EAHP Statements on Hospital Pharmacy 2014

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

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

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 management processes. 7) Hospital pharmacists should

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 assured that their health data are updated, complete and secured due to in part the contribution of hospital pharmacists in the developing procedures and evaluation of their medication records.

Doctors and nurses may rely on the hospital pharmacists' knowledge of the new technology and collaborate in order to have complete and secure health patient records with improved availability by being accessible by new devices, such as laptops, tablets, kiosks, smartphones, etc.

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.

develop, together with other healthcare professionals, criteria in order to focus the activities of the **Hospital Pharmacy ensuring** optimal outcomes for patients. Health systems have limited resources and these should be used responsibly.

All patients will receive required treatment and 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.

Health systems have limited resources and these should be used responsibly. 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.

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.

II. Selection, Procurement & Distribution Statement **Patients**

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.

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

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

Healthcare Professionals

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:

Hospital Pharmacists

Ethical, transparent and professional:

	guaranteeing the quality of patient's	legal and professional standards and	- Under pharmacy control and
	medication and the equity of access.	provide the right medicines to be	technically competent staff;
	A good procurement process will	prescribed in the appropriate	 Guided by the principle of
	have an impact on patient outcomes	formulation for administration.	procuring for safety and efficacy
	by having high quality medicines		- Guided by principles of equity of
	available in the right place and at the		access and ensuring
	right time.		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
9) Hospital pharmacists should	Patients can be assured that the	Hospital pharmacists have a	Hospital pharmacists should collaborate
have responsibility for the	selection and all process use of	responsibility to ensure that the	with doctors and nurses on the wards in
management of medicine use	medication and other health	medicines prescribed by doctors and the	order to have detailed procedures for
processes and medicine related	technologies (e.g. medicine-related	medication related devices to be used by	the medicine use process, the selection
technologies.	devices) in the hospital are under	nurses for the patients needs are of	and use of medicine-related devices
-	the authority of hospital pharmacists	appropriate quality. Doctors and nurses	such as administration devices, giving
	whose expertise is available to all.	should have sufficient information	sets, infusion pumps and computer-
	Having a clear chain of responsibility	available to use medicines safely and	controlled dispensing cabinets, as well as
	with the professionals well trained in	correctly and that this should be	the selection of drugs and
	medications ensures the medication	accessible in a timely manner to	pharmaceutical products to be included
	supply for the patient in a cost	healthcare professionals and to patients.	in the ward stock.
	effective manner	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.	
10) Hospitals should utilise a	Patients can be assured that the	Healthcare professionals must be aware	Hospital pharmacists should establish
medicine formulary system, local,	medicines used in the hospital	that in the hospital all medicines	formulary system procedures linked to
regional and/or national. The	undergo a robust assessment	prescribed and administered are	guidelines and evidence based
medicine formulary system should	process underlying the formulary	selected based on an evidence based	pathways. A reliable information system

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be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence.	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.	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.	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.
11) Procurement must be according to the medicine formulary and informed by the formulary selection process. This must be a transparent process and any conflicts of interest should be disclosed.	Patients can rely on the medicines available in hospital because they are all assessed by experts for patient 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.	Doctors and nurses must be aware that there is an agreed list of medicines (formulary) 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 (DTC)	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 Drug and Therapeutics Committee (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.
12) Each hospital pharmacy should have contingency plans for	Patients can be assured that contingency plans for shortages are	Doctors will face fewer barriers in prescribing habits and nurses will face	Hospital pharmacists should establish contingency plans for shortages and

shortages and purchases for all medicines and products under its responsibility. well established by hospital pharmacists to obtain all medication 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.

fewer problems, while there are contingency plans for medicines 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.

purchases in emergencies for medicines and all products under their 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

13) Hospital pharmacy departments should have responsibility for all medicines logistics in hospitals either directly or by educating others. This includes proper storage, preparation, dispensing, and distribution conditions for all medicines and pharmaceutical products used in the hospital, including investigational medicines.

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 medicines required are available in the best conditions when patients need them, 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.

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.

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

III. Production & Compounding				
Statement	Patients	Healthcare professionals	Hospital Pharmacists	
15) Medicines not commercially	Not all medicines that patients need	Not all medicines that patients need are	Hospital pharmacies should have the	
available for special groups of	are commercially available.	commercially available. Pharmacists are	facilities or arrangements in place for	
patients that require compounding	Pharmacists are the only healthcare	the only healthcare professionals	the production of medicines for	
or production should be prepared	professionals who have the	educated in producing safe medicines	individual or small patient populations,	
by a hospital pharmacy. This	professional education and facilities	for individual patients or small	when not commercially available. The	
process should also consider the	to prepare safe medicinal products	population and should do so if required.	hospital pharmacist should be aware of	
need for supply after discharge.	for individual patients or small	Healthcare professionals can be assured	compounding and production practices	
	populations.	of the quality and safety of these	within the hospital and should attempt	
		medicines produced.	to conduct this activity within the	

16) Hospital pharmacists should appropriately develop pharmacymanaged injectables using aseptic technique where no commercially manufactured product is available.	Injectable mixtures are prone to contamination. For patients especially neonatal and paediatric, this can have serious consequences. The pharmacy should therefore develop services to improve the safety of such injectable mixtures.	Preparing mixtures that are to be injected are at an increased risk to contamination, if not properly prepared. 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.	hospital pharmacy in the interest of quality and patient safety Hospital pharmacists should make a register of preparations that are made on the ward. 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.
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.	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 other healthcare professionals to avoid patient harm.	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.	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.
18). Hazardous medicines including cytotoxics, radiopharmaceuticals and gene therapy should be prepared and administered under appropriate conditions that minimise the risk of contaminating the product and exposing hospital personnel and patients to harm.	Hazardous medicines such as cytotoxics, radiopharmaceuticals and gene therapy need special handling. Hospital pharmacists have the facilities and the skills to produce safe preparations.	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.	Centralised cytotoxic preparation using safe technique and appropriate technology should be implemented in every hospital handling such drugs. 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.
19) Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with national or international quality standards.	To avoid harm to patients, medicines must be produced using high quality ingredients. National and internationally validated methods should be used in the pharmacy in order to guarantee the quality of the starting materials and as a consequence the final product.	Healthcare professionals should be aware of the quality of the products prepared by the pharmacy. To assure that all starting materials and as consequence the final product have high quality hospital pharmacists should use national and international validated methods (pharmacopeia and similar standards).	All ingredients used in preparations should be analysed using national and internationally validated methods (pharmacopeia and similar standards). 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.
20) Before preparation the	Individual preparations can improve	The decision on whether an individual	Pharmacy preparations are not advisable
pharmacist should verify whether	the outcome of patients. If there is a	preparation may improve the patient's	if a suitable pharmaceutical equivalent
preparations are of added value	perceived benefit for a particular	outcome is a complex one and doctors	with a marketing authorisation is
due to medical, pharmaceutical or	patient/patient group, a discussion	and pharmacists should therefore make	available. Before preparation the
personal reasons, needed by a	between the prescriber and the	a joint assessment of the risk/benefit	pharmacist should verify whether a
specific patient or by specific	pharmacy should take place,	balance considering all aspects	pharmaceutical equivalent is available,
population groups with particular	especially if there is a commercially	(therapeutic, pharmaceutical,	taking into account pharmaceutical form
needs.	available suitable pharmaceutical	environmental and personal).	and the strength.
	equivalent.	The professionals involved in patient	
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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 professionals.	All patients should be informed about the risk/benefit assessment for their treatment.	in this assessment for determining the added value of a pharmacy preparation.	together with doctors and other healthcare professionals criteria for the risk/benefit assessment. This criteria may consider The individual situation of the patient The availability of a validated formula The availability of ingredients of pharmaceutical quality The equipment necessary for safe preparation (e.g. clean rooms) The experience and skill of personnel
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.	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.	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.	Patients have the right to get the best quality of medicines independently from industrial production or individual preparation. Hospital pharmacists should guarantee that 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 f safe administration 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.
22) An appropriate system for	In case of adverse events a patient	In case of adverse events, doctors or	In case of adverse events the pharmacy
quality control and quality	has the right to receive all	nurses should have the possibility to	has to demonstrate that all quality
assurance should be in place;	information necessary to check	examine the manufacturing records to	requirements were fulfilled in the
ensuring traceability for pharmacy	whether the event was unavoidable	see whether the produced medicines	production of the medicine of interest.
produced and compounded	and not due to ineffective	fulfilled all quality requirements. This is	
medicines, in the interest of patient	treatment. Thus a tracking system is	only possible if the pharmacy	Hospital pharmacists should:
safety.	necessary to assure the information	implements an appropriate tracking	Define written procedures for all
	flow.	system.	individual preparations
			Record all individual
			preparations in a database
			Create a tracking system

IV. Clinical Services				
Statement	Patients	Healthcare professionals	Hospital Pharmacists	
23) Hospital pharmacists should be	Collaborative care is recognised to	Collaborative care is recognised to	Hospital pharmacists should provide	
involved in all patient care areas to	provide the best outcomes for	provide the best outcomes for patients.	basic clinical services to the greatest	
prospectively influence	patients.	Therapeutic decision-making is an	extent possible and should pursue the	
collaborative therapeutic decision-	Therapeutic decision-making is an	interdisciplinary activity where all	expansion of these activities.	
making and should have access to	interdisciplinary activity where all	healthcare professionals should be	Hospital pharmacists should be	
the patients' health record.	healthcare professionals should be	involved. Healthcare professionals can	integrated into health care teams and	
	involved. Patients should be aware	rely on Hospital pharmacists to	accepted as decision-makers regarding	
	that Hospital pharmacists contribute	contribute to safe, efficacious and cost-	medication use.	
	to the safe and effective use of	effective use of medication. Full access	Hospital pharmacists should have full	
	medication. Full access to all clinical	to all clinical data of patients is required	access to all clinical data of patients in	
	data of patients allows Hospital	to fulfil this role	order to fulfil this role.	
	pharmacists to fulfil their role.			
24) Clinical pharmacy services	Patients are aware that hospital	Errors can occur during prescription and	Hospital pharmacists should manage	
should continuously develop	pharmacists during their clinical	administration of medicines, as	medication therapy for high risk	
systems to improve medicine	activities should be consulted and	highlighted in scientific literature.	patients. Hospital pharmacists should	
management to optimise patient	may intervene before, during and	Healthcare professionals should employ	have an overview of all medication	

25) Hospital pharmacists are an integral part of all patient care teams assisting with therapeutic decision-making and advising on clinical pharmacy and patient safety issues. Hospital pharmacists need to be accessible for patients	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	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 and ending with the assessment and monitoring of its efficacy and tolerability for patients after administration. 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	therapies for patients under their care and record pharmaceutical interventions with the aim to improve quality and safety of all medication use. 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
and other healthcare professionals to assist most effectively.	issues. Due to their education hospital pharmacists are a bridge between different healthcare professionals (such as doctors and nurses) wherever medication is requested.	pharmaceutical care for patients.	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

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			monitor all patients who receive
			medicines to ensure appropriate
			medication use and optimal outcomes.
27) Pharmacists' clinical	In the interest of patient safety the	Healthcare professionals can expect	Hospital pharmacists are accountable for
interventions should be	patients' health records should be	hospital pharmacists to contribute to	their practice, including pharmaceutical
documented in the patients' health	complete, exhaustive and include all	patients' health records ensuring they	advice, validation and any
record	contributions provided by all health	are complete, exhaustive and accurate.	recommendation. All interventions
	care professionals involved in their	This includes pharmaceutical advice,	should be documented in the patients'
	care, including interventions made	recommendations and all interventions	health records for reasons of
	by hospital pharmacists.	conducted by the pharmacy team. The	traceability, necessity, and patient
		documentation is also necessary to	safety. Hospital pharmacists should
		support any therapeutic decision by	contribute in the definition of
		doctors.	procedures and a classification system of
			such records.
28) Hospital pharmacists should	When a patient is transferred	Complex medication treatments need	Hospital pharmacists should contribute
promote seamless care by	between healthcare settings there is	clear information transfer which should	to transfer all medication information
contributing to medication	a risk of error due to lost information	be provided by using the comprehensive	whenever patients are moved in another
information transfer whenever	in the process, as highlighted in	knowledge and understanding of	sector of care including different units of
patients move between healthcare	scientific literature. Patients can	medicines of hospital pharmacists.	the hospital. Hospital pharmacists
settings in or outside the hospital.	expect hospital pharmacists to		should attempt to resolve any
	transfer information about their		medication related issues and use a
	medication whenever they are		pharmacy information record to
	moved to another healthcare		communicate this information. If not
	setting, to provide safe and optimal		established hospital pharmacists should
	continuation of treatment.		establish this record.
29) Hospital pharmacists should	Inappropriate handling of medicines	Healthcare professionals can rely on	Hospital pharmacists should facilitate
ensure that patients are educated	can reduce and even eliminate the	hospital pharmacists to provide	the provision of instructions, education
on the appropriate use of their	effect of medicines. Patients (or their	adequate information (written	and counselling to patients and/or their
medicines.	caregivers) can rely on hospital	instructions and verbal counselling) to	caregivers when deemed appropriate.
	pharmacists to provide information	patients regarding their medication. If	
	about their medicines, so that they	appropriate, additional education	
	can manage their medication	regarding medication use can be	
	independently, ensuring optimal	provided. This is so that the patients can	
	outcomes and to prevent re-	manage their medication independently	
	admission. Hospital pharmacists	or with the assistance of a caregiver to	
	have the responsibility,	ensure optimal outcomes.	

	competencies and the interest to provide this advice.		
30) Pharmacists should inform and advise on and oversee the use of medicines outside of their marketing authorisation (off label use).	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. Any use of these medicines in this way should be discussed with the hospital pharmacist before prescription and/or administration.	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.	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.

V. Patient Safety and Quality Assurance				
Statement	Patients	Healthcare professionals	Hospital Pharmacists	
31) The "seven rights" (the right	Hospital pharmacists aim to ensure	Hospital pharmacists aim to ensure that	Hospital pharmacists should promote	
patient, right medicine, right dose,	that patients receive the right drug	patients receive the right drug at the	the availability of internal procedures	
right route, right time, right	at the right dose, via the right route	right dose, via the right route at the right	that describe the fulfilling of the "seven	
information and right	at the right time. Patients should be	time. Only medicines administered at	rights" of the patient.	
documentation) should be fulfilled	informed about their medication and	the correct time are effective. Hospital	Hospital pharmacists should be involved	
in all medicines-related activities in	are entitled to be provided with all	pharmacists ensure that the seven rights	in the education of health professionals	
the hospital.	information regarding their	of the patient are adhered to, assisting	on the "seven rights".	
	treatment. Documentation and	other healthcare professionals.	Hospital pharmacists should supervise	
	information are also required for	Complete documentation is vital for	that the internal procedures are	
	continuous assessment.	accountability and continual assessment.	respected and must document their	
		Hospital pharmacists should assist other	pharmaceutical interventions.	
		healthcare professionals completing		
		relevant documentation and checking all		
		aspects of medication before		
		administration.		

32) 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.	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	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.	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.
33) Hospital pharmacists should ensure the development of quality assurance strategies for medication practices, including the use of observation methodology and Clinical Incident Reporting System (CIRS) to detect errors and identify priorities for improvement.	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. 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. * Events, situations, or errors that took place but were captured before reaching the patient. (www.ismp.org)	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 misses are essential to improve patient safety.	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 pharmacists should develop simple, rules-based approaches to advancing patient safety.
34) Hospital pharmacists should	Medication errors can occur due to	Evidence-based systems or technology	Hospital pharmacists should define the

demand the state of the discrete	failures of the constant of the constant	and and the second section of the sectio	
decrease the risk of medication errors by implementing evidence-based systems or technologies systems.	failures of the procedures. Scientific literature suggests one way to decrease errors is by implementing evidence-based systems or technology systems (e.g. scantechnology or unit dose distribution).	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.	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
35) The medicines administration process should be designed so that transcription steps between the original prescription and the medicines administration record are eliminated .reduced to the minimum.	Transcription (handwriting) of the medical prescription onto the health care record of patients is prone to errors and should be eliminated by implementing safer systems.	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.	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.
36) High risk medicines should be identified and appropriate procedures implemented that assure additional checks or other error prevention strategies prior to dispensing and administration.	Errors with high risk medicines may be fatal for patients, it is therefore necessary that independent check procedures prior to administration are implemented. Hospital pharmacists should be involved in this process to ensure patient safety.	The prescription of high risk medicines is prone to errors which could be fatal and should be validated by hospital 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.	Hospital pharmacists should identify high risk medicines used in the hospital. Hospital pharmacists should define the 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. Iabelling of intravenous tubing near insertion site to prevent misconnections use of enteral feeding catheters

37) Hospital pharmacists should ensure that medicines are securely stored throughout the hospital and are packaged and labelled so to assure identification, maintain integrity until immediately prior to use and facilitate correct administration.	To assure safe administration and avoid any confusion, medicines should be packaged and labelled adequately and stored appropriately prior to use. Unambiguous and complete labelling is paramount to avoid any confusion, misinterpretation or administration error in the whole process.	All medicines should be packaged and labelled adequately and stored appropriately prior to use in order to avoid confusion or medication errors. Unambiguous and complete labelling is paramount to avoid any confusion, misinterpretation or administration error in the whole process.	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 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. Hospital pharmacists should ensure that medicines stored on the wards and prepared on the wards meet the required safety criteria. Hospital pharmacists should report inadequate labelling and packaging of purchased medicines to the authorities.
38) Hospital pharmacists should promote the reporting of adverse drug reactions and notification to regional or national	Adverse drug reactions can occur and must be monitored constantly after marketing approval. The aim of pharmacovigilance reporting	Reporting of adverse drug reactions is a requirement in order to obtain sufficient data to improve quality and safety of medication practices. Hospital	Hospital pharmacists should promote national adverse drug reaction reporting systems, or the establishment of a system if regional or national
pharmacovigilance reporting programs where these are available. The monitoring data should be regularly reviewed to	programs is to enable authorities to collect the necessary data update the risk-benefit assessments regarding medicines.	pharmacists can support healthcare professionals to increase reporting and review medication practices.	pharmacovigilance reporting systems are not already in place. Hospital pharmacists should assist health care professionals to increase reporting.
improve the quality and safety of medication practices.			Hospital pharmacists should be involved reviewing and monitoring data and define any action needed to improve

			internal medication practices.
39) Hospital pharmacists should	Administration of a medication to a	All healthcare professionals are	Hospital pharmacists should assist with
promote accurate recording of all	patient with allergy may be fatal.	responsible to ensure allergy	the definition of allergy (and
allergies and <mark>c</mark>ontraindications in	The patient's health record should	information is in the patients' health	intolerance), the location of the patients
the patients' health record. This	include allergy data and the	record. The information should be	health record where the information
information should be accessible	information has to be checked prior	available during the medication use	should be included and the internal
and evaluated prior to prescription,	to prescription and administration.	process so that all possible allergies can	procedure when and how allergies are
dispensing and administration of	·	be taken into consideration prior to	checked (yes-no).
medicines.		medication use.	
		Pharmacists can support doctors by	Hospital pharmacists involved in the
		performing comprehensive medication	medication process (e.g. validation of
		histories and documenting accordingly.	prescription, preparation of medication,
			distribution) must ensure that the
			information is available prior to proceed
			other activities.
40) Hospital pharmacists should	Medicines dispensed by the	Traceability of medicines is an important	Hospital pharmacists should ensure a
support and implement systems	pharmacy can be subject to recall	topic not only in case of recall but also to	system that enables tracing of
that allow traceability of all	and should be identified as soon as	track administration of specific products	distributed medicines.
medicines dispensed by the	possible to avoid administration of a	such as biological medicines.	
pharmacy.	qualitatively inadequate product or		Hospital pharmacists should define the
	to enable to contact the patient if		list of medicines that require tracing of
	necessary.		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.
41) Hospital pharmacists should	Multidisciplinary collaboration	Hospital pharmacists assist other	Hospital pharmacists should ensure that
ensure that the information	improves medicines utilisation and	healthcare professionals by giving	the officially recognised drug
resources needed by other	so patient safety. To guarantee	adequate information and	information by the authorities is
healthcare professionals and	correct preparation and	recommendations to have a complete	available to all healthcare professionals.
patients for safe medicines use,	administration of medicines health	prescription that permits correct	If such references are not available, a list
preparation, dispensing and	care professionals require specific	preparation, administration and use of	of generally accepted references should
administration are accessible at the	competencies and need to have	medicines.	be provided.
point of care.	access to adequate information and		

recommendations at the point of care.	Adequate information and recommendations should be available while preparing and administrating medicines.	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.

VI. Education and Research				
Statement	Patients	Healthcare Professionals	Hospital Pharmacists	
42) 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.	Only well trained pharmacists can provide the best service for patients, thus the need for hospital pharmacy practical training during undergraduate studies. 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, which could be achieved through multidisciplinary education.	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 healthcare team that are highly educated in the medication management, so that they can rely on their recommendations. To promote collaborative care it is necessary to inform other health professionals to become more aware of the competencies achieved by	Hospital pharmacists should collaborate with the academic staff of the clinical team in order to advise them on pharmacy and prescribing courses. Competency is essential and enables the collaboration with other health professionals. Collaborative care can be only realised if other health professionals are aware of the competencies achieved by pharmacist's education.	
43) Post graduate education in the	The selection, supply, prescription	the competencies achieved by pharmacist's education. Multidisciplinary education is one way to achieve this. The selection, supply, prescription and	The lack of an EU level mutual	
hospital setting, with a final	and administration of medicines	administration of medicines used in a	recognition of Hospital Pharmacy as a	
assessment of individual	used in a hospital setting are	hospital setting are complex processes.	structured specialisation creates	

45) The training of all other staff	Patients can be assured that all staff	Healthcare professionals can be assured	Hospital pharmacists work together with
44) 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 and should include Continuous Professional Development (CPD).	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, practical training, specific roles and Continuous Professional Development (CPD).	Healthcare professionals should be aware that the hospital pharmacist is in a position to provide professional support within the healthcare team to assist the prescribing and administration of medicines due to an 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.
competency is essential to ensure that where pharmacists are providing hospital pharmacy services, patients benefit from the highest levels of expertise.	complex processes. Training to fulfil various competencies to work independently is needed in addition to the basic education of a pharmacist. Post graduate education (practical and theoretical) is essential to ensure that all patients benefit from the highest level of medication expertise.	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.	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. 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. 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.

of postgraduate training programmes for hospital	the healthcare team	field.	
benefits of patients. Research methods should be part	research, which could be provided by hospital pharmacists, as part of	on scientific research and hospital pharmacists should be proactive in this	cost-effective use of medicines.
the use of medicines for the	medicines. This should be based on	processes. This process should be based	improve safe, effective, appropriate and
methods and systems to optimise	achieve the safest and best use of	and systems to optimise medication	methods, systems and services to
improving and creating new	processes in the hospital in order to	pharmacist in developing new methods	implementing and assessing new
actively engage in research into	hospital pharmacists in optimising	from the expertise of a hospital	engaged in research by developing,
47) Hospital pharmacists should	Patients can rely on the expertise of	those responsible for medicines associated with additional hazards. Doctors and nurses have a lot to benefit	Hospital pharmacists must be actively
		professionals responsible for administration of medicines, especially	
		This should include prescribers and	
		handling them.	
		and precautions are taken when	
		and chemotherapeutic drugs are known	
		medicines used in the hospital. It is essential that the hazards of injectable	well as education on pharmacovigilance
	administration of medicines.	the best administration practices for all	administration of hazardous drugs as
	matters, including prescription and	provided by the hospital pharmacists on	This should include education on the
	orientation and education on such	Nurses can benefit from the courses	·
patients	are the specialists providing	drugs and pharmacovigilance issues	of the hospital.
patients	medicines use. Hospital pharmacists	This includes how to handle hazardous	scientific committee and the authorities
to healthcare providers regarding best practices for medicine use for	continuous education, namely regarding best practices for	courses provided by hospital pharmacists regarding medication use.	practices for medicines use and administration, in collaboration with the
provide orientation and education	professionals should have	from the continually updated education	programs and courses regarding the best
46) Hospital pharmacists should	For patient safety all healthcare	For patient safety doctors can benefit	Hospital pharmacists should develop
		and set by a nationally recognised body.	nationally recognised body.
of practice.	within their role.	required competency is co-ordinated	competency is co-ordinated and set by a
for the attainment of defined scope	needed to provide safe practice	their activities. Their training and	completely. Their training and required
formalised, harmonised, including the details of defined competencies	assistants) are trained to the adequate level of competency	assistants, has the adequate level of competency and training needed for	assistants, and must be able to be confident and trust their work
processes should be nationally	processes, such as technicians and	pharmacies, such as technicians and	pharmacy, such as technicians and
involved in medication use	involved in the medication use	that all staff working in hospital	other professionals within the hospital

	T		
pharmacists.			
48) Hospital pharmacists should be	Patients can contribute to the	Hospital pharmacists can be relied on to	Hospital pharmacists should actively
actively involved in the	development of new drugs by	establish safe procedures and protocols	participate in the management of clinical
management and medicine use	providing their informed consent to	to comply with legislation concerning	trials and be responsible for the
processes relating to clinical trials.	participate in a trial; testing of new	the use of the investigational medicines	accountability, the preparation and the
	medicines under the supervision of	and their management.	distribution of the investigational
	the principal investigator and a		medicines.
	hospital pharmacist, who checks the		
	quality and safety of the products.		
	The hospital pharmacist is		
	responsible for the preparation and		
	distribution of these investigational		
	medicines.		