Production & Compounding

Statement	Patients	Doctors/Nurses (Healthcare professionals)	Hospital Pharmacists
1) Medicines not commercially available for special groups of patients including neonatal and paedriatic patients should be prepared by the hospital pharmacy.	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.	Not all medicines needed to treat patients are commercially available. Pharmacists are the only health professionals educated in producing safe medicines in small scale. Doctors and nurses can rely on their expertise. New Proposal: 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 of safety of these medicines produced.	Hospital pharmacy should have the facilities for the production of medicines for individual or small patient populations, when not commercially available. The Hospital Pharmacist should be aware of preparation and production practices within the hospital and should attempt to conduct this activity in the hospital pharmacy.
2) Hospital pharmacists should develop pharmacy-managed injectable admixture services using aseptic technique.	Injectable mixtures are prone to contaminations which can be fatal for patients especially neonatal and paediatrics ones. The pharmacy should therefore develop services to improve the safety of such preparations.	Preparing mixtures that are to be injected are prone to contamination and this is an important responsibility. Other healthcare professionals on the ward do not have the training or the facilities of the hospital pharmacies. Thus centralised services in the pharmacy can support healthcare professionals by and nurses in improving the safety of such preparations.	Hospital Pharmacists should make an inventory of preparations made at the ward. Hospital Pharmacists should check the capacity of their staff and facilities in order to produce medication. Hospital Pharmacists should aim to centralise aseptic preparations by offering Good Manufacturing Practice (GMP) based services.
3) When reconstitution takes place in the ward, a Hospital pharmacist should approve written procedures and ensure that the staff involved in reconstitution are appropriately trained.	Not all injectable preparations, especially in emergency situations can be prepared by the pharmacy. In such cases hospital pharmacists have the competency to define safe procedures to be used by other health professional to avoid patient harm.	Not all injectable preparations, especially in emergency situations can be prepared by the pharmacy. In such cases hospital pharmacists should support other healthcare professional nurses and doctors by describing feasible procedures for safe 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. In addition the staff preparing the medicines should have received training and be competent to undertake preparation or this high risk patient group.

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4). Hazardous medicines including cytotoxics should be prepared under environmental conditions that minimize the risk of contaminating the product and exposing hospital personnel to harm.	Hazardous medicines like cytotoxics need special care to avoid unsafe procedures and contamination of the patients. Hospital Pharmacists have the facilities and the skills to produce safe preparations.	Hazardous medicines like cytotoxics 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.	Centralized cytotoxic preparation using safe technique and appropriate technology should be implemented in every hospital handling with such drugs. Hospital Pharmacists should be responsible that no cytotoxic drugs are prepared at the ward even in emergency situations.
5) Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards. 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.	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 consequence of the final product.	Healthcare professionals should be aware of the quality of on the products prepared by the pharmacy. To assure that all starting materials and as consequence of the final product have high quality the pharmacy Hospital Pharmacists should use national and international validated methods (pharmacopeia and similar standards).	All ingredient 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 GMP and analysed according to pharmacopoeial standards should be used.
6) Before preparation the pharmacist should verify whether preparations are of added value due to medical, pharmaceutical or personal reasons, they are needed by a specific patient or by specific population groups with particular needs. **The professionals involved in patient care should jointly assume responsibility in this**	Individual preparations can improve the outcome of patients. This should be balanced against the risk of missing experience and scientific evidence of the therapy used. Therefore pharmacists and doctors should together make an assessment of the risk/benefit balance considering all aspects (therapeutic, pharmaceutical, environmental and personal). All patients should be well informed about the risk/benefit assessment	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). It is a right of patients to get transparency of this decision.	Before accepting an individual preparation Hospital Pharmacists should check together with the doctors whether a commercially available alternative may be a better choice Hospital Pharmacists should develop together with doctors and other healthcare professionals a 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

Comment [AB2]: Shouldn´t this be in the patients side

assessment and essential information should be given to the patient, if available, based on the product dossier	as they primary right.		• The equipment necessary for safe preparation (e.g. clean rooms) • The experience and skill of personnel
7) A pharmacist should be able to refuse a prescription for a pharmacy preparation if a suitable pharmaceutical equivalent is available on the national market and/or the individual prescription has no added value. **He should inform the physician that a suitable pharmaceutical equivalent is available and discuss with the physician if there is a specific need to dispense a pharmacy preparation**	In interest of patient's safety pharmacists are obliged to refuse prescriptions if they judge the risk/benefit being negative. To mitigate any consequence for the outcome of the patient's pharmacists should proactively propose alternatives to the prescribing doctors and discuss with them whether specific needs justify the risk of the individual prescription.	In interest of patient's safety pharmacists are obliged to refuse prescriptions if they judge the risk/benefit being negative. Commercially available products are quality assured and less prone to errors than individual preparations. Nevertheless specific needs of the patient and the clinical situation may justify the prescription. Refusing a prescription pharmacists start a process with the aim to achieve a jointly responsibility.	If collaborative assessment with the prescribing doctors is not possible before prescription Hospital Pharmacists should refuse the prescription if adequate medicines are commercially available in order to start a process to jointly asses the specific needs of the patient and the clinical situation
8) 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**	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 row materials is appropriate • The packing material is appropriate and compatible to the product

Comment [DP1]: Too technical for patients? – More appropraite in Dr side.

Comment [DP3]: Isnt it a legal obligation to use a licensed product before a off license of indivdual prepared one? If so then HPs are protected by the law. I am not sure I agree with the „should be able to refuse"aspect of this statement.

from production to administration.			• The labelling is unambiguous, complete and based on principle of f safe administration
9) An appropriate system for reporting quality and safety issues should be put in place which allows for a link between the product, the preparing and dispensing pharmacies, and the preparation process.	In case of adverts events a patient has the right to get all information necessary to check whether the event was unavoidable and not due to a defeat medicine. Thus a tracking system is necessary to assure the information flow.	In case of adverts events doctors or nurses should have the possibility to check whether the produced medicines fulfilled all quality requirements. This is only possible if the pharmacy implements an appropriate tracking system.	In case of adverts events the pharmacy has to demonstrate that all quality requirements were fulfilled in the production of the medicine of interest. Hospital pharmacists should • Define written procedures for all individual preparations • Record all individual preparations in a database • Create a tracking system

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