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Innovative management of healthcare sector reforms in selected Member States of the European Union

Introduction

One can hardly imagine a subject closer to the lives of EU citizens than an analysis of how EU law and policy have influenced, and will continue to influence, the health systems of the 28 Member States. In principle, in light of Article 152 of the EC Treaty, national authorities are solely responsible for healthcare. Yet, though the Member States are free to decide how to deliver and organize health services, they must do so in compliance with other aspects of EU Treaties, in particular with the fundamental freedoms and elements of competition law. Put differently, national health systems are not enclaves of national sovereignty insulated from European market integration.

The EU is built on the concept of four freedoms: free movement of goods, services, people and capital. To make these freedoms realizable the EU has, over many years, enacted laws to ensure, first, that goods and services provided across borders are of an appropriate quality (exemplified by the European Commission (EC) safety mark on many goods) and, second, that freedom for people to move is not constrained by their health (by ensuring that they can obtain healthcare when outside their home country) (Bauman, 2011: 32–34).

The challenge now facing the EU's legislators is how to ensure that these two goals are fully aligned. While many of the elements required to deliver high-quality healthcare are subject to European standards, such as the licensing of pharmaceuticals

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and certain technical aspects of health technology, there is still much to be done to ensure that European Union citizens can be confident that any care they receive outside their own Member State will be safe and of high quality.

The key Regulation (EC) No. 883/2004 provides that the insured – mainly workers – do not lose their social security when moving to another Member State of the European Union. In fact, the provisions of the Regulation apply to all areas of social security, namely: sickness, maternity, invalidity, old-age, unemployment, family, early retirement, support for the survivors, accidents at work and occupational diseases, compensations in the event of death. In this context, the Regulation also provides for healthcare services needed while in temporary stay outside of the competent State, deemed as necessary from the medical point of view (urgent care). Furthermore the Regulation provides for the possibility to go to a Member State other than the competent State so to benefit from its specific healthcare services (planned care). (Mossialos, Dixon, McKee, 2000: 197–198).

Alongside with these provisions there are those of the Directive – 2011/24/EU which establishes the right of patients to freely choose their healthcare provider. In addition, the Directive introduces rules aimed to ensure that patients benefit from safe and high-quality cross-border healthcare, to protect the rights of patients who will go to any other Member State, to make sure that patients receive all the information necessary to exercise their rights, to build an efficient system of cooperation among different health systems of the Member States by facilitating cooperation and mutual assistance amongst countries.

Innovative approaches in Italy

The authorities have implemented a number of policies to control expenditure on pharmaceuticals, based on (i) limits to expenditure dynamics and (ii) control of pharmaceuticals prices. Expenditure rules on pharmaceutical products have existed since 2001; however, since 2012, a new rule was introduced, foreseeing thresholds for pharmaceutical products supplied by pharmacies or, directly, by the ASLs. The rule establishes two expenditure ceilings for pharmaceutical products (including patient co-payments) expressed as a percentage of the financing level for the National Health Service contributed by the State. For 2014, such percentages are set as follows: a) 13.3% for pharmaceutical products supplied by pharmacies or, directly, by the ASLs; b) 2.4% for pharmaceutical products supplied by hospitals. The expenditure ceilings must be respected both at regional and national levels.

Concerning price control policies, the initial price of a new pharmaceutical product is based on clinical performance, economic evaluation and on the cost of existing treatments. There are controlled price updates. Price setting involves important negotiations between the Italian Pharmaceutical Agency (*Agenzia Italiana del Farmaco* – AIFA) and the pharmaceutical companies, and negotiations take into consideration

the social impact of the disease, the effect of the medicines, the expected utilisation and financial impact, prices in other countries, prices of similar products in Italy. Discounts, payback and price freezes and cuts are some of the mechanisms used to directly control expenditure (Balicki, 2013: 5).

There is a positive list of reimbursed products which is based on health technology assessment information/ economic evaluation. Reference pricing for reimbursement purposes is also applied. For medicines for which generics are available the reimbursement level is set at the lowest price of the drugs in a group (defined as drugs with same active ingredient, bioequivalent form and therapeutic indications), and the cheapest price must be at least 20% lower than the originator product. For those without generics, the reimbursement level of a new drug is based on a sort of average cost of a defined group of medicines that are related but slightly different chemically.

Authorities promote rational prescribing by physicians through treatment and prescription guidelines complemented with education and information campaigns on the prescription and use of medicines and the monitoring of prescribing behaviour (by regions and ASLs). GPs receive feedback on their prescription patterns. Authorities also pursue information and education campaigns directed at patients and some regions have introduced a small fee for either pack or receipt to make patients more sensitive to the cost of medicines and encourage a rational use of medicines on the patients' side. There is an explicit generics policy. Generic sales' targets are set by the Italian Pharmaceutical Agency. Generic substitution takes place i.e. pharmacies are obliged offer the generic medicine when available. If patients refuse a generic, they will have to pay difference between the reimbursement price of the branded drug and the pharmacy retail price of the cheapest available generic. Generics are exempted from the mandatory discount of pharmacies to the NHS so as to encourage pharmacies to hold and sell generics.

Following a pilot period, a comprehensive information and monitoring system (National Healthcare Information System) – using 130 indicators and covering population health status, budgetary and economic efficiency, organisation climate and staff satisfaction, patient satisfaction, performance indicators (appropriateness, quality) and effectiveness in reaching regional targets - is now fully operational. A comprehensive set of indicators has been introduced by the latest Health Pact, for evaluating the performance of regional health services[1]. Several regions have adopted the system which uses standard codes. As a result, Italy will be able to gather extensive information at regional and sub-regional levels, which is publicly available on a website allowing for public comparisons. Such a system, allows regions to identify good practices as well as areas for improvement. Physicians are being monitored in terms of their activity and compliance with guidelines as well as their prescription

[1] See: Health care Pact 2010–12, article 2.

behaviour. They receive feedback on their prescription patterns. Health Technology Assessment is undertaken at various levels although there is no national structure responsible for conducting, promoting, coordinating or financing HTA, resulting in a non-systematic evaluation of health technology. There are clinical guidelines for medical interventions and medicines established through the National Programme on Clinical Guidelines.

The central Government through the Ministry of Health sets and monitors public health priorities in terms of process, outcomes and the reduction of health inequalities. As section 1 suggests, there are some risk factors that can translate into a significant burden of disease and financial costs. The latest National Health plan lists a number of priority areas for health promotion and disease prevention which is proposed as good practice across the regions. However, health promotion and disease prevention activities have not yet received the same emphasis as in other countries in the EU, as seen by its pattern of expenditure and some indicators. Public and total expenditure on prevention and public health services as a percentage of GDP were below the EU average (0.1% and 0.1% vs. 0.2% and 0.3% in 2013). Public and total expenditure on prevention and public health services as a percentage of total current health expenditure were well below the EU average (0.7% vs. 2.2% and 0.7% vs. 2.7% in 2013). Vaccination rates are about the EU average (96.1% vs. 96% in 2012). They are higher than in the 1980s but show a recent decrease over the decade. Screening rates for cervical and breast cancer are not high (39.8% and 61% of the target population in 2012) (Yazbeck, Robida, 2013: 223–229).

The challenges of the pharmaceutical market in Poland

Over the last decade, salaries in the health care sector have been constantly slightly below the average salaries in the overall economy. Between 2003 and 2013 gross wages fluctuated around 75–80% of the average, but in 2006 they increased dramatically reaching 91%. The level of wages varies according to function: in 2006 physicians and specialists earned 148% of the average wage, nurses and midwives 85% and unskilled personnel 75%. Hospitals are financed on the basis of the contracts concluded between individual entities and the National Health Fund. A uniform classification of hospital services, mainly based on defining individual groups of procedures and prices for basic units serves as a basis for those contracts. (Abel-Smith, 1994: 80–83).

When looking at hospital activity, inpatient discharges – per 100 000 inhabitants – are below the EU average (13965 vs. 16231 in 2013) and the number of day case discharges is well below – less than half – the EU average (2904 vs. 6120 in 2012). Although it has doubled since 2003, the proportion of surgical procedures conducted as day cases (17.2%) is still well below the EU average (28.1%o in 2012). As mentioned earlier, the overall hospital average length of stay is about the EU average

(8 days in 2012). These figures suggest that there may be some room to increase hospital throughput/efficiency notably by improving the way surgical treatments are conducted (i.e. more use of day case surgery). Total spending on pharmaceuticals has been increasing constantly over the last decade, reaching in 2013 almost 150% of the 2003 value (in constant prices). The fast growth in sales was not accompanied by an increase in reimbursement financing: the total value of reimbursed drugs increased over the same period (2003–2013) by a mere 17%. Consequently, private expenditure on pharmaceuticals has risen dramatically, by 62%.

The pharmaceutical market in Poland is divided into two segments: open (through pharmacies) and closed (through hospitals) markets. Over the last decade, the value of drugs sold has increased in both markets, while the quantity has decreased in hospitals and remained stable in pharmacies. These developments suggest a sharp increase in the average price of hospital drugs, driven mainly by a growing use of original drugs. In the open market, the shares of reimbursed and over-the counter drugs were broadly equal until 2004. Since then a significant increase in the quantity of prescribed and reimbursed drugs has exceeded significantly that of the OTC drugs (Włodarczyk, 1999: 67–71).

However, in terms of value the gap between the growth rates of the two groups has been much narrower, which suggests a much higher price dynamics of the OTC pharmaceuticals, resulting from high effectiveness of advertising campaigns and insufficient competition between the OTC drugs producers. More detailed analysis of the structure of the pharmaceutical market shows that the increase in the share of imported drugs is linked to the fall in their relative price, as well as the growth in the total value of sold generics, driven mainly by the relative increase in their prices rather than quantities sold. The Centre for Health Care Quality Monitoring provides independent accreditation on the basis of a published set of standards. Quality requirements, national guidelines and standards are developed based on independent expertise. Further schemes include developing a better system to evaluate services. The use of technology assessment is increasing, leading to evidence-based contracting of services.

Public (0.1%) and total (0.2%) expenditure on prevention and public health services as a percentage of GDP are below the EU average (0.2% and 0.3% in 2013). They do not compare better as a percentage of total current health expenditure, with both public and total expenditure on prevention and public health services below the EU average (respectively 1.5% vs. 2.1% and 2.4% vs. 2.7% in 2013). It seems rather low given the comparatively low achievement in life expectancy and healthy life expectancy figures. While the data compares fairly well as far as life-styles are concerned, it may be very valuable to focus on disease prevention activities according to the most recent pattern of risk factors (circulatory system diseases and cancers). While vaccination rates are above the EU average (99% vs. 96% in 2012) screening rates are indeed extremely low, both for cervical cancer and for breast cancer (respectively 49% and 15.4% of the target population in 2012).

The United Kingdom's implemented reforms

The authorities have implemented a number of policies to control expenditure on pharmaceuticals. There are no separate pricing and reimbursement decisions for reimbursed medicines. The Pharmaceutical Price Regulation Scheme controls the price of branded medicines and the profits pharmaceutical companies can make on selling drugs to the NHS. If companies make too high a profit on NHS reimbursed drugs, they must either reduce the price or repay the NHS. The Drug Tariff sets reimbursement prices for generics. The price of over-the counter medicines is not regulated. There are controlled price updates and authorities use price-freezes and cuts. There is a negative list of reimbursed products. The authorities promote rational prescribing by physicians through treatment and prescription guidelines (the British National Formulary and the BHF for Children and NICE guidance on clinical and cost--effectiveness effects of interventions) complemented with monitoring of prescribing behaviour and education and information campaigns on the prescription and use of medicines (Müller, Braun, Gress, 2000: 23–31).

These are coupled with pharmaceutical budgets. For example, PCTs use a commonly defined list of recommended drugs which are considered sufficient to meet the needs of patients as cost-effectively as possible and GPs may be asked to justify prescribing outside the recommendations. There are also prescribing advisers employed at various levels of the organisation to encourage rational and cost-effective prescribing and reviewing prescribing behaviour. Some PCTs also run prescribing incentives schemes with GPs so that they receive a (modest) bonus if they use cost-effective clinically appropriate prescribing. A large amount of prescribing data is available, practice by practice, to prescribers and advisers to encourage improvement.

There are also information and education campaigns directed at patients and cost-sharing to encourage a rational use of medicines on the patients' side. In England, patients pay a fiat rate prescription charge for each item dispensed via an NHS prescription, unless one qualifies for exemption. There is an explicit generics policy although generic substitution cannot take place i.e. pharmacies are obliged to dispense the product prescribed by the doctor. However, doctors are strongly encouraged to prescribe by their generic name for good professional practice (so pharmacists can provide the patient the cheapest product available) and for value for money reasons. For many years, the DoH published the share of generic prescribing as an indicator. The National Prescribing Centre provides a wide range of material and training to promote generic prescribing. Prescribing advisers also encourage generic prescription (Pavolini, Guillén, 2013: 45–49).

The UK has an extensive information management and statistics systems and comprehensive data is gathered on physician and hospital activity and quality and on health status. Data is provided at the health authority level and by provider. There is extensive and public information comparing Trusts in terms of activity and quality

(clinical outcomes, use of appropriate processes, patient satisfaction and experience). Physicians are monitored in terms of activity and compliance with clinical guidelines and given feedback on their prescription behaviour. Nevertheless, there are some information gaps in some areas which may be important for decision making.

The National Institute for Health and Clinical Excellence (NICE) conducts and gathers information on health technology assessment and conducts economic evaluation and cost-effectiveness analysis which is used to define whether new interventions and medicines should be covered by the health system and to what extent (level of reimbursement) as well as to define clinical guidelines. The central government through the DoH sets and monitors public health priorities in terms of process, outcomes and the reduction of health inequalities. There are some risk factors that can translate into an important burden of disease and financial costs (Brook, McGlynn, Cleary, 1996: 966–970).

Authorities have in recent years emphasised health promotion and disease prevention measures as a means to reduce the burden of disease (e.g. what is called in Scotland the killer diseases) and reduce health inequalities and therefore to ensure the long-term sustainability of the system. There is, however, no information on public and total expenditure on prevention and public health services as a % of GDP as a % of total current health expenditure. Vaccination rates are below the EU average (92% vs. 96% in 2012) and lower than in 2003 (95%), while screening rates for cervical and breast cancer are quite high (78.5% and 70.5% of the target population in 2012).

Conclusion

This article analyses many of the cross-border aspects in health care reforms where a blurring of 'social security' (associated with non-market, non-competitive structures, constrained within geographical borders, collective responsibility and redistribution – a matter for 3 given Member States) and 'normal economic activity' (associated with markets and competition, free movement across borders, individual rights and regulation – a matter for the EU's internal market) has occurred. Indeed, where such blurring occurs and healthcare – which has otherwise been founded upon a stark distinction between these two opposing concepts – interfaces with EU law and policy, there are important challenges. Part of the challenge for the future, then, is to reconceptualize this relationship (social security/welfare as part of the EU internal market) so as to develop robust and helpful contributions from EU law and policy for health systems governance in Europe.

Healthcare systems in the three selected Member States are evolving in response to rising costs, rising population expectations and ageing societies. The choice of reform or policy options adopted in response to these changes may fall under the scrutiny of the Commission, under soft law mechanisms or the European Court of Justice (ECJ) applying economic legislation. In any case, Member States can no longer rely

on the EU's inertia in the field of health policy. Once a Member State shifts its health services from a model based essentially on solidarity to one including market-based principles, the uncertainty surrounding the scope of application of EU law could result in unintended consequences. Such reforms may unintentionally broaden the market's influence on health services, despite the dampening effect of the 'services of general economic interest' clause in the EC Treaty.

The leveraging of best practices and other soft law techniques must be carefully considered in the context of each situation. Specific allowances for the protection of comprehensive national welfare system and the simultaneous capacity building of Poland – the youngest of the three presented Member States – its welfare systems need to be built into long-term EU strategies. To achieve this, additional EU enforcement capabilities, along with appropriate incentive structures, are necessary. Additionally, neither increased regulation nor soft law will resolve underlying national disparities in power, financing and capacity. The safeguarding of strong welfare systems in wealthier nations (the UK) and simultaneous strengthening of social structures (Italy) is a challenging goal necessitating a new transformative approach as far as new Members States are concerned. Social protection and equality can best be augmented by establishing a robust and transparent supranational policy framework.

What is clear in respect of the current 'asymmetry', however, is that long-term planning and a coherent policy framework would mitigate some of the negative impacts of the patchwork approach that otherwise results. We might point to the successes of EU environmental protection policy, where there is explicit Treaty stipulation of Community competences. At the same time, it is not immediately clear how best to bridge or remedy the gap between politics and economics in the health area; at least not without making changes at the level of the Treaty.

The new modes of innovative management, soft law and open method of coordination, in particular, have been forwarded as a means to address the gap (these modes of governance have also been used with some degree of success in combination with hard laws in EU environmental policy). While such approaches have the potential to bring dividends in respect of Member States' and other stakeholders' mutual learning and in being an inclusive and deliberative dynamic, this is first contingent: on the ECJ and other soft law approaches generating meaningful results. Compared to internal market law, the ECJ is still in some thing of an embryonic stage, and its results are therefore somewhat uncertain. One visible output is perhaps the proposal for a directive on the application of patients' rights in cross-border health care.

For the analysed Member States this raises a question in respect of protecting the social basis of their health systems and, indeed, social cohesion more generally. For it has been suggested that economic integration in Europe may lead to a 'gradual and indirect process of social policy erosion'. Without necessarily endorsing this view, it is clear that the Member States will have to be careful due to demographic trends, the mounting costs of healthcare, the world crisis in social security, taxpayers' revolts, excessive bureaucratization and so on.

References

Abel-Smith B. (1994), *An Introduction to Health: Policy*, "Planning, and Financing", London: Longman.

Altman S., Blendon R. (eds) (1979), *Medical Technology: The Culprit Behind Health Care Costs? Washington*, DC: Government Printing Office.

Balicki M. (2013), *Problemy służby zdrowia w UE – diagnoza i recepty*, "Warszawskie debaty o Polityce Społecznej", 10: 5, Wydawnictwo Fundacji Friedrich-Ebert-Stiftung, Warszawa 2013; full text: www.feswar.org.pl/fes2009/pdf_doc/debaty10.pdf [Access on 20th August 2014].

Bauman Z. (2011), *Zdrowie i nierówności społeczne*, [in:] *44 listy ze świata płynnej nowoczesności*. Kraków, Wydawnictwo Literackie.

British Standards Institution (2012), *Health services. Quality management systems Guide for the use of EN ISO 9004: 2000 in health services for performance improvement.* London, British Standards Institution.

Brook R., McGlynn E., Cleary P. (1996), *Measuring quality of care,* "The New England Journal of Medicine", 335(13): 966–970.

ISTAT (2011, 2012, 2103). *Indagine multiscopo ISTAT su famiglie*, ISTAT multipurpose survey on families, Rome, Italian National Institute of Statistics.

Italian Ministry of Health (2013), *OECD Health Ministerial Meeting,* Paris, Organisation for Economic Co-operation and Development.

Mossialos E., Dixon A., McKee M. (2000), *Paying for the NHS*, "British Medical Journal", 320: 197–198.

Müller R., Braun B., Gress S. (2000), *Allokative und distributive Effekte von Wettbewerbselementen und Probleme ihrer Implementation in einem sozialen Gesund-heitswesen am Beispiel der Erfahrungen in den Niederlanden*, [Allocative and Distributional Effect of Competition and Problems with its Implementation in a Social Health Care System: the Example of the Netherlands], Bremen, University of Bremen.

Pavolini E., Guillén A.M. (eds.) (2013), *Health Care Systems in Europe under Austerity*, Institutional Reforms and Performance, Palgrave Macmillan.

Włodarczyk C. (1999*), Reforma opieki zdrowotnej,* [in:] Kolarska-Bobińska L. (red.), *Druga fala polskich reform*, Warszawa.

Yazbeck A., Robida A. (2013), *Implementing clinical pathways in hospital in Italy. Poster presentation*. 26 April 2013, 15th European Forum on Quality Improvement in Health Care, London.

Streszczenie

Innowacyjne zarządzanie reformami w sektorze ochrony zdrowia w wybranych krajach członkowskich Unii Europejskiej

Unia Europejska nie odgrywa zasadniczo formalnej roli w dziedzinie opieki zdrowotnej. Nie istnieją bowiem normy unijne w zakresie organizacji opieki zdrowotnej. Organizacja służby zdrowia i systemu ubezpieczeń zdrowotnych należy do kompetencji państw członkowskich. Kraje te we własnym zakresie reformują swoje systemy ochrony zdrowia. Systemy ochrony zdrowia w poszczególnych krajach UE różnią się więc między sobą. Analizie porównawczej poddano systemy trzech wybranych krajów: Włoch, Polski i Wielkiej Brytanii.

Słowa kluczowe: innowacyjne zarządzanie w służbie zdrowia, prawo unijne, system opieki zdrowotnej

Keywords: innovative management of healthcare, European Union law, system of public health