Are regulations of community pharmacies in Europe questioning our pro-competitive policies?

Maria Lluch

Summary: Drawing on a recent European Court of Justice ruling against the freedom of establishment of community pharmacies in Germany, this article addresses the tensions in European health care systems that arise between regulating community pharmacies and striving for competition in order to stimulate better quality services. It spans the different types of policies that are currently applied to community pharmacies – restrictions on ownership; restrictions on establishment; registration and licensing; restricting distribution to pharmacy outlets; limiting opening hours; and incentives (pricing and reimbursement) – and provides experiences on the impact of (de)regulation in different Member States. The author concludes by raising some of the trade-offs when (de)regulating community pharmacies in general and advocates for liberalising ownership, in particular.

Keywords: pharmacies, Europe, regulation, competition

On 19 May 2009, the European Court of Justice (ECJ) ruled against the freedom of establishment of community pharmacies in Germany. The court case, which lasted for three long years, was questioning the 800-year-old German Pharmacies Act under which only registered pharmacists may operate a pharmacy – with a maximum of three branches; hence, pharmacy chains continue to be banned while pharmacists continue to enjoy their monopoly. Germany is not the only country in Europe with regulations limiting pharmacy ownership: Austria, Spain or Hungary have been cited by the German government and professional associations alike. At the other end of the spectrum, countries including the Netherlands, Ireland and the UK hardly restrict ownership although it is mandatory that a pharmacist, as an employee, is always present and supervises the dispensing of prescriptions.

Why regulate community pharmacies?
Pharmacists play a key role in the delivery of health care. They are responsible for checking and filling prescriptions and traditionally have been involved in the production of patient-specific preparations. With the growing importance of the over-the-counter (OTC) segment of the market and of self-medication, they are increasingly acting as health advisers providing counselling to patients. Thus, their range of services covers not only pharmaceutical specialities but also a number of pharmaceutical services to patients including, for example, health promotion activities. As a result of the relevant role that pharmacists play in the delivery of health care, community pharmacies in the majority of the cases are highly regulated in most Member States of the European Union (EU). Key areas of regulation relate not only to ownership issues (for example, limitation of ownership to pharmacists, and limits to the ownership of multiple pharmacies prohibiting pharmacy chains) but also to the establishment of pharmacies (for example, a needs assessment, or demographic/geographic regulations); registration and licensing issues; distribution of pharmaceutical products outside a pharmacy; opening hours; and pricing, remuneration and incentives issues, given that government backed health insurance or general taxation is the key payer of these services.

Member States and stakeholders justify these restrictions claiming that they ensure the independence of the service provider and facilitate access to pharmaceuticals, whilst guaranteeing equity, quality and safe provision of pharmacy services. These restrictions can result in a monopoly for pharmacists. Governments claim to use reimbursement and incentive mechanisms as a mechanism to counter the inefficiencies of such monopolies.

The OECD in its 2001 report on Regulatory Reform in Ireland contested the logic of these regulations. 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 about at a time when the debate on the deregulation of public services was taking place in several EU Member States. One of the sectors receiving attention was health care, including community pharmacies. 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, while access to quality pharmacy services will

Maria Lluch is reading for a PhD, LSE Health, London School of Economics and Political Science. Email: m.lluch@lse.ac.uk
remain stable, if not improved, by the opening of new outlets. In sum, deregulation claims to make the market more efficient whilst key areas like equity and access are not compromised.

Together with deregulation in a number of areas of the public sector, the regulation of community pharmacies in Europe was questioned at European Commission\(^2\) and Member State levels.\(^3\) Advocates of deregulation, such as the Office of Fair Trading in the UK or the Internal Market and Services Directorate General at EU level, argued that it would stimulate competition and improve efficiency. Opponents of deregulation, such as the Consejo General de Colegios Oficiales de Farmaceúticos (CGCOF)\(^6\,7\) in Spain, or Pharmaceutical Group of the European Union\(^8\) at EU level, claimed that liberalising community pharmacies would potentially be detrimental to the delivery of quality services.

The recent ECJ ruling\(^1\) recognising that the rules on ownership and operation of pharmacies can be restricted to pharmacists has only spiced up the debate.

**Implications of ownership restrictions**

A common set of values for European health care systems – universality, access to good quality care, equity and solidarity\(^9\) – are the pillars resulting from the health acquis communautaire, hence, Member States and any institution within the EU would strive to ensure that those are preserved before implementing any policy, act, ruling or recommendation.

Some of the restrictions imposed on community pharmacies may be justified to a certain extent. For example, Spain regulates the location for the establishment of pharmacies, guaranteeing access and geographical equity, to 99% of the population,\(^10\) whilst in England more relaxed regulations it is claimed offer access to (an arguably inflated) 96% of the population.\(^11\)

One may therefore contend that regulation in Spain does more good than harm by ensuring a very high level of coverage.

In contrast, some restrictions are not necessary for guaranteeing the right to health care. Restrictions on pharmacy ownership may be one example. Advocates for restricting ownership claim that it has an positive impact on the quality of health care delivery. Clearly, the presence of a pharmacist is required to ensure quality of care\(^12\) but this is a completely different issue from ownership. There is no evidence proving the association between ownership and quality of care; in a community pharmacy, quality of care is guaranteed simply by the presence of a pharmacist.

Liberalising the system by divorcing ownership from pharmaceutical activity, thus eliminating restrictions on ownership, therefore may have different implications. The immediate implication is the greater numbers of pharmacy chains, not necessarily being owned by pharmacists. These are often associated with operational efficiencies. Moreover, evidence from the UK\(^3\) and Iceland\(^13\) indicates that liberalising the market can stimulate competition, including price competition on OTC drugs with consequent benefits for society. At a later stage, market consolidation and vertical integration may take place, as has occurred in Norway\(^13\) or in the UK in the case of the takeover of Boots by Alliance Unichem. In the long-run, this may run the risk of oligopoly, given that a small number of chains would be the principal players in the field. This would mean that pharmacists as professionals would lose their monopoly but another type of monopoly would appear. Although it seems reasonable to eliminate restrictions in ownership, other types of mechanism should be designed to counter too high a degree of market dominance by pharmacy chains.

Liberalisation also has implications for other stakeholders, such as pharmacist professional associations. In countries where ownership is regulated, these associations play a key role. Governments may delegate them the power to ensure that the rules are implemented appropriately. Spain offers a marvellous example in this case. The CGCOF represents the interests of all pharmacists holding a license, as well as the interests of community pharmacy owners and ensures that regulations are respected. Thus professional, commercial and trade interests, health care priorities and legal issues all fall within the ambit of one institution. In liberalised markets, as in the UK, there are two institutions in the field each with a different role. The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales; the primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The National Pharmacy Association is the trade association for community pharmacy owners and has virtually all community pharmacies enrolled within its membership. The Association provides its members with professional and commercial support, as well as representing the interests of community pharmacy in dialogue with Government, both at a national and European level. In the light of these two realities, it is not difficult to understand why entities such as CGCOF do not support liberalising ownership.

The impact of liberalising the ownership of community pharmacies on other stakeholders beyond pharmacy owners or chains and professional pharmacy associations is unlikely to be negative. Pharmacists would still be required behind the counter, and as far as this happens, the quality of care is unlikely to suffer: patients will receive at least the same quality of care. If price competition on OTCs is also evident then there may be additional benefits for society.

**Conclusions**

European health care systems need to find a balance between the values they are committed to – solidarity, equity, availability and access to health care – while striving for efficiency and competition, providing options that benefit the society and help contain health care expenditure, in particular to meet the challenge of an increasingly ageing population. Restricting ownership has not proven to be a threat these European values, whilst they seem to improve efficiency and competitiveness.

This piece of research, although aimed at the European level, has provided an overview of experiences from several Member States. More research including analysis of in-depth experiences of the different models in operation in all Member States, looking at each type of restriction and reform in the field of community pharmacies, is needed to take the case further.

The ECJ ruling\(^1\) stated that “Articles 43 EC and 48 EC do not preclude national legislation, such as that at issue in the main actions, which prevents persons not having the status of pharmacist from owning and operating pharmacies”. It should not be concluded that the ECJ wants to preserve a regulation that makes our health care systems less competitive or that the ECJ is against pro-competitive policies as far as the health acquis communautaire is not threatened; it only means that often the ECJ tends to avoid ruling against Member State legislation, in particular when there are further implications to be addressed before liberalisation is achieved. Despite this, steps in the form of recommendations and later on European directives should be encouraged to ensure the efficiency
and competitiveness of our health care systems. However, when formulating pro-competitive policies, risks associated with over-monopoly should also be addressed, preferably avoiding ad-hoc interventions, as has been learnt from experiences in Norway and Iceland.

REFERENCES


Hospital privatisation in Poland

Peggy Watson

Summary: Hospital privatisation has been highly contentious and has progressed slowly in Poland. Shortly after winning the 2007 elections, the Civic Platform Party proposed legislation for compulsory, universal and total hospital privatisation. The law was passed by Parliament but later annulled by presidential veto and a fall-back plan for optional hospital privatisation put in its place. This came into force in April 2009. However, the economic crisis has placed a question mark against the new programme. This article outlines the social processes involved in the privatisation of hospitals since the introduction in 1999 of major health care reform.

Keywords: debt, social dialogue, economic crisis, protest, Poland

The 1999 health care reforms

In 1999 Poland went through a series of social sector changes, which constituted a ‘second wave’ of reforms in the transition to capitalism. These changes included health, pensions, education and territorial administration.

The health care reforms introduced changes in the mechanism of financing laid down in the 1997 Law on Universal Health Insurance which came into force in January 1999. This introduced a system of financing based on the Bismarckian social insurance model, whereby insurance funds are raised from a compulsory deduction from taxable income, originally set at 7.5%. The rate was raised following debates, increasing by 0.25% annually between 2003 and 2007 until it reached its current level of 9%.

The insurance funds were designed to finance the direct costs of health services to patients through contracts between service providers and purchasers. The latter originally took the form of sixteen Regional Sickness Funds (kasy chorych), one in each of the new voivodeships (regions), together with one Sickness Fund for uniformed services. Following criticisms, the sickness funds were replaced in 2003 by a centralised National Health Fund (NFZ – Narodowy Fundusz Zdrowotny). This performed largely the same functions and had a branch in each voivodeship.

The original decision to set the premium at 7.5% of taxable income had a critical effect on the subsequent provision of health care. The figure represented a substantial reduction on the level of 10% advocated by health care professionals and the 10%–11% that had also been mentioned in earlier bills. The issue had been vigorously contested during the first half of 1998, with the action committee KOROZ (The Committee for the Defence of Health Care Reform – Komitet Obrony Reformy Ochrony Zdrowia) being formed at this time.

Given that the income base from which premiums were deducted was low, with many of those in employment on modest levels of pay and about one-fifth of the working population officially unemployed at the time, the decision resulted in a sharp drop in the public funding available for clinical care. Health care funding was pushed below 4% of Gross Domestic Product (GDP). Coupled to the fact that Poland had one of the lowest GDP per capita rates in Europe, this represented a very modest level of funding indeed.

Peggy Watson

Peggy Watson is at the Homerton College, Department of Sociology PPSIS, University of Cambridge.

Email: pw125@cam.ac.uk