REPORT OF DELPHI ROUND 1: EXECUTIVE SUMMARY

Background

EAHP is developing European Statements on Hospital Pharmacy to form a shared expectancy between hospital pharmacists, patients and healthcare professionals on the practice of hospital pharmacy across Europe.

The statements, which will be voted on at the <u>European Summit on Hospital Pharmacy</u> (14-15 May 2014) will form the basis of EAHP's work in developing hospital pharmacy standards across Europe, provide an ongoing focus for its educational activity, and a bedrock of pan-European practice benchmarking. The statements will constitute the expectancy of hospital pharmacy service delivery in European countries.

The work develops from the 2008 *Global Statements of Hospital Pharmacy Practice* developed by the International Pharmaceutical Federation (FIP) and known as 'the Basel Statements'. The proposed European statements, as put forward at the commencement of Delphi Round 1, were developed via a review of the Basel Statements by a working group of hospital pharmacists from across Europe, led by EAHP Director of Professional Development Aida Batista.

To ensure the statements reflect the full diversity of national health systems, and the shared aspirations of hospital pharmacists, patients and healthcare professionals, EAHP is conducting a rigorous Delphi consensus finding consultation. What follows is an Executive Summary of the first round of Delphi consultation conducted between the 15th November 2013 and the 6th December 2013.

Nominated delegates from EAHP's 34 national member associations, alongside 34 European patient and professional groups who had registered to be part of the European Summit on Hospital Pharmacy (14-15 May 2014), were invited to take part in the consultation process.

Participants voted and commented on all 48 statements. In Delphi Round 1, 28 statements achieved strong agreement, with the remaining 20 achieving agreement. Following the close of the deadline for Delphi Round 1, the independent moderation and facilitation team led by Professor Neal Maskrey reviewed the debates and the points raised during the consultation and prepared recommendations for statement amendment:

- In most cases, clarification of wording, small typographical or grammatical changes have been made. In a minority of statements new portions and elements to a statement have been recommended as would be expected in a Delphi process.
- No new statements were proposed.
- One statement (previous 3.9) has been moved to the section on clinical services (new 4.4), with corresponding change to all running orders.

Section	Statement number	Delphi Round 1 Statement	Delphi Round 2 statement	Notes
1.1	1	The overarching goal of hospital pharmacists is to optimise patient outcomes through the judicious, safe, efficacious, appropriate, and cost effective use of medicines.	The overarching goal of the hospital pharmacy service is to optimise patient outcomes through working within multidisciplinary teams in order to carry out the judicious, safe, efficacious, appropriate, and cost effective use of medicines.	Change reflects universality of multidisciplinary team as the basis of care provision.
1.2	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.	At a European level, 'Good Hospital Pharmacy Practice' guidelines based on the best available evidence should be developed. These guidelines should assist national efforts to define recognised standards across the scope and levels of hospital pharmacy services and should include corresponding human resource and training requirements.	Change to acknowledge "best available evidence", together with minor wording changes to increase clarity of phrasing.
1.3	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 a Pharmacy in the Hospital.	Health authorities should ensure that each hospital pharmacy is supervised by a pharmacist with sufficient working experience in the hospital settings, and preferably with explicit, specialist training and demonstration of competence in hospital pharmacy. All hospitals must have access to hospital pharmacy services, including those without a pharmacy in the hospital.	Reworded to reflect a balance between experience and explicit training and demonstration of competence.
1.4	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 medicine use processes and to meet health needs and priorities across public and private sectors that optimise patient outcomes	Hospital pharmacists should work with health authorities, hospital administrators and other locally relevant stakeholders to develop hospital pharmacy human resource plans. These should be aligned to engage hospital pharmacists as supervisors in all steps of all medicine use processes to meet health needs and priorities across public and private sectors that optimise medicines use and patient outcomes.	Wording now reflects the option of a wider range of stakeholders, and wording separates the development of HR plans from their implementation.
1.5	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	Hospital pharmacists should take the lead in coordinating the activities of multidisciplinary, organisation-wide Drug & Therapeutics Committees. They should have appropriate representation as full members of these Committees which should oversee and improve all medicines management policies and procedures including those related to unlicensed and off-label use of medicines, novel investigational medicines, and anti-counterfeit medicines strategies.	Rewording clarifies the role of hospital pharmacists in relation to Drug and Therapeutic Committees.

1.6	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.	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.	No changes.
1.7	7	Hospital pharmacists should 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.	Hospital pharmacists should develop, in collaboration with other stakeholders which include other healthcare professionals, patients and the public, criteria to enable the prioritisation of the activities of the Hospital Pharmacy. Health systems have limited resources and these should be used responsibly to optimise outcomes for patients.	Rewording strengthens and clarifies the role of stakeholders.
2.1	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.	Procurement of pharmaceuticals is a complex process and a core activity of hospital pharmacists. Hospital pharmacists should establish transparent procurement processes based on principles of safety and quality of medicines, in line with best practice and national legislation.	Transparency added to wording.
2.2	9	Hospital pharmacists should have responsibility regarding the management of medicine use processes and medicine related technologies.	Hospital pharmacists should take the lead in developing, monitoring, reviewing and improving medicine use processes and processes for the use of medicine related technologies. Responsibility for such processes and their use should be clearly defined, and may vary according to the medicine, the medicine related technology, the health care setting and the multidisciplinary team delivering care.	Revised wording represents the responsibility is shared with other health care professionals.
2.3	10	Hospitals should utilise a medicine formulary system, local regional and/or national. The medicine formulary system should be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence.	Hospitals should develop, maintain and use a medicines formulary system, which may be local, regional and/or national. The medicine formulary system should be linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence including patient outcomes and pharmacoeconomic evaluations where these are available.	Revised wording includes patient outcomes and pharmacoeconomic evaluations.

2.4	11	Procurement must be according to the medicine formulary and informed by the formulary selection process.	Procurement should usually be according to the medicine formulary and informed by the formulary selection process. A robust process should also be in place to appropriately procure medicines not included in the formulary where their use is indicated for the safe and effective care of individual patients.	Off-formulary procurement included in revised wording.
2.5	12	Each hospital pharmacy should have contingency plans for shortages and purchases for medicines and all products under its responsibility.	In collaboration with other local and national health organisations, each hospital pharmacy should have contingency plans for shortages of medicines, and for other health care products which it procures.	Collaboration with others included in revised working.
2.6	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.	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.	No changes.
2.7	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 confirmed by the hospital pharmacist.	Unless specifically precluded by national legislation or regulations, hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients. All patients should have an evaluation of the appropriateness of all their medication including herbal and dietary supplements on admission. All the medicines used by patients should be entered on the patient's medical record and confirmed by the hospital pharmacist.	Caveat added to statement concerning national regulations precluding the use of medicines brought into hospital by patients.
3.1.	15	Medicines not commercially available for special groups of patients that require compounding or production should be prepared by a hospital pharmacy.	Medicines not commercially available that require compounding or production should be prepared by a hospital pharmacy.	Simplification of wording.
3.2	16	Hospital pharmacists should appropriately develop pharmacy-managed injectables using aseptic technique.	Hospital pharmacists should ensure that appropriate techniques and Good Manufacturing Practice are applied in the manufacture and preparation of parenteral and other products supplied by the pharmacy.	Clarification and rephrasing requirement indicated by Delphi 1 comments

3.3	17	When reconstitution takes place in the ward, a hospital pharmacist should approve written procedures and ensure that the staff involved in reconstitution is appropriately trained.	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.	No significant change.
3.4	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.	Hazardous medicines including cytotoxics, radiopharmaceuticals and gene therapies should be prepared in appropriate conditions that minimise the risk of contaminating the product and exposing hospital personnel and patients to harm.	No significant change.
3.5	19	Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards.	Hospital pharmacists should ensure that compounded and produced medicines are consistently prepared to comply with quality standards.	No change.
3.6	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 pharmaceutical equivalent. Essential information about the product, based on the product dossier should be made available to patients and other healthcare professionals.	Before pharmacy manufacture or preparation of a medicine, the hospital pharmacist should ascertain whether there is a suitable commercially available pharmaceutical equivalent, and if necessary discuss with the health care team whether pharmacy preparation is appropriate for a specific patient or group of patients.	Delphi 1 comments indicated revision to reflect a dialogue with colleagues as opposed to a refusal.
3.7	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.	Before 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 throughout the process from production to administration.	Minor wording change.
3.8	22	An appropriate system for quality control and quality assurance should in place, ensuring traceability for pharmacy produced and compounded medicines, in the interest of patient safety.	In the interest of patient safety, an appropriate system for quality control and quality assurance should be in place, ensuring traceability for pharmacy produced and compounded medicines.	Minor wording change.
3.9	23	Hospital pharmacists should be involved in all patient care areas to prospectively influence collaborative therapeutic	Hospital pharmacists should be involved in all patient care settings to prospectively influence collaborative,	Minor wording change; should be moved to section 4, probably after

		decision-making and should have access to the patients' health record.	multidisciplinary therapeutic decision-making; they should have access to the patients' health record.	4.2 or 4.3.
4.1	24	Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients outcomes.	Clinical pharmacy services should continuously develop to manage medication therapy to optimise patients' outcomes.	No significant change.
4.2	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.	Hospital pharmacists should be an integral part of all patient care teams advising especially on therapeutics, clinical pharmacy and patient safety issues; they should play a full part in decision making in partnership with patients and other health care professionals.	Rephrased to reflect Delphi 1 comments to include "full part in decision making in partnership with patients".
4.3	26	All prescriptions should be reviewed and validated by a hospital pharmacist prior to dispensing and administration of medication	Whenever the clinical situation allows, all prescriptions should be reviewed and validated as soon as possible by a hospital pharmacist; this review should preferably take place prior to the dispensing and administration of medication.	Caveats added to reflect clinical realities following comments from Delphi 1.
4.4	27	Pharmacists' clinical interventions should be documented in the patients' health record.	Pharmacists' clinical interventions should be documented in the patients' health record.	No changes
4.5	28	Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings.	Hospital pharmacists should promote seamless care by contributing to medication information transfer whenever patients move between healthcare settings.	No changes
4.6	29	Hospital pharmacists should ensure that patients are educated on the appropriate use of their medicines	As an integral part of all patient care teams, hospital pharmacists should ensure that patients are given appropriate information on the use of their medicines.	Some revision of the statement was possible to reflect the pharmacist as one member of the team caring for the patient, and also that the role is to provide information with patient autonomy still governing the decisions they make about their medicines.
4.7	30	Pharmacists should inform and advise on and oversee the use of medicines outside of their marketing authorisation (off label use).	Pharmacists should inform and advise on the use of medicines outside of their marketing authorisation (off label use).	"Oversee" considered inappropriate since prescribing responsibility rests with the prescriber for off-label prescribing.

5.1	31	The "seven rights" (the right patient, right medicine, right dose, right route, right time, right information and right documentation) should be fulfilled in all medicines-related activities in the hospital.	The "seven rights" (the right patient, right medicine, right dose, right route, right time, right information and right documentation) should be fulfilled in all medicines-related activities in the hospital.	No changes
5.2	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	Hospitals should seek review of their medication practices by an external quality assessment accreditation programme. Hospitals should act on reports as appropriate to improve the quality and safety of their practices.	Clarification of wording.
5.3	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	Hospital pharmacists should ensure the development of appropriate quality assurance strategies for medication practices including the use of observation methodology, Medication Error Reporting Systems (MERS), and Clinical Incident Reporting System (CIRS) to detect errors and identify priorities for improvement.	MERS added in following Delphi 1 comments.
5.4	34	Hospital pharmacists should decrease the risk of medication errors by implementing evidence-based systems or technologies systems	Hospital pharmacists should help to decrease the risk of medication errors by disseminating evidence-based approaches to error reduction including computerised decision support.	Rewording to reflect the required multi-dimensional approach to reducing medication errors.
5.5	35	The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated.	The medicines administration process should be designed such that transcription steps between the original prescription and the medicines administration record are eliminated.	No changes
5.6	36	High risk medicines should be identified and appropriate procedures implemented that assure checks prior to dispensing and administration.	High risk medicines should be identified and appropriate procedures implemented that assure checks prior to prescribing, dispensing and administration.	"Prescribing" added.
5.7	37	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. 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.	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. 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	No changes.

			administration.	
5.8	38	Hospital pharmacists should 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	Hospital pharmacists should promote the reporting of adverse drug reactions to regional or national pharmacovigilance programmes.	Since the responsibility for analysising reports rests with regional or national authorities, the second sentence in this statement was revised
5.9	39	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.	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.	No changes. Requirement is to PROMOTE the recording, not to do it personally.
5.10	40	Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.	Hospital pharmacists should support and implement systems that allow traceability of all medicines dispensed by the pharmacy.	No changes.
5.11	41	Hospital pharmacists should ensure that the information resources needed for safe medicines use, preparation and administration are accessible at the point of care	Hospital pharmacists should ensure that the information resources needed for safe medicines use, including both preparation and administration, are accessible at the point of care.	No changes.
6.1	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	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.	No changes.
6.2	43	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.	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.	No changes
6.3	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	A European-wide competency framework to regularly assess performance and training needs of hospital pharmacists should be developed and implemented. This should contain core minimum competencies which would be applicable to all hospital pharmacists; given the heterogeneity of hospital pharmacy practice in different countries, additional national competency frameworks should be considered.	Comments from Delphi 1 indicated some concerns about the feasibility of a European-wide competency framework and assessment for hospital pharmacists after initial training and when they are established in their career paths.

6.4	45	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.	A European-wide competency framework and training programme to support all other staff involved in medication use processes should be developed and implemented.	Rephrasing to match wording in statement 44.
6.5	46	Hospital pharmacists should provide orientation and education to healthcare providers regarding best practices for medicine use for patients.	Hospital pharmacists should provide orientation and education to other healthcare providers on best practices for medicine use.	Minor rewording changes.
6.6	47	Hospital pharmacists should actively engage in research into improving and creating new methods and systems to optimise the use of medicines for the benefits of patients. Research methods should be part of postgraduate training programmes for hospital pharmacists.	Hospital pharmacists should actively engage in hospital pharmacy practice research which describes improving existing and creating new methods and systems to optimise the use of medicines for the benefit of patients. Research methods should be part of postgraduate training programmes for hospital pharmacists.	Minor rewording to clarify.
6.7	48	Hospital pharmacists should be actively involved in the management and medicine use processes relating to clinical trials.	Hospital pharmacists must be actively involved in the management and medicine use processes relating to clinical trials.	"Should" changed to "must".