For personal use only. Not to be reproduced without permission of the editor
(permissions@pharmj.org.uk)

How British pharmacy practice is likely to be affected by changes in Europe

In this fifth article in a series leading to a consultation among members about the Royal Pharmaceutical Society's Pharmacy 2020 project, **Stuart Anderson**, associate dean of studies at the London School of Hygiene and Tropical Medicine, looks at the European dimension

Pharmacy in Britain has always been strongly influenced by events beyond its borders, and over the coming years its relationship with Europe will play an ever-increasing role. Since the UK joined the EU in 1973 the impact of Europe has increased steadily; today few aspects of life are immune from European laws, directives and regulations. The European dimension now extends to most aspects of pharmacy in Britain, from pharmaceutical goods and services to the education, regulation and mobility of pharmacists. Today European directives apply to every stage of the pharmaceutical supply chain from the development, manufacture and marketing of medicines, to wholesaling and retailing, and to the practice of pharmacy in its many settings.

This article highlights key differences between countries and significant developments in Europe that are already having an impact on the practice of pharmacy in Britain. The situation is changing rapidly: European directives appear, recommendations from inquiry reports are accepted, and the European Court makes rulings, many of which have considerable implications for pharmacy. European influence over pharmacy in Britain will become ever greater.

Current and future EU member states

One of the features of the EU has been its rapid growth. The 1951 Treaty of Paris was signed by just six countries; between 1973 and 2007 there were six waves of enlargement; the UK (along with Denmark and Ireland) joined in 1973. Greece, Spain and Portugal joined in the 1980s. In 1994 the European Economic Area (EEA) was established, allowing Iceland, Liechtenstein and Norway access to the single market. German reunification brought further enlargement in 1989, and Austria, Sweden and Finland joined in 1995.

Further expansion occurred in 2004 with the accession of 10 countries, mostly from Eastern Europe. Romania and Bulgaria joined at the beginning of 2007, bringing EU membership to 27 countries. There are currently three candidate countries: Croatia, The Former Yugoslav Republic of Macedonia and Turkey. In addition the western Balkan countries of Albania, Bosnia and Herzegovina, Montenegro and Serbia are all officially recognised as potential candidates. By 2020 the total membership of the EU could be 34 countries, with a population of nearly 600 million people.

European goals and institutions

The countries of Europe demonstrate great diversity in social, political and economic development, and this is reflected in their health care systems, in the regulation of pharmaceuticals, and in the practice of pharmacy. The central role of European institutions has been to promote convergence. Their primary focus has been economic, on free movement and competition issues, but they are also involved in more detailed issues such as the harmonisation of authorisation procedures, in national prices and profit regulation, in reimbursement issues, in rational drug use and in advertising.

The European Commission is the body with the legal responsibility for setting, promoting and enforcing the principles of European law. The Commission is slowing imposing greater convergence on national practice by passing harmonising legislation, using two main mechanisms: it passes so-called "positive" harmonisation instruments such as regulations and directives, and it enforces the primary treaty rules on competition and free movement ("negative" harmonisation), under which member states have to amend their own legislation where this represents a barrier to the free movement of goods and services.

Health care in Europe

The countries of Europe operate a great variety of health care systems and they spend hugely differing sums on health care (see Table). While Luxembourg, Switzerland and Norway all spend over £3,000 pa per capita on health care, five current EU member states all spend less than £300 pa per capita. Substantial differences are also seen in total health care expenditure as a percentage of GDP. Germany and France spend around 11 per cent on health care, while Estonia and Slovakia both spend less than 6 per cent. In all countries this figure seems likely to rise in the coming years.

Populations are ageing, resulting in higher costs and fewer people to pay for them. In Britain the number of people aged over 85 is expected to rise to about four million by 2051. Fifteen million people have a long-term health condition, and they account for 80 per cent of GP consultations. Developments in medical technology are changing the type of care provided in hospitals. People will increasingly be treated nearer their own homes, outside the hospital environment, in facilities such as polyclinics and urgent care centres. Developments in information technology will facilitate information sharing, decision support, and remote diagnosis and treatment. All this provides enormous opportunities and challenges for pharmacists throughout Europe.

Whether or not the provision of health care services should be subject to the rigours of the free market has been a cause of much debate within Europe. The European Parliament recently voted overwhelmingly to reject a proposal from its Internal Market Committee to reintroduce health care services into the Directive on Services in the Internal Market. The new directive specifically excludes health care and pharmaceutical services provided by health professionals. Pharmaceutical services are likely to remain matters for individual governments for the foreseeable future.

Pharmacy workforce

The number of pharmacists per 100,000 population for each country is shown in the Table. Malta and Monaco have around 220 pharmacists per 100,000 population, while Bulgaria and Romania have fewer than 20. The proportion of pharmacists in pre-2004 countries is double that in post-2004 countries. However, high proportions are not all in western Europe, and low ones all in eastern Europe: Cyprus and the Netherlands both have fewer than 20 pharmacists per 100,000 population.

These large differences are a reflection of many factors, including differences in the number of other health professionals, particularly doctors, and also of other groups having different pharmaceutical qualifications. The Scandinavian countries offer two pharmaceutical qualifications: the master of pharmacy degree takes five or six years to complete and the bachelor of pharmacy degree takes three years. In Norway and Sweden the latter is the qualification of the prescriptionist. The two groups have similar responsibilities, but those with the bachelor's degree cannot own and run a pharmacy. In the Netherlands it takes six years to qualify as a pharmacist and, as in the Scandinavian countries, qualified staff

Pomortzeff/Dreamstime

other than pharmacists play a more important part in dispensing than elsewhere in Europe. In Britain the role of the pharmacy technician seems set for further development.

Pharmacist mobility

Increased mobility of workers has been one of the core principles of the EU, and arrangements now exist for the free movement of pharmacists between European countries. Pharmacists who are nationals of an EEA state, who hold a qualification listed in the pharmacy directive and which has been awarded in an EEA state, have an automatic right of entry to the British register, once they have proved their identity, paid the fees, signed declarations of good health and conduct, and agreed to abide by the Royal Pharmaceutical Society's Code of Ethics.

So far the number of EU pharmacists entering the British register has been relatively small. For several years the largest single group of EU entrants to the British register came from Spain. The figures peaked in 2003, when 323 Spanish pharmacists registered in Great Britain. In 2003 some 481 pharmacists were qualified by virtue of residency in the EU or EEA. Between August 2005 and July 2006, 476 pharmacists registered through the European route. The most popular entry country was Poland with 179 pharmacists, followed by Spain with 127 (see Table).

Recent EU directives address remaining barriers to the mobility of heath professionals within Europe. Directive EC2005/36/EC states that pharmacists registered anywhere in the EEA can take temporary and occasional work in any other member state without having to register with that country's professional regulator. The UK government has taken the view that any requirement relating to continuing professional development would be an unjustifiable restriction on European freedom to provide services. The implications for the future are clear: pharmacists from any EU member state will be able to work in the UK for any length of time. It seems likely that increasing numbers of them will do so, particularly as English is now taught as a second language in most European countries.

Education of pharmacists

Despite a number of directives relating to pharmaceutical education there remain wide variations in pharmaceutical qualifications and educational requirements in different countries. Most countries, including the UK, signed up to the Bologna Process in 1999, which would lead to a European Higher Education Area (EHEA) by 2010.

The implications for pharmacy education in the UK are considerable. The EHEA is based on a three-cycle degree system (bachelor, master and doctor, over three, two and three years, respectively). The European Credit Transfer System needs to be universally adopted, and diploma supplements need to be awarded along with the degree. Pharmacy education, and indeed higher education across the UK, is currently grappling with these issues, all of which will need to be resolved by 2010.

Just how much change will be necessary remains to be seen. The Bologna Process has so far allowed for a large degree of local discretion. However, there are signs that ministers are becoming impatient with the lack of coherence between national approaches. The recent London Communiqué noted that much more effort was required to implement national qualifications frameworks compatible with the overarching Framework for Qualifications of the EHEA.

Role of pharmacists in Europe

The impact of pharmacists in Europe has increased steadily over the past 10 years or so. From being largely marginalised, the pharmacist has come to be seen as a key member of the health care team. This largely follows concerns about the rapidly increasing costs of pharmaceuticals. Governments have come to recognise the important role that pharmacists can have in promoting the optimal use of medicines and contributing to the cost effective use of limited resources.

Although in most EC countries a majority of pharmacists work in community pharmacies, the average population served by a community pharmacy varies enormously (see Table). Throughout Europe the trend is towards more clinically focused community pharmacy services, with pharmacists taking on more and more activities previously undertaken by doctors. Medicines management activities will expand, services to support people with long-term conditions will develop, and medication use reviews will become widespread. The prescribing rights of pharmacists will also be further extended.

The public health role of pharmacists is now widely recognised throughout Europe. The Europharm Forum in 2003 reviewed ways in which practising pharmacists could contribute to reducing health risks and promoting health. The best European practices for mobilising pharmacists for public health campaigns were examined. They included the UK government's strategy for pharmacy, and the multi-professional smoking cessation network in Glasgow. In the UK, the public health role of the pharmacist will become increasingly important in the years ahead.

Regulation of pharmaceuticals

Pharmaceuticals have been a focus of the commission's attention for many years, and the situation relating to the regulation of pharmaceuticals in Europe is now highly complex. In developing their pharmaceutical policies governments have to balance a number of competing demands: maintaining public health, providing health care, and supporting industry. Parallel trade ("intra-brand" competition) and use of generics ("inter-brand" competition) are both of interest to the Directorate-General for Competition, since both are considered essential elements of a single market.

The pharmaceutical industry remains vehemently opposed to parallel importing. Recent actions in the European Court have challenged the ability of the European Commission to force manufacturers in Europe to make unlimited quantities of medicines available to companies known to be involved in parallel importing. However, most of the main European wholesalers are now involved in parallel trading, and it is difficult to see how this trend can be reversed at this stage.

Table: Pharmacy-related statistics compared in the countries of Europe

	Total annual health care expenditure per capita in 2004	Pharmaceuticals expenditure per capita in 2004	Number of pharmacists per 100,000 population	Pharmacists entering British Register Aug 05–Jul 06	Average population served by a community pharmacy
Pre-2004 EU country					
Austria	1,877	245	60	3	8,000
Belgium	1,733	208 (2003)	114	2	5,300
Denmark	2,208	207	49	4	18,300
Finland	1,449	236	112	2	3,000
France	1,946	369	106	6	2,700
Germany	1,911	286 (2003)	58	16	3,800
Greece	1,020	178	82	6	1,400
Ireland	1,762	218	97	1	3,100
Italy	1,415	294	115	40	3,400
Luxembourg	3,235	277 (2002)	82	–	5,600
Netherlands	1,865	184 (2002)	19	1	6,300
Portugal	872	201 (1998)	95	12	3,900
Spain	1,070	244	87	127	2,200
Sweden	1,928	238	66	28	11,400
United Kingdom	1,684	235	51	*19	4,800
European Economic Area countries plus Switzerland					
Iceland	2,405	356	130	–	–
Liechtenstein	–	√–	–	–	–
Norway	2,950	279	37	1	10.200
Switzerland	3,081	320	60	1	4,200
EU members after 2004					
Bulgaria	–	–	13	–	–
Cyprus	632	–	18	–	–
Czech Republic	421	76 (2002)	55	7	–
Estonia	250	-	42	1	–
Hungary	435	91 (2002)	52	10	–
Latvia	205	–	–	1	–
Lithuania	230	–	69	3	–
Malta	666	–	203	9	–
Poland	224	66	66	158	–
Romania	–	–	6	–	–
Slovakia	247	85 (2003)	52	6	–
Slovenia	765	-	40	–	–
Candidate countries					
Albania	–	–	40	–	–
Bosnia and Herzegovina	–	–	9	–	–
Croatia	–	–	53	–	–
Montenegro	–	–	19	–	–
Serbia	–	–	19	–	–
TFYR Macedonia	–	–	15	–	–
Turkey	175	32 (2000)	32	–	–

**Registrants joining from Northern Ireland*

Sources: OECD Health Database, World Development Indicators (World Bank), World Health Report: Core Health Indicators (WHO), Consumer Trends, Populations Projections Database, UN Population and Vital Statistics Report 2007, Decision Resources Inc.

There are also tensions between national objectives and those at the European level, which are often concerned with the relative performance of Europe compared with other regions of the world. A report for the Directorate-General for Enterprise in 2000 concluded that the competitiveness of the European pharmaceutical industry had declined relative to the US, with large differences between member states. It found that many national pharmaceutical markets in Europe were not competitive enough.

Differences in health care systems between countries are reflected in both expenditure on pharmaceuticals and the numbers of pharmacists available. The Table shows pharmaceutical expenditure per capita in selected OECD countries. In France, expenditure on prescription and over-the-counter medicines is around £380 pa per capita, while in Poland it is less than £70. But in all countries total pharmaceutical expenditure is rising, and pharmacists are seen as having a crucial role in ensuring optimal use of limited resources.

Conclusions

Europe will undoubtedly continue to have a major impact on the practice of pharmacy in the UK. However, progress is likely to be faster in some areas than in others. Remaining barriers to the mobility of health professionals are being removed, and by 2020 the inward movement of pharmacists from EU countries could be substantial. The pharmacy workforce will be more fluid and flexible, with greater use being made of non-pharmacists. There will also be significant changes in the medicines available. New drugs will be ever more expensive, and parallel imports and use of generics are likely to increase. There will be further consolidation of the wholesaling sector, and significant growth in vertical integration, with the growth in chain pharmacies in many European countries where they are currently absent. However, a common market for pharmaceuticals in Europe still seems a long way off. Indeed, there remains great uncertainty about what a fully harmonised market for medicines would mean for member states.

In many areas Britain is leading the way, with supportive policy statements and an enabling pharmacy contract. The impact of Europe on pharmacy is growing fast, and perhaps the only thing we can be really sure of is that pharmacy in 2020 will be extremely different from what it is today.