PGEU, EAFP, EPSA, EIPG, EAHP Statement on future modifications on the Directive on the Recognition of Professional Qualifications

PGEU – EPSA – EAFP – EIPG – EAHP Joint Statement on future modifications on the Directive on the Recognition of Professional Qualifications

INTRODUCTION

The pharmacists' profession welcomes the last revision of the Directive on the Recognition of Professional Qualifications [Directive 2013/55/EU]. We are particularly pleased with the revision of the article regulating pharmacists' activities [Art. 45§ 2]. We believe that the current provision properly reflects harmonised pharmacy practices in the Union.

As the Commission has recently appointed Spark Legal Network to conduct a study which is intended to assist in assessing whether to propose an adaptation of the minimum training requirements for the profession of pharmacists under Article 44(3) and point 5.6.1 of Annex V Directive 2005/36/EC, the Pharmaceutical Group of the European Union (PGEU), the European Association of Faculties of Pharmacy (EAFP), the European Pharmaceutical Students' Association (EPSA), the European Industrial Pharmacists Group (EIPG) and the European Association of Hospital Pharmacists (EAHP) would like to make some proposals on these provisions.

In particular, we would like to suggest some modifications to:

- Annex 5.6.1 describing the list of subjects for the training of pharmacists
- Article 44. 3 describing the knowledge and skills that need to be acquired during the training of pharmacists.

These provisions have not been changed since 1985. We believe that our suggestions, which seek to showcase the current training of pharmacists, will build on the spirit of modernisation that was the basis of the last revision of the Directive. In addition, they will add consistency to the text following the last modification to the provision of pharmacists' activities as well as reflecting the scientific progress and innovation in practice.

Please find below our proposals (new provisions are in bold).

PROPOSED CHANGES

1. Annex V 5.6.1 ~~course of training for pharmacists~~ **list of subjects for the training of pharmacists**

— Plant ~~**and animal**~~ biology
— Physics
— General and inorganic chemistry
— Organic chemistry
— Analytical chemistry**, including analysis of medicinal products**
— Pharmaceutical chemistry
— General and applied biochemistry (medical)**, including molecular biology**
— Anatomy, physiology**, pathology** and medical terminology
— Microbiology**, immunology and epidemiology**
— Pharmaceutical **and biopharmaceutical** technology**, including pharmaceutical compounding**
— Pharmacognosy
— **Regulatory sciences, quality of pharmaceutical products and quality assurance**
— Pharmacology and pharmacotherapy
— **Clinical** toxicology
— **Genetics and pharmacogenomics including personalised therapies**
— **Clinical Pharmacy**
— Pharmaceutical care
— **Pharmacy practice**
— Legislation and professional ethics.
— **eHealth**
— **Public health**
— **Health economics and pharmacoeconomics**

Article 44 § 3 training for pharmacists list of knowledge and skills

Training for pharmacists shall provide an assurance that the person concerned has acquired the following knowledge and skills:

(a) adequate knowledge **and skills** of medicin**al products related to their formulation, development, production, analysis and wholesale distribution**
(b) adequate knowledge **and skills** of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products **and medical devices.**
(c) adequate knowledge **and skills** of the metabolism and the effects of medicinal products and of the action of toxic substances, and of the use of medicinal products, **including** their use in **pharmacotherapy**
(d) adequate knowledge **and skills** to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge
(d (a)) adequate knowledge and skills to advise patients on medical terminology and the use of medicines, including non-prescription medicines in self-care
(e) adequate knowledge **and skills** of the legal and other requirements associated with the pursuit of pharmacy
(f (new)) adequate knowledge and skills on medicines safety in order to manage the appropriate use and risks associated with the use of medicines
(g (new)) adequate knowledge and skills on the governance and use of database approaches, health informatics, digital literacy and technologies

(h (new)) adequate knowledge and skills on the prevention, management and control of infectious diseases, including on vaccine-preventable diseases, vaccinology and antimicrobial resistance

(i (new)) adequate knowledge and skills to advise patients on the prevention and management of non-communicable diseases and related public health promotion, including nutrition, smoking-cessation, and exercise

(j (new)) adequate knowledge of health policy including health economics and health technology assessments

(k (new)) adequate knowledge and skills to perform clinical risk management on medication use, including the monitoring of dosing, drug-disease and drug-drug interactions and analysing laboratory/clinical data and pharmacovigilance

(l (new)) adequate knowledge and skills to provide adequate advice, treatment and referral for patient ailments

(m (new)) adequate knowledge and skills on clinical biology and laboratory medicine to perform, analyse and interpret laboratory data and point-of-care tests

(n (new)) adequate knowledge and skills about research methods to support the conduct and dissemination of research

(o (new)) adequate knowledge and skills on regulatory sciences to understand the legal controls applied to medicinal products

(p (new)) adequate knowledge and skills on interprofessional education, communication and the promotion of health education

(q (new)) adequate knowledge and skills on the impact of pharmaceuticals in the environment and to advise individuals and communities on the appropriate handling and disposal of pharmaceuticals

ANNEX I -- JUSTIFICATIONS

(A) Annex V 5.6.1 ~~course of training for pharmacists~~ **list of subjects for the training of pharmacists**

List of subjects for the training of pharmacists: A course covers topics taught over a specific period of time. Annex V is a list of subjects and therefore this wording seems more accurate.

(B) Plant ~~and animal~~ biology

The deletion of 'animal biology' from the list of subjects is supported by the European Pharmaceutical Students' Association (EPSA) survey that analysed Pharmacy Curricula in 25 EU countries, 1 EFTA country and 3 EU candidate countries (ANNEX II). The survey conducted by EPSA confirms this is not a subject in the majority of countries consulted.

(C) Analytical chemistry**, including analysis of medical products**

For the sake of accuracy 'including analysis of medicinal products' has been moved from "Organic chemistry to 'Analytical chemistry' as illustrated by the EPSA survey mentioned above.

(D) Pathology

The inclusion of this subject is supported by the fact that pathology links to physiology and a proper appreciation of both these subjects is needed to understand pharmacology and pharmacotherapy (the uses, effects and modes of action of drugs and the medical treatment by means of medicines) .

The inclusion of 'pathology' on the list of subjects for pharmacists training is supported by the survey conducted by the European Pharmaceutical Students' Association (EPSA) that analysed Pharmacy Curricula in 25 EU countries and 1 EFTA country, among other European countries. Indeed, the survey, as attached in Annex II, confirms this topic is covered overall in a large majority of the consulted countries.

(E) General and applied biochemistry (medical), **including molecular biology**

This addition is supported by the above-mentioned survey conducted by the EPSA. Indeed, this survey confirms that general and applied biochemistry should also include 'molecular biology' as this is overall covered in the pharmacy curricula in a majority of EU/EFTA member States. The pipeline of pharmaceutical companies has changed over the past two decades and currently biopharmaceuticals represent one third of worldwide sales of medicinal products. This is increasing each year.

(F) Microbiology, **immunology and epidemiology**

The addition of immunology and epidemiology to the list of subjects of the pharmacy curricula is supported by the above-mentioned survey conducted by the European Pharmaceutical Students' Association. The survey indeed confirms immunology and epidemiology currently constitute a subject of the pharmacist education in most countries consulted. In most cases, they are covered as part of other subjects, such as microbiology. This is also supported by the scientific and technical advancements on these areas which have been promoted by the increasing surge of threats to public health, including pandemics.

Understanding the Immune system is pivotal to understanding 3 major approaches to preserve human health as follows:

- Development of Vaccines which in the current COVID 19 pandemic does not need further justification for its inclusion in any curricula.

- The birth of Immunotherapeutics (e.g. Monoclonal Antibodies, mABs) and in particular the concept of immune-oncology where the body's own immune system or T cells are activated to recognise cancer cells and destroy them. Prior to the COVID 19 pandemic it was estimated in 2017 that approximately 40% of Pharma Pipelines were biological in nature (Vaccines, mABs, proteins etc). Pharmacists need to be aware of how these potent biologics work and affect treatment.

- CAR-T therapies or the delivery of Living Drugs. In CAR-T therapies – T cells from Patients are harvested and biologically engineered with the insertion of Antigen designed to attach to cancer cells and induce lysis of the cancer cell.

Epidemiology is a cornerstone of public health. It deals with the incidence, distribution and control of disease and other factors related to health. It is needed for the curriculum in order for pharmacists to understand healthcare management and for them to be in a position to discuss health outcomes, pharmaceutical care and disease prevention with patients.

(G) Pharmaceutical **and biopharmaceutical technology, including pharmaceutical compounding**

The addition of '**biopharmaceutical technology**' is supported by the above-mentioned survey carried out by the European Pharmaceutical Students' Association (EPSA)[1]. In some universities biopharmaceutical technology is offered as a standalone course when in others it is part of other courses such as bioproduction, pharmaceutical industry, biochemistry, pharmaceutical technology, etc. The inclusion of this topic is also particularly important in the light of the increasing role of biological medicinal products, current and anticipated, for the treatment of patients[2].

This is also supported by the outcome of the PHAR-IN report which looked at Competences for industrial pharmacy practice in biotechnology")[3]

The addition of '**pharmaceutical compounding**' is also supported by the survey carried out by EPSA[4], which illustrated this topic is mostly offered as part of other courses, namely pharmaceutical technology although in some universities this is included in the pharmacy curricula as a standalone course.

In addition, this is supported by the current text of the Professional Qualifications Directive. Indeed, Article 45 §2 (a) already sets out that the Member States shall ensure that the qualified pharmacists are able to gain access to and pursue at least the following activities:

a) **preparation of the pharmaceutical form** of medicinal products;
e) **preparation**, testing, storage and supply **of medicinal products** in **pharmacies** open to the public;
f) **preparation**, testing, storage and dispensing **of medicinal products** in **hospitals**

[1] See Annex II
[2] EvaluatePharma® World Preview 2015, Outlook to 2020, June 2015, pages 21-22. http://www.evaluategroup.com/WP2015
[3] A European Competence Framework for Industrial Pharmacy Practice in Biotechnology (mdpi.com)
[4] See Annex II

In order to pursue the above-mentioned technical and complex pharmaceutical activities, an inclusion of pharmaceutical compounding in the training programme of pharmacists is not only required but also accurately reflects the content of the training programme for pharmacists.

(H) Regulatory sciences, quality of pharmaceutical products and quality assurances

All pharmacists need to understand regulatory sciences as they play a crucial role in the development, production, quality assurance and supply of medicinal products. Pharmacists dispensing a medicinal product need to understand the basis of the product's Summary of Product Characteristics and its leaflet and package labelling which they supply to the patient.

The addition of '**regulatory sciences, quality of pharmaceutical products and quality assurances'** in the list of subjects of Annex V point 5.6.1. is supported by the above-mentioned survey carried out by the European Pharmaceutical Students' Association (EPSA)[5]. Indeed, the results of this survey support the inclusion of this subject to better reflect the scientific and technological developments affecting the training of pharmacists.

This topic relates to processes of quality assurance, to ensure that pharmaceutical products are developed and manufactured to the highest quality standards and, in addition, provides knowledge on the associated risk assessment methods. In addition, this is supported by the outcome of the PHAR-IN report which looked at Competences for industrial pharmacy practice in biotechnology")[6]. Moreover, the requirement for the inclusion of pharmaceutical regulatory sciences is established in the Statements on Pharmacy and Pharmaceutical Sciences Education by the International Pharmaceutical Federation (FIP) (2017). The Statements were developed by FIP to guide the pharmacy education global evolvement.

(I) Clinical toxicology

We suggest to add "Clinical" as the toxicology taught should refer to humans. Clinical toxicology is the management and prevention of adverse effects from medicines and other chemicals in humans.

In light of the results of the survey conducted by the EPSA, the term 'clinical toxicology' is widely used across European Member States to refer to this stand-alone subject of the pharmacy curricula. This is therefore suggested to reflect current terminology used in pharmacy curricula across Europe.

(J) Genetics and pharmacogenomics including personalised therapies

The addition of 'genetics and pharmacogenomics including personalised therapies' is supported by the results of the EPSA survey as this shows a clear trend to include such topics in the pharmacists training across EU universities because of the scientific and technical advancements affecting the pharmacist profession on these areas in the last 15 years.

The pharmacogenetic aspects in the optimisation of therapy and the relevance of personalised therapies is emphasised in health care systems in Europe so as to ensure patient safety and sustainability of care. These considerations and services are a requirement in the practice of pharmacy and hence pharmacy education has included the subjects in the minimum training list.

(K) Clinical Pharmacy

[5] See Annex II

[6] A European Competence Framework for Industrial Pharmacy Practice in Biotechnology (mdpi.com)

This addition is again supported by the results of the EPSA survey which confirms a majority of EU Member States include 'clinical pharmacy' as a stand-alone subject within the training programme of pharmacists.

This subject relates to clinical risk management on medication use and analysing laboratory/clinical data for the in management of acute and chronic communicable and non-communicable diseases. In hospital and community services pharmacists are participating in optimisation of pharmacotherapy through collaborative practice, in patient monitoring, assessment of clinical risk management on medication use and analyses and interpretation of laboratory and clinical data. The introduction of clinical pharmacy in curricula as a subject meets the requirements of having pharmacists that are able to provide these minimum services within professional settings. (Azzopardi LM. Pharmacy Practice in Western Europe In: Encylopedia of Pharmacy and Clinical Pharmacy. Elsevier, 2019).

(L) Pharmaceutical care

This is supported by the survey carried out by the European Pharmaceutical Students' Association (EPSA)[7] that analysed Pharmacy Curricula in the EU countries. In some universities, pharmaceutical care is offered as a standalone course when in others it is part of other courses such as dispensing, pharmacy practice, pharmacotherapy pharmaceutical assistance, social pharmacy, pharmacology, etc.

Pharmaceutical care refers to providing patient care and attend patient needs in relation to their medical treatment. It includes, inter alia, providing information and advice on medicines and their appropriate use, and offering personalised support for patients who administer their medication, which are professional activities covered respectively in Article 44§ 2 (g) and (i) of the Professional Qualifications Directive as updated in 2013 (Directive 2013/55/EU amending Directive 2005/36/EC). This addition would therefore make consistent Annex V point 5.6.1 with Article 44 of the Professional Qualifications Directive.

(M) Pharmacy practice

This is supported by the current text of the Directive and will reflect the new content that follows the progress of the pharmacist's profession.

The introduction of Pharmacy Practice as a subject in the list consolidates the principles of medication dispensing, distribution and administration of medicines, patient management and concordance, collaborative practice and interprofessional practice, health systems including services for special patient population. The taught aspects support the learning experience from the six months of traineeship.

According to article 44§ 2, pharmacists' qualifications shall attest at least five years' duration including four years of theoretical and practical training and six months of traineeship. The article also explain that the training cycle should include the programme describe in Annex V .6.1. However, this programme only enumerates the hard-core courses of the curricula without a proper reference to practical training or the compulsory traineeship. We believe this vacuum should be filled with our proposal. In addition, the new proposal may facilitate or enhance new courses that are the result of the development of the pharmacy role. For instances this will cover areas such as communication that will be useful to improve the consultation techniques needed for new services provided in the pharmacy.

[7] See Annex II

Moreover, Pharmacy Schools within Universities will not need to change their programmes following this change.

(N) eHealth

Over the last decades, the development of health informatics and digital technologies have enormously impacted the health sector including the pharmacist profession, especially through the increased use of electronic databases in pharmacy practice. This includes dispensing e-prescription, checking for medication interactions when accessing electronic medication records, providing support for adherence via a mobile app or telephone call, or acting as the patient's entry point into the health system[8,9]. Pharmacists are at the forefront of enhancing evidence-based information to the public. We believe this should be reflected in the pharmacy curricula as this is necessary not only to reflect technical developments but also to ensure pharmacists are fit to exercise their profession as well as to respond to the European Commission's intention to reinforce digital skills of health professionals[10].

(O) Public health

The addition of 'public health' is supported by the results of the EPSA survey which confirms that a majority of EU Member States include overall the topic of 'public health' within the training programme of pharmacists across the consulted countries. In addition, this is consistent with the professional activity described in Article 45 §2 (j) as modified by Directive 2013/55 amending Directive 2005/36/EC which states that qualified pharmacists should be able to pursue the task of 'contribution to local or national public health campaigns'.

(P) Health economics and pharmacoeconomics

Health economics can be divided into health policy, health service organisation and economic evaluation in health. It is a tool to help prioritise competing health care interventions. Pharmacoeconomics evaluates the cost benefit and cost-effective analysis of medicines and helps make decisions on the use of medicines.
Pharmacists are crucial in using pharmacoeconomic analysis to influence expenditure and distribution of resources on medicines. Also, they are key to practice-based commissioning and improving the efficiency of health services.

This addition of 'health economics and pharmacoeconomics' is supported by the results of the EPSA survey which confirms that a majority of EU Member States include the topic of health economics and pharmacoeconomics within the training programme of pharmacists overall across the consulted countries.

Article 44 §3 describing the knowledge and skills that need to be acquired during the training of pharmacists. General comment applicable to the whole paragraph 3 of Article 44:

Article 44§ 3 should include "*adequate knowledge and skills*" in each point rather than just "*knowledge*" as only by acquiring both the knowledge (i.e. theories) and skills (i.e. practical abilities) on all the areas covered

[8] García-Queiruga M, Margusino-Framiñán L, Martín-Herranz I, et al. Implementation of an e-Interconsultation system between a hospital pharmacy service and primary care pharmacy units in a health area.
[9] Samartín-Ucha M, Piñeiro-Corrales G, Continuity of Care Group from the EOXI Vigo. Model of teleconsultation pharmaceutical integrated in the electronic clinical history of the patient. Farm Hosp 2019;43:1–5.
[10] European Commission Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society

by the current text as well as those we suggest adding or updating in our response, pharmacists would be adequately prepared (in other words 'qualified') to fully exercise their profession. The below justifications take into account the changing roles of pharmacists which were acknowledged by the Expert Panel on effective ways of investing in Health in one of their recent reports[11].

Moreover, the updating and development of the knowledge and skills are in support of the transformation in the pharmaceutical workforce as it evolves to meet the Pharmaceutical Workforce Development Goals as outlined by the International Pharmaceutical Federation based on WHO Global Strategy for Human Resources for Health (FIP, The FIP Development Goals: Transforming global pharmacy, 2020). The inclusion of the knowledge and skills for the minimum training also addresses the four pillars which have been identified by the EU Commission in the Pharmaceutical Strategy for Europe[12], November 2020.

(Q) (a) adequate knowledge **and skills** of medicin**al products related to their formulation, development, production, analysis and wholesale distribution**

This addition reflects more accurately than the current wording of paragraph (a) the knowledge and skills that are to be acquired during the pharmacy education which will enable the qualified pharmacist to exercise his/her profession in the different possible settings across the pharmaceutical supply chain or health system (i.e., pharmaceutical industry, wholesale distribution, hospital or community pharmacy). This is supported by the PHARMINE project[13] funded by the EU Life Long Learning Programme on pharmacy education which covered each of these activities.

(R) (b) adequate knowledge **and skills** of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products **and medical devices**

There is a drive to see more patients treat themselves and a delivery device is the "medicine to patient "interface that can offer patients convenience and ease of use. The pharmacist is the person who coaches the patient on their use. Hospital pharmacists are the main professionals responsible for the purchase, management and dispensing of sterile medical devices such as drug eluting stents and catheters.

The addition of 'medical devices' is necessary to reflect the scientific and technical advancements on the whole spectrum of pharmaceuticals and pharmaceutical technology. Pharmacist training within EU Member States should indeed include adequate knowledge and skills not only of medicinal products but also of medical devices. This practice is for example reflected in the training of French pharmacists who are obtaining knowledge about medical devices in the last year of their studies[14].

(S) (c) adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances, and of the use of medicinal products, **including their use in pharmacotherapy;**

The description of this knowledge is incomplete without the added modification. Pharmacists not only learn about medicinal products and their metabolic effects of those medicines, but they also learn how to treat a

[11] Expert Panel on effective ways of investing in Health (EXPH). Task shifting and health system design. June 2019.
[12] (https://ec.europa.eu/health/human-use/strategy_en)
[13] PHARMINE: Pharmacy Practice 01 Oct 2011, 9(4):169-187
[14] Bourdon O, Ekeland C, Brion F. Pharmacy education in France. Am J Pharm Educ. 2008;72(6):132.

disease with medication. One example of pharmacy interventions in this field is medication optimisation for older patients[15].

(T) (d) adequate knowledge **and skills** to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge

As mentioned above, Article 44§ 3 should include "*adequate knowledge and skills*" in each point rather than just "*knowledge*" as only by acquiring both the knowledge (i.e. theories) and skills (i.e. practical abilities) on all the areas covered by the current text as well as those we suggest adding or updating in our response, pharmacists would be adequately prepared (in other words 'qualified') to fully exercise their profession.

(U) (e (new) adequate knowledge and skills to advise patients on medical terminology and the use of medicines, including non-prescription medicines and use of medicines in self-care

This is supported by a modification[16] of the Directive 2005/36/EC that inserted new pharmacists' activities including: "personalised support for patients who administer their medication". Patients often rely on the pharmacist to treat minor ailments such as cough or constipation. The Directive recognised this established practice that reflects the progress of the pharmacy profession. Such activity is sustained by adequate training on how to advise patients on medicines management and in particular to provide counselling on appropriate use of non-prescription medicines.

(V) (f) ~~(e)~~ adequate knowledge **and skills** of the legal and other requirements associated with the pursuit of pharmacy

As noted above, Article 44§ 3 should include "*adequate knowledge and skills*" in each point rather than just "*knowledge*". Only by acquiring both the knowledge (i.e. theories) and skills (i.e. practical abilities) on all the areas covered by the current text as well as those we suggest adding or updating in our response, pharmacists would be adequately prepared (in other words 'qualified') to fully exercise their profession.

(W) (g (new)) adequate knowledge on medicines safety in order to manage the appropriate use and risks associated with the use of medicines

This modification is supported by the pharmacovigilance legislation[17] . Pharmacists have new obligations under the pharmacovigilance legislation and their knowledge needs to be fit for this purpose. In particular, pharmacists might need to be asked to assess, record and report the impact of medicines in patients or groups of patients. Therefore, pharmacists need to acquire the knowledge that will allow them to deal with the risks associated with the use of medicines.

(X) (h) (new)) adequate knowledge and skills on the governance and use of database approaches, health informatics, digital literacy and technologies

The Falsified Medicines Directive establishes new obligations for pharmacists. In particular, since February 2019, pharmacies are involved in a medicines verification system[18] supported by a complex structure.

[15] Spinewine, A., Fialová, D. & Byrne, S. The Role of the Pharmacist in Optimizing Pharmacotherapy in Older People. Drugs Aging 29, 495–510 (2012).
[16] Directive 2013/55EU of the European parliament and of the Council of 20 November 2013
[17] Article 59 (a) (ii) second paragraph Directive 2001/83/EC. Modification introduced by Directive 2010/84/EU
[18] Article 54a (d) Directive 2011/62/EU

Pharmacists are required to work with a particular technological setting. In addition, new EU law[19], including the Regulation on veterinary medicinal products (Regulation 2019/6) and the Medical Devices Regulation (Regulation 2017/745) and recent EU policy papers[20,21] establish respectively obligations and recommendations on recording and electronic recording that may require the acquisition of new knowledge on information management and technology, including on the collection, analysis and protection of healthcare data. Therefore, the scientific and technological progress of the profession and current EU law requires the introduction of this new knowledge and skills.

(Y) (i (new)) adequate knowledge and skills on the prevention, management and control of infectious diseases, including on vaccine-preventable diseases, vaccinology and antimicrobial resistance

This is supported by the increasing resurgence in certain communicable and preventable diseases, such as tuberculosis (TB - particularly in HIV positive patients) and outbreaks of measles[22]. The threat from the seasonal influenza virus of up to 70.000 deaths in Europe a year[23] and a broader failure of antimicrobial treatments as a result of antimicrobial resistance (AMR)[24] are evermore present. Additionally, with the recent rise in migration and movement of people between countries and continents, threats from beyond Europe's boarders such as Ebola and Zika have also posed a threat.

Pharmacists are identified by the European Commission[25], European Parliament[26] and Council of the European Union[27] as key actors in the prevention, management and control of infectious diseases, and these same instances have highlighted the need to strengthening the training of healthcare professionals related to infection prevention, management and control, antimicrobial resistance and vaccine-preventable diseases.

Stewardship teams are for instance a useful tool which aims to optimise clinical outcomes, reduce the overuse of antibiotics, limit the selection of antimicrobial resistant strains and reduce excessive costs attributable to sub-optimal antimicrobial use. Pharmacists are indispensable members of these teams since in accordance with their skills they support the team by reviewing antibiotic treatment duration, advising on the cessation of inappropriate antibiotic treatment and educating other healthcare professionals on the restricted use of certain antibiotics[28].

(Z) (j) (new)) adequate knowledge and skills to advise patients on the prevention and management of non-communicable diseases and related public health promotion, including nutrition, smoking-cessation, and exercise.

This is added to reflect the evolution of pharmacy practice in the last decades from medicine dispensing towards patient care, public health promotion and disease prevention. This addition also responds to the inclusion by Directive 2013/55/EU in Article 45 §2 (j) of a reference to pharmacists' contribution to local or national public health campaigns.

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[19] Article 59 (a) (ii) second paragraph Directive 2001/83/EC. Modification introduced by Directive 2010/84/EU

[20] European Parliament Motion for Resolution on Enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (12 December 2019)

[21] European Commission's Communication 'Transformation of Health and Care in the Digital Single Market, empowering citizens and building a healthier society

[22] https://www.who.int/csr/don/06-may-2019-measles-euro/en/

[23] https://www.ecdc.europa.eu/en/seasonal-influenza/facts/factsheet

[24] https://antibiotic.ecdc.europa.eu/en/publications-data/antibiotic-resistance-increasing-threat-human-health

[25] https://ec.europa.eu/health/amr/sites/amr/files/amr_guidelines_prudent_use_en.pdf

[26] http://www.europarl.europa.eu/doceo/document/TA-8-2018-0354_EN.html

[27] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018H1228(01)&from=GA

[28] Amann S, Neef K, Kohl S. EAHP Position Paper Antimicrobial resistance (AMR). European Journal of Hospital Pharmacy 2019;26:175-177.

Indeed, pharmacists, in addition to dispensing medicines, currently offer more and more patient-centred services such as screening and management of non-communicable diseases, including cardiovascular diseases, diabetes, and cancer. This also reflects the critical contribution of nutrition[29], physical exercise[30] and smoking cessation[31] to healthcare and disease prevention.

Pharmacists' advice in nutritional and dietary matters as well as in smoking cessation is a fundamental element in the prevention of disease and health promotion, as well as in the treatment of non-communicable diseases such as diabetes, obesity and cancer. In addition, pharmacies offer a wide range of food products, as dietetics or medicated dietetics, particularly baby milk, hydrolyzed protein, including the diet therapy type, or for gastrointestinal disorders or hypocaloric regimes for the treatment of obesity.

(AA) (k) (new)) adequate knowledge of health policy including health economics and health technology assessments

As mentioned in the suggested changes to the current list of subjects, the addition of 'health economics and pharmacoeconomics' is supported by the results of the EPSA survey which confirms that a majority of EU Member States include overall the topics of health economics and pharmacoeconomics within the training programme of pharmacists across the consulted countries. Pharmacists are expected to gain knowledge on health policy issues in order to pursue their profession adequately.

(BB) (l (new)) adequate knowledge and skills to perform clinical risk management on medication use, including the monitoring of dosing, drug-disease and drug-drug interactions and analysing laboratory/clinical data and pharmacovigilance

The inclusion of these knowledge and skills caters for the subject of pharmacology and pharmacotherapy which is currently included under Annex V point 5.6.1 but which is not adequately reflected in the current list of knowledge and skills under Article 44 §3 of PQD. As revealed by the EPSA survey, this subject is still relevant as it is included in the pharmacy curricula of a majority of EU Member States. It is also in line with the suggested inclusion of 'clinical pharmacy' within the list of subjects. Finally, this is also supported by the updated list of pharmacist activities described in Article 45 §2 (h) which states the pharmacist training should make the concerned professional able to conduct the necessary reporting of adverse reactions of pharmaceutical products to the competent authorities.

(CC) (m (new)) adequate knowledge and skills to provide adequate advice, treatment, and referral for patient ailments

Pharmacy curricula should allow pharmacy students to acquire these knowledge and skills in order to reflect the evolution of pharmacy practice focusing on patient care. Increasingly, the pharmacist's task is to ensure that a patient's medicine therapy is appropriately indicated, the most effective available, the safest possible, and convenient for the patient. They have also a referral role for patient ailments. Pharmaceutical care is the subject of the pharmacy curricula, which we suggested to include in the list of subjects above, which corresponds to the acquisition of these knowledge and skills.

(DD) (n (new)) adequate knowledge and skills on clinical biology and laboratory medicine to perform, analyse and interpret laboratory data and point-of-care tests

[29] http://www.euro.who.int/en/health-topics/disease-prevention/nutrition/nutrition
[30] WHO/Europe | Physical activity
[31] Preventing noncommunicable diseases (who.int)

This inclusion responds to the need to reflect the scientific and technical progress on the area of clinical biology and laboratory medicine, and the inclusion of 'molecular biology' in the general and applied biochemistry subject which is indeed part of the current training for pharmacist in a majority of Member States, as shown by the EPSA survey.

(EE) (o (new)) adequate knowledge and skills about research methods to support the conduct and dissemination of research

This inclusion reflects the current knowledge and skills that pharmacist training should allow for pharmacists to be able to conduct research methods associated with different fields of pharmacy, including the formulation, development, production, and analysis of medicinal products. This also relates to research in the fields of clinical pharmacy and pharmaceutical care for research areas such as pharmacy practice, medication use, patient safety and ethics**.**

(FF)(o (new)) adequate knowledge and skills on regulatory sciences to understand the legal controls applied to medicinal products

This inclusion reflects regulatory skills needed for qualified pharmacists to understand the processes of quality assurance, to ensure that pharmaceutical products are developed and manufactured to the highest quality standards and understand the associated risk assessment methods. This also reflects new terminology used for the scientific and technical rules and requirements that are necessary to assess the efficacy, safety and quality of medicinal products.

(GG) (p (new)) adequate knowledge and skills on interprofessional education, communication, and the promotion of health education

This inclusion is in line with pharmacist' role to provide information and advice on medicinal products, including on their appropriate use as well as on contributing to local or national health promotion campaign. Indeed, communication skills are essential for carrying out these activities, which are indeed included in the list of pharmacists' activities embedded in Article 45§2 (g) and (j) of Directive 2005/36/EC as updated in 2013 (Directive 2013/55/EU). Such activities are sustained by adequate training on how to communicate and interact effectively and harmoniously with patients and other healthcare professional which has increasingly gained importance for improving patient care[32]. Training on interprofessional education has also become a key role in pharmacy practice in the last 10-15 years.

(HH) (q (new)) adequate knowledge and skills on the impact of pharmaceuticals in the environment and to advise individuals and communities on the appropriate handling and disposal of pharmaceuticals

This inclusion is necessary to reflect the increasing importance of considering environmental aspects of pharmaceuticals production, use and disposal at EU level. As part of their role in improving public health, pharmacists see it as their duty to advise citizens on environmental health and safety. This includes advising on appropriate handling, adherence and disposal as well providing information to the public on the availability of 'greener' pharmaceuticals where such information is available. Indeed, the majority of the European population can return expired or unused medicines to their community pharmacy[33].

[32] Pourrat X, Corneau H, Floch S, et al. Communication between community and hospital pharmacists: impact on medication reconciliation at admission. Int J Clin Pharm 2013; 35: 656–63.
[33] 191114E-PGEU-Position-Paper-on-Pharmaceuticals-in-the-Environment.pdf

The inclusion of such knowledge and skills is also supported by the European Commission's recommendation, within its Strategic approach to pharmaceuticals in the environment, of exploring, in cooperation with relevant stakeholders, how environmental aspects could become part of medical training and professional development programmes[34]. The adopted European Parliament Resolution on a strategic approach to pharmaceuticals in the environment (2019/2816(RSP))[35] also calls on the Member States and the Commission to promote training for healthcare professionals, including pharmacists, and awareness raising campaigns for patients, on the prudent use of pharmaceuticals.

[34] strategic_approach_pharmaceuticals_env.PDF (europa.eu) (page 8)
[35] https://www.europarl.europa.eu/doceo/document/TA-9-2020-0226_EN.pdf

ANNEX II – EPSA SURVEY: DATA ANALYSIS OF PHARMACY CURRICULA IN EUROPE

Introduction:

Between the 7th - 26th September 2020, the European Pharmaceutical Students' Association (EPSA) carried out a Survey on the Pharmacy Curricula in Europe. The aim of the survey was to receive one answer per country from all European countries that are Members of EPSA in order to provide input for the update on Annex V 5.6.1 Training programme for pharmacists in the Professional Qualifications Directive.
As a result, EPSA received answers from 29 European countries, 25 which were EU Countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Malta, The Netherlands, Poland Portugal, Romania, Slovakia, Slovenia, Spain and Sweden. Additionally, there were 4 answers from non-EU countries: North Macedonia, Serbia, Switzerland and Turkey.

Method:

The Survey consisted of two types of questions:
1. Does your university curricula cover subject X? (*Yes, as a separate subject / Yes it is covered within other subject(s) / No)*
2. Which subjects at your university cover subject X?
EPSA's Member Associations were provided with a document that included the definitions of each subject.

After receiving the complete number of responses, a spreadsheet with the data was created. The spreadsheet tabs contain the following:
Tab 1: Form responses from the survey.
Tab 2: Responses for each subject presented per country.
Tab 3: Statistics Overview with tables representing the percentages of responses per subject. This is presented in **Table 1** of the Analysis below.
Tab 4: Final table of results.
Tab 5: Recommendations for each subject were concluded with graphs, as seen in **Table 2** below.

Based on the analysis of the subjects, if a subject received the minimum threshold of 18 positive responses (62.07%) overall (either as a separate subject or covered within other subjects), it qualified to be part of the inclusion criteria for the curricula. This criteria was set at 62.07% (18 countries) because this percentage was the baseline for a large number of subjects.
According to this, two categories were created:

>62.07% (18 countries) covered overall = included	<62.07% covered overall = not included

Analysis:

The responses for each subject are presented in **Table 1.** This table is ranked from highest to lowest percentages as per the Column 3 "Does your university curricula cover this subject?: Yes, it is covered overall".

Table 1. Number of responses for subjects taught in Faculties of Pharmacy across Europe.

	Does your university curricula cover this subject?

Subject	Yes, as a separate subject	Yes, it is covered within other subject(s)	Yes, it is covered overall	No (EU/non-EU)	Should it be included?
Pharmacology	93.10% (27)	6.90% (2)	100.00% (29)	0.00% (0)	**yes**
Microbiology	86.21% (25)	13.79% (4)	100.00% (29)	0.00% (0)	**yes**
Analytical Chemistry including Analysis of Medicinal Products	79.31% (23)	20.69% (6)	100.00% (29)	0.00% (0)	**yes**
Pharmaceutical Chemistry	79.31% (23)	20.69% (6)	100.00% (29)	0.00% (0)	**yes**
Physiology	75.86% (22)	24.14% (7)	100.00% (29)	0.00% (0)	**yes**
Immunology	58.62% (17)	41.38% (12)	100.00% (29)	0.00% (0)	**yes**
Clinical Toxicology	51.72% (15)	44.83% (13)	100.00% (29)	3.45% (1)	**yes**
Organic Chemistry	86.21% (25)	10.34% (3)	96.55% (28)	3.45% (1) (1/0)	**yes**
Biochemistry	86.21% (25)	10.34% (3)	96.55% (28)	3.45% (1) (1/0)	**yes**
Physics	62.07% (18)	34.48% (10)	96.55% (28)	3.45% (1) (1/0)	**yes**
General Chemistry	62.07% (18)	34.48% (10)	96.55% (28)	3.45% (1) (1/0)	**yes**
Pathology	58.62% (17)	37.93% (11)	96.55% (28)	3.45% (1) (0/1)	**yes**
Pharmacognosy	68.97% (20)	24.14% (7)	93.10% (27)	(1/0)	**yes**
Anatomy	58.62% (17)	34.48% (10)	93.10% (27)	6.90% (2) (2/0)	**yes**
Legislation	58.62% (17)	34.48% (10)	93.10% (27)	6.90% (2) (2/0)	**yes**
Pharmaceutical Compounding	31.03% (9)	62.07% (18)	93.10% (27)	6.90% (2) (2/0)	**yes**
Virology	10.34% (3)	82.76% (24)	93.10% (27)	6.90% (2) (2/0)	**yes**
Pharmaceutical Technology	68.97% (20)	20.69% (6)	89.66% (26)	10.34% (3) (3/0)	**yes**
Clinical Pharmacy	65.52% (19)	24.14% (7)	89.66% (26)	10.34% (3) (2/1)	**yes**
Plant Biology	62.07% (18)	27.59% (8)	89.66% (26)	10.34% (3) (3/0)	**yes**
Inorganic Chemistry	55.17% (16)	31.03% (9)	86.21% (25)	13.79% (4) (4/0)	**yes**

Molecular Biology	37.93% (11)	48.28% (14)	86.21% (25)	13.79% (4) (2/2)	**yes**
Genetics	24.14% (7)	62.07% (18)	86.21% (25)	13.79% (4) (4/0)	**yes**
Quality of Pharmaceutical Products	10.34% (3)	75.86% (22)	86.21% (25)	13.79% (4) (2/2)	**yes**
Professional Ethics	34.48% (10)	48.28% (14)	82.76% (24)	17.24% (5) (5/0)	**yes**
Pharmacy Practice	65.52% (19)	13.79% (4)	79.31% (23)	20.69% (6) (5/1)	**yes**
Pharmaceutical Care	41.38% (12)	37.93% (11)	79.31% (23)	20.69% (6) (5/1)	**yes**
Regulatory Science	13.79% (4)	65.52% (19)	79.31% (23)	20.69% (6) (5/1)*	**yes**
Pharmacogenomics	17.24% (5)	58.62% (17)	75.86% (22)	24.14% (7) (7/0)	**yes**
Quality Assurance	17.24% (5)	58.62% (17)	75.86% (22)	20.69% (6) (5/1)	**yes**
Health Economics	34.48% (10)	34.48% (10)	68.97% (20)	31.03% (9) (7/2)	**yes**
Epidemiology	24.14% (7)	44.83% (13)	68.97% (20)	31.03% (9) (7/2)	**yes**
Public Health	24.14% (7)	37.93% (11)	62.07% (18)	37.93% (11) (8/3)	**yes**
Digital Literacy	17.24% (5)	41.38% (12)	58.62% (17)	41.38% (12) (9/3)	no
Medical Terminology	13.79% (4)	44.83% (13)	58.62% (17)	41.38% (12) (10/2)	no
Social Science	24.14% (7)	31.03% (9)	55.17% (16)	44.83% (13) (11/2)	no

Health Informatics	20.69% (6)	31.03% (9)	51.72% (15)	48.28% (14) (12/2)	no
Animal Biology	06.90% (2)	34.48% (10)	41.38% (12)	58.62% (17) (14/3)	no

Conclusion:
The subjects that should be included in the pharmacy curricula are presented in **Table 2,** Column 1**.**

Table 2. Subjects to be included in the pharmacy curricula in Faculties of Pharmacy across Europe according to the EPSA criteria.

Subjects included	**Subjects not included**
Plant Biology	Animal Biology
Physics	Medical Terminology
General Chemistry	Social Science
Organic Chemistry	Health Informatics
Analytical Chemistry including Analysis of Medicinal Products	Digital Literacy
Pharmaceutical Chemistry	
Biochemistry	
Physiology	
Microbiology	
Pharmacology	
Clinical Pharmacy	
Pharmaceutical Technology	
Pharmacognosy	
Pharmacy Practice	
Inorganic Chemistry	
Molecular Biology	
Genetics	

Pharmacogenomics	
Anatomy	
Pathology	
Virology	
Immunology	
Epidemiology	
Pharmaceutical Compounding	
Clinical Toxicology	
Legislation	
Professional Ethics	
Pharmaceutical Care	
Regulatory Science	
Quality Assurance	
Quality of Pharmaceutical Products	
Public Health	
Health Economics	

This survey was conducted and analysed by Piotr Nawrocki (Policy Affairs Coordinator) and Jess McNamara (Vice President of European Affairs) from EPSA.

References:

EPSA Survey on Pharmacy Curricula in Europe 2020: https://docs.google.com/spreadsheets/d/1-DOd6yt6BAHgqDIeglGAZ9BA3cFKK-uZjdnMpu4H9Qw/edit#gid=789201381