countries, however. Moreover, when restructuring has revolved around hospital closures alone the expected savings have not materialised because hospitals in this region are often the main providers of social care and have not been replaced by more cost effective services.

Reform of the old public health system "Sanepid" is still a major challenge. There have been some advances in strengthening health promotion. But working across sectoral boundaries is difficult, owing to, among several reasons, an overmedicalised culture, weak ministries of health, and powerful lobbies, such as tobacco groups, that oppose legislation on improving public health.

Almost everywhere in the region reformed health systems need to focus on providing high quality, evidence based care. Although much has already been done in some countries, important challenges remain in many parts of the former Soviet Union, where the legacy and strong ideology of Soviet science[11] has persisted and where ineffective treatments are still widely used.

Improvements in the quality of care have been linked to better planning of human resources to balance skill mix, train staff, strengthen professional standards, and provide better incentives. Motivating and retaining staff is now an imperative; lowly paid health professionals in central and eastern Europe can now move abroad to work, and those from the new member states of the European Union are being welcomed by their western neighbours who face severe shortages of healthcare staff.[12]

Perhaps the biggest obstacle in implementing reforms has been the absence of effective stewardship by governments. Too often, policy makers have lacked an overall perspective of health systems, focusing their efforts on only partial initiatives. Nor have they exercised effective leadership or established appropriate regulatory infrastructures. In addition, limited technical capacity and lack of appropriate information systems have hindered the introduction of often very complex reforms.

Most importantly, governments have often lacked the political will to reform health care. The political honeymoon during the first years of transition was short lived and the instability caused by frequent changes of government in many countries has been a major cause for the failure of such reforms.[1]

The challenges that faced health systems in this region in 1990, when political transition began, must have seemed insurmountable. Yet some countries have transformed their health systems relatively successfully. The challenge now is to ensure that those who are still struggling with reform can benefit from the experiences of those who have been more successful.

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Competing interests: None declared.

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Supply and regulation of medicines

Costs of prescribing are rising, and patients may pay the price

Since the collapse of communist governments the pharmaceutical sector has changed considerably. Previously, the healthcare systems organised the manufacture and supply of drugs centrally and often suffered shortages or surpluses. They rarely developed new drugs or used foreign medicines. The state supplied all medicines either free of charge or for minimal fees paid by patients. After 1990 the healthcare sector was liberalised, the governments' manufacturing and distribution networks for drugs became private industries, and markets opened to Western imports. More recently governments have reintroduced regulation into the drugs market, partly in an attempt to restrain rises in expenditure, and partly in response to joining the European Union (EU).

The pharmaceutical market in central and eastern Europe is relatively small, comprising around 8% of the value of the EU-15 market (based on the previous 15 member states rather than the current 25). It has

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low levels of expenditure compared with western Europe, but has grown rapidly—by 16% annually over the past five years, with potential for further huge growth.[1]

There are two main reasons for this growth. Firstly, doctors now prefer to prescribe imported branded drugs, believing them to be superior to locally manufactured generic drugs[2] and responding to aggressive marketing.[3] Secondly, no government has limited the importation of medicines. In addition, the market will grow further as prescribers shift from treating mainly acute infectious diseases to treating chronic non-communicable conditions.

These countries have struggled to meet the demands for medicines within limited resources, prompting re-regulation of drug pricing and reimbursement. They regulate the prices of reimbursed drugs by several mechanisms including negotiation, international comparisons, regulating domestic producers' prices, maximum price setting, and reference pricing (setting a price for a low cost drug and then refusing to pay more for any other version of that drug or perhaps for any related drug).[4]

Many states have introduced restrictive lists of drugs for public reimbursement. Although inclusion criteria for these vary, common requirements are based on considerations of safety, efficacy, and cost. These lists may allow full, partial, or no reimbursement, according to disease severity and type of patient or drug. But such lists have become more limited in some countries than others, shifting the cost of pharmaceuticals from the public purse on to households. Equity of access to treatment is poor in such countries, particularly for the more vulnerable social groups,[5] and many patients cannot afford to buy necessary medicines. In Latvia, for example, only 25% of pharmaceutical expenditure is covered by statutory sickness insurance.[6]

Thee countries that recently joined the EU have updated their laws and procedures for pharmaceutical regulation in line with those already established in the EU, introducing procedures for mutual recognition of licensing, pharmacovigilance, and improved exchanges of information among national regulatory agencies. All drugs on the market must now conform to EU requirements on good manufacturing practice and drug information. Meeting these criteria has imposed considerable expense on local pharmaceutical manufacturers that produce mainly generic drugs.

Intellectual property rights will also be harmonised over the next few years. The innovative pharmaceutical industry of the Western world wants strict 10 year periods of market exclusivity for data (when generic manufacturers cannot use data submitted for the original licence application to support their own application) to prevent countries with less rigorous laws for intellectual protection from exporting less expensive parallel products to western Europe. The new EU member states argued unsuccessfully for this exclusivity to last only six years, partly to protect their own industries, but also to preserve affordable access to medicines. As a result, some countries may have to remove lower cost generics from the market. On the other hand, this may also open the way to investment within these states by pharmaceutical manufacturers,[7] attracted by tax incentives and cheap labour.

The countries of central and eastern Europe have paid little attention to promoting rational drug use. Prescription rates in these countries are high, reflecting patients' expectations and historical patterns. Informal or unofficial payments from patients to their doctors may also be a factor. Prescribing policies have rarely gone beyond the use of lists and standard treatment guidelines,[8] and these have not been accompanied by positive or negative incentives or education. The rapid rise in the number of products available has increased the need for ongoing programmes of professional education and for better independent information on drugs for both physicians and pharmacists.[9]

The news is not all bad, however. Some patients have gained better treatment for certain conditions: for example, new chemotherapeutic drugs have led to higher cure rates for cancers in central and eastern Europe[10 11] and to better control of hypertension in the Czech Republic and Hungary.[12] Patients' difficulties in accessing drugs and increased private costs will exert pressure for greater public provision of medicines in some countries. This may be sustained by the countries' growing economies, but changes in cost containment will continue. The effects of these changes on access to medicines will need to be watched. Countries could gain by greater collaboration within the region, as already practised by Estonia, Latvia, and Lithuania.[3]

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Competing interests: EAM has undertaken studies funded by the EU in the states of central and eastern Europe.

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