and avoid human resource shortages through sustainable strategies for workforce supply, recruitment, and retention.</p>
<p>5) Hospital pharmacists must be members of Drug & Therapeutics Committees to oversee all medicines management policies and procedures, including those related to off-label use and novel investigational medicines.</p>	<p>Patients can be assured all medication policies and practices are co-ordinated through one multidisciplinary committee in the hospital. The medication use process appraisal is done by a multidisciplinary team which includes hospital pharmacists, who are experts in medication.</p>	<p>Doctors and nurses base their practice of prescribing and administration of drugs (including those related to off-label use and investigational medicines) on policies and procedures established by the Drug & Therapeutics Committee, a multidisciplinary team that includes several experts including hospital pharmacists.</p>	<p>Hospital pharmacists are key resource of the Drug & Therapeutics Committee. The Hospital Pharmacist must provide all the relevant information to the committee as well as managing the practice changes that arise from the committee decisions. This will be measured by the change management processes and clinical audits.</p>

<p>6) Hospital pharmacists should 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. Hospital pharmacists must be involved in the design, specification of parameters and evaluation of ICT within the medicines processes.</p>	<p>Modern advances in technology can improve patient safety regarding medication use. The eHealth and mHealth technologies help patients use their medicines more effectively and safely from anywhere they are. Patients can be sure that their health data are completed reliable and secured because of the contribution of hospital pharmacists in the developing procedures and evaluation of their medication records.</p>	<p>Doctors and nurses may rely on the hospital pharmacists knowledge on the new technology and collaborate in order to have complete and secure health patient records easily accessible from anywhere by all new devices, such as laptops, tablets, kiosks, smartphones, etc.</p>	<p>Modern advances in technology can improve patient safety regarding medication use. For this reason hospital pharmacists should be involved in the planning, and utilisation of these technologies.</p>
<p>7) Health systems have limited resources and their use should be based on rational use. Hospital pharmacists should develop, together with other healthcare professionals, criteria in order to focus the activities of the Hospital Pharmacy ensuring the maximum outcomes for patients.</p>	<p>All patients will receive treatment required and the care by hospital pharmacists where appropriate. It is important to identify criteria in order to focus on the activities of the hospital pharmacy ensuring the best possible outcome for patients in line with the available resources.</p>	<p>Health systems have limited resources and their use should be based on rational use. Hospital pharmacists should develop, together with other healthcare professionals, criteria in order to focus on the activities of the hospital pharmacy ensuring the minimal impact for patients.</p>	<p>Criteria should be developed in-formally together with other healthcare professionals and administrators. The criteria should be rational, ethical and based on agreement of all parties.</p>

II. Selection, Procurement & Distribution			
Statement	Patients	Healthcare Professionals	Hospital Pharmacists
<p>8) Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital pharmacists should establish procedures of procurement based in principles of safety and quality of medicines according to the best practices and in line with national legislation.</p>	<p>Patients can be assured that the processes of selection and purchase of all medicines used in hospitals for inpatients and outpatients are undertaken / supervised by pharmacists, to ensure the appropriate safety and quality. The medication for patient's treatments is selected with all the ethical, professional, legal and transparent procedures</p>	<p>Doctors and nurses need to be aware that procurement is a complex process and when managed by pharmacists and competent staff ensures that appropriate quality control and safety measures are in place to provide the medicines required to patients. To avoid medication errors pharmacists minimize look- and sound alike (LASA) medicines on the formulary. The procurement process will address all</p>	<p>Standard operating procedures must be in place to guide the procurement process. These operating procedures must be in compliance with legal requirements, professional and ethical. They should be audited and regularly reviewed to ensure the process is transparent. The procurement process must be:</p> <ul style="list-style-type: none"> - Ethical, transparent and professional;

	<p>guaranteeing the quality of patient's medication and the equity of access. A good procurement process will have an impact on patient outcomes by having high quality medicines available in the right place and at the right time.</p>	<p>legal and professional standards and provide the right medicines to be prescribed in the appropriate formulation for administration.</p>	<ul style="list-style-type: none"> - Under pharmacy control and technically competent staff; - Guided by the principle of procuring for safety and efficacy - Guided by principles of equity of access and ensuring accountability to relevant governing and legal entities; - Supported by strong quality assurance principles; - Regularly reviewed and updated on its operational principles to fit different settings and emerging needs; - Guided by best utilisation of finance resources
<p>9) Hospital pharmacists should have responsibility for the management of medicine use processes and medicine related technologies.</p>	<p>Patients can be assured that the selection and all process use of medication and other health technologies (e.g. medicine-related devices) in the hospital are under the authority of hospital pharmacists whose expertise is available to all. Having a clear chain of responsibility with the professionals well trained in medications ensures the medication supply for the patient in a cost effective manner</p>	<p>Hospital pharmacists have a responsibility to ensure that the medicines prescribed by doctors and the medication related devices to be used by nurses for the patients needs are of appropriate quality. Doctors and nurses should have sufficient information available to use medicines safely and correctly and that this should be accessible in a timely manner to healthcare professionals and to patients. Having a clear line for consultation on all medicine related devices means that the concerns of prescribers are taken into consideration when selecting the devices for use in the hospital.</p>	<p>Hospital pharmacists should collaborate with doctors and nurses on the wards in order to have detailed procedures for the medicine use process, the selection and use of medicine-related devices such as administration devices, giving sets, infusion pumps and computer-controlled dispensing cabinets, as well as the selection of drugs and pharmaceutical products to be included in the ward stock.</p>
<p>10) Hospitals should utilise a medicine formulary system, local, regional and/or national. The medicine formulary system should</p>	<p>Patients can be assured that the medicines used in the hospital undergo a robust assessment process underlying the formulary</p>	<p>Healthcare professionals must be aware that in the hospital all medicines prescribed and administered are selected based on an evidence based</p>	<p>Hospital pharmacists should establish formulary system procedures linked to guidelines and evidence based pathways. A reliable information system</p>

<p>be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence.</p>	<p>system. Standardisation of concentrations of medicines should be used in order to avoid medication errors, increasing patient safety. Paediatric, neonatal and critical care patients are especially at risk of medication error and thus standardisation of medication use is very important in those groups.</p>	<p>formulary system. This selection is linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence, supported by a reliable information system and also considering the risks associated with medicine use. Medicines will be provided in the formulation and concentrations appropriate for the patient groups in line with available resources.</p>	<p>should provide accurate, timely, and accessible information and should help to promote the use of standard concentrations of medicines. In the selection of medicines for the formulary international, national and local treatment guidelines and protocols and manufacturer information should all be considered. The formulary should be accompanied by a comprehensive internal information system to guarantee the proper use of the listed medicines. Accurate, timely, and accessible information should be available promoting the use of standard concentrations especially for high risk patient groups.</p>
<p>11) Procurement must be according to the medicine formulary and informed by the formulary selection process.</p>	<p>Patients can rely on the medicines available in hospital because they all are assessed by experts for their safety, appropriateness and cost effectiveness in accordance to the best national and international practice. All members of the care team are well informed about the medicines used in the hospital.</p>	<p>Doctors and nurses must be aware that there is an agreed list of medicines within the hospital which have been approved for use. Medicines that are not on the formulary, but considered necessary for the patient's treatment, can be submitted for consideration, assessment and addition to it. The assessment process will be undertaken in an ethical and professional manner. The pharmacist will procure medicines in accordance with the evidence based decisions of the Drug and Therapeutics Committee</p>	<p>Hospital pharmacists should establish procedures for procurement based on the hospital formulary. There should be appropriate procedures in place to assess medicines for addition to the formulary. The assessment process should be undertaken ethically and fairly. Hospital pharmacists as part of the DTC must provide all the relevant information to the committee and manage the practice changes that arise from the committee decisions. This will be measured by the change management process and clinical audits.</p>
<p>12) Each hospital pharmacy should have contingency plans for shortages and purchases for all medicines and products under its</p>	<p>Patients can be assured that contingency plans for shortages are well established by hospital pharmacists to obtain all medication</p>	<p>Doctors will face fewer barriers in prescribing habits and nurses will face fewer problems, while there are contingency plans for medicines</p>	<p>Hospital pharmacists should establish contingency plans for shortages and purchases in emergencies for medicines and all products under their</p>

<p>responsibility.</p>	<p>needed or alternative supplies. This includes whenever there is a shortage it or an emergency, ensuring a continuous supply of medicines is a high priority for the pharmacy service.</p>	<p>shortages and purchases in emergencies established by hospital pharmacists. Ensuring the appropriate medicines are available for the patients is a high priority for the pharmacy department. Hospital pharmacists' goal is to minimise any interruption to the treatment of the patients. If a medication required for prescribing is not obtainable the pharmacist will discuss with doctors the possible alternative treatments. Hospital pharmacists will advise on contingency supplies for emergencies and for supply shortages and will enable ease of access to government schemes for medication access, as appropriate.</p>	<p>responsibility . They should organise a formal mechanism for pharmacists to request designated funds, if this possibility exists to procure medicines for the patients. Hospital pharmacists should have clear and transparent policies for procurement during shortages and during emergencies. Hospital pharmacists should remain knowledgeable about all government schemes to assist with the supply of medication and should engage with all procedures to aid with the supply of medications to patients in line with available resources</p>
<p>13) Hospital pharmacy departments should have responsibility for all medicines logistics in hospitals. This includes proper storage, preparation, dispensing, and distribution conditions for all medicines and pharmaceutical products used in the hospital, including investigational medicines.</p>	<p>Patients can rely on the conditions of storage, preparation, dispensing, distribution and administration of medicines in the hospital. The pharmacist who is the expert in the management of medicines within the hospital is responsible for ensuring that the medicine required is available in the best conditions when patients need it, including investigational medicines. That means that medicines are stored in appropriate conditions and that other healthcare professionals have sufficient information available on how to prepare and administer them to patients.</p>	<p>Doctors and nurses should be aware that all logistics procedures for medicines, including investigational medicines, and pharmaceutical products are under the control of hospital pharmacists. Their specialised training provides the assurance that the recommendations made on the storage, preparation, dispensing and distribution of medicines will aim to ensure the integrity of the medicine in the hospital. They are also available to provide information required to prepare and administer the medicine safely.</p>	<p>Hospital pharmacists should have the responsibility for all medicines logistics in hospitals, including the proper storage, preparation, dispensing, and distribution conditions for all medicines, including investigational medicines and pharmaceutical products used in the hospital. Hospital pharmacists should establish standard operational procedures on the appropriate storage, preparation and distribution of medicines. Hospital pharmacists should clearly set out the distribution processes having regard to the nature of the product and the correct ordering, dispensing storage and handling requirements. Hospital pharmacists should address the needs of the healthcare professional to have user friendly access procedures in place that</p>

			address the professional responsibilities. Hospital pharmacists should have a complaints/comments system in place to identify issues with the distribution systems
14) Hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients, by evaluating the appropriateness of all medication including herbal and dietary supplements. All the medicines brought by patients should be registered on the medical record.	For patients' safety, all medication, herbal and dietary supplements brought into the hospital should be registered in patient's medical record, used, and stored according to the policies established in the hospital. Patients' specific medication policies should assist in increasing patient's knowledge of their medication and increase adherence.	Doctors and nurses can rely on the support of hospital pharmacist to establish policies regarding the use and storage of medicines, herbal and dietary supplements brought to hospital by the patients in order to ensure patient safety if the use of such medication and other products is required. Doctors, nurses and hospital pharmacists should collaboratively complete the patient's record concerning all the medicines brought into the hospital by the patient, including the herbal and dietary and should follow the policies established.	Hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients, including the evaluation of appropriateness of herbal and dietary supplements. Hospital pharmacists have a duty of care to assist patients in managing their medications. Patient own medication policies should address adherence and medication issues across the primary secondary care interface.

III. Production & Compounding			
Statement	Patients	Healthcare professionals	Hospital Pharmacists
15) Medicines not commercially available for special groups of patients that require compounding or production should be prepared by a hospital pharmacy.	Not all medicines that patients need are commercially available. Pharmacists are the only healthcare professionals who have the professional education and facilities to prepare safe medicinal products for individual patients or small populations.	Not all medicines that patients need are commercially available. Pharmacists are the only healthcare professionals educated in producing safe medicines for individual patients or small population and should do so if required. Healthcare Professionals can be assured of the quality and safety of these medicines produced.	Hospital pharmacy should have the facilities or arrangements in place for the production of medicines for individual or small patient populations, when not commercially available. The Hospital Pharmacist should be aware of compounding and production practices within the hospital and should attempt to conduct this activity in the hospital pharmacy.
16) Hospital pharmacists should appropriately develop pharmacy-managed injectables using aseptic	Injectable mixtures are prone to contamination for patients especially neonatal and paediatrics ones, which	Preparing mixtures that are to be injected are at an increased risk to contamination, if not properly prepared.	Hospital pharmacists should make a register of preparations that are made on the ward.

<p>technique.</p>	<p>can have serious consequences. The pharmacy should therefore develop services to improve the safety of such injectable mixtures.</p>	<p>Other healthcare professionals on the ward do not have access to the facilities of the hospital pharmacies. Thus centralised services in the pharmacy can support healthcare professionals by improving the safety of such preparations.</p>	<p>Hospital pharmacists should check the capacity of their staff and facilities in order to reconstitute medication. Hospital pharmacists should aim to centralise aseptic preparations by offering Good Practice for the preparation of medicinal products based services.</p>
<p>17) When reconstitution takes place in the ward, a hospital pharmacist should approve written procedures and ensure that staff involved in reconstitution are appropriately trained.</p>	<p>Not all injectable preparations can be prepared by the pharmacy. In such cases, hospital pharmacists have the competency to define safe procedures to be used by another healthcare professionals to avoid patient harm.</p>	<p>Not all injectable preparations can be prepared by the pharmacy. In such cases, hospital pharmacists should support other healthcare professionals, nurses and doctors by describing feasible procedures for safe and preparation and administration.</p>	<p>Where it is not feasible for the hospital pharmacy to prepare such medicines e.g. they do not have aseptic facilities, then hospital pharmacists should be involved in ensuring there are appropriate policies and protocols in place for preparation to be undertaken safely at ward level. Only reconstitution considered low risk should be prepared at ward level. In addition the staff preparing the medicines should have received training and be competent to undertake reconstitution.</p>
<p>18). Hazardous medicines including cytotoxics, radiopharmaceuticals and gene therapy should be prepared under appropriate conditions that minimise the risk of contaminating the product and exposing hospital personnel and patients to harm.</p>	<p>Hazardous medicines such as cytotoxics, radiopharmaceuticals and gene therapy need special handling. Hospital pharmacists have the facilities and the skills to produce safe preparations.</p>	<p>Hazardous medicines such as cytotoxics, radiopharmaceuticals and gene therapy can harm healthcare professionals if prepared on the ward. Hospital pharmacists have the facilities and the skills to produce safe preparations and thus reduce the risk of such harm.</p>	<p>Centralised cytotoxic preparation using safe technique and appropriate technology should be implemented in every hospital handling with such drugs.</p> <p>Hospital Pharmacists should ensure that policies are in place to prohibit the preparation of cytotoxic drugs at ward level, including when they are clinically needed in emergency situations.</p>
<p>19) Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply</p>	<p>To avoid harm to patients, medicines must be produced using high quality ingredients. National and internationally validated methods</p>	<p>Healthcare professionals should be aware of the quality of the products prepared by the pharmacy. To assure that all starting materials and</p>	<p>All ingredients used in preparations should be analysed using national and internationally validated methods (pharmacopeia and similar standards).</p>

<p>with quality standards.</p>	<p>should be used in the pharmacy in order to guarantee the quality of the starting materials and as a consequence the final product.</p>	<p>as consequence the final product have high quality hospital pharmacists should use national and international validated methods (pharmacopeia and similar standards).</p>	<p>Certificates of external providers should also fulfil the requirements of such standards. The risk assessment should consider the contribution of active pharmaceutical ingredients and excipients to the safety profile of the pharmacy preparation. Where appropriate, active pharmaceutical ingredients manufactured according to best practice and analysed according to pharmacopoeial standards should be used. The chemical, pharmaceutical and microbiological quality of the starting materials should be fit for pharmaceutical use and be demonstrated on the basis of validated methods.</p>
<p>20) Before preparation the pharmacist should verify whether preparations are of added value due to medical, pharmaceutical or personal reasons, needed by a specific patient or by specific population groups with particular needs. The hospital pharmacist should be able to refuse a request for a pharmacy preparation if there is a suitable commercially available pharmaceutical equivalent. Essential information about the product, based on the product dossier should be made available to patients and other healthcare</p>	<p>Individual preparations can improve the outcome of patients. If there is a perceived benefit for a particular patient/patient group, a discussion between the prescriber and the pharmacy should take place, especially if there is a commercially available suitable pharmaceutical equivalent.</p> <p>All patients should be informed about the risk/benefit assessment for their treatment.</p>	<p>The decision on whether an individual preparation may improve the patient's outcome is a complex one and doctors and pharmacists should therefore make a joint assessment of the risk/benefit balance considering all aspects (therapeutic, pharmaceutical, environmental and personal). The professionals involved in patient care should jointly assume responsibility in this assessment for determining the added value of a pharmacy preparation.</p>	<p>Pharmacy preparations are not advisable if a suitable pharmaceutical equivalent with a marketing authorisation is available. Before preparation the pharmacist should verify whether a pharmaceutical equivalent is available, taking into account pharmaceutical form and the strength. Hospital pharmacists should develop together with doctors and other healthcare professionals criteria for the risk/benefit assessment. This criteria may consider</p> <ul style="list-style-type: none"> • The individual situation of the patient • The availability of a validated formula

<p>professionals.</p>			<ul style="list-style-type: none"> • The availability of ingredients of pharmaceutical quality • The equipment necessary for safe preparation (e.g. clean rooms) • The experience and skill of personnel
<p>21) When making a pharmacy preparation, the pharmacist should always undertake an appropriate risk assessment in order to determine the level of the quality system which should be applied to the preparation of the medicinal product. Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured through the whole process from production to administration.</p>	<p>If the risk/benefit assessment is positive the pharmacist should decide about the necessary level of interventions necessary to optimize the quality of the produced medicine. Unambiguous and complete labelling is paramount to avoid any confusion, misinterpretation or administration error in the whole process.</p>	<p>Doctors and nurses should rely on the pharmacist as the expert in deciding about the necessary level of interventions necessary to optimize the quality of the produced medicine. Unambiguous and complete labelling is paramount to avoid any confusion, misinterpretation or administration error in the whole process.</p>	<p>Patients have the right to get the best quality of medicines independently from industrial production or individual preparation. Hospital pharmacists should guarantee that</p> <ul style="list-style-type: none"> • The facilities of the pharmacy are adequate • The personnel is trained • The production procedure is defined and validated • The quality of all starting materials is appropriate • The packaging material is appropriate and compatible to the product • The labelling is unambiguous, complete and based on principle of safe administration <p>Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured through the whole process from production to administration.</p>
<p>22) An appropriate system for quality control and quality assurance should in place, ensuring traceability for pharmacy produced</p>	<p>In case of adverse events a patient has the right to get all information necessary to check whether the event was unavoidable and not due</p>	<p>In case of adverse events, doctors or nurses should have the possibility to examine the manufacturing records to see whether the produced medicines</p>	<p>In case of adverse events the pharmacy has to demonstrate that all quality requirements were fulfilled in the production of the medicine of interest.</p>

<p>and compounded medicines, in the interest of patient safety.</p>	<p>to a ineffective medicine. Thus a tracking system is necessary to assure the information flow.</p>	<p>fulfilled all quality requirements. This is only possible if the pharmacy implements an appropriate tracking system.</p>	<p>Hospital pharmacists should</p> <ul style="list-style-type: none"> • Define written procedures for all individual preparations • Record all individual preparations in a database • Create a tracking system
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<p>IV. Clinical Services</p>			
<p>Statement</p>	<p>Patients</p>	<p>Healthcare professionals</p>	<p>Hospital Pharmacists</p>
<p>23) Hospital pharmacists should be involved in all patient care areas to prospectively influence collaborative therapeutic decision-making and should have access to the patients' health record.</p>	<p>Collaborative care is recognised to provide the best outcomes for patients. Therapeutic decision-making is an interdisciplinary activity where all healthcare professionals should be involved. Patients should be aware that Hospital pharmacists contribute to the safe and effective use of medication. Full access to all clinical data of patients allows Hospital pharmacists to fulfil their role.</p>	<p>Collaborative care is recognised to provide the best outcomes for patients. Therapeutic decision-making is an interdisciplinary activity where all healthcare professionals should be involved. Healthcare professionals can rely on Hospital pharmacists to contribute to safe, efficacious and cost-effective use of medication. Full access to all clinical data of patients is required to fulfil this role</p>	<p>Hospital pharmacists should provide basic clinical services to the greatest extent possible and should pursue the expansion of these activities. Hospital pharmacists should be integrated into health care teams and accepted as decision-makers regarding medication use. Hospital pharmacists should have full access to all clinical data of patients in order to fulfil this role.</p>
<p>24) Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients outcomes.</p>	<p>Patients are aware that hospital pharmacists during their clinical activities should be consulted and may intervene before, during and after treatment.</p>	<p>Errors can occur during prescription and administration of medicines, as highlighted in scientific literature. Healthcare professionals should employ the hospital pharmacists' clinical pharmacy skills in high-risk situations where pharmaceutical care is required (such as management of anticoagulation therapy, antimicrobial therapy, and therapeutic drug monitoring). Hospital pharmacists can contribute to the appropriate use of medicines at all stages, starting with the perceived need for a particular medicine for prescribing</p>	<p>Hospital pharmacists should manage medication therapy for high risk patients. Hospital pharmacists should have an overview of all medication therapies for patients under their care and record pharmaceutical interventions with the aim to improve quality and safety of all medication use.</p>

		and ending with the assessment and monitoring of its efficacy and tolerability for patients after administration.	
25) Hospital pharmacists are an integral part of all patient care teams to assist with therapeutic decision-making and advise on clinical pharmacy and patient safety issues. This ensures that Hospital pharmacists are accessible for patients and other healthcare professionals.	Patients can be assured that Hospital pharmacists are part of patient care teams providing knowledge and skills regarding medicines and their use to assist with therapeutic decision-making and advise on clinical pharmacy and patient safety issues. Due to their education Hospital pharmacists are a bridge between different healthcare professionals (doctors and nurses) wherever medication is requested.	Healthcare professionals can rely on the participation of hospital pharmacists in patient care teams to assist with therapeutic decision-making and advice on clinical pharmacy and patient safety issues. This should be widely encouraged and considered as a basic step in routine pharmaceutical care for patients.	Hospital pharmacists must develop sustainable clinical services and maintain a consistent high standard of practice in order to ensure optimal patient outcomes. It is necessary to invest in training and specialisation to develop greater clinical accuracy, experience and awareness. National and European guidelines should assist hospital pharmacists in the implementation and development of such programs.
26) All prescriptions should be reviewed and validated by a hospital pharmacist prior to dispensing and administration of medication.	Patients can rely on hospital pharmacists as they contribute to reducing the risk of medication errors. Hospital pharmacists also contribute to the appropriate use of medicines to reach the optimal patient outcomes by monitoring all patients receiving treatment.	Healthcare professionals can rely on hospital pharmacists to contribute to reduce the risk of medication errors. They also contribute to the appropriate use of medicines by providing advice regarding the medication therapy as well as monitoring the patients	Hospital Pharmacists should systematically review and validate all prescriptions prior to dispensing and administration of medication Hospital Pharmacists should contribute in the definition of procedures for correct prescription and administration of medicines. Hospital pharmacists should continue to monitor all patients who receive medicines to ensure appropriate medication use and optimal outcomes.
27) Pharmacists' clinical interventions should be documented in the patients' health record	In the interest of patient safety the patients' health records should be complete, exhaustive and include all contributions provided by all health care professionals involved in their care, including interventions made by hospital pharmacists.	Healthcare professionals can expect hospital pharmacists to contribute to patients' health records ensuring they are complete, exhaustive and accurate. This includes pharmaceutical advice, recommendations and all interventions conducted by the pharmacy team. The documentation is also necessary to	Hospital pharmacists are accountable for their practice, including pharmaceutical advice, validation and any recommendation. All interventions should be documented in the patients' health records for reasons of traceability, necessity, and patient safety. Hospital pharmacists should

		support any therapeutic decision by doctors.	contribute in the definition of procedures and a classification system of such records.
28) Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings	When a patient is transferred between healthcare settings there is a risk of error due to lost information in the process, as highlighted in scientific literature. Patients can expect hospital pharmacists to transfer information about their medication whenever they are moved to another healthcare setting, to provide safe and optimal continuation of treatment.	Complex medication treatments need clear information transfer which should be provided by using the comprehensive knowledge and understanding of medicines of hospital pharmacists	Hospital pharmacists should contribute to transfer all medication information whenever patients are moved in another sector of care including different units of the hospital. Hospital Pharmacists should attempt to resolve any medication related issues and use a pharmacy information record to communicate this information. If not established hospital pharmacists should establish this record.
28) Hospital pharmacists should ensure that patients are educated on the appropriate use of their medicines.	Inappropriate handling of medicines can reduce and even eliminate the effect of medicines. Patients (or their caregivers) can rely on hospital pharmacists to provide information about their medicines, so that they can manage their medication independently, ensuring optimal outcomes and to prevent re-admission. Hospital pharmacists have the responsibility, competencies and the interest to provide this advice.	Healthcare professionals can rely on hospital pharmacists to provide adequate information (written instructions and verbal counselling) to patients regarding their medication. If appropriate, additional education regarding medication use can be provided. This is so that the patients can manage their medication independently or with the assistance of a caregiver to ensure optimal outcomes.	Hospital pharmacists should facilitate the provision of instructions, education and counselling to patients and/or their caregivers when deemed appropriate.

V. Patient Safety and Quality Assurance			
Statement	Patients	Healthcare professionals	Hospital Pharmacists
30) The "seven rights" (the right patient, right medicine, right dose, right route, right time, right information and right documentation) should be fulfilled	Hospital pharmacists aim to ensure that patients receive the right drug at the right dose, via the right route at the right time. Patients should be informed about their medication and	Hospital pharmacists aim to ensure that patients receive the right drug at the right dose, via the right route at the right time. Only medicines administered at the correct time are effective. Hospital	Hospital pharmacists should promote the availability of internal procedures that describe the fulfilling of the "seven rights" of the patient. Hospital pharmacists should be involved

<p>in all medicines-related activities in the hospital.</p>	<p>are entitled to be provided with all information regarding their treatment. Documentation and information are also required for continuous assessment.</p>	<p>pharmacists ensure that the seven rights of the patient are adhered to, assisting other healthcare professionals. Complete documentation is vital for accountability and continual assessment. Hospital pharmacists should assist other healthcare professionals completing relevant documentation and checking all aspects of medication before administration.</p>	<p>in the education of health professionals on the "seven rights". Hospital pharmacists should supervise that the internal procedures are respected and must document their pharmaceutical interventions.</p>
<p>31) Hospital medication practices should be reviewed by an external quality assessment accreditation program. Hospitals should act on reports following regular external quality assessment inspections to improve the quality and safety of their practices.</p>	<p>The safety of patients is the primary goal of the hospital pharmacist. Hospitals that fulfil quality and safety criteria from external accreditation programs ensure that continuing improvement practices are implemented in order to minimise errors</p>	<p>The medication practice process is very complex and external assessment programs help to identify critical aspects of the organisation and initiate appropriate preventive/corrective measures to achieve patients' safety.</p>	<p>Hospital pharmacists should conduct self assessment activities to identify critical aspects in the medication process and communicate them internally to other healthcare professionals and hospital administrators Hospital pharmacists should promote adherence to external quality assessment inspections/audits. Hospital pharmacists should be involved and lead projects to improve quality and safety of the medication practices as risk management process. Examples include projects in areas of patient safety protocols, active pharmacovigilance, therapeutic reconciliation, discharge counselling and follow up, and transition of care programs.</p>
<p>32) Hospital pharmacists should ensure the development of quality assurance strategies for medication practices, including the use of observation methodology to detect errors and identify priorities for improvement.</p>	<p>Healthcare teams continually review the medication procedures to improve safe medication practices for patients. Despite the continuous efforts to do this, mistakes and errors do occur. Reporting of errors and events of near misses* are essential to improve patient safety.</p>	<p>Healthcare professionals should collaborate with the hospital pharmacist to improve patient safety, by developing strategies for medication practices, including different methods to detect errors and identify priorities for improvement. Reporting of errors and events of near</p>	<p>Hospital pharmacists should promote the reporting of errors and events of near-misses by all health professionals in the hospital. Hospital pharmacists should be actively involved in the discussion forum that analyses the events and identifies corrective measures. Hospital</p>

	<p>Patients can rely on the strategies implemented in hospitals for quality assurance to detect errors and identify priorities for improvement and prevent the same error occurring.</p> <p>* Events, situations, or errors that took place but were captured before reaching the patient. (www.ismp.org)</p>	<p>misses are essential to improve patient safety.</p>	<p>pharmacists should develop simple, rules-based approaches to advancing patient safety</p>
<p>33) Hospital pharmacists should decrease the risk of medication errors by implementing evidence-based systems or technologies systems.</p>	<p>Medication errors can occur due to failures of the procedures. Scientific literature suggests one way to decrease errors is by implementing evidence-based systems or technology systems (e.g. scan-technology or unit dose distribution).</p>	<p>Evidence-based systems or technology systems (e.g. scan-technology, electronic prescribing or unit dose distribution) are useful instruments to improve prescription practices and avoid adverse events. Evidence-based systems or technology systems are also useful instruments to improve preparation and administration practices and avoid medication errors.</p>	<p>Hospital pharmacists should define the appropriate system to implement in their hospitals (such as automated prescription-filling, unit dose distribution, bar coding, or others) to improve patient safety. Hospital pharmacists should make sure that all conditions are fulfilled prior to implementation. Hospital pharmacists should establish the safety rules regarding processes/technology used and monitor the new process and assess the impact on medication errors</p>
<p>34) The medicines administration process should be designed so that transcription steps between the original prescription and the medicines administration record are eliminated.</p>	<p>Transcription of medical prescription on patients' health care records is prone to errors and should be eliminated by implementing safe systems.</p>	<p>In order to achieve patient safety transcription of medical prescriptions on patients health care records should be eliminated as it is known to be a major cause of medication errors.</p>	<p>Hospital pharmacists should define together with other healthcare professionals the medication process to proceed with prescribed medicines and their administration without transcription. Ideally an electronic integrated system of prescription, pharmaceutical validation and administration should be defined by users, implemented and monitored.</p>
<p>35) High risk medicines should be identified and appropriate procedures implemented that</p>	<p>Errors with high risk medicines may be fatal for patients, it is therefore necessary that independent check</p>	<p>The prescription of high risk medicines is prone to errors which could be fatal and should be validated by hospital</p>	<p>Hospital pharmacists should identify high risk medicines used in the hospital. Hospital pharmacists should define the</p>

<p>assure additional checks prior to dispensing and administration.</p>	<p>procedures prior to administration are implemented. Hospital pharmacists should be involved in this process to ensure patient safety.</p>	<p>pharmacists prior to dispensing, compounding or administration. High risk medicines should be checked for the "seven rights" prior to administration independently by two health care professionals according to the appropriate and approved in-process checking.</p>	<p>appropriate in-process checking prior to administration. Hospital pharmacists should be actively involved in the implementation of the procedures. Examples of best practice are e.g.</p> <ul style="list-style-type: none"> • labelling of intravenous tubing near insertion site to prevent misconnections • use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines • dispensing ready-to-administer dilutions of concentrated electrolyte products (such as potassium chloride and sodium chloride) • Oral syringes that are distinctly different from hypodermic syringes
<p>36) 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.</p> <p>Premises, facilities and pharmaceutical knowledge should be appropriate for the preparation of the medicinal product and correct labelling should be assured through the whole process from production to administration.</p>	<p>To assure safe administration and avoid any confusion, medicines should be packaged and labelled adequately and stored appropriately prior to use.</p> <p>Unambiguous and complete labelling is paramount to avoid any confusion, misinterpretation or administration error in the whole process.</p>	<p>All medicines should be packaged and labelled adequately and stored appropriately prior to use in order to avoid confusion or medication errors.</p> <p>Unambiguous and complete labelling is paramount to avoid any confusion, misinterpretation or administration error in the whole process.</p>	<p>Hospital pharmacists should consider criteria of labelling and packaging when purchasing medicines and should guarantee appropriate labelling and packaging of medicines produced by the hospital pharmacy.</p> <p>Hospital pharmacists should ensure that medicines stored on the wards and prepared on the wards meet the required safety criteria.</p> <p>Hospital pharmacists should report inadequate labelling and packaging of purchased medicines to the authorities.</p>
<p>37) Hospital pharmacists should</p>	<p>Adverse drug reactions can occur</p>	<p>Reporting of adverse drug reactions is a</p>	<p>Hospital pharmacists should promote</p>

<p>promote the reporting of adverse drug reactions and the forwarding of these to regional or national pharmacovigilance reporting programs where these are available. The monitoring data should be regularly reviewed to improve the quality and safety of medication practices.</p>	<p>and must be monitored constantly after marketing approval. The aim of pharmacovigilance reporting programs is to enable authorities to collect the necessary data update the risk-benefit assessments regarding medicines.</p>	<p>requirement in order to obtain sufficient data to improve quality and safety of medication practices. Hospital pharmacists can support healthcare professionals to increase reporting and review medication practices.</p>	<p>national adverse drug reaction reporting systems, or the establishment of a system if regional or national pharmacovigilance reporting systems are not already in place. Hospital pharmacists should assist health care professionals to increase reporting. Hospital pharmacists should be involved reviewing and monitoring data and define any action needed to improve internal medication practices.</p>
<p>38) Hospital pharmacists should promote accurate recording of all allergy information in the patients' health record. This information should be accessible and evaluated prior to prescription and administration of medicines</p>	<p>Administration of a medication to a patient with allergy may be fatal. The patient's health record should include allergy data and the information has to be checked prior to prescription and administration.</p>	<p>All healthcare professionals are responsible to ensure allergy information is in the patients' health record. The information should be available during the medication use process so that all possible allergies can be taken into consideration prior to medication use. Pharmacists can support doctors by performing comprehensive medication histories and documenting accordingly.</p>	<p>Hospital pharmacists should assist with the definition of allergy (and intolerance), the location of the patients health record where the information should be included and the internal procedure when and how allergies are checked (yes-no). Hospital pharmacists involved in the medication process (e.g. validation of prescription, preparation of medication, distribution) must ensure that the information is available prior to proceed other activities.</p>
<p>39) Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.</p>	<p>Medicines dispensed by the pharmacy can be subject to recall and should be identified as soon as possible to avoid administration of a qualitatively inadequate product or to enable to contact the patient if necessary.</p>	<p>Traceability of medicines is an important topic not only in case of recall but also to track administration of specific products such as biological medicines.</p>	<p>Hospital pharmacists should ensure a system that enables tracing of distributed medicines. Hospital pharmacists should define the list of medicines that require tracing of batch number on the patients' health record and guarantee that all health care professionals are informed and proceed. Hospital pharmacists should implement a system that enables automatic batch tracing on the patients' health record e.g. using barcoding.</p>

<p>40) Hospital pharmacists should ensure that the information resources needed for safe medicines use, preparation and administration are accessible at the point of care.</p>	<p>Multidisciplinary collaboration improves medicines utilisation and so patient safety. To guarantee correct preparation and administration of medicines health care professionals require specific competencies and need to have access to adequate information and recommendations at the point of care.</p>	<p>Hospital pharmacists assist other healthcare professionals by giving adequate information and recommendations to have a complete prescription that permits correct preparation, administration and use of medicines. Adequate information and recommendations should be available while preparing and administering medicines.</p>	<p>Hospital pharmacists should ensure that the officially recognised drug information by the authorities is available to all healthcare professionals. If such references are not available, a list of generally accepted references should be provided. Hospital pharmacists should develop written recommendations for specific medicines that require special attention to ensure correct preparation and administration. Hospital pharmacists should purchase and distribute ready-to-use medicines whenever possible and available..</p>
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VI. Education and Research			
Statement	Patients	Healthcare Professionals	Hospital Pharmacists
<p>41) Undergraduate pharmacy curricula should include an introduction to hospital pharmacy practice. The role of hospital pharmacists should be promoted in the curricula of other health professionals.</p>	<p>Only well trained pharmacists can provide the best service for patients. Patients can expect qualified well trained professionals in hospital pharmacy, so that all hospital pharmacy services are safe and of a high quality. Other healthcare professionals should be aware of the high level of education of hospital pharmacists in order to promote collaborative care.</p>	<p>Doctors should expect in the clinical team a well-educated pharmacist in hospital pharmacy, who can convey the highest level of professionalism and support for prescribing. Nurses can expect colleagues in the team highly educated in the medication management, so that they can rely on the decisions coming from them. To promote collaborative care it is necessary to make other health professionals more aware of the competencies achieved by pharmacist's education.</p>	<p>Hospital pharmacists should collaborate with the academic staff of the clinical team in order to advise them on prescribing courses. Competency is essential and enables the collaboration with other health professionals. Postgraduate training and specialisation programs based on a competency framework should be created and monitored by national societies and accredited by appropriate authorities. The content of these programs should be equivalent in all countries in Europe. Collaborative care can be only realised if other health professionals are aware of the competencies achieved by</p>

			pharmacist's education.
42) Post graduate education in the hospital setting, with a final assessment of individual competency is essential to ensure that where pharmacists are providing hospital pharmacy services, patients benefit from the highest levels of expertise.	The selection, supply, prescription and administration of medicines used in a hospital setting are complex processes. Training to fulfil various competencies to work independently is needed in addition to the basic education of a pharmacist. Post graduate education is essential to ensure all patients benefit from the highest level of medication expertise.	The selection, supply, prescription and administration of medicines used in a hospital setting are complex processes. The lack of an EU level mutual recognition of Hospital Pharmacy as a structured specialisation creates substantial differences in the qualifications of pharmacists working in hospitals. Post graduate education is essential to ensure all patients benefit from the highest levels of knowledge, skill and experience in medication.	The lack of an EU level mutual recognition of Hospital Pharmacy as a structured specialisation creates substantial differences in the qualifications of pharmacists working in hospitals. Post graduate education is essential to ensure all patients benefit from the highest levels of knowledge, skill and experience in medication. The basic education required by European Directive 2005/36/EC does not provide sufficient competences. Following review of this directive a pan-European framework to recognise hospital pharmacy as a specialisation can be developed in line with similar specialisations in other fields of healthcare.
43) Hospitals should use a European accepted competency framework to assess individual human resource training needs and performance of hospital pharmacists. This should be defined and used regularly to assess all candidates.	To assure that in all European countries pharmacists provide a similar level of service to patients it is necessary to harmonise the education by creating a competency framework based on job description, skills, education, specific roles and Continuous Professional Development (CPD).	Healthcare professionals should be aware that the hospital pharmacist is in a position to provide professional support to assist the prescribing and administration due to appropriate and continuous education harmonised at the European level.	The training of hospital pharmacists should be standardised across Europe and recognised. Any accepted framework should enable hospital pharmacists to develop the required skill set in a supportive environment while meeting their Continuous Professional Development (CPD) for their registration.
44) The training of all other staff involved in medication use processes should be nationally formalised, harmonised, including the details of defined competencies for the attainment of defined scope of practice.	Patients can be assured that all staff involved in the medication use processes are trained to the adequate level of competency needed to provide safe practice within their role.	Healthcare professionals can be assured that all staff working in hospital pharmacies has the adequate level of competency and training needed for their activities. Their training and required competency is co-ordinated and set by a nationally recognised body.	Hospital pharmacists work together with other professionals within the hospital pharmacy and must be able to be confident and trust their work completely. Their training and required competency is co-ordinated and set by a nationally recognised body.

<p>45) Hospital pharmacists should provide orientation and education to healthcare providers regarding best practices for medicine use for patients</p>	<p>For patient safety all healthcare professionals should have continuous education, namely regarding best practices for medicines use. Hospital pharmacists are the specialists providing orientation and education on such matters, including prescription and administration of medicines.</p>	<p>For patient safety doctors can benefit from the continually updated education courses provided by hospital pharmacists regarding medication use. This includes how to handle hazardous drugs and pharmacovigilance issues. Nurses can benefit from the courses provided by the hospital pharmacists on the best administration practices for all medicines used in the hospital. It is essential that the hazards of injectable and chemotherapeutic drugs are known and precautions are taken when handling them. This should include prescribers and professionals responsible for administration of medicines, especially those responsible for medicines associated with additional hazards.</p>	<p>Hospital pharmacists should develop programs and courses regarding the best practices for medicines use and administration, in collaboration with the scientific committee and the authorities of the hospital. This should include education on the administration of hazardous drugs as well as education on pharmacovigilance</p>
<p>46) Hospital pharmacists should actively engage in research into new methods and systems to improve the use of medicines for the benefits of patients.</p>	<p>Patients can rely on the expertise of hospital pharmacists in optimising processes in the hospital in order to achieve the safest and best use of medicines. This should be based on research, which could be provided by hospital pharmacists.</p>	<p>Doctors and nurses have a lot to benefit from the expertise of a hospital pharmacist in developing new methods and systems to optimise medication processes. This process should be based on scientific research and hospital pharmacists should be proactive in this field.</p>	<p>Hospital pharmacists must be actively engaged in research by developing new methods and systems to improve the use of medicines.</p>
<p>47) Hospital pharmacists should be actively involved in the management and medicine use processes relating to clinical trials.</p>	<p>Patients can contribute to the development of new drugs by providing their informed consent to participate in a trial; testing of new medicines under the supervision of the principal investigator and a hospital pharmacist, who checks the quality and safety of the products. The hospital pharmacist is</p>	<p>Hospital pharmacists can be relied on to establish safe procedures and protocols to comply with legislation concerning the use of the investigational medicines and their management.</p>	<p>Hospital pharmacists should actively participate in the management of clinical trials and be in responsible for the accountability, the preparation and the distribution of the investigational medicines</p>

	responsible for the preparation and distribution of these investigational medicines.		
48) Pharmacists should inform and advise on and oversee the use of medicines outside of their marketing authorisation (off label use).	<p>Medicines are thoroughly tested and regulated before prescribed and given to patients. There may be times they are used in a way for which they are not approved, under the supervision of the doctor.</p> <p>Any use of these medicines in this way should be discussed with the hospital pharmacist before prescription and/or administration.</p>	<p>Medicines should be used under the conditions of the marketing authorisation for which they are approved. For certain patient groups or indications there may be a rational reason to use a medicine outside of its marketing authorisation (off label use). This decision should be taken in consultation with the pharmacy department who will advise regarding the indications/patient group for which a medicine is licensed for and if it is appropriate to be used in another way for a specific patient/patient group.</p>	<p>Pharmacy departments should proactively inform other healthcare professionals of the approved indications and conditions for approved medicines. Use outside of the marketing authorisation may be justified if there is sufficient evidence to support its use in that way. This decision must be done in collaboration with hospital pharmacists because responsibility and liability may be shared between all staff involved in the process, and they need to be aware of this.</p>

DRAFT 23 OCT 2023