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Contents

Responding to the challenge of chronic diseases: lessons from England?

Ellen Nolte and Martin McKee

Perhaps the greatest challenge that will face health systems around the world this century will be how to develop effective responses to the growing burden of chronic diseases. Several interlinked factors come together to create this challenge. Many chronic diseases are a consequence, albeit not always inevitable, of the ageing process. However, unlike in past generations, for whom the onset of a disease such as diabetes could mean a rapid death, we now have the means to keep people alive but on treatment for their diseases.

In a world where fertility rates are declining, this means that there is now a much higher proportion of the population living with chronic diseases and, in many cases, multiple diseases. Many older people will be receiving treatment for a combination of conditions that will often include some degree of hypertension, heart failure, angina, obstructive airways disease, or arthritis. And the list of complex chronic diseases is constantly growing. In many industrialized countries there is an ageing cohort of individuals living with HIV infection who will have to add a complex mix of life-sustaining treatments for non-communicable diseases to their already complex combination of anti-retroviral therapy. AIDS, once considered a rapidly progressive fatal condition, with treatment, has become yet another chronic disease.

To these must be added those people whose cancers are suppressed or prevented from recurring by long-term administration of drugs, such as anti-oestrogens, or who are receiving therapy to replace some natural substance, such as thyroid or sex hormones. It is easy to see how a typical family doctor may be looking after a hundred or more people who are taking a cocktail of drugs, each subject to possible interactions and each competing for potentially disordered metabolic pathways, to create a specific combination of products circulating in a single patient that has never been the subject of a detailed evaluation.

Challenges

Such people have long-term needs for expert health care. However, the complexity of their needs means that no single professional can be expected to provide it all. Each person will, in practice, provide most of the care they require themselves, increasingly with the assistance of monitoring equipment that would once have been found only in a laboratory. People with diabetes, used to monitoring their own blood glucose levels and titrating their doses in response to these readings, have long shown what is possible. Advances in testing kits will extend this possibility to many others. However, they also require professional care. An individual with complicated diabetes may manage their condition perfectly well on a day to day basis but will, from time to time, still require review by their primary care team. The care they receive at this level will be increasingly within the framework of a nurse-led service, drawing where necessary on the skills of a family doctor, a dietician and foot care specialist, among others. In addition, they may also need specialized assessments by an ophthalmologist, to manage any diabetic eye problems, a cardiologist, for the cardiovascular complications of diabetes, or a nephrologist, for those individuals who develop kidney impairment.

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The World Health Organization Regional Office for Europe, the Governments of Belgium, Finland, Greece, Norway, Spain and Sweden, the Veneto Region of Italy, the European Investment Bank, the Open Society Institute, the World Bank, the London School of Economics and Political Science (LSE) and the London School of Hygiene & Tropical Medicine (LSHTM).

Here lies the problem. In many countries health care remains based on a model of an acute episode of care, in which the patient attends a single health professional. Instead, what is needed is a system that empowers patients to take control of their own condition while providing them with the means to navigate effectively through the complex maze that is the modern health care system.

A forthcoming project by the Observatory will be exploring these issues is detail, examining how the burden on health systems is changing and examining evidence for effectiveness of the many different solutions being explored in health systems. In this article we examine the situation in one country, England, where considerable thought has gone into how best to tackle these issues.

Policy developments in England

About 60% of the adult population in England report some chronic health problem.[1] They place disproportionate demands on the health care system. The 15% of people with three or more chronic problems account for about 80% of consultations with general practitioners and 30% of inpatient days. In recognition of these facts, the government has undertaken two major reviews, chaired by Sir Derek Wanless. These have highlighted the need for sustained investment in policies that will prevent the growth of chronic diseases in the future. Calculating a fully-engaged scenario, in which optimal resources are directed at interventions that prevent the onset and progression of important diseases, many of them chronic, will lead to substantial savings in health care expenditure in the future. The Department of Health has identified better management of chronic diseases as a key priority in its 2004 National Health Service Improvement Plan.[2] This builds on a series of earlier activities, in particular the National Service Frameworks (NSFs), and envisages the rapid take-up of 'cost-effective' drugs that have been approved by the National Institute of Clinical Excellence (NICE). The NSFs comprise an integrated set of evidence-based recommendations to tackle major health problems. They cover primary and secondary prevention, diagnosis and treatment, and rehabilitation, and specify the roles to be played by purchasers and the diverse providers of health care. For example, for coronary heart disease, the NSF identifies as immediate priorities the establishment of smoking cessation clinics, rapid access diagnostic facilities for patients with chest pain, quantified improvements in the speed of thrombolysis for those with myocardial infarctions, and enhanced use of drugs such as beta-blockers and statins by those recovering from an infarction.

The Improvement Plan sets out a systematic approach that takes account of the level of support needed by patients with long-term conditions, involving self-management, disease management and case management. This has, to a considerable extent, drawn on models adopted by managed care organizations in the United States, particularly the population management model implemented by Kaiser Permanente, and United HealthCare's Evercare model of case management.[3] These are currently piloted in a number of Primary Care Trusts (PCTs), responsible for providing primary medical care and community nursing services in England and for purchasing secondary care (for an overview see www.networks.nhs.uk/3.php).

All PCTs in England are expected to implement some form of case management by 2008, backed by the appointment of over 3000 'community matrons' to support around 250 000 patients with complex chronic conditions.[2] The anticipated benefits include improved quality of care and, by preventing or delaying complications of conditions, reduced (emergency) admissions and long hospital stays, in line with the targets set out in the public service agreement between the Department of Health and the Treasury to reduce emergency bed days by 5% by 2008.[4] The evidence available so far from the nine Evercare pilots of case management in England is, however, inconclusive as to whether substantial reductions in emergency admissions can be achieved.[5,6] The emerging evidence is stimulating a reappraisal of the much vaunted benefits of these American models, coupled with a recognition that it may be easier to achieve striking benefits in the United States, where the outcome of many common chronic diseases is so much poorer than in Europe (for example, deaths from diabetes among young people are about five times higher than in Europe).[7] This does not, however, mean that there is nothing to learn from the American experience; there are lessons from those models that have been able to develop effective integration of care. It does, however, counsel against the uncritical adoption of models developed elsewhere.

The primary care team plays a crucial role in these reforms. Consequently, they have been supported by a new system of paying for primary care, based on a complex (some might argue over-complex) quality and outcomes framework designed to provide appropriate financial incentives to encourage general practices to provide ongoing high quality management of ten chronic conditions including diabetes, hypertension and asthma.

It is still too early to say whether these initiatives will be successful. The integrated nature of the English National Health Service, with its well developed multi-professional teams and its many mechanisms to bridge the divide between primary and secondary care is already somewhat further up the learning curve than those systems where there is much greater fragmentation, especially where the concept of the liberal profession, with its emphasis on medical independence, is deeply ingrained. Perhaps the greatest risk, given the very short attention span of British ministers, is that the many ideas being implemented will be themselves subject to a new set of reforms dreamed up by a minister anxious to make his or her mark by rejecting all that went before. Compared with most European health systems, the English National Health Service has been in a state of almost permanent revolution in recent years, While this gives British speakers much to talk about at conferences, as they struggle to keep up to date with changes taking place as they are travelling to their destination, it can be deeply demoralizing for those who are

constantly being reorganized, as well as creating a collective institutional amnesia. If the current ministerial team can break with tradition and let these reforms run their course, then there may be much to learn.

References

1. Wilson T, Buck D, Ham C. Rising to the challenge: will the NHS support people with long term conditions? *BMJ* 2005;330:657–61.

2. Department of Health. *The NHS Improvement Plan. Putting People at the Heart of Public Services*. London: Department of Health, 2004.

3. NHS Modernisation Agency. *10 High Impact Changes for Service Improvement and Delivery*. London: Department of Health, 2004.

4. Department of Health. *Technical Note for the Spending Review 2004 Public Service Agreement 2005–2008*. Department of Health www.dh.gov.uk/AboutUs/HowDHWorks/ServiceStandardsAndCommitments/DHPublicServiceAgreement/fs/en

5. UnitedHealth Europe. *Assessment of the Evercare Programme in England 2003–2004*. London: UnitedHealth, 2005.

6. Boaden R, Dusheiko M, Gravelle H, Parker S, et al. *Evercare Evaluation Interim Report: Implications for Supporting People with Long-term Conditions*. Manchester: National Primary Care Research and Development Centre, 2005.

7. McKee M, Nolte E. Responding to the challenge of chronic disease: ideas from Europe. *Clinical Medicine* 2004;4:336–42.

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Disease management in Germany

Jonas Schreyögg and Reinhard Busse

Traditionally, one of the main characteristics of the German health care system is the strict separation of ambulatory and inpatient care. Ambulatory care is nearly exclusively provided by the Physicians' Associations, while most hospitals only provide inpatient care. Regulation and remuneration largely differ between the ambulatory and inpatient sectors. According to a study conducted by the Advisory Council for Concerted Action in Health Care this 'sectorization' of health care delivery is a major reason for the overuse of services, economic inefficiencies and the under-use of resources for most common chronic diseases.[1]

Since 1993 sickness funds and providers have been allowed to offer new models of care, thus enabling sickness funds to design specialized programmes for insurees with chronic diseases or population-based programmes. As this did not result in any significant action, a new initiative was launched as part of the SHI Health Reform Act in 2000. The aim was to improve cooperation between ambulatory physicians and hospitals as well as other health care professionals on the basis of contracts between sickness funds and individual providers or provider networks. However, physicians' associations and sickness funds could not agree on certain standardized guidelines for these programmes (as both had no incentive to establish them), resulting in only a few initiatives, mainly programmes for insurees with chronic diseases.[2]

Disease management programmes

To improve the quality and cost-effectiveness of health care for chronic conditions, disease management programmes (DMPs) were introduced by law in 2002. Minimum standards were defined for the conditions type 2 diabetes, breast cancer, coronary heart disease, and asthma/chronic obstructive lung disease. These minimum requirements included:

- treatment guidelines for providers;
- necessary quality assurance measures;
- conditions and process of patient enrolment;
- training of, and information for, providers and patients;
- documentation;
- evaluation of effectiveness and costs; and
- duration of programme accreditation.[3]

Based on these legally defined minimum requirements, sickness funds are allowed to selectively contract with providers and design their own DMPs for the legally defined conditions. To provide an incentive for sickness funds to introduce these programmes, and to avoid low participation rates, insurees registered in DMPs are treated as a separate category in the Risk Structure Compensation (RSC) scheme.* Sickness funds are compensated for the average expenditure of all DMP participants for each defined condition across funds (by age and sex). Thus, sickness funds with a high share of DMP participants receive a higher budget from the RSC scheme. For instance, in 2003 they received an average amount of €5198 for registered insurees with breast cancer compared to €2596 per 'regular' insuree.

* The RSC scheme was introduced in 1994 to equalize the playing field in the competitive statutory health insurance market by redistributing revenues among sickness funds to compensate for different expenditures due to different risk structures and to adjust for different fund revenues due to insurees' varying income levels.

Therefore, chronically ill insurees have become attractive for sickness funds due to this higher compensation and, if programmes are designed properly, funds have the opportunity to increase quality of care, reduce costs and increase allocative efficiency. So far (to March 1 2005), 3275* programmes (2763 for diabetes, 388 for breast cancer and 124 for coronary heart disease) have been accredited by the Federal Insurance Authority and more than one million insurees have been registered in DMPs. All programmes are subject to mandatory evaluation three years after their initial accreditation. The Federal Insurance Authority has defined lengthy catalogues (28 pages each for diabetes and breast cancer) for this evaluation, which will be conducted by contracted experts.[4]

The role of 'integrated care programmes'

In addition to the standardized DMPs, the Statutory Health Insurance Modernisation Act (in force since January 2004) requires sickness funds to spend 1% of their expenditure on 'integrated care programmes', for which they have wide contractual freedom. Programme resources, which are derived from regular remuneration to ambulatory care providers and hospitals, must be invested within three years; otherwise, these monies must be paid back to the respective providers.

The aim of integrated care programmes is similar to DMPs, but conditions are not defined, there are no minimum requirements regarding the structures of provided care and there is no extra compensation from the RSC. Sickness funds can even decide not to focus on a specific condition and instead to initiate population-based programmes to increase cooperation between different providers, especially amongst different sectors. In practice, however, population-based integrated care programmes are often used for conditions not defined under the standardized DMPs.

* The high number is due to the fact that DMPs have to be accredited for each sickness fund region separately.

Achievements and prospects

The developments to date show that insurees with chronic diseases are increasingly becoming a target group for sickness funds which are required to design programmes for chronic diseases by taking into account economic as well as clinical considerations. However, the Federal Association of SHI Physicians questioned whether sickness funds have the knowledge to review claims data and plan programmes successfully.[2] Indeed, sickness funds are tied to a certain budget for administrative costs and thus do not have much flexibility to hire new staff for manageing DMPs or integrated care programmes. This inflexibility is somewhat contradictory as DMPs are considered to be one element of generating competition between sickness funds, but funds do not have the necessary means to differentiate themselves from one another – for instance, with regard to offering higher quality DMPs. Another criticism is raised by physicians claiming that only minimum standards have been defined for DMPs and improved outcomes are not very likely. The mandatory evaluation of programmes will provide the first empirical evidence on their level of success.

References

1. Advisory Council for Concerted Action in Health Care. *Appropriateness and Efficiency. Over-, Under- and Misuse* (Report 2000/2001; Vol. III) Bonn: Federal Ministry of Health, 2001. www.svr-gesundheit.de/gutacht/gutalt/gutaltle.htm.

2. Busse R. Disease management programs in Germany's statutory health insurance system. A Gordian solution to the adverse selection of chronically ill people in competitive markets? *Health Affairs* 2004,23(3):56–67.

3. Busse R, Riesberg A. *Health Care Systems in Transition – Germany*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004.

4. Bundesversicherungsamt [Federal Insurance Authority]. *Kriterien des Bundesversicherungsamtes zur Evaluation strukturierter Behandlungsprogramme bei Diabetes mellitus Typ 2 (4.11.2004)/ Brustkrebs (21.12.2004).* Available at: www.bva.de/Fachinformationen/Dmp/Evaluation-Diabetes-2.pdf www.bva.de/Fachinformationen/Dmp/Evaluation-Brustkrebs.pdf

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Type 2 diabetes programmes in Europe

Hans Dubois and Vaida Bankauskaite

Diabetes is a chronic and progressive disorder that is wide-spread in every European country. Type 1 diabetes (low levels of insulin production) mainly occurs in childhood, while type 2 diabetes (insulin resistance/deficiency) usually occurs after the age of 40 and accounts for 85-95% of all diabetes in developed countries. Type 2 diabetes prevalence rates vary greatly across Europe, from 2.0% in Iceland to 10.2% in Germany, and is growing due to ageing populations and the increasing prevalence of obesity. Neglected treatment may cause numerous complications, including vascular disease, stroke, renal failure and blindness. Therefore, good management of this chronic condition increases life expectancy, improves quality of life and saves costs for society.[1,2,3] While diabetes programmes usually focus on several types of diabetes, and are sometimes part of broader programmes,* we look at type 2 diabetes programmes in Europe.

Strategies in type 2 diabetes programmes

The 1989 St Vincent Declaration, initiated by the International Diabetes Federation and the World Health Organization, triggered the creation of numerous diabetes programmes and diabetes task forces across Europe. Countries employ different strategies in type 2 diabetes programmes, such as needs-assessment, prevention, care and treatment, and education (Box 1).

The needs-assessment strategy serves to obtain information about treatment and care needs as well as risk factors. Belgium and Sweden have opted for this strategy by creating a diabetes patients register. Another example is the PBS Diabetes Population Prevalence model developed in the UK to predict levels of prevalence in specific areas. Such data is important: for example, in Finland an estimated 23.8% of all type 2 diabetes cases remain undiagnosed.[4] In general, data about diabetes patients are scarce in countries of central and eastern Europe but there is also little data in industrialized European countries.[1]

Prevention strategies probably make up the largest part of type 2 diabetes programmes, with most, including those in Israeli (submitted to the Ministry of Health in May 2005), Norway (to be presented to parliament by Autumn 2005) and the Italian 2004 national campaign, focusing on preventive measures. Prevention methods are diverse. For example, the Finnish programme recommends that patients complete a type 2 diabetes risk-assessment form in health care centres so that advice can be targeted towards high-risk individuals.

The third strategy targets care and treatment. For example, some Swedish county councils have introduced a new method for improving cooperation in health care, including diabetes care, between primary and hospital care. General practitioners (GPs) from health care centres share information about their work in hospitals and, in turn, inform the primary level about problems and issues that arise in hospital clinics.[5] Such integrated care initiatives are an important aspect in this third type of strategies. Social health insurance

Box 1: Examples of type 2 diabetes programmes

Needs-assessment	**Patient registers/data bases**
	Prediction models
	Early diagnosis (screening of risk groups)
Prevention	**Lifestyle change stimuli**
	Risk-group awareness
	Research promotion
Care and treatment	**Treatment protocols**
	Lifestyle change stimuli
	Better cooperation between primary, secondary and specialist care
	Early diagnosis of complications
	Diabetes units
	Focus on neglected aspects of care (e.g. psychological assistance)
	Research promotion
Education	**Patient self-help education**
	Health care professional education

* For example, in England a national diabetes programme was launched in 1999 within the framework of the 1998 National Health Plan, which targets several specific illnesses.

countries have, or are developing, several financial incentives for sickness funds and physicians to improve diabetes care: the Dutch Ministry proposes to compensate sickness funds ex-ante for every type 2 diabetes patient enrolled (for type 1 diabetes this is already the case), and in Germany, where risk-adjustment is mainly based on age and sex, a similar mechanism is being discussed. (See article on Germany in this issue)

Lastly, patients' and health professionals' education is receiving more attention. By helping patients to cope with their illness on a daily basis, care is improved and has potential cost savings. Some countries train medical and paramedical personnel for the establishment of well-organized diabetic clinics (Cyprus) or provide diabetes training for nursing practitioners to relieve physicians of basic diabetes care (the Netherlands). Several countries also provide diabetes education programmes to patients. Belgium has had two pilot projects running since January 2005 and October 2004 respectively: the *Leuven* project focuses on educating and supporting GPs to decrease the burden on specialists, while the *Aalst* project focuses on educating patients.

Implementation challenges

Like other initiatives, type 2 diabetes programmes fail mostly because of changes in policy priorities or lack of resources. In Slovenia, for example, in 1995 a draft programme to set standards of care and create a quality of care monitoring system was not accepted by the Ministry of Health due to lack of funds. In Lithuania, after a relatively successful start-up during the early 1990s, many of the diabetes schools and outpatient clinics with foot care facilities** were closed, and the National St Vincent Task Force ceased working due to a change in government priorities.

A common issue is that the existence of a formal diabetes programme is only the first step towards implementation. Therefore, the challenge lies in transforming (often nationally) outlined targets to actual improvements in diabetes care. For example, a 1996 Diabetes Plan by the Spanish region of Valencia still has not established the planned diabetes units in many hospitals due to insufficient funding.

Another challenge refers to the optimum mix of strategies in type 2 diabetes programmes. Diabetes programmes usually involve many sectors and actors, and have multiple objectives. It is therefore essential for countries to develop the best tool-mix so that specific needs can be addressed efficiently. Nevertheless, countries can still learn from each other's experiences: Cyprus and Slovenia are using the comprehensive Finnish programme, adopted in 2003, as a basis for developing their own type 2 diabetes programmes.

Finally, it seems that both top-down and bottom-up initiatives are important in achieving objectives. On the one hand, grass-root initiatives can be triggered by national programmes and can draw on national frameworks. For example, the Department of Health and the UK Diabetes Expert Group developed criteria, available through the internet, for local diabetes education programmes.[2] On the other hand, national programmes derive many benefits from the hands-on experience of local programmes and non-governmental initiatives. Many initiatives come from health care professionals, diabetes patient associations or local governments, and national plans often play no role. For example, diabetes associations in Spain and the Netherlands created their own patient education programmes, and in 2004, the Austrian Diabetes Association published guidelines that are accessible through its website. In the UK, three Primary Care Trusts and Acute Trusts appointed a project officer to liaise with primary and secondary care so that diabetes patients with vascular disease would not need to make multiple visits.[2]

Conclusions

While absent 15 years ago, type 2 diabetes programmes have become common across Europe. However, most plans are still in the initial phase and as data are scarce, their impact is difficult to assess. The comprehensiveness of the specific strategies applied in diabetes programmes differs a great deal across Europe, while resources and country-specific circumstances limit the selection of tools to achieve programme objectives.

It is a challenge to bridge the gap between design and implementation of type 2 diabetes programmes. Lastly, the term 'national programme' often creates the illusion that improved diabetes care can best be imposed from above. However, bottom-up initiatives (sometimes within a national framework) are increasingly being implemented.

References

1. International Diabetes Federation. *Diabetes Atlas Second Edition*. Brussels: International Diabetes Federation, 2003.

2. Department of Health. *Improving Diabetes Services – The NSF Two Years On*. London: Department of Health, 2005.

3. Gray A, Raikou M, McGuire et al. Cost-effectiveness of an intensive blood glucose policy in patients with Type 2 diabetes, (UKPDS 41), *BMJ* 2000;320:1373–78.

4. Finnish Diabetes Association. *Programme for the Prevention of Type 2 Diabetes in Finland 2003–2010*. Tampere: Finnish Diabetes Association, 2003.

5. Glenngård AH, Frida Hjalte F, Svensson M, Anell A, Bankauskaite V. *Health Care Systems in Transition: Sweden*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2005, forthcoming.

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** Improved foot care is important as diabetes can lead to foot ulceration, infection and amputation.

News

Health insurance reforms in The Netherlands

The new Health Insurance Act passed its final hurdle on 14 June 2005 with the Dutch Senate backing the government's bill by 45 votes to 24, mainly with the support of the Christian Democrats and right-of-centre VVD party. The legislation had previously been passed in the lower house of parliament without the support of the largest opposition party, the Social Democrats.

In a major reform of the health insurance system, the new legislation will come into force from 1 January 2006 and effectively unites the old compulsory health insurance scheme (ZFW) for people below a certain income level and all social security recipients – currently covering 63% of the population – and private health insurance.

The new, compulsory insurance scheme will now cover the entire population and will be provided by private insurers, with the sickness funds operating on a for-profit basis. Insurees will pay a flat-rate premium but some will be compensated through an income-related, government subsidy. 'No claim' discounts have also been introduced. Insurers must offer a minimum basic package of medical care that is similar to the existing social health insurance scheme and they must accept all citizens who apply regardless of age or medical history. In particular, as risk-rating is not allowed, insurers cannot charge higher premiums to the elderly or people who may need higher levels of medical care. Moreover, health insurers can choose to reimburse patients for their medical care costs or to provide a patient with medical services by contracted health practitioners and providers (variations are possible).

The unification of social and private health insurance has been a hotly debated issue within Dutch health care for over two decades. Both the 'Dekker Report' in 1987 and later the 'Simon Plan' in the 1990s advocated a single mandatory health insurance scheme but faced strong opposition from key stakeholders, including health insurers, employers and physicians. This reform aims to contain health care costs by encouraging competition between insurers and better negotiated contracts between insurers and health care providers. It is not clear whether these objectives will be achieved but the reform will certainly provide ample material for study by health policy researchers. We hope to report on developments in future issues of *Euro Observer*.

Recent ECJ rulings

The European Court of Justice has delivered some recent judgements in health-related fields, including:

Homeopathic medicinal products

An ECJ ruling (Case C-444/03) has relaxed the registration requirements for homeopathic drugs. The ruling follows a request by the Berlin Administrative Court to clarify the interpretation of Articles 14 and 15 of Directive 2001/83 on the Community Code relating to medicinal products for human use after the Federal Institute for Drugs and Medical Devices (BfArM), the competent body for drug authorization in Germany, dismissed an application by the company Fackler KG to register a homeopathic product ('metaipecac'). In adopting European drug law, the German Drug Act provides for a simplified registration procedure for homeopathic medicinal products. Registration may be denied if the product fails a quality assurance test or there is justified suspicion of harmful effects. However, the Act also does not permit registration if the use of the drug as a homeopathic product is not generally known.

Interpreting this last provision, the BfArM declined the registration application for metaipecac on the grounds that general awareness of its use as a homeopathic medicinal product had not been substantiated. The product is a new combination of homeopathic substances which are individually known and described in various bibliographic sources. But the BfArM took the view that general awareness of its various constituent substances was not sufficient to satisfy the statutory requirements for recognition of the homeopathic product in its own right.

The ECJ found that the interpretation did not comply with Articles 14 and 15 of the Community Code which requires only that an applicant's registration dossier describe how the homeopathic stock or stocks from which the combination is derived are obtained and controlled. A bibliographic record showing that the effects of the homeopathic medicinal product itself have been identified is not required. According to this judgement, the German national legislation establishes requirements that are excessively restrictive with respect to the simplified registration procedure. In future, the BfArM and the German courts will need to apply the correct interpretation of the law pursuant to the ECJ ruling.

The end of the Swedish monopoly on retail sales of medicinal preparations?

Since 1970, the retail sale of medicinal preparations in Sweden has been undertaken by Apoteket, a company under state control, which enjoys a sales monopoly. The ruling in Case C-438/02 states that the system of selecting medicinal products for sale operated by Apoteket is liable to place at a disadvantage medicinal preparations from other EU member states compared to Swedish medicinal preparations.

The ruling comes in the wake of criminal proceedings commenced by the Swedish authorities against Mr Krister Hanner, the general manager of Bringwell International. The company breached the Swedish rules governing Apoteket's sales monopoly by selling, in Stockholm in

2001, 12 packages of nicotine patches and nicotine chewing gum, both of which fall within the description of medicinal preparations under the relevant Swedish legislation. The Swedish court hearing the case sought clarification from the ECJ to ascertain whether or not the state sales monopoly on medicinal preparations in Sweden was contrary to Community law.

The Court found that Apoteket is a 'state monopoly of a commercial character' within the meaning of Community law. While the total abolition of such monopolies is not required, as far as sales monopolies are concerned, they must not be arranged in such a way that trade in goods from other member states is placed at a disadvantage compared with trade in domestic goods. The Court observed that the Swedish arrangements do not provide either for a purchasing plan or for a system of calls for tender that provide an opportunity for producers of medicinal products that are not selected for sale by Apoteket to ascertain the reasons or to contest the decision before an independent supervisory authority. In contrast, under its statutory agreement, Apoteket appears to be entirely free to select the product range of its choice.

The Court concluded that the Swedish arrangements do not ensure that all discrimination is ruled out and no other measures exist which might compensate for this lack of safeguards. In the absence of a product selection system which excludes all discrimination against medicinal preparations from other member states, the retail sales monopoly in Sweden breaches Community law. Does this spell the end of the current retail sales monopoly for medicines? Since the Swedish government can respond to this ruling by changing Apoteket's procurement policies to introduce an open tender scheme, the monopoly (with these amendments) may still continue.

Tax Credits for R&D

The ECJ has ruled that French legislation which restricts the benefit of a tax credit only to research carried out in France restricts the freedom to provide services (Case C-39/04).

The French General Tax Code allows a tax credit to industrial, commercial or agricultural undertakings for expenditure relating to scientific and technical research activities carried out in France. Laboratoires Fournier, which manufactures and sells pharmaceuticals products, calculated its tax credit claim on the basis of research expenditures that included research commissioned from centres based in various other member states. After the Audit Directorate in France disallowed that expenditure for the purposes of calculating the tax credit, Laboratoires Fournier commenced proceedings in the Administrative Court in Dijon.

In its clarification to the national court, the ECJ affirmed that direct taxation falls within the competence of the member states which must exercise this competence consistently with Community law. The French General Tax Code subjects different tax arrangements on research activity (which is a provision of services) depending on whether it is carried out in France or in other member states. The Court was of the opinion that this legislation is based indirectly on the place of establishment of the service provider and is liable to restrict its cross-border activities. Consequently, the tax-credit benefit accorded to research undertaken only in France is contrary to the principle of freedom to provide services.

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