Health Policy 95 (2010) 245–254

Contents lists available at ScienceDirect

Health Policy

journal homepage: www.elsevier.com/locate/healthpol

Impact of regulation of Community Pharmacies on efficiency, access and equity. Evidence from the UK and Spain

Maria Lluch*, Panos Kanavos

LSE Health, London School of Economics and Political Science, Houghton Street, London WC2A 2AE, UK

ARTICLE INFO

Keywords:
Community Pharmacy
UK
Spain
Access
Efficiency
Equity
Incentives
Reimbursement
Pharmacy (de)regulation
Liberalisation
EU health policy

ABSTRACT

In this paper, we focus on regulatory restrictions on Community Pharmacies and whether these have an impact on efficiency, access and equity and thus in the delivery of services community pharmacists provide to patients. Primary data collection through semi-structured interviews and secondary data collection through literature review have been used with a particular focus on Spain (a country where Community Pharmacy is strictly regulated) and the UK (a country where Community Pharmacy is considered liberalised by EU standards). The findings indicate that improved pharmacy operational efficiency is the result of appropriate incentive structures, ownership liberalisation and OTC price freedom as is the case in the UK. Equity and access seem to be better achieved by establishing geographic, demographic or needs-based criteria to open new pharmacies (as is the case in Spain). In sum, there are useful lessons for both countries: the UK could look into the policies applied in Spain that increase access and equity whilst Spain could adopt some of the policies from the UK to increase efficiency in the system.

1. Background and conceptual framework

Community Pharmacies (CPs) are in the majority of cases highly regulated in most EU Member States. Key areas of regulation relate to the establishment of pharmacies (e.g. through needs assessment); registration and licensing issues; ownership issues (e.g. limitation of ownership to pharmacists, and limits to the ownership of multiple pharmacies prohibiting pharmacy chains); distribution of pharmaceutical products outside a pharmacy; opening hours; and pricing, remuneration and incentives issues given that often government health insurance is the key payer of these services (a detailed description is provided in Table 1).

Member States and stakeholders justify these restrictions claiming that they ensure the independence of the service provider, facilitate access to pharmaceuticals, guarantee equity of the service, and the quality and safe provision of pharmacy services. Further, reimbursement and incentive mechanisms represent a tool to improve efficiency.

The OECD, in its 2001 report on "Regulatory Reform in Ireland", contested the logic of pharmacy regulation [1]. It argued that the creation of a protected monopoly to cross-subsidise unprofitable activities was not the right solution. In fact, keeping up with competitors is what usually stimulates quality-improving services. This came at a time when the debate about deregulation of public services was taking place in several EU Member States [2]. One of the sectors receiving attention was health care, and CPs. The rationale behind deregulation in the pharmacy sector is the expectation that liberalisation will increase competition and thus succeed in lowering, or at least containing (public) expenditure, whilst access to quality pharmacy services will remain stable if not improved by the opening of new outlets. In sum, deregulation claims to make the market more efficient whilst equity and access would not be com-

* Corresponding author. Tel.: +44 20 7852 3795; fax: +44 20 71075305.
E-mail addresses: m.lluch@lse.ac.uk (M. Lluch), p.g.kanavos@lse.ac.uk (P. Kanavos).

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doi:10.1016/j.healthpol.2009.11.002

Table 1
Regulatory framework and restrictions for CPs in Europe.

Regulatory item/restriction	Description	Issues looked at	Areas of likely impact
Restrictions on location and numbers	Looking into geographic and demographic criteria to open a pharmacy. These regulations have an impact on the distribution of pharmacies and consequences on access, equity and price competition issues.	Geographic criteria; Demographic criteria	Access, equity; price competition
Restrictions on ownership	Looking into whether a pharmacy can be owned only by pharmacists or not and whether there is room for pharmacy chains. It could potentially have an impact on efficiency (price and quality included as aspects of efficiency).	Pharmacists only? One owner one pharmacy? Pharmacy chains?	Efficiency
Distribution – points of sale	Looking into whether additional channels of distribution outside pharmacies are allowed such as OTC products being sold in other outlets including supermarkets or mass merchandiser stores; GPs dispensing in rural areas; ePharmacy (*entities that sell medicines or medicinal products on the internet, in contrast with the concept of ePharmacy used by the NHS in the UK*). It is likely to have an impact on competition efficiency (price, patient safety) and access.	Additional channels of distribution outside pharmacies; GPs dispensing in rural areas; ePharmacy	Efficiency; access
Registration and licensing	Looking into whether pharmacies need to be registered and licensed to sell prescription drugs and to what extend supervision of a pharmacist is required. It is likely to have an impact in healthcare planning and public health initiatives as well as patient safety, thus translating into efficiency issues.	Registration to sell prescription drugs; Pharmacist supervision	Efficiency
Opening hours	Looking into restrictions around them, whether there is a minimum or a maximum and flexibility of opening times. It is likely to have an impact on access.	Minimum opening hours; maximum opening hours; flexibility of opening times	Access
Pricing, remuneration and incentives mechanisms	Looking into price regulation for reimbursable and non-reimbursable drugs. Contracting, remuneration and incentives mechanisms from the NHS to CPs will also be looked at. It is likely to have an impact in efficiency.	Reimbursement remuneration mechanisms; incentives	Efficiency

Source: adaptation of Mossialos and Mrazek [17] and Vogler et al. [16].

promised. Table 1 provides an overview of the areas of regulation in CPs and its likely impact.

The regulation of CPs in Europe was questioned at EC [2] and at Member State levels [3]. Advocates of deregulation, such as the UK Office of Fair Trading (OFT) or The Internal Market and Services DG at EU level, argue that it would stimulate competition and improve efficiency [3,2]. Opponents of deregulation, such as CGCOF (Consejo General de Colegios Oficiales de Farmacéuticos) [4,5] in Spain or PGEU (the Pharmaceutical Group of the European Union) [6] at European level, claim that liberalising CPs would potentially be detrimental to the delivery of quality health services. From the 1990s onwards, policy considerations took place accordingly in most Member States, leading to both, dramatic liberalisations with somehow unexpected results in countries like Iceland or Norway [7–9] and more conservative approaches, such as Denmark, allowing the distribution of certain OTC medicines outside pharmacies [10].

The issue of deregulation has been examined by the European Court of Justice in a number of cases such as the case of the recent ECJ ruling in May 19th, 2009 [11] recognising that the rules on ownership and operation of pharmacies can be restricted to pharmacists. Other cases on the topic are still being assessed as it is the Italian case from November 2008 [12] where limiting or precluding the possibility of extending the daily, weekly or annual opening times of individual pharmacies is being questioned.

This debate only reflects the dual nature of the pharmacy sector in general and CPs in particular, having an impact on both, health and industrial policies [13–15]. In the light of the above debate and this dual nature, the objective of this paper is to assess the impact of pharmacy regulations on access, equity and efficiency from a healthcare and from a market perspective. In order to do this, a framework including these three main indicators – efficiency, access and equity – using two perspectives, healthcare and market dimensions, for each of them has been set. Section 2 discusses the methodology, whilst Section 3 presents the key results and Section 4 considers the policy implications. Finally, Section 5 draws the main conclusions.

1.1. Conceptual framework

Efficiency will be defined as allocative efficiency which encompasses both health policy and industrial policy objectives and is broader (than technical efficiency) [16]. Allocative efficiency is achieved when the production of goods and services is optimised to a degree that the combined welfare of consumers and producers is maximised [3]. A combination of the two approaches is used in this framework. From a healthcare policy perspective, it will be assumed that a pharmacy works efficiently if, after the core dispensing activity, additional efforts can enhance competitiveness (improving quality of healthcare delivered). When examining efficiency from an industrial policy perspective the areas examined will include: pharmaceutical expenditure and cost reduction strategies; impact on price liberalisation (exclusively on OTC given that pre-