Ref 16.11.30E 001

PGEU GPUE

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

PGEU Response to EC consultation Health Technology Assessment (HTA)

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

The Pharmaceutical Group of the European Union (PGEU) welcomes the European Commission's efforts to gather views and opinions regarding the future of EU cooperation on HTA and the opportunity to respond to this consultation.

The PGEU would like to highlight the importance of the collection, analysis and synthesis of "real-world evidence" concerning pharmaceuticals, medical devices, healthcare technologies and public health interventions. In particular, PGEU would like to stress the importance of real-world evidence in the context of the HTA in primary healthcare setting.

Community pharmacists are the most accessible healthcare professional in Europe and are situated in close proximity to patients and the general population in their local communities. Pharmacists can be accessed within 30 minutes for 98% of the European population[1] and are often the final contact with the patient before a pharmaceutical, a device or another health intervention is supplied. Unfortunately, we believe that community pharmacists, an important stakeholder, has often been overlooked by HTA bodies in the HTA process.

Approximately 93.8% of all medicines in Europe are dispensed in the primary care setting, most of which in community pharmacies[2]. Additionally, 100% of pharmacies in Europe are computerised, 100% have an internet connection (of which 95.8% is broadband) and many utilise electronic pharmacy management programmes[3]. Dispensing, reimbursement, ePrescription data is collected and securely stored in pharmacy management programmes and supplied to relevant national authorities. In February 2019, a European Medicines Verification System will be established according to the Falsified Medicines Directive (FMD) to prevent the entry of "falsified" medicines into the European medicines supply chain. Community pharmacists will need to verify authenticity of and "check out" from the system the "safety features" applied to individual packages of medicines. In the context of "real world evidence", pharmacies will be able to read and record an individual serial number of a medicine pack within their pharmacy management programme and link it to other relevant data contained therein.

Today, pharmacists, the experts in medicines, play a vital role in pharmacovigilance, adherence, medicines optimisation, support for chronic disease management, delivery of public health campaigns, promotion of healthy lifestyles and preventative measures. When considering pharmacovigilance, pharmacists help to prevent adverse drug reactions (ADRs) by providing information to patients on the safe and rational use of medicines. Additionally, where a suspected ADR does occur, pharmacists provide support to the patient and report the suspected ADR to the relevant competent authorities. As such, pharmacists, by reporting ADRs (in particular for new medicines subject to additional monitoring), help to reduce the effect of "type

[1] Survey of Chain of Trust Project, under EC Public Health Programme (Grant Agreement N° 2009 11 13) http://www.chainoftrust.eu
[2] Number is based on standard units. IMS Data 2015.
[3] PGEU Statement on eHealth 2016 http://pgeu.eu/en/press/235:pr-european-pharmacists-renew-ehealth-statement.html

I" error which may arise from clinical trials with a high degree of participant withdrawal or a participant profile which was not representative of the population under treatment.
Concerning adherence, we know that 50% of patients will not be adherent to long-term therapies[4], costing the EU €125 billion a year[5]. However, a recent study from England[6] evaluating a pharmaceutical service for patients starting a new medicine for a chronic disease showed the service improved adherence by 10% whilst also being cost-effective. Regarding evidence for primary prevention, a recent example of community pharmacists providing a cost saving intervention can be found in Portugal[7], with the pharmacy-based needle exchange service preventing HIV and Hep C infections. As such, pharmacists have a crucial role to play in achieving positive health outcomes in practice, representing value for the investment made by policy makers, health systems payers, patients and the pharmaceutical and medical devices industries.

In conclusion, community pharmacists have developed the necessary infrastructure and culture to implement innovative technologies and services with the ultimate goal to deliver significant benefits to the public. Pharmacoeconomics and Health Technology Assessment are subjects that are increasingly prevalent in the undergraduate pharmacy training programmes aiming to make pharmacy graduates familiar with the complex evaluation of health interventions (technologies), namely medicines, concerning their relative/comparative efficacy, safety and cost-effectiveness.

Therefore, PGEU would like to call on Member States and the European Commission to involve community pharmacy in HTAs as well as related policies and initiatives (for ex.: EUnetHTA Joint Action).

When considering economic aspects of HTA, the different situations across countries should be taken into account, given that the vast majority of HTA are carried out at national/regional level.

First of all, HTA authorities vary across countries in terms of their institutional setting. They have also heterogenous tasks and objectives: for instance, some are regulatory bodies, whereas others cover advisory and/or coordination activities.

Therefore, di Member States approach HTA differently; the health economic component differs and depends on the chosen methodology, capacity, culture and available resources. The assessment of these HTA components is normally based on the following criteria: cost effectiveness (CEA) and cost minimisation analysis (CMA). However, in some countries these criteria are benchmarked according to specific cost effectiveness thresholds, while in others this analysis is based on the calculation of an efficiency frontier. Other methodologies adopted in Health Technology Assessments across EU Member States include cost and economic analysis, comparative analysis, post-marketing surveillance and systematic reviews.

Given these well-established different methodologies across Member States and their sovereignty to design and organise their health systems as well as the delivery of health services and medical care (as recognised by Article 168 of the Treaty of the Functioning of the EU and the Court of Justice's well-

[4] http://www.who.int/chp/knowledge/publications/adherence_report/en/
[5] Medi-Voice project http://cordis.europa.eu/result/rcn/46801_en.html
[6] http://www.nottingham.ac.uk/~pazmjb/nms/downloads/report/index.html
[7] http://www.ispor.org/research_pdfs/54/pdffiles/PHS135.pdf

established case-law), ***PGEU supports a voluntary cooperation among Member States on economic assessment of HTA.*** This approach would permit respecting the existing diversity in terms of both practices and methodologies used at national level for HTA and ensures that national specificities can be taken into account.

In conclusion, the PGEU recommends that HTA bodies, national competent authorities and other stakeholders engage with community pharmacists and their national representative bodies to support the collection, analysis and synthesis of real-world evidence in primary care.

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