PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

Expert Panel Opinion on the Definition of Primary Care

PGEU RESPONSE

Expert Panel Opinion on the Definition of Primary Care – PGEU Response

1 PGEU is the European association representing community pharmacy. Our members are the associations and chambers of pharmacists from 34 European countries.

2 We welcome the opportunity to comment on the Expert Panel opinion on the frame of reference in relation to primary care.

Demographic Change and Medicines Use

3 The opinion notes some key demographic and epidemiological challenges facing health care systems (line 390). It is worth stressing the importance of medication and medication related problems in this context. The rise of chronic disease and an aging population entails an increased use of medication (and of course a need to better detect and manage chronic disease), and thus inevitably a greater exposure to the risk of adverse drug reactions (ADRs), side-effects, medication interactions and the effects of polypharmacy[1]. There is evidence that elderly citizens are at greater risk of these issues[2], and that they are a major cause of hospitalisation among the elderly.[3] Already, poor adherence to medication is a significant problem for health systems[4,5] and polypharmacy presents considerable challenges. These problems are likely to intensify with the ensuing demographic change.

3 At the same time, cultural developments point towards a degree of increased patient autonomy or empowerment, as the opinion correctly identifies. This may manifest itself in a greater need for lifestyle advice and possibly self-care and self-medication.[6]

4 In both of these respects, we believe community pharmacy is a key member of the primary healthcare team. It is difficult to conceive that the risks of increased medication use as mentioned above can be effectively managed without the use of pharmacists' skills and training. Additionally, the wide exposure of community pharmacists to a large cross section of the population, and the easy accessibility of community pharmacies themselves, make them an obvious resource for assistance and advice for patients who are seeking to manage their own health and health care[7].

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[1] Romana A, Kamath L, Sarda A, Muraraiah S and Jayanthi CR. Polypharmacy leading to adverse drug reactions in elderly in a tertiary care hospital. *Int J Pharm Bio Sci* 2012 3(3):218-224

[2] Lee JK, Grace KA and Taylor AJ. Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial. *JAMA* 2006 296:2563-2571

[3] O'Connor MN, Gallagher P, Byrne S and O'Mahony D. Adverse drug reactions in older patients during hospitalisation: are they predictable? *Age and Ageing* 2012 41(3):771-776

[4] Hiligsmann M, Rabendra V, Bruyère O and Reginster J. The clinical and economic burden of non-adherence with oral bisphosphonates in osteoporotic patients. *Health Policy* 2010 96(2):170-177

[5] Medi-Voice project http://cordis.europa.eu/fetch?CALLER=FP6_PROJ&ACTION=D&DOC=3019&CAT=PROJ&QUERY=1170700793308&RCN=75025

[6] World Health Organization. Ottawa Charter for Health Promotion. Ottawa: First International Conference on Health Promotion, 1986.

[7] Pharmaceutical Group of the European Union (PGEU). European Community Pharmacy Blueprint; for optimisation of health outcomes to individual patients and value for health systems across Europe. 2012, Brussels, PGEU

Definitions of Primary Care

5 Although the definition of Primary Care in the Alma Ata declaration [line 531] is non – exhaustive, PGEU believes the reference to the 'provision of essential drugs' needs to be elaborated slightly. While access to medication is key to a properly functioning primary health care system (we discuss pharmacy's role in this below), access in itself is not enough. For the reasons set out above, the rational and appropriate use of medication cannot be divorced from questions of access. And, as we will argue below, rational and appropriate use of medication means using the full resources of the primary care health professionals.

6 Starfield's definition of Primary Care and that of the Institute of Medicines have a common thread – the key role of Primary Care in addressing a range of needs. This is seen in Starfields's reference to 'the first point of reference for all new needs' and the reference to 'a large majority of personal health care needs' in the Institute of Medicine definition[8,9].

7 The discussion of the definitions in the Opinion identifies a tension here – while primary care is initially non-specialised and comprehensive, to function effectively it must be able to respond to differentiated needs (line 593-594). PGEU believes that well-functioning primary care combines facility of access (the first point of contact, as in Starfield's first 'c'), with the efficient coordination of response. A concrete example of this in a pharmacy context helps cast some light on this.

8 Imagine two scenarios in which a patient seeks pharmacy services. The first (the most common) might be where a patient has received a prescription for a medication from a prescribing physician. This might be from a local family doctor, in which case the patient has already contacted the primary care system, but this is not necessarily the case - the patient could also be bringing a prescription from a secondary source such as a hospital or a specialist. In the context of the problem of ADRs, side-effects, medication interaction and polypharmacy referred to above, the optimal service the patient can receive would ensure that such risks are addressed. This is a problem of co-ordination between secondary and primary care, but also between different primary care health professionals, since such problems cannot always be addressed without the participation of the prescriber in the process (there may need to be an adjustment to or clarification on the prescription).

9 In Europe the necessary coordination does rarely extends beyond informal contacts. Prescribers are not trained in ADRs, management of side-effects, medication interactions and management of polypharmacy, and do not always have accessible or comprehensive records. Comprehensive pharmacy based medication records are also uncommon, although this is changing (see below) and systematic reconciliation between secondary and primary care is rare[10].

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[8] Starfield B. Is primary care essential? *Lancet* 1994; 344: 1129–1133.
1920

[9] Starfield B. Primary Care: Balancing Health Needs, Services, and Technology. Oxford
1921 University Press, 1998.

[10] European Association of Hospital Pharmacists. Inter-sector Communication: Communication between community and hospital pharmacy sectors: The results of an EAHP and EuroPharm Forum collaboration survey. 2013. Brussels, EAHP. Available from http://www.eahp.eu/news/what-status-hospital-and-community-pharmacy-communication

The Dossier Pharmaceutique

Article L 1111-23 of the French public health law provided the legal basis for establishment of the Pharmaceutical record (the 'Dossier Pharmaceutique' or 'DP') in January, 2007. The Dossier Pharmaceutique includes all the medicines dispensed to the patient in any participating community pharmacy located in France in the last 4 months, be it prescribed medicine or non-prescription medicines sold over the counter. Every pharmacy is required to offer this service, but the DP is only created once a patient has consented and they have the right for it to be deleted at anytime.

The data is collected at the point of dispensing or sale and stored in a centralised secure server. Only pharmacists and the professionals legally entitled to dispense medicines have access to this professional tool, with both their health professional insurance card and the patient's insurance card. The DP supports pharmacists in verifying that there are no interactions between medicines prescribed, that there are no contra-indications with the state of the patient's health. It helps to ensure that the patient doesn't suffer from harmful secondary effects. The DP provides the pharmacist with a global view of the patient's different treatments. In this way, the patient benefits from greater security and personalised advice**.**

In addition the DP allows patients using different pharmacies than their usual location (e.g. over weekends or when on vacation, at work, etc.), to fully benefit from pharmacy services as the pharmacist on duty is in a position to provide suitable advice in light of the other medicines that have been dispensed or sold to the patient recently.

By 12 May 2014, 22.297 French community pharmacies operated the Dossier Pharmaceutique; comprising 98,6% of all community pharmacies in France. Around 32 million pharmaceutical records were created.

Additionally, hospital pharmacists now have the possibility to use the DP (read and write access) to facilitate medicines reconciliation between primary and secondary care settings.

Similar systems to the DP are under development in Austria, Belgium, Italy and Norway.

10 The second scenario is where a patient presents with symptoms in the pharmacy. This is common, substantially as a function of pharmacy accessibility (see below). The pharmacist must respond to the symptoms presented to him or her. Typically, the pharmacist will provide relevant self-care advice, recommend an over-the-counter medication or product to the patient or otherwise 'signpost' the patient to alternative source of care (usually but not exclusively, a primary care physician). Often the pharmacists will do all three. Again however the universal signposting function of pharmacies is not widely appreciated[11] , and rarely documented.

11 Co-ordination in Primary Care therefore must, inevitably, look at how all health professionals active in communities can better collaborate.

[11] Pharmaceutical Services Negotiating Committee. Community Pharmacy Contractual Framework. 2005. PSNC, London. Available from http://psnc.org.uk/psncs-work/about-community-pharmacy/

Primary Care Collaboration in the Netherlands

It's well known that patients frequently suffer serious adverse reactions due to unintended medication interactions, prescription errors and haphazard pill-taking regimens. Part of the problem is that historically community pharmacists and physicians tend to work in silos. They each take care of patients within their own professional environment. The communication they end up having with each other is by telephone or fax, and they share only snapshots of information at the end.

Dr. Paul van Gijn, a Dutch general practitioner, and Eva Siedenburg, a pharmacist in the same Dutch city, have worked out a remedy. The two professionals are working together supported by other healthcare team members such as practice nurses and pharmacy staff in Akelei Health Centre, The Hague caring for 10.000 registered patients.

In addition to regular meetings and discussions of individual cases, technology is used to support communication between the two professionals and centre care around needs of the individual patient. Information contained in the patient record from pharmacist and physician computer systems is uploaded on a Dutch open health care communication system. Every time this information is uploaded into the application it is documented as a snap shot with date and time: for each patient data can be compared over time. The pharmaceutical care plan that is agreed between Dr van Gijn and Ms Siedenburg shows what has already been achieved and what action points are still needed. Both professionals perform a clinical medication review in collaboration with the patient based on information from this web-based application. Patients receive a printed version of their "own" care plan. It helps to structure the development of a pharmaceutical care plan and to document a complete patient record including both pharmaceutical and medical data. The development of a personal care plan improves patient's beliefs and use of medicines and improves quality of care.

"Physicians when they prescribe medication assume that patients will take it as instructed, but patients don't always do this," Dr van Gijn says. "The situation complicates even more when patients visit multiple physicians and pharmacists. "I had patients that were taking multiple medication for their multiple conditions and no one was taking responsibility or had a complete knowledge of what they were on," Dr van Gijn says**.** "Using the system I can send the pharmacist a note requesting a consult and she would look at the medication and send her recommendation back to me, all electronically**."**

"We needed to find a way to deal with this in an effective manner. The integrated electronic care record formalized relationships between physicians and pharmacists. This translates into a personalized, relevant consultation that helps all parties. It extended the reach of general practitioners and recognizes the unique, specialized cognitive skills of pharmacists. Overall it helps our patients to take charge of their therapy, understand their medication and stay home longer and gives us a 'kick' in a daily practice." says Ms Siedenburg.

The Pharmacy Network

11 As suggested, the second scenario is relatively common because, as a general rule, pharmacies do not require appointments, operate extended opening hours including night services, and provide a relaxed and informal environment. It remains the case that pharmacies are widely dispersed and are found both in rural and economically unattractive areas[12]. There is some evidence that accessibility may be a key element in the attractiveness of some services to patients – where for example, pharmacy based vaccination services have

[12] PGEU Annual Survey 2012. Brussels, PGEU.

been offered, vaccination rates have generally increased, and this at least partly attributable to the provision of vaccination on a local and 'walk-in' basis. Indeed, evidence suggests that community pharmacists are the health professions with the greatest patient exposure[13,14].

Adaptation of Primary Care

12 We welcome the recognition given in the opinion of the fact that community pharmacists are increasingly involved in meeting patients' needs and expectations (line 798), and the importance of collaboration and the pharmacists' role within it (line 764). The practice of community pharmacy itself is undergoing considerable change. While pharmacy maintains its key role in providing advice on medication, there appears to be a growing recognition that better use of the pharmacy interface can make a significant contribution to both improving medicines use, and the detection and management of chronic disease. While there is very significant evidence that pharmacy interventions are effective in terms of outcomes for patients[15,16,17,18,19,20,21], there is also a growing body of evidence that pharmacy interventions are in addition cost effective [22,23,24].

[13] The Bow Group. Delivering Enhanced Pharmacy Services in a Modern NHS: Improving Outcomes in Public Health and Long-Term Conditions. 2010. The Bow Group, London. Available from http://www.bowgroup.org/policy/delivering-enhanced-pharmacy-services-modern-nhs-improving-outcomes-public-health-and-long

[14] Irish Pharmacy Union. IPU Review May 2014. Available from http://ipu.ie/publications-40196/ipu-review-25861.html

[15] Naik-Panvelkar P, Armour C, Rose JM and Saini B. Patient Preferences for Community Pharmacy Asthma Services: A Discrete Choice Experiment. *Pharmacoeconomics*. 2012 30(10):961-976

[16] Santschi V, Chiolero A, Paradis G, Colosimo AL and Burnand B. Pharmacist Interventions to Improve Cardiovascular Disease Risk Factors in Diabetes: A systematic review and meta-analysis of randomized controlled trials. *Diabetes Care*. 2012 35:2706-2717

[17] Adunlin G and Mahdavian S. The Effectiveness of Pharmacist Interventions on Asthma Management: A Systematic Review. *Journal of Asthma & Allergy Educators*. 2012 3(6):264-273

[18] Aslani P, Rose G, Chen TF, Whitehead PA and Krass I. A community pharmacist delivered adherence support service for dyslipidaemia. *European Journal of Public Health*. 2011 21(5):567-572

[19] PJ Online. Almost all patients using pharmacy flu vaccination service would use it again. *The Pharmaceutical Journal*. 2011 286:291

[20] Hawksworth GM, Corlett AJ, Wright DJ and Chrystyn H. Clinical pharmacy interventions by community pharmacists during the dispensing process. *Br J Clin Pharmacol*. 1999 47:695-700

[21] Blenkinsop A, Anderson C and Armstrong M. Systematic review of the effectiveness of community pharmacy-based interventions to reduce risk behaviours and risk factors for coronary heart disease. *Journal of Public Health Medicine*. 2010 25(2):144-153

[22] PJ Online. Pharmacist interventions contribute to huge savings. *The Pharmaceutical Journal*. 2010 285:579

[23] The Kings Fund. Data briefing: Emergency hospital admissions for ambulatory care-sensitive conditions. 2012. The Kings Fund, London. Available from http://www.kingsfund.org.uk/publications/data-briefing-emergency-hospital-admissions-ambulatory-care-sensitive-conditions

[24] Elliott RA, Barber N, Clifford S, Horne R and Hartley E. The cost effectiveness of a telephone-based pharmacy advisory service to improve adherence to newly prescribed medicines. *Pharmacy World & Science*. 2008 30(1):17-23

The conSIGUE **research project**[25]**:**

The conSIGUE Project is coordinated by the Spanish General Council (Consejo General de Colegios Oficiales de Farmacéuticos) and the University of Granada

The aims of the project are to:

- assess the impact of Medication Review with Follow up (MRF-up) on elderly polymedicated patients.
- Determine the cost-effectiveness of Medication Review with Follow up.

The service consists of identifying drug related problems (DRPs), and the prevention and resolution of negative outcomes related to medication (NOM) on a continuous, systematic and documented basis, in cooperation with the patient, and with the rest of the health care professionals. The ultimate aim is to ensure secure specific outcomes are achieved which serve to improve the patients' quality of life.

The process of the intervention is as follows: once the service is offered and accepted by the patient, a structured interview with the patient takes place. Afterwards, a study and assessment stage are performed followed by an action plan where the pharmacist proposes interventions with the patient and/or the doctor (personalised dosage systems, proposal to adjust the treatment, counselling and education, etc). Finally there is an evaluation and a follow-up stage with the patient.

The study was performed by 178 pharmacies, 250 pharmacists on 1,403 patients.

Results show:

- **A 56% reduction in the percentage of uncontrolled health problems**
- **A 49% reduction in patients who referred have visited emergency units**
- **A 55% reduction in patients who referred have been hospitalised**
- **An improvement in patients' perceived quality of life** by 6.5 points on average (adjusted).
- **A reduction of 0.15 medicines** per patient on average (adjusted).

The MRF-up service is cost-effective even when used the most conservative setting.

13 Below are just a few examples of new services recently developed in European community pharmacies.

New Medicines Services – UK, France

In the UK the New Medicines Service (NMS) provides support for people with long-term conditions who have been prescribed a new medicine to help improve their adherence. This service, provided by pharmacists is initially focused on particular patient groups and conditions, such as those receiving medication for diabetes, hypertension, asthma and anticoagulant / antiplatelet medication. Patients are recruited at the point of dispensing, counselled on any relevant points about the new medication and provide consent to participate in the service. Within two weeks either a face-to-face (in-

[25] Pharma Portal. Spain. Available from http://www.portalfarma.com/Profesionales/InvestigacionFarmacia/conSIGUE/Documents/Resultados-Definitivos-Programa-Consigue-Impacto-2011-2014.pdf. Summary in English: http://www.portalfarma.com/Profesionales/InvestigacionFarmacia/conSIGUE/Documents/14-03-27-Resumen-conSIGUE-Impacto-Divulgacion-English-version.pdf

pharmacy) or telephone consultation takes place where the pharmacist conducts a semi-structured interview in order to identify any problems, side-effects, concerns or non-adherence to the new medication. At this point referral can be made to the patient's GP if required or appropriate advice can be provided by the pharmacist and a date arranged for a final consultation within a two week period. In either case, this interaction with the patient is also an opportunity for the pharmacist to provide dietary and healthy lifestyle advice to the patient. The service continues to be funded by the National Health Service and after the first 18 months of provision a total of 236,408 NMS cycles were completed representing a total of 224,554 patients.[26]

In France, a similar service began in early 2013 where patients are able to consult with their pharmacist on the management of their long-term anticoagulant medication (the so called 'Vitamin K Antagonists', VKAs). The service consists of at least two consultations a year with a pharmacist who provides appropriate advice and counselling on taking the medication and the associated clinical monitoring parameters, so crucial to the safe and effective management of this medication (e.g. maintaining a target 'INR – International Normalised Ratio' level when taking warfarin). If necessary, the patient can be referred to their GP upon giving consent for further management. The French administration initiated this service in order to reduce overdosing, excessive bleeding and associated hospital admissions as anticoagulants are the primary cause of iatrogenic incidents in France.[27]

This service is soon to be expanded to all include all anticoagulants, however as of the 15th of May 2014, 121.440 consultations had taken place involving 14.224 pharmacies. In France, much like the UK, a general framework for medicines services has been defined and later in 2014 a new service will be launched for asthmatics in France. This service aims to improve adherence to prescribed inhaler therapies, either as the patients start a new treatment or when they resume a previously prescribed treatment. It will involve at least two patient-pharmacist consultations in order for the patient to receive the appropriate information, guidance and advice.

Asthma Service in Belgium

In Belgium, an Asthma Service was recently introduced where patients are able to have a highly structured conversation with their pharmacist when starting an inhaled corticosteroid for asthma. This service is initiated by the pharmacist, prescribed by a doctor or requested by the patient. As with the British and French examples above, two counselling sessions take place in the same pharmacy, several weeks apart with a recommended interview duration of 15 to 20 minutes.[28] In the first six months of this service almost 10.000 patients we enrolled and there are plans to widen the scope of the inclusion criteria, potentially broadening the service to even more patients in the future.

Vaccination in Ireland

Since new legislation was introduced in Ireland to enable pharmacists to supply a prescription-only medicine (influenza vaccine/adrenaline) without a prescription, pharmacists in Ireland have been administering influenza vaccines since the 2011/2012 'flu season. There are now 907 pharmacies

[26] Pharmaceutical Services Negotiating Committee. New Medicines Service (NMS). 2014. PSNC, London. Available from www.psnc.org.uk/services-commissioning/advanced-services/nms

[27] Agence nationale de sécurité du médicament et des produits de santé (ANSM, The French Medicines Agency). 2014. Paris, ANSM. Available from http://ansm.sante.fr/Dossiers/Anti-vitamine-K-AVK/Prevention-des-hemorragies-provoquees-par-les-traitements-anticoagulants-anti-vitamine-K-AVK/%28offset%29/0

[28] Saevels J. Asthma Service in Belgian Pharmacies. Presentation delivered on 12th May 2014 at the PGEU Professional Issues Working Group, Brussels, Belgium

providing this service and in the most recent 2013/2014 season over 40.000 patients were vaccinated by pharmacists.[29] This activity will allow community pharmacists to contribute to a significant advancement towards the EU target of vaccinating 75% of the older age groups of the population.

14 These services exploit the pharmacy interface, but crucially, depend for their effectiveness on the development of network arrangements with other health professionals.

15 For these reasons we strongly endorse the comments in the Opinion from line 777 – 790. We see primary care as collaborative and we as pharmacists having a key role in that collaboration, and one that is growing in importance.

Financing

16 The type of pharmacy remuneration can be used by the governments to promote a shift to a more patient-oriented service instead of a product-oriented service.

Remuneration can be used to introduce key changes in the role of the community pharmacist and to provide a large range of services.

It also can be used to promote accountability of the community pharmacist for the use of public spending, providing benefits to the whole population[30].

On the other hand, the integration of care, including Pharmacy in the primary healthcare funding can lead to a more collaborative model of care, improving the cooperation and the sharing of information between different levels of care and between different health professionals.

In addition, it may also contribute to the improvement of health and financial results if the financing system of pharmacies is aligned with the performance targets of the other primary healthcare providers.

It is fundamental to establish a contractual framework for the provision of pharmacy services based on the following principles:

- To maximize positive health outcomes
- Provide an answer to the unmet health needs of the population
- Improve access to health services, especially in regions with reduced access to other healthcare providers
- Enhance therapeutic adherence and reduce medicines waste
- Provide integration and coordination of care
- The funding should be linked to the fulfilment of objectives (health outcomes, cost-effectiveness)

[29] Irish Pharmacy Union. IPU Review May 2014, p10-16. Available from http://ipu.ie/publications-40196/ipu-review-25861.html

[30] Huttin, C. A critical review of the remuneration systems for pharmacists. *Health Policy.* 1996 36:53-68

Conclusion and Research Questions

17 In the context of an ever expanding aging population, with multimorbidity and polypharmacy, and growing pressures on European healthcare systems, community pharmacists are ideally placed to tackle these issues at the heart of our communities. With ease of access, (no appointment necessary), a highly trained healthcare professional, capable of managing minor ailments and long-term chronic medications, of providing 'flu vaccines and other services, and who can collaborate with other healthcare professionals can ultimately benefit our patients for the better, and the PGEU believes community pharmacists should be part of the core of the primary care definition.

18 Future research questions could focus on cost-benefit analyses of pharmacy-based interventions in primary care, the development of the pharmacist's role in collaboration with other primary healthcare professionals and legal challenges surrounding the development of pharmacy services. Additionally, future research should focus on the potential for public financing of pharmacy services.