

## PHARMACY IN THE EUROPEAN UNION: TRESPASSING ONTO MEDICINE?

Livio Garattini<sup>1</sup> and Nicholas Freemantle<sup>2</sup>

### Affiliation:

<sup>1</sup> Centre for Health Economics, Institute for Pharmacological Research Mario Negri IRCCS, Ranica, Italy.

<sup>2</sup> Institute of Clinical Trials and Methodology, University College London, London, UK.

**Corresponding author:** Livio Garattini. E-mail: [livio.garattini@marionegri.it](mailto:livio.garattini@marionegri.it)

### Compliance with ethical standards:

*Funding:* No sources of funding were used to conduct this study or prepare this manuscript.

*Conflict of interest:* Nicholas Freemantle and Livio Garattini have no conflicts of interest directly relevant to this article.

### Introduction

Pharmacy has been historically regarded as an intermediate discipline between health and chemistry [1], rooted in drug development, production, and compounding. Until relatively late in the last millennium the vast majority of pharmacists used to make drugs, regardless of whether working at hospital or in community. Nowadays these tasks have been almost lost following the large-scale manufacturing of pharmaceuticals by industry, and dispensing has remained the major traditional activity of pharmacists. In the long run these changes have weakened the historical combination of pharmacist's profession and education [2]. Although still focused on scientific subjects (e.g. physics and biology), the latter has been inevitably affected by the domestic regulation of the former, especially in the community domain – still by far the most important labor market for pharmacy graduates. At present, pharmacy education has found a wide range of uneven solutions in the European countries, starting from the minimum duration of graduation, which ranges from three (in the Scandinavian countries) to six years (in France and the Netherlands) [DTP2].

In the new millennium healthcare pharmacists have started claiming that the focus of their services – delivered as acknowledged leading drug therapy experts – has been increasingly shifted from the 'product' to the 'patient' regardless of their work domain [Molto3]. Switching the motto from 'getting the right drug to each patient' to 'getting the drug therapy right for each patient' [Kehrer4], both hospital and community pharmacists are expected to increasingly contribute in reducing clinical errors and eventually improving the efficient use of health care resources [Pharmine5]. Clinical pharmacy and pharmaceutical care [CP&PhC6] are the two most cited concepts to support this trendy shift.

### Two clear-cut settings

Any patient's drug therapy can be phased in three steps **in practice**: prescription, distribution and administration. Traditionally, each one of these steps can be easily ascribed to a specific health professional at hospital – respectively the physician, the pharmacist and the nurse [7]. The supposed progression of the hospital pharmacist's role from simply moving boxes and handling supplies to providing clinical services to patients should warrant that seven 'rights' are always respected for all pharmaceutical therapies – right patient, dose, route, time, drug information and documentation [8]. The most recent (hot) argument is why hospital pharmacists should not be allowed to prescribe drugs in Europe too, like in other continents [PECO7]. Although opposed by the medical profession from the outset, this already happens in England and Ireland – a move somehow favored by the recent shortage of physicians (the traditional prescribers) in these countries. Beyond requiring strong clinical knowledge (diagnostic skills included), the claim to extend prescribing rights is likely to bring hospital pharmacists – who are usually employees in their workplace – in conflict with their medical colleagues. Yet it might imply legal litigations with patients and their relatives in case of negative outcomes, a costly 'side effect' that many European hospital pharmacists might not be necessarily pleased to accept.

The professional framework of European pharmacists in community is very different from those at hospital. Community pharmacies are predominantly private shops in almost all European countries [9], no matter whether mainly owned by a single pharmacist (like in France, Italy and Spain) or a big chain (like in the NL and the UK); therefore, commercial considerations are (inevitably) crucial for its profitability. Overall, community pharmacists have always a potential 'conflict of interest' when employed in a private pharmacy, on account of their dual role of health professionals and commercial agents. The clear evidence of the importance of commercial reasoning is the wide range of other products sold in private pharmacies besides drugs, including some which are in conflict with **the** pharmacist's education (e.g. homeopathic products). Professionally, most European community pharmacists are still responsible only for checking prescriptions. To our knowledge, the only (partial) exception are Dutch community pharmacists, who can intervene on prescriptions whether these do not respect national guidelines or do not seem suitable for an individual patient [10]. Conversely, Italian community pharmacists employed in para-pharmacies and health corners of large-scale retail outlets are forbidden

to dispense ethical medicines despite their graduation, being only allowed to deliver over-the-counter drugs [11]. The only realistic excuse to justify this odd limit seems to be the defense of financial privileges matured by community pharmacies hereditarily owned by single pharmacists [12].

### **Two overlapping concepts**

Clinical pharmacy was originally defined as the area of pharmacy concerned with the science and practice of rational medication use [CP13]. Thanks to this health science discipline, pharmacists are expected to provide patient care that optimizes pharmaceutical therapies. Pharmaceutical care followed it and was originally defined as the responsible provision of drug therapies for achieving definite outcomes that improve patients' quality of life [14]. The underlying recommendation was to move toward a patient-centered philosophy of clinical practice aimed at improving the therapy outcomes. Although a recent survey evidenced that pharmaceutical care is mainly associated with community pharmacies in Europe [15], the two concepts are widely used and mixed together in both primary and secondary care [CP&PC6]. Yet, despite various attempts followed to further define and differentiate clinical pharmacy from pharmaceutical care, the two concepts are still closely related and overlapping. Trying to achieve a synthesis, the practice of clinical pharmacy should embrace the philosophy of pharmaceutical care [CP13], being the patient the primary target for both of them.

From theory to practice, a pharmacist patient-centered care would require to counsel patients directly for medication therapies and collaborate with the other healthcare professionals (especially physicians and nurses) within multidisciplinary teams [CP13]. Consistently with pharmaceutical care, the former activity would involve a narrative approach aimed at developing communication and empathy skills with patients, while the latter would imply to provide additional patient-related services of clinical pharmacy [CP&PC6]. As a consequence of the continuously increasing number of elderly people, multimorbidities have become a common phenomenon in Europe and polypharmacy an obvious consequence of it [Molto3], with many patients daily taking four or more medicines. So, medication review – a structured evaluation of a patient's medicines with the aim of optimizing its use and improving health outcomes [Griese16] – has become a frequently cited concept in the literature, sort of 'umbrella term' including drug therapy adherence and medicines reconciliation too [BJCP17].

In general, although it seems pretty obvious to expect positive results from clinical pharmacy services and pharmaceutical care philosophy **of practice [18]**, it is hard to prove them based on clinical evidence. Many interventions are hard to standardize, hence its outcomes in trials too **[PECO7,ERP9]**. Yet most studies have been conducted on small samples in single facilities, probably pushed by pharmacists to demonstrate the usefulness of their services, thus its results cannot be generalized. On account of scant clinical evidence, cost-effectiveness analyses focused on arguable trade-offs between additional costs of clinical pharmacy services and potential savings on other healthcare services **at local level** can only add further confusion. However, needless to say that any pharmacist can provide a good clinical service regardless of the healthcare setting, such as any other health professional who does her/his job in the interests of patients.

### **Policy implications**

The new wave of pharmacists' patient-centered care in Europe still seems to be a reaction against the demotion of their traditional role after the manufacturing revolution, somehow masking a perceived identity crisis. To depict a realistic scenario for a rational follow-on evolution of the pharmacist's role in health care, **it is worth differentiating between hospital and community, two very different settings in terms of healthcare policy.**

#### ***Hospital***

Rather than arguably claiming prescription rights, hospital pharmacists should strengthen their pivotal role of pharmaceutical 'gatekeepers' to improve the appropriateness of prescriptions and eventually generate savings in pharmaceutical expenditure **[19]**. Being in the right position to advise prescribers as drug experts, hospital pharmacists could reinforce their role by specializing in specific therapeutic areas and affirming their independent opinions within multidisciplinary teams to enhance cost-effective prescriptions. Once medical specialists have made their diagnosis and prescribed a drug therapy (if necessary), the selection of the most appropriate drug could be double checked by hospital pharmacists. Moreover, to help free-up work time of their clinical colleagues, hospital pharmacists could eventually discuss the preferred route of drug administration and/or form with problematic patients.

#### ***Community***

The **proposal for** clinical services provided by community pharmacists is inevitably affected by its **potential** remuneration **for pharmacies**. Although amongst the most easily accessible

and highly visible healthcare professionals in primary care, many European community pharmacists still work in small to medium shops, which must ensure (high) return on its investments [Soares20]. This becomes paramount in countries where the 'one pharmacist–one pharmacy' rule still largely holds. The real marketing plus of pharmacies is to attract additional customers for other health products and services thanks to the monopoly on reimbursable drugs. It would be crucial to pinpoint a systematic regulation for remuneration of both drug delivery and additional clinical services. Otherwise pharmaceutical care might remain a disputable concept in practice, potentially driven by commercial incentives when intervening on prescriptions – especially in countries like Italy where the remuneration for reimbursable drugs is still a (high) proportion of prices to the public, and not a (flat) fee for the dispensing service delivered like in the UK [ERP<sup>21</sup>]. Last but not least, we think that a minimum of three years before graduation should be enough for a pharmacist to start working in a community pharmacy and avoid feeling overqualified for her/his daily activities of dispensing drugs. By the way, this is the minimum duration in all European faculties but medicine and veterinary.

In conclusion, despite the great weakness of the EU in this field – inherited (like in many others) by a piecemeal framework at national level – and its present lack of political strength, we are still fiercely convinced that thorough European solutions are potentially the best ones in the long run.

## REFERENCES

- 
- 1 Pearson GJ. Evolution in the practice of pharmacy—not a revolution! *CMAJ*. 2007;176(9):1295–6.
  - 2 Garattini L, Padula A. From pharmacy faculty to pharmacy shop: still a logical pathway in Europe? *Drugs Ther Perspect*. 2018;34(2):85–8.
  - 3 Moltó-Puigmartí C, Vonk R, van Ommeren G, Hegger I. A logic model for pharmaceutical care. *J Health Serv Res Policy*. 2018;23(3):148–57.
  - 4 Kehrer JP1, Eberhart G, Wing M, Horon K. Pharmacy's role in a modern health continuum. *Can Pharm J*. 2013;146(6):321–4.
  - 5 Atkinson J. The Country Profiles of the PHARMINE Survey of European Higher Educational Institutions Delivering Pharmacy Education and Training. *Pharmacy (Basel)*. 2017;5(3). pii: E34.
  - 6 Franklin BD, van Mil JW. Defining clinical pharmacy and pharmaceutical care. *Pharm World Sci*. 2005;27(3):137.
  - 7 Garattini L, Padula A. Hospital Pharmacists in Europe: Between Warehouse and Prescription Pad? *Pharmacoecon Open*. 2018;2(3):221–4.
  - 8 Anonymous. The European statements of hospital pharmacy. *Eur J Hosp Pharm* 2014;21:256–8.
  - 9 Garattini L, Padula A. Pharmaceutical Care in Italy and other European countries: between care and commerce? *Postgrad Med*. 2018;130(1):52–4.
  - 10 Teichert M, Schoenmakers T, Kylstra N, et al. Quality indicators for pharmaceutical care: a comprehensive set with national scores for Dutch community pharmacies. *Int J Clin Pharm*. 2016;38(4):870–9.
  - 11 Garattini L, van de Vooren K, Curto A. Will the reform of community pharmacies in Italy be of benefit to patients or the Italian National Health Service? *Drugs Ther Perspect*. 2012;28(11):23–6.
  - [12] Santuari A. Legal and organisational innovation in the Italian pharmacy system: commercial vs public interest. *Health Econ Policy Law*. 2017;12(4):495–513.

- 
- 13 Anonymous. The definition of clinical pharmacy. *American College of Clinical Pharmacy. Pharmacotherapy.* 2008;28(6):816-7.
  - 14 Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990;47(3):533-43.
  - 15 Dreischulte T, Fernandez-Llimos F. Current perceptions of the term clinical pharmacy and its relationship to pharmaceutical care: a survey of members of the European Society of Clinical Pharmacy. *Int J Clin Pharm.* 2016;38(6):1445-6.
  - 16 Griese-Mammen N, Hersberger KE, Messerli M, Leikola S, Horvat N, van Mil JWF, Kos M. PCNE definition of medication review: reaching agreement. *Int J Clin Pharm.* 2018 Oct;40(5):1199-208.
  - 17 Blenkinsopp A, Bond C, Raynor DK. Medication reviews. *Br J Clin Pharmacol.* 2012;74(4):573-80.
  - 18 Lombardi N, Wei L, Ghaleb M, Pasut E, Leschiutta S, Rossi P, Troncon MG. Evaluation of the implementation of a clinical pharmacy service on an acute internal medicine ward in Italy. *BMC Health Serv Res.* 2018 10;18(1):259.
  - 19 Garattini L, Padula A. 'Appropriateness' in Italy: a 'magic word' in pharmaceuticals? *Appl Health Econ Health Policy.* 2017;15(1):1-3.
  - 20 Soares IB, Imfeld-Isenegger TL, Makovec UN, Horvat N, Kos M, Arnet I, Hersberger KE, Costa FA. A survey to assess the availability, implementation rate and remuneration of pharmacist-led cognitive services throughout Europe. *Res Social Adm Pharm.* 2020;16(1):41-7.
  - 21 Garattini L, Curto A, Padula A. Reimbursable drug classes and ceilings in Italy: why not only one? *Eur J Health Econ.* 2016;17(8):923-6.