Eurohealth

RESEARCH • DEBATE • POLICY • NEWS

Volume 17 Number 1, 2011

Pharmaceutical policy and the effects of the economic crisis

Focus on the Baltic states: Estonia, Latvia, Lithuania

Systematic review: reference pricing for pharmaceuticals
Germany: pharmaceutical reform • Hungary: the decline in nursing staff

COMMENT

Pharmaceutical policy reforms in response to the financial crisis

The 2008 financial crisis affected many sectors across the globe, including budgets available for health systems. The trend of rising pharmaceutical expenditure in many Baltic states in recent years has now been curtailed by governments using an arsenal of policy tactics. This issue of Eurohealth presents three articles based on presentations from experts in Estonia, Latvia and Lithuania for a Baltic Policy Dialogue on this topic run by the European Observatory on Health Systems and Policies.

Although the reforms differ by country, they have been observed to include: changes to price setting and reference pricing mechanisms; reductions in reimbursement rates for outpatient pharmaceuticals, thus increasing out of pocket payments for patients (with the exception of Lithuania); increases in the VAT rate; and efforts towards increasing the use of less expensive medicines through improving generic penetration. The latter efforts relate to a number of policies – providing encouragement and obligations for generic prescribing at the physician level and generic dispensing at the pharmacy level, as well as running public awareness campaigns designed to increase the uptake of generics.

Each of the articles looks at policy efforts in the health system towards reducing public spending on pharmaceuticals and examines trends in expenditure. The focus remains on identifying major policy changes affecting the pharmaceutical sector implemented during and after the financial crisis.

Two of the articles in the health policy section carry on the pharmaceuticals theme. Galizzi et al. provide results of a systematic literature review on reference pricing, where findings on theoretical and empirical literature are disentangled. Furthermore, Ognyanova and colleagues analyse legislation in November 2010 in Germany related to reorganising the pharmaceutical market within the social health insurance system. This Act follows the international trend of linking decisions on pharmaceutical pricing and reimbursement to a product's benefit assessment and cost-effectiveness assessment compared to treatment alternatives.

For the Hungarian health system, Stubnya and colleagues identify a major concern caused by the triple burden of nurse emigration and withdrawal from the profession, as well as a reduction in the number of trainee nurses. The training process for nurses is detailed, followed by a presentation of the decreasing trends in graduate and certified nurses. Recommendations for addressing this "critical nursing situation" are provided and calls made for urgent intervention from government.

Watch this space for exciting developments in the next issue of *Eurohealth*

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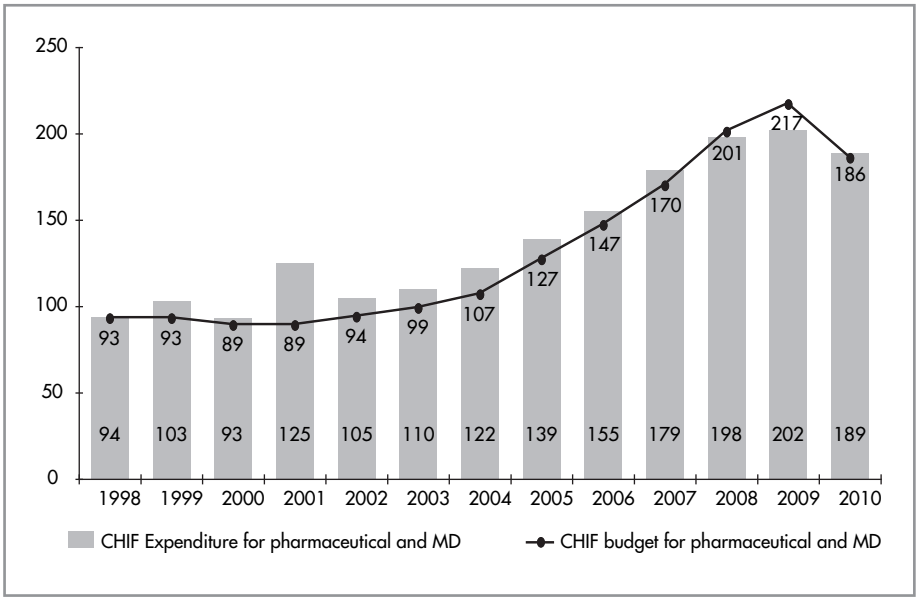
Pharmaceutical policy and the effects of the economic crisis: Lithuania

Kristina Garuoliene, Tomas Alonderis, Martynas Marcinkevičius

Expenditure on health for the 3.3 million inhabitants in Lithuania is financed primarily via compulsory health insurance contributions, with contributions depending on income. The Ministry of Health is responsible for implementing pharmaceutical policy as well as ensuring the efficient and safe use of pharmaceuticals at socially acceptable prices. Currently 4.3% of Gross Domestic Product (GDP) is spent on health care (related to the National Health Insurance Fund (NHIF) budget) excluding private expenditure, with pharmaceuticals accounting for 16%. In 2009, the NHIF spent an average of €376.50 per insured person, similar to other Central and Eastern European countries.[1]

Responding to the economic crisis, a *Plan for the Improvement of Pharmaceutical Accessibility and Price Reduction* was approved in July 2009. The main objectives of the Plan were: to halt the growth in NHIF expenditure for reimbursable pharmaceuticals; reduce public expenditure on pharmaceuticals; provide patients with more information about medicinal products and extend freedom of choice*; and to make the pharmaceutical sector more ethical and transparent. The Plan measures were applied to all stakeholders in the pharmaceutical market: manufacturers, wholesalers, pharmacy chains, individual pharmacies, physicians and competent authorities. The Ministry of Health was also concerned about rising out-of-pocket (OOP) expenditures for pharmaceuticals and decided to reintroduce price regulation for non-reimbursable pharmaceuticals (prices for reimbursable pharmaceuticals are already regulated).

Figure 1: Compulsory Health Insurance Fund (CHIF) expenditure on reimbursed pharmaceuticals and medical devices (MD) for ambulatory care (Euros millions)



Source: [2]

Pharmaceutical consumption and expenditure

Due to the financial crisis, Lithuania was obliged to cut back on public spending for pharmaceuticals in 2010. The 2010 NHIF budget (for reimbursable outpatient pharmaceuticals) was about 8% lower than real expenditure in 2009. Due to financial sustainability, NHIF expenditure for pharmaceuticals had to be decreased by 8% in 2010. The NHIF was almost successful in meeting the 8% reduction as expenditure on pharmaceuticals decreased by 6.2% in 2010.

During the period 2005–2008, total pharmaceutical expenditure in ambulatory care grew by an average of 14% per annum. From 2008, expenditure started to decrease by an average of -2.2% per annum between 2008 and 2010 (see Table 1).

While NHIF expenditure for pharmaceutical reimbursement decreased, prescription numbers increased (see Table 2). It is important to emphasise that the pharmaceutical reimbursement level did not decrease during the economic crisis. In fact, the number of prescriptions fully reimbursed increased by 9%. Thus, expenditure on pharmaceuticals decreased without a reduction in accessibility. Moreover, the regulation of prices for non-reimbursable pharmaceuticals decreased prices by about 11%.[2]

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* From 1 May 2010 pharmacies are obliged to install computer monitors to provide information to patients about the prices of medicines and medical devices.

Table 1: Total expenditure on pharmaceuticals for ambulatory care 2005–2009 (Euros pharmaceuticals at wholesaler prices)

	2005	2006	2007	2008	2009	2010
Total expenditure on pharmaceuticals	305.1	356.4	408.9	436.1	408.3	397.6
Prescription pharmaceuticals	213.1	247.1	281.3	299.5	284.9	276.4
Over the counter (OTC pharmaceuticals	92.0	109.3	127.5	136.7	123.4	121.2

Source: [3]

Table 2: Compulsory Health Insurance Fund volume and expenditure for reimbursed pharmaceuticals and medical devices for ambulatory care according reimbursement level (Euros millions)

Reimbursement level	2008		2009		2010	
	Number of prescriptions	Expenditure	Number of prescriptions	Expenditure	Number of prescriptions	Expenditure
100%	3,526,930	123.71	3,722,624	130.29	3,850,412	123.21
90%	65,441	0.63	60,302	0.73	58,856	0.82
80%	6,606,710	67.66	6,477,315	65.03	6,609,038	59.94
50%	1,175,614	5.88	1,115,398	5.60	1,122,905	5.25
Total	11,374,695	197.88	11,375,639	201.64	11,641,211	189.22

Source: [2]

Pharmaceutical pricing and reimbursement policies

Cost reduction was achieved by implementation of various pharmaceutical and reimbursement regulation measures, which were included in the 2009 Plan. Firstly, from 2010 there were new requirements for generic pricing such that the first generic had to be priced 30% below the originator, while the second and third generics must be priced at least 10% below the first generic to be reimbursed. In addition, where more than three products with the same International Nonproprietary Name (INN) are reimbursed, the originator must not be priced higher than 60% above the cheapest generic for continued reimbursement.[4]

Secondly, new rules have been implemented with regards to INN prescribing. The regulations were tightened in 2010, with originator name prescribing only allowed for biologic pharmaceuticals. In addition from 1 May 2010, all pharmacists were obliged to provide data on prices to patients via computer screens and have an obligation to have the cheapest products in pharmacies. Thirdly, price volume agreements schemes are administered by the NHIF under the Ministry of Health. Since 2008, such schemes have been obligatory for all new pharmaceuticals that will increase the Statutory Health Insurance Fund's pharmaceutical budget compared with current treatment approaches for the target patient population. Once instigated, price volume schemes are currently valid for a minimum of three years. If agreed sales volume (expenditure) exceeds the agreed target, pharmaceutical companies must refund all or part of the difference.[7] During the crisis period, new pharmaceuticals, which would have led to an increase in expenditure to the NHIF budget, were not included in the positive list.

With regards to generics, there is a correlation between the number of products available per INN and the average reimbursed prescription price, such that generic entries drive down the reimbursement price (see Table 3). As a result, the NHIF spends less for such INNs while in reality the patients may choose either the cheapest generic (with the minimum co-payment) or the originator product (and pay more out-of-pocket).

The total number of issued reimbursed prescriptions increased by 2.5% in 2010. The number of presciptions for original brands is decreasing, while the number of prescriptions for generic products is slightly increasing. Prescriptions for generic products make up 47% of all prescription volume in the first quarter of 2010 compared to 42% in the same period in 2008.

Incentives for rational and cost-effective pharmaceutical use

Various demand-side measures to encourage the rational and cost-effective use of pharmaceuticals have been collated under

Table 3: Genericisation effect on average reimbursed prescription price

INNs	Average prescription price Q1 2008 (EUR)	Number of different manufactured products Q1 2008	Average prescription price 2010 (EUR)	Number of different manufactured products 2010	Average prescription price change (%)
Nebivololum	17.4	1	6.4	11	-63%
Lercanidipinum	18.3	1	10.6	4	-42%
Olanzapinum	163.0	2	59.4	7	-64%
Perindoprilum + Indapamidum	14.7	2	7.4	3	-50%
Clopidogrelum	57.7	1	23.5	10	-59%
Perindoprilum	11.0	2	7.5	6	-32%
Latanoprostum	22.5	1	14.7	3	-35%
Valsartanum	15.7	2	12.6	4	-20%
Escitalopramum	28.2	1	18.1	9	-36%
Natrii montelucastum	45.7	1	14.1	6	-69%

Source: [2]

the '4 Es' methodology, i.e., education, engineering, economics and enforcement.[6] Several measures have been implemented including:[7]

Education

- Some guidelines in are place to encourage the rational use of medicines; however, they are not obligatory.
- Audits undertaken where the NHIF expects excessive prescribing costs. Sanctions can include refunds where there are excessive prescribing costs.

Economics

- Patients pay an additional co-payment for a more expensive product (molecule – Anatomical Therapeutic Chemical Level 5) than the current reference price. In addition, since 2010 there is an obligation by pharmacists to display prices in pharmacies and stock the cheapest generic.
- At least 50% co-payment for the proton pump inhibitors for the majority of indications, lower co-payment for the statins of 20%. However, statins only reimbursed for secondary prevention.

Engineering

- Since 1 July 2004, physicians should prescribe by INN unless concerned with issues such as bioavailability and side-effects of the generic.
- Many physicians though still prescribe by originator name, as there have been limited sanctions to date and pharmaceutical companies continue to market their brands (originators) to physicians, as well as help alleviate additional co-payments via discounts to community pharmacies.
- However in 2010, compulsory INN prescribing apart from biological products was introduced unless prior permission was obtained from the hospital or Polyclinic Therapeutic Committee.
- Price: volume agreements (applies to new drugs).

Enforcement

- Prescriptions are monitored to make sure physicians comply with reimbursement restrictions, for example, on statins.[8]
- However, these supply side measures did not lead to rational pharmaceutical prescribing. Little was done to monitor and evaluate prescribing

The development of a list of the 'top-ten' pharmaceuticals (most popular INN by Defined Daily Dose (DDD) consumption) indicates that more evaluation on prescribing quality has to be performed in Lithuania. The benzodiazepine group pharmaceutical Lorazepam is the third (in 2008) and fourth (in 2009) most prescribed pharmaceutical in Lithuania (see Table 4). It is relevant to note that there are no statins or metformin (the most prescribed pharmaceutical in other countries) in the 'top-ten list'.

The NHIF collects data on dispensing from community pharmacies. These data include not only pharmaceutical based information involving aggregation of data on pharmaceutical use at various levels, but also information on indications, patient information (age, data, location, co-morbidity), and prescriber information (age, gender, type of practice).

It is very difficult to promote the rational

Table 4: Top-ten pharmaceuticals (according DDD consumption) in the three Baltic countries

Estonia		Latvia		Lithuania	
INN	DDD/ 1,000 inhabitants/day	INN	DDD/ 1,000 inhabitants/day	INN	DDD/ 1,000 inhabitants/day
Ramipril	55.83	Enalaprilum	24.54	Ramipril	38.94
Acetylsalicylic acid + magnesium oxide	35.83	Diclofenacum	21.52	Perindopril	36.56
Amlodipin	35.18	Perindoprilum	19.03	Trimetazidin	28.59
Metoprolol	21.23	Amlodipinum	18.44	Lorazepam	19.77
Enalapril	20.18	Omeprazolum	16.29	Diclofenac	17.91
Xylometazoline	18.66	Atorvastatinum	16.26	Nebivolol	17.11
Diclofenac	18.03	Bisoprololum	11.87	Ibuprofen	16.32
Enalapril + Hydrochlorothiazide	17.14	Metoprololum	11.74	Xylometazolin	15.07
Fosinopril	14.87	Ramiprilum	11.7	Omeprazol	13.55
Omeprazole	13.24	Metforminum	9.72	Enalapril	13.27
Total	250.19		161.11		217.09

Source: [2]

use of pharmaceuticals in Lithuania: the Ministry and Health Insurance Fund do not have a specific budget for promoting the rational use of pharmaceuticals.

Conclusions

The main observation is that the reduction in pharmaceutical expenditure was achieved without decreasing the availability of pharmaceuticals. Nevertheless, it is very important that the implemented supply side regulation measures will be directed not only reimbursed pharmaceutical prices, but also at manufacturers' prices or retail price regulation. The decrease in pharmaceutical expenditure without decreasing the availability of pharmaceuticals was achieved by implementing different supply and demand side regulation measures for all players in the pharmaceutical market.

Special indicators (including the high consumption of benzodiazepins, low consumption of statins, and high consumption of OTC pharmaceuticals at about 30% of all expenditure) demonstrate that there is a need for the evaluation of prescribing and the promotion of the rational use of pharmaceuticals.

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Pharmaceutical policy and the effects of the economic crisis: Estonia

Dagmar Rüütel and Katrin Pudersell

Estonia's health care is mainly publicly funded through solidarity-based mandatory health insurance contributions in the form of an earmarked social payroll tax, which amounts to almost two thirds of total health care expenditures. The Ministry of Social Affairs (MoSA) is responsible for funding emergency care for the uninsured as well as for ambulance services and public health programmes. Municipalities have a relatively small, yet diverse role in health financing. Private expenditures comprise about one quarter of all health care expenditure (see Table 1), mostly through out-of-pocket payments (OOP) in the form of co-payments for pharmaceuticals and coverage of dental care.

The Estonian Health Insurance Fund (EHIF) is the core purchaser of health care services for the insured. The majority of revenue comes from the earmarked part of the social tax on wages (13%) and social tax paid on behalf of benefit recipients from the state budget. The health insurance system covers about 95% of the population. Contributions are related to employment, but the share of non-contributing individuals covered (such as children and adolescents until 18, pensioners, registered unemployed people) represents almost half of all insured people. In the long term, this threatens the financial sustainability of the health system, as the narrow revenue base is mostly related to the level of wages and the rate of employment. The unemployment rate, constant at 4% throughout the last decade, increased to over 15% by the end of 2009.

In recent years, regulations have been adjusted further to harmonise with EU legislation and to respond to emerging needs, including readjustments due to the difficult economic situation. In order to set a clear vision for the future and bring various initiatives under one umbrella a National Health Plan, covering the whole health system from 2009–2020, was approved by the government in 2008. The general objective of the strategy is to increase the number of healthy years of life by reducing mortality and morbidity rates.

Income-related inequality in health financing and utilisation

The overall pre-financing of the Estonian health care system is progressive, meaning that households with higher gross incomes pay more. On the other hand OOPs are regressive, meaning that although poorer households spend less on health care in absolute terms, they spend more as a proportion of their total income. Considering pre-financing and OOPs together, overall health care financing is mildly progressive. That is, households with higher gross incomes pay relatively more towards health care financing (see Figure 1). The average spending on OOPs per household per month in 2006 was 100 Krooni (equivalent to €6.40).

During 2000–2007, about 3% (15,000) households dropped below the national absolute poverty line after taking OOPs

Table 1: Sources of health care financing in Estonia by institution (%)

Source	Health expenditure		Health expenditure + temporary incapacity benefits	
	2000	2007	2000	2007
Public sector	76.4	75.6	79.3	78.7
Central government	8.4	9.7	7.3	8.5
Local government	2.0	1.7	1.8	1.5
Health Insurance Fund	66.0	64.2	70.2	68.8
Private sector	23.3	23.3	20.4	20.3
Households	19.7	21.9	17.3	17.7
Private insurance	1.0	0.3	0.8	0.3
Private enterprise	2.6	1.1	2.2	0.9
Foreign sector	0.3	1.1	0.3	1.0
Total	100	100	100	100

Source: (2)

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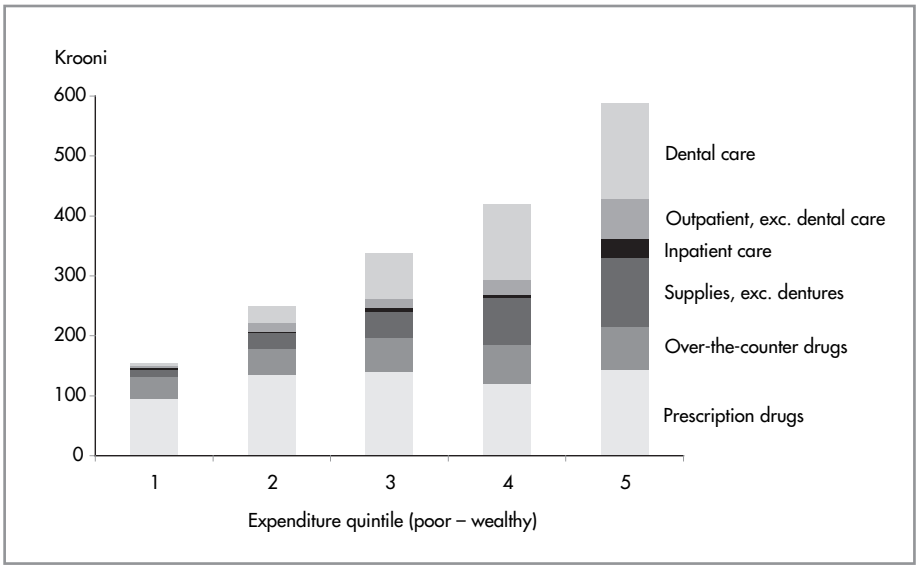
Figure 1: Average spending on out of pocket payments in 2006



Source: [2]

into account. The main risk group is single pensioners, of whom about 11% fall into this category. For those services more dependent on OOPs, such as outpatient pharmaceuticals and dental care, there are either more inequalities in utilisation or households face higher risk of impoverishment. For services with very little need for OOPs, such as in-patient care or emergency care, where there was no impoverishment, little difference in utilisation by income level has been seen.

Pharmaceuticals pricing and reimbursement policies

The aims of pharmaceutical policy in Estonia, set in 2002, are as follows: to ensure the effectiveness, safety, quality and accessibility of pharmaceuticals, as well as to support their rational use.

Outpatient pharmaceuticals are sold only by pharmacies. Estonia has a relatively large number of pharmacies; approximately one pharmacy per 2,700 inhabitants in 2009. The majority of pharmacies are in six chains, although 90% of the retail turnover accrues to the two largest full-line wholesalers. About 20% of pharmacies pertain to vertically consolidated companies; other relationships with wholesalers are determined by collaborative agreements. The same maximum wholesale and retail mark-ups are applied to all companies and for both prescription-only and over-the-counter pharma- ceuticals.

Pharmaceuticals are reimbursed based on the positive list. All pharmaceuticals on the list have a 50% reimbursement level (up to €12.80 per prescription), higher reimbursement levels (75% and 100%) are linked with certain diagnoses (diagnosis-based reimbursement). The criteria for the classification of diagnoses are set out in the Health Insurance Act, and include severity of illness, risk of an epidemic and loss in quality of life. Additional reimbursement is offered for some population groups: 90% reimbursement for children below the age of 16, as well as for the disabled and retired people; while children below four years old receive all pharmaceuticals with a 100% reimbursement. There is also a complementary compensation system from the EHIF for patients with high annual expenses for pharmaceuticals (from €383.51 up to €1278.20), whereby 50% to 75% of exceeded sum will be repaid.

Pharmaceutical pricing regulations comprise two measures: concluding price agreements with the marketing authorisation holders (MAHs) and setting reference (ceiling) prices. The agreements are concluded for certain reimbursable pharmaceuticals: firstly, for patented pharmaceuticals (no generic competition), and secondly, for the two cheapest pharmaceuticals within every generic group. The decision on the price of patented pharmaceuticals is taken simultaneously with the decision on reimbursement, so the processes of pricing and reimbursement are interconnected. Both external and internal price referencing in these cases is carried out comparing the requested price with prices in all other EU countries, and with the prices of appropriate clinical alternative pharmaceuticals already in use. Agreements stipulate the maximum price of the pharmaceutical and the MAH's commitment to ensure continuous availability of the pharmaceutical at a wholesale level. Agreements are valid for one year, after which they are prolonged automatically, unless either side proposes to change any of the settings. In every prolongation the MoSA checks prices in other countries and initiates price reduction if relevant. In the case of generic pharmaceuticals, internal price referencing is very much simplified: the first generic product needs to be at least 30% cheaper than the originator, the next three need to be at least 10% cheaper than the previous product and further pharmaceuticals must not exceed the cheapest price of the listed pharmaceutical.

Estonia has applied the same reference price system since 2002. Pharmaceuticals are grouped on the basis of active ingredients (full Anatomical Therapeutic Chemical code) and route of administration. Cost per unit of the second cheapest package is taken as the reference to all other packages within the group. Price agreements are concluded for these two pharmaceuticals; other prices within the group are unregulated. Therefore, reference prices are retail prices for each package that the EHIF takes as the maximum price for reimbursement. In cases where the patient chooses, or the doctor or pharmacist recommends a pharmaceutical whose price exceeds the reference price, the patient has to pay the difference between the reference price and the retail price, meaning that the patient's co-payment rate increases.

Enacting changes in the positive list – adding new pharmaceuticals (patented or generic) and recalculating pharmaceutical reference prices – takes place on a quarterly basis. The system has been very effective from a cost-containment perspective, as new generic pharmaceuticals are quickly reimbursed and reference prices are consequently rapidly updated. Also it appears that the prices of reimbursed pharmaceuticals have not increased, but have instead reduced year on year. However, the reduction in reference prices has not achieved a reduction in patient co-payment rates. As patients are quite reluctant to change the brand they are accustomed to using, and neither doctors nor pharmacists encourage the change, in fact reducing the reference price often results in an increase and rarely in a decrease to the patient's expenditure, due to the increase in the use of patient co-payments. Thus, co-payment rates for pharmaceuticals in Estonia have

been one of the highest in the EU (Figure 2).

Anti-tuberculosis and antiretroviral pharmaceuticals, as well as vaccines for determined patient groups, are publically procured. Hospitals buy pharmaceuticals through their own hospital pharmacies, where manufacturers and wholesalers offer different discounts and rebates, so that pharmaceuticals can be acquired at an acceptable price level.

Developments in pharmaceutical policy due to the economic downturn

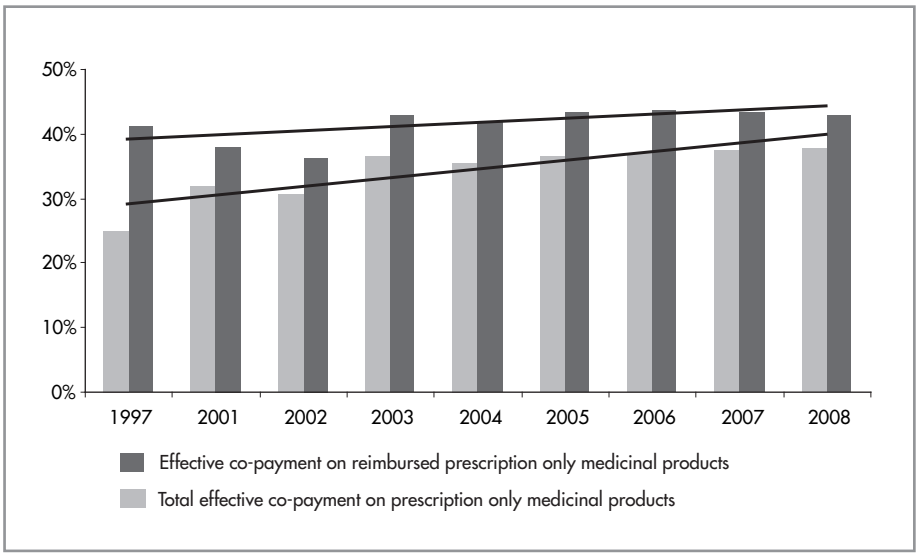
In Estonia, Gross Domestic Product (GDP) growth was between 7.1%–11.4% from 2001 to 2007, followed by a slight decrease of 3.6% in 2008 and a considerable drop of 14.1% in 2009. Overall health expenditure has been stable at around 5%–6% of GDP.

At the time of the economic downturn many readjustments were made with the purpose of maintaining a balance between access to health care services and financing measures, such as introducing a 15% co-insurance for inpatient nursing care, decreasing the prices of health care services by 6%, decreasing the treatment of cases in specialist care, and reducing sick-leave benefits. Increasing the VAT of pharmaceuticals from 5% to 9% in 2009 accounted for €6 million in additional expense to the EHIF.

As the patient co-payment rates for prescription-only and reimbursed pharmaceuticals were gradually increased to 43% and 39% respectively, any reduction of reimbursement levels was not believed to be a reasonable solution. Furthermore, as the EHIF's pharmaceutical expenditure gradually decreased to 15.6% of total health care expenditure, no further reductions relating to pharmaceuticals were planned.

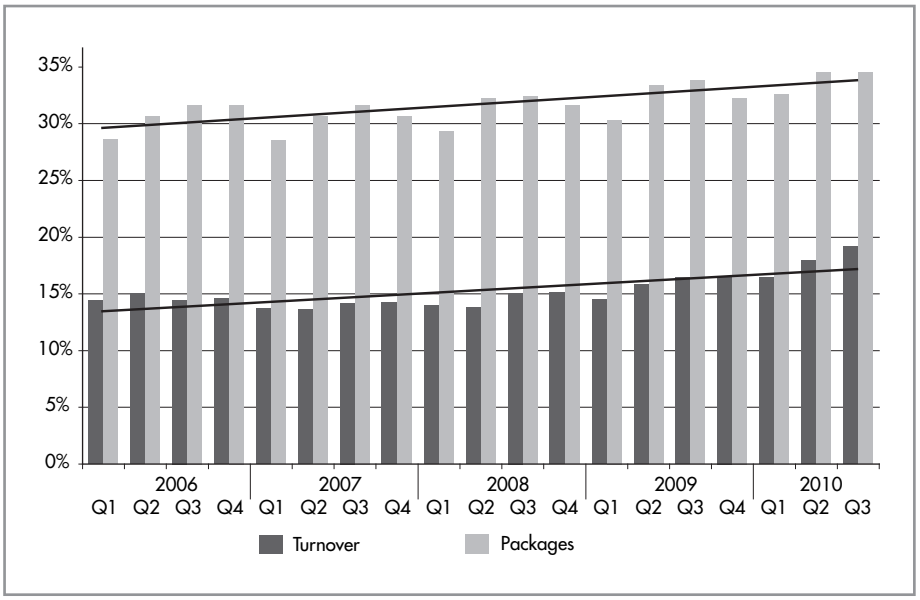
At the same time, concern has risen about the very large patient co-payment rate that could mean the rejection or withdrawal of outpatient pharmacotherapy, raising the need for future emergency care and hospitalisation. Also, as the use of cheaper generics has been generally low, considerable numbers of generic MAHs restricted their portfolio due to economic difficulties, meaning that many cheaper pharmaceuticals were withdrawn from the Estonian market. Two changes in the legal system were implemented: first regarding requirements on prescribing of pharmaceuticals by doctors, and second regarding

Figure 2. Total effective co-payment rate on prescription-only pharmaceuticals in Estonia



Source: [3]

Figure 3. Share of generic pharmaceuticals in wholesale



Source: State Agency of Medicines

the offering of pharmaceuticals by pharmacists. Additionally, a public awareness campaign was started called "Price is the only difference (choose optimally priced pharmaceuticals at the pharmacy)", and the State Agency of Medicines began to give special attention to the real availability of cheaper pharmaceuticals in pharmacies.

Before 2010, doctors could prescribe pharmaceuticals both by active substance, using the International Nonproprietary Name (INN) or by trade name, if it was necessary due to whatever reason. Similarly, pharmacists had an obligation to inform patients about the selection of pharmaceuticals, but not to provide or offer the cheapest choices. Currently, doctors are obliged to prescribe pharmaceuticals using the INN, unless there is a concrete medical reason not to do so (the reason has to be recorded on the prescription and explained to the patient), and pharmacists are obliged to provide and offer the cheapest suitable pharmaceutical. Nevertheless, patients have the right to refuse substitution and buy pharmaceuticals that are more expensive if they wish.

During the public awareness campaign, a public discussion emerged about the quality of original and generic pharmaceuticals. Surprisingly, some prominent doctors and pharmacists, and even

members of parliament, expressed the belief that cheaper or generic pharmaceuticals were not of comparable quality to originators and may cause more side-effects. Also, some doctors noted that creating awareness about pharmaceutical prices and patient co-payments was not their task. Nevertheless, the patient co-payment rate started to decrease (to 36% in the third quarter of 2010) and the use of generic pharmaceuticals has somewhat gone up (Figure 3).

Conclusions

Because the changes towards decreasing the patient co-payment rate are recent, it is too early to draw any conclusions or expect considerable progress. Many problems which threaten the efficiency of pharmacotherapy have been revealed, such as insufficient education of doctors and pharmacists and their uncertainty about patients' financial ability to buy and use pharmaceuticals regularly and for as long as recommended. In addition to improved awareness, further developments in decreasing the patient co-payment rate could be based on a digital prescription system (introduced from 2010) from where doctors can obtain information about the buying-out of prescriptions. Similarly the supervising authorities obtain information about the quality of health care and the prescribing and sales patterns of different pharmacy service providers. Also, there is a clear need to investigate the economic drivers and motivation packages for health care and pharmacy service providers, to strengthen cooperation to achieve better accessibility of pharmaceuticals in Estonia.

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Pharmaceutical policy and the effects of the economic crisis: Latvia

Daiga Behmane and Janis Innus

The Latvian health care system has undergone a remarkable transformation in the years since independence and is now in the process of consolidating new structures and institutional arrangements. The State has abolished the highly centralised system that characterised the Soviet period. It has focused on the decentralisation of health care delivery, administration and financing, full or partial privatisation of provider institutions and the establishment of independent primary care practices. All of this has resulted in a wide variety of legal forms of health care providers and institutions.

While these reforms were taking place, Latvia also became affected in 2008 by the international economic crisis. The Latvian government responded by cutting the State budget. These decisions were set against a decrease in Gross Domestic Product (GDP) of 19% in 2009. Tax revenues also decreased.[1] The government decided that the most prudent remedy was to reduce public expenditure together with the implementation of structural reforms.

The Latvian health sector is funded by the State budget; consequently, the government reduced the health care budget by 13% between 2008 and 2009 and by a further 14% in 2010 – a total cut of 25% from 2008 to 2010.[2] Within the changes to the health care budget, the Ministry of Health also implemented several structural reforms to the health care system. The Ministry of Health decided to make the best use of the limited resources available by giving priority to primary health care, coverage of essential medicines and outpatient specialist services, while at the same time reducing hospital capacity which was far above the European Union average and that of comparator countries.[3]

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It is important to understand the context of these cuts; the total expenditure of the health care budget – including public and private spending – per inhabitant in Latvia is approximately 10% of average health care expenditure in EU-15 Member States.[4]

The general rate of VAT was increased from 18% to 21% in 2009, while the rate of reduced VAT, applied to medicines and medical devices, was increased from 5% to 10% in the same period.

Pharmaceutical consumption and expenditure

The value of the total pharmaceutical market in Latvia in 2009 was LVL 195.7 million,[5] equivalent to €278.5 million; this was 4.4% less than in 2008. The reimbursement budget decreased by 7.1% compared to 2008 and amounted to LVL 71.7 million, equivalent to €102 million, equating to €45 per capita in 2009 compared to €48 per capita in 2008.

The Ministry of Health also needed to reduce costs for the reimbursement of pharmaceuticals. Primary care was set as a priority, so cuts in the reimbursement of pharmaceuticals were proportionally smaller than cuts in the inpatient health care sector.

Accordingly, the Cabinet of Ministers amended Regulations No. 899 on the Reimbursement of Pharmaceuticals. These came into force on 1 March 2009; their effects were a reduction in the percentage of reimbursement for certain diagnoses from 75% to 50% and from 90% to 75% for other diagnoses. Thus, the financial burden was partially shifted to patients. At the same time, 100% reimbursement was maintained for the most severe diagnoses, such as oncology and endocrinology. Con-

currently, other cost-containment measures were reinforced: pharmaco-therapeutic reference groups were extended and more attention was given to the international comparison of pharmaceutical prices.

The rate of co-payments for a range of products increased as a result of the decrease in reimbursement rates for certain diagnoses as well as a result of the extension of reference groups (Anatomical Therapeutic Chemical level 3 to 5). Consequently, there was an increase in patient co-payment of 59% in 2009 compared to 2008.[6] The average level of patient co-payments in the reimbursement system was approximately 30% in 2009.

The average number of reimbursed prescriptions was 4.82 million in 2009, and the average cost per prescription paid by the State was LVL 14.87, equivalent to €21.16 compared to 4.89 million prescriptions, with an average cost LVL 15.77 equivalent to €22.44 in 2008. It is important to note that the total consumption of pharmaceuticals increased – as measured by the Defined Daily Dose (DDD)/1000 inhabitants/day – in 2009 by 1.5%.

Most of the co-payment increases were for cardiovascular system diseases. The reduction in the rate of reimbursement was a short-term measure to reduce costs; it was understood that it could seriously affect public health indicators in the longer term. The rate of reimbursement for cardiovascular diseases was increased to the previous level of 75% from 1 November 2010.

Pharmaceutical reimbursement in Latvia

As already noted, the pharmaceutical reimbursement system is based on the severity and chronic nature of the disease with 100%, 75% and 50% reimbursement rates. The Positive List of Pharmaceuticals is detailed by the Centre of Health Economics and decisions on reimbursement are based on the assessment of relative therapeutic value and cost-effectiveness, as well as an analysis of the impact on the budget.

The Positive List consists of three parts: List A – the reference product list; List B – non-interchangeable products; and List C – expensive products with special reimbursement conditions. There were 1,236 products on the Positive List in 2010; 897 in List A, 321 in List B and 18 in List C. These products belong to 342 international non-proprietary names (INNs).

Taking into account the low level of funding for the system of reimbursement – €45 per patient/per year – the system can be said to be very restrictive and contains a variety of conditions of reimbursement for expensive treatments, for example the reimbursement for targeted patient groups, for second or third line treatments and other recommendations. As a result of the high impact on the health care sector budget, several new pharmaceutical products have been refused reimbursement even when the products appeared to be cost-effective.

At the same time, a great deal of attention has been paid to other cost-containment measures, such as therapeutic group referencing, fostering generic competition, international price comparisons and stronger negotiations with pharmaceutical companies on pricing policies.

The Centre of Health Economics re-evaluated the cost-effectiveness and prices for the treatment of HIV/AIDS in 2009 and specified recommendations for the prescribing of pharmaceuticals. Previously, the pharmaceuticals for HIV/AIDS were purchased centrally but have been included in the reimbursement system since 2010. On the basis of an evaluation of cost-effectiveness and negotiations with companies on price reductions based on international comparisons, the Centre of Health Economics made significant price reductions – from 3% to 49% – compared to prices in 2009. This enabled treatment for an increasing number of patients for the same amount of money.

The Social Safety Net

The most important tool in the provision of health care services is the implementation of the Social Safety Net strategy. The Social Safety Net was introduced in Latvia at the end of 2009 and is financed from a loan from the World Bank.[7] The new Social Safety Net Strategy provides additional protection and better targeting of public resources for the poor. These measures have the potential to improve efficiency, maintain solidarity and focus on performance improvement in the health system.

The purpose of the Strategy is to develop a variety of safety measures to minimise the social effects of the financial crisis and cuts in public expenditure. Most of the Social Safety Net spending in health care is intended to cover the co-payment of patients for health care services and to provide 100% reimbursement of medicinal products for the less well off – those who receive less than LVL 120 per month, equivalent to €170. It is planned that this measure will end on 31 December 2011.

Pharmaceutical pricing and reimbursement policies

Prior to the economic crisis there were many tools in the pharmaceutical reimbursement system to ensure rational and cost-effective use of medicines. These included: recommendations for rational pharmacotherapy; a reference pricing system and generic substitution that have existed since the middle of 2005; and the Baltic Guidelines on Economic Evaluation of Medicines which were created in 2002. There are two schemes for applying mark-ups for pharmaceuticals. The reduced mark-ups of wholesale and retail pharmacies are applied to reimbursed products.

The legislation strongly recommends generic substitution and a pharmacy has an obligation to offer cheaper alternative products to make possible the reduction of reimbursement costs. When the patent expires it becomes possible to use generic medicines. Consequently, the prices of patented products can generally decrease by up to 50% and sometimes by as much as 80%–85%.[8] This makes it possible to cover the increased costs generated by the increased number of patients. There are on average three to four manufacturers of generic products per INN. This provides an element of significant competition.

Despite the availability of generic substitution at a cheaper price compared to the originator, doctors still often prescribe the originator as a result of aggressive promotion by pharmaceutical companies. There are some conditions implemented in the legislation to protect patients: a doctor must inform patients that a cheaper alternative is available; while pharmacists must replace a prescription of originator by a generic if the patient wants it and if a doctor has not prohibited it. The additional co-payment made by patients is approximately 10% of the total budget of the pharmaceutical reimbursement system. These patient co-payments could be reduced if patients choose a reference product where possible.

Regarding changes in medicines used in the inpatient sector, a new development occurred in 2007. The Centre of Health Economics, in collaboration with medical practitioners and professional associations of health care specialists, developed a Hospital Drug List. The main criteria for the inclusion of a product onto this list is the

same as in the reimbursement system described above but with the focus on inpatient care.

Conclusions

Latvia has had to reduce the costs of the health care system as a result of the economic crisis. This has also affected the financing for reimbursed medicines. Taking into account the fact that pharmaceutical reimbursement plays a significant role in primary health care, it is very important to provide access to reimbursed medicines for as many people as possible. By implementing several activities, the State has ensured the needs of patients, although the level of co-payments made by patients has increased. It is not possible to see and evaluate the results of these changes in the current short time period. Therefore, further efforts need to be undertaken to assess the long-term effects of these developments and to ensure the sustainability of access to health care services.

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Pharmaceutical reform 2010 in Germany:

Striking a balance between innovation and affordability

Diana Ognyanova, Annette Zentner and Reinhard Busse

Summary: The German Parliament passed a reform aiming to reorganise the regulatory framework for pharmaceuticals in order to curb growing expenditure. For the first time, all newly-licensed pharmaceuticals will be subject to benefit assessment. While pharmaceuticals without added benefit compared to treatment alternatives should be included in the reference pricing system, innovative pharmaceuticals with clear added value should be subject to price negotiations. Earlier cost-containment measures reinforce rebate contracts and introduce a three-year freeze on pharmaceutical prices.

Key words: Pharmaceutical reform, cost-effectiveness assessment, pricing, reimbursement, Germany

The pharmaceutical market in Germany

Germany is the third largest pharmaceutical market in the world and the largest in Europe. It is one of the few EU countries where until now pharmaceutical companies have been largely free to set prices. Pharmaceutical coverage is comprehensive, with a high level of public funding. In principle all licensed pharmaceuticals (apart from a few exceptions) can be prescribed by a physician and are eligible for reimbursement through Statutory Health Insurance (SHI). Exceptions include, among others, licensed pharmaceuticals appearing on a so-called negative list (until 2010), lifestyle and over-the-counter pharmaceuticals.[1]

The SHI spends 19% of its budget on pharmaceuticals. In 2009, SHI spending on pharmaceuticals (excluding vaccines) reached €32.4 billion, a 4.8% increase compared to 2008. The reasons for this are a 3% increase in the number of prescriptions, as well as an increase of 3.7%in the cost of the average prescription.[2]

German pharmaceutical prices have been found to be amongst the highest in the Organisation for Economic Co-operation and Development (OECD), both for patented and generic pharmaceuticals, at either manufacturer or retail level.[3] According to a recent publication, the 50 top-selling patented pharmaceuticals are on average 48% more expensive than in Sweden. For generic pharmaceuticals the corresponding figure is 98%.[2]

As Germany is a reference country for most EU Member States, higher price levels are reflected in the pharmaceutical prices of other countries. Furthermore, the system of free pricing makes Germany a preferred destination for market launches of new products. With patented pharmaceuticals being identified as the main driver of expenditure growth, the recent reform, not surprisingly, primarily targets producers of patented pharmaceuticals.

While most off-patent pharmaceuticals, especially those subject to generic competition, are reimbursed up to a set maximum reference price level, the vast majority of patented pharmaceuticals are usually not subject to price restrictions.

Since 2000, the sales of patented pharmaceuticals have almost doubled, reaching €13.2 billion in 2009. 85% of the sales of patented pharmaceuticals are not subject to reference pricing or any kind of price regulation. Sickness funds in Germany are hence price takers for patented pharmaceuticals, which represents a major obstacle to reducing pharmaceutical expenditure.

A particular problem is posed by pharmaceuticals which enjoy patent protection, but contain only very minor variations of already established active pharmaceutical ingredients and have the same or similar pharmacological effects as the original patented pharmaceutical (known as 'me-too' pharmaceuticals). In 2009, €2.3 billion was spent on 'me-too' pharmaceuticals.[2]

In 1989, Germany, as the first country to do so, introduced a reference pricing system which sets a maximum reimbursement ceiling for groups of pharmaceuticals: those with the same active ingredients, i.e. an off-patent branded original plus generics (Level 1); those with comparable active ingredients and effects (Level 2) or those with different

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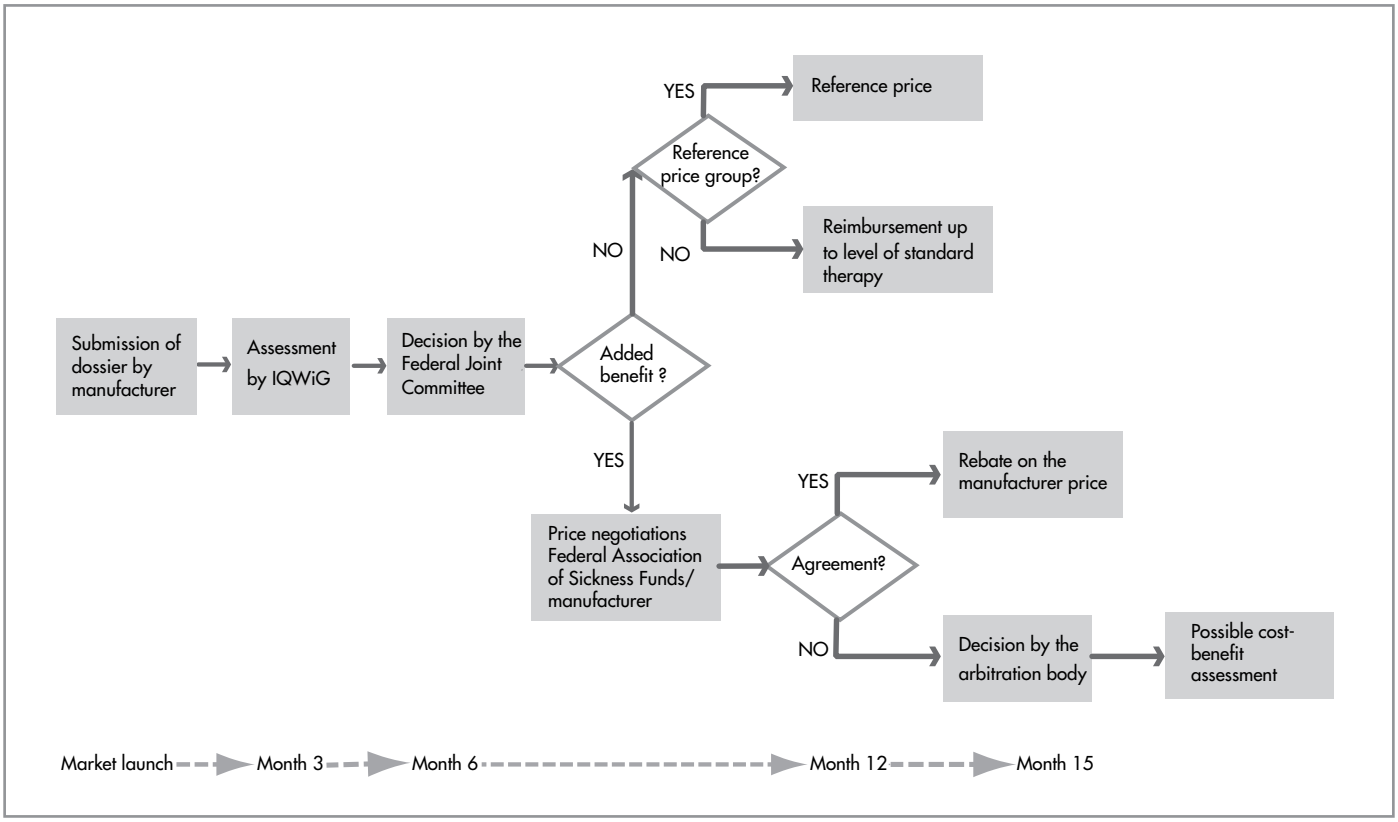
Figure 1: Pharmaceutical reform 2010



Source: [6]

substances with comparable effect (Level 3).[4] In 2009 the reference pricing system covered approximately 44% of pharmaceutical sales reimbursed under the SHI and 74% of all prescriptions. While SHI expenditure on pharmaceuticals excluded from the reference pricing system rose by 8.9% in 2009, expenditure on pharmaceuticals within the reference pricing system dropped by 2% compared to the previous year.[2]

In 2004 the reference pricing system was extended to include patented pharmaceuticals in the Level 2 category. Explicitly excluded from the reference pricing system, however, were pharmaceuticals which represent a therapeutic improvement compared to treatment alternatives. In order to assess the therapeutic added benefit of pharmaceuticals, post-licensing evaluation was introduced in Germany in 2004 when the Institute for Quality and Efficiency in Health Care (IQWiG) was established. It generally does not act independently; assessments are commissioned by the Federal Joint Committee.

Cost-effectiveness assessment was made legally possible in Social Code Book V through the 2007 Act to Strengthen Competition in Statutory Health Insurance in order to set a maximum level of reimbursement for pharmaceuticals with existing standard therapy and an added benefit.[5]

However, because assessments were only performed if the Federal Joint Committee commissioned them, i.e., for a selected number of prioritised pharmaceuticals, a considerable number of patented pharmaceuticals without demonstrable added therapeutic benefit have not been assessed with regard to their added benefit and are therefore not subject to reference pricing. According to Schwabe and Paffrath, potential savings could amount to €4.1 billion if patent-free pharmaceuticals are prescribed rather than equivalent expensive patented 'me-too' products, coupled with consistent use of the cheapest generics and prohibition of the use of controversial pharmaceuticals.[2]

Pharmaceutical reform 2010

In November 2010, in order to curb prices, Parliament passed a reform act (Act to Reorganise the Pharmaceutical Market in the SHI), which aims to strengthen the assessment of the benefit of pharmaceuticals. The reform came into effect on 1 January 2011. Whenever a new pharmaceutical enters the market, pharmaceutical companies will now be obliged to produce a scientific dossier demonstrating its added therapeutic benefit compared to treatment alternatives.

Taking into consideration the dossier submitted by the pharmaceutical company, the Federal Joint Committee will then evaluate the added benefits of the new pharmaceutical. In this context, the Federal Joint Committee may – and in practice will – authorise IQWiG to review the dossier and claims made. The assessors shall also be legally entitled to receive and review the licensing documents. Within three months the Federal Joint Committee must publish its assessment report on the internet.

Following hearings with experts and the pharmaceutical manufacturer, the Federal Joint Committee will come to a decision on the added benefit within three months of publication of the assessment report. Based on that decision, one of two courses of action will follow (Figure 1):

1. *Pharmaceuticals that do not offer additional therapeutic benefits* compared to

treatment alternatives (supposedly the majority) will be directly included in Germany's reference pricing system.

The reform stipulates that all classes of branded pharmaceuticals which do not demonstrate added value will be eligible for reference pricing. In case a pharmaceutical cannot be classified in an existing reference price group, the level of reimbursement should not exceed the costs of the standard treatment.

If a pharmaceutical company receives a negative assessment with regard to the additional benefit of a pharmaceutical, it can ask for a renewed assessment no sooner than after one year.

2. *Pharmaceuticals that demonstrate a clinical added value* will be subject to price negotiations between the Federal Association of Sickness Funds and the respective pharmaceutical company, in consultation with the Association of Private Health Insurance Companies.

   Negotiations will address the level of rebate on the manufacturer price according to the level of added benefit and the agreement will apply to both statutory and private health insurance. Within the first year after marketing authorisation, the pharmaceutical manufacturer is free to set the price, while negotiations are being undertaken.

   If no agreement is reached during this first year, an arbitration body – consisting of representatives of the sickness funds, the pharmaceutical industry and neutral members – has three months to set a price that takes into consideration international prices. The price set by the arbitration body applies to all health insurers with retrospective effect starting one year after marketing authorisation. Both parties can appeal the decision by asking the Federal Joint Committee for a cost-effectiveness assessment, which in turn might lead to a different price.

   Each sickness fund, in order to ensure access to innovative pharmaceuticals, is allowed to conclude contracts with selected pharmaceutical manufacturers, complementing or modifying the collective price negotiation scheme.

Further reform measures, which were passed by the German Parliament in June 2010 as part of the Act to Amend SHI Relevant and Other Regulations, comprise a freeze on pharmaceutical prices (technically only for SHI, i.e. not affecting private health insurance) and an increase from 6% to 16% in the mandatory rebate SHI imposes on manufacturers of pharmaceuticals outside of the reference pricing system. These price control measures apply for the period from 1 August 2010 to 31 December 2013.

The government expects that the reform measures will lead to savings for the SHI of up to €2.2 billion. However, it is debatable whether price negotiations will reduce costs so considerably, as pharmaceutical firms might simply start negotiations with a price already in mind, for example, prices that already have a discount factored in. Such concerns are supported by the experience that some pharmaceutical companies raised prices by exactly the amount of the increased mandatory rebate two weeks before the latter came into effect on 1 August, thereby effectively circumventing any price reduction.

Another major criticism refers to the fact that orphan drugs are basically excluded from the obligation of benefit assessment after licensing. Benefit assessment is foreseen only if sales exceed €50 million in twelve months. Hence patients with rare diseases are at a disadvantage, because licensing does not guarantee the added benefits of orphan drugs.[7]

International reference pricing is expected to play an important role in future. The reform stipulates that from 2011 onwards prices in other European countries should be taken into consideration by the arbitration body when determining the price levels of pharmaceuticals. Germany, in turn, is a reference for many European countries. The reform will therefore not only have a significant impact in the country but also in Europe where Germany, along with France and the United Kingdom, is considered one of the most influential reference countries in terms of pricing.

Conclusion

The German pharmaceutical reform of 2010 follows an international trend of linking pricing and reimbursement decisions to systematic, evidence-based benefit and increasingly also the cost-effectiveness assessment of pharmaceuticals compared to treatment alternatives. While Germany has been rather reticent, some countries have gained considerable experience in this approach. Nevertheless, post-licensing evaluation procedures and methods still vary among countries and international collaboration in health technology assessment is expected to play a trend-setting role.[8] The challenge in all countries will be to strike a balance between innovation, affordability and cost-effectiveness

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Nurses in Hungary:

An analysis of the decline in staffing levels

Gusztáv Stubnya, Julianna Csetneki and Zoltán Balogh

Summary: A reduction in the number of health care professionals working in Hungary has been caused by the acceptance of work abroad and people leaving the profession. For nurses specifically, there has also been a significant decline in the number of people choosing the profession. Currently in Hungary, a career in nursing does not offer great opportunities for young people due to the low pay and the severely restricted fringe benefits and other allowances. Over the past few years, the health portfolio has neither proved itself capable of resolving this problem, nor in improving attitudes towards and appreciation of nurses. This article not only analyses the situation, but also attempts to outline how it may be possible to improve the situation with nurses.

Key words: Hungary, nursing, staff, quitting the profession, migration

Challenges with training nurses

The aim of training is to develop experts with a holistic set of skills, prepared to the currently required scientific standard, who are fully capable of carrying out nursing/carer tasks, helping patients of varying ages, and who are able to meet the needs of unhealthy people to the degree required. One reason for the catastrophic development of nurse staffing levels lies in the training itself. Perhaps the single greatest problem of the current training system is that the vocational secondary schools, tried and trusted under the old system, are no longer in operation. A nursing qualification can be obtained in one of two ways: within the framework of the National Qualification Register (OKJ) training or Bachelor of Science (BSc) training. One problem is that there is only one year's difference between the duration of an OKJ nursing course and a BSc college diploma nursing training course, but there is no mobility between the two qualifications.

BSc training

Since the introduction into domestic education of the Bologna system, a BSc in nursing has also been available. This is similar to the OKJ as it is based on the school-leaving examination and organised within the framework of training at higher education institutions. Such courses run for eight semesters. In order to gain a BSc it is necessary to have an intermediate, "C" type state-recognised language examination, or an equivalent school-leaving examination certificate or diploma in one of the official languages of the member states of the European Union, Russian, or in a nationality/ethnic minority language.

A significant proportion in the nursing profession choose to enrol on a BSc course. Due to the high proportion of nurses selecting this course, it is not possible to establish the proper professional hierarchy in the current system. Of course, a high level degree is not in itself a disadvantage (a well trained workforce undoubtedly raises the standard of the profession and health care provision), but because of the relatively low nurse staffing levels it is common to find qualified nurses or specialist nurses with diplomas carrying out very basic nursing activities. This already difficult situation is worsened by the fact that only a few graduates start work directly with patients in hospitals and clinics. Table 1 shows the number of people who received a college-level nursing qualification between 2001 and 2008.

OKJ training

The OKJ nursing qualification awarded for a course organised by the Ministry of Health is an advanced level vocational qualification based on the school-leaving examination. The form of training can be in a school system or adult education forum, with a training period of three years for a maximum of 4,600 hours. The number of students currently attending full-time OKJ training is extremely low, courses are not filled, and the nursing profession itself does not offer an attractive career opportunity for young people who have completed their studies. Currently in Budapest, there are only 55 students in all years of training; therefore an insignificant number of career-starter nurses will be graduating.

Again with the relatively low numbers of nurses with vocational qualifications it is common to find that basic nursing activities are also carried out by nurses with degrees or diplomas. However, the complete opposite of this situation can also be observed in some institutions, that is, workers with low-level qualifications carry out specialist nursing duties, which naturally represents a potentially far greater risk. In order to avoid these and similar situations from arising, the Clinical Centre of Semmelweis University organises its own specialist nurse and specialist assistant training in order to arm nurses and assistants with the highest possible theoretical knowledge and practical skills in order to carry out their work. Semmelweis University provides training towards vocational qualifications, with 86 individuals

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Table1: Number of people receiving a college-level nursing qualification, 2001–2008

Academic year	Full-time study	While working	Total (persons)
2001	242	527	769
2002	256	374	630
2003	177	352	529
2004	144	380	524
2005	140	409	549
2006	145	382	527
2007	101	401	502
2008	129	392	521
Total number	1,334	3,217	4,551
Total %	29	71	100

Table 2: Number of graduate nurses, 2001–2007

Academic year	Full-time study	While working	Total (persons)
2001	516	3,034	3,550
2002	238	1,953	2,191
2003	280	2,315	2,595
2004	198	2,456	2,654
2005	261	2,454	2,715
2006	267	1,622	1,889
2007	317	1,080	1,397
Total number	2,077	14,914	16,991
Total %	12	88	100

qualifying in various disciplines in 2007, 76 in 2008 and 168 in training in 2009.

The number of people finishing nurse training while also working has similarly fallen year after year as indicated in Table 2. This was particularly true in 2007. 87.7% of the 16,991 nurses who qualified between 2001 and 2007 acquired a diploma while also working. With regard to the fact that these people are already working in the health services, once they graduate the nurse staffing level does not increase, while the hospitals and clinics employing them during their years of training have to somehow manage when they are absent for training days, including professional work experience and exams. Employers, for instance, Semmelweis University, frequently also cover teaching and examination costs.

The main reason for low nurse staffing levels: emigration

Aside from the lack of new recruits to the profession there are numerous causes behind the sharp decline in the number of health care professionals, of which one – emigration to take up work abroad – is particularly prominent. The majority of staff members have an intermediate language qualification and internationally recognised diploma, therefore they are rated as a particularly sought-after labour force in countries with a developed health care culture which can benefit greatly from their qualifications and skills. As a consequence of clear and unambiguous EU regulations on the subject, it is now much easier to find work that matches qualifications. There is a significant difference in the daily and weekly workload, again in favour of foreign workplaces. Professional areas of competence are clarified; fellow foreign doctors commend the preparedness of specialist nurses and in the course of work look on them as partners. Another aspect of considerable relevance is the fact that wages in certain countries can be four to five times (and occasionally up to seven times) those in Hungary. Indeed, in certain specialist areas, e.g., anaesthesiology, intensive therapy or oncology, pay can be even higher.

According to the latest figures from the Office of Health Authorisation and Administrative Procedures (EEKH), in 2009 419 nurses, seven midwifes and 106 other health care professionals requested official certificates of their diplomas so that they could take up positions abroad. This again was an increase on previous years. In 2005, 239 health care professionals reported to the Office, with this number dropping to 113 in 2006, 127 in 2007 (the year of health care reforms), 153 in 2008 and back up to 532 in 2009.

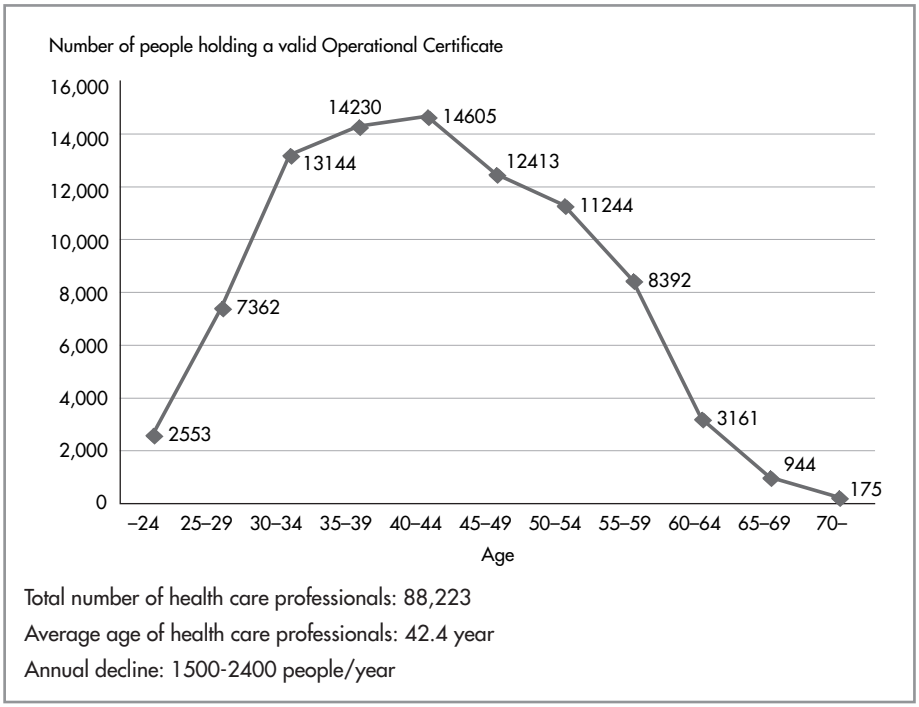
Most doctors and nurses (499 people) requesting certificates were interested in working in the United Kingdom. Other popular destination countries included Germany (284), Italy (147), Austria (146), France (103) and Sweden (100). Experience shows that a proportion of doctors and nurses requesting certification end up staying in Hungary. In other words, it is likely that fewer Hungarian health care workers undertake work abroad in their own profession than the statistics indicate, but the growing trend still provides food for thought and seen in the light of the number of those graduating in Hungary, it is a most worrying development.

Other causes behind the decline in staffing levels: ageing, career changes, financial problems

Another reason for the decline in the nurse numbers is that many of them are retiring; moreover, the proportion of middle-aged, highly experienced nurses remaining in the system is low (see Figure 1).

The situation is further aggravated by the fact that many people are leaving the profession as a consequence of recent health reforms. Nurses dismissed from hospitals that have either been closed down or had

Figure 1: Distribution of health care professionals by age, 2011



Source: EEKH Healthcare Professionals Operational Register, February 2011

their profiles modified cannot work as public employees during their period of notice unless they are willing to lose all their benefits and allowances. However, for many people this would represent a loss of earnings of an amount they are not willing to risk, so instead they seek out work opportunities elsewhere.

Over and above what has already been stated, the health sector is burdened with numerous other difficulties: the problems of financing; the low level of wages and other allowances; and the lack of other benefits. There have been no substantive wage increases in the heath sector for several years, so that today a career in nursing is not attractive financially. Many people quit the profession because of problems involved in making a living, instead seeking out jobs where the opportunities to earn more are greater. This is all the more disheartening because the profession is mainly losing highly qualified, experienced nurses for this reason. The management of some institutions that have taken stop-gap measures aimed at increasing wages have sometimes achieved their objectives temporarily. It cannot be denied however that these gestures and unstructured measures do not represent a genuine, long-term solution to these problems.

It is important not to forget that not only do employees face significant difficulties, employers are in the same position. As a result of insufficient financing, they are only able in part to provide the fundamental material working conditions for nursing. The equipment intended to ease the work of nurses is not only obsolete but only available in limited quantities; furthermore, buildings are outdated, while beds and mattresses are worn. The enforced reduction in material expenditures frequently hinders the material supply necessary for nursing, which impacts on only one group even more sensitively than the nurses: the patients themselves.

Conclusions and recommendations

It does not take an expert on the subject to be able to clearly see that the number of new graduate nurses is continually falling and that ever fewer of those who have graduated are actually working in the health service. Parallel to this is the dramatic increase in the proportion of those emigrating, quitting the profession and retiring. In other words, too few are entering the system and very many are leaving, which not only makes it likely, but rather it is a solid certainty, that the negative trend apparent in the nursing profession will – without some form of intervention – continue.

There is no doubt that a solution to the now critical nursing situation will require social cohesion and urgent intervention at the governmental level. The financing problems of the institutions must be settled, which will allow for an improvement in material conditions, and by resolving wages, those nurses still in the profession can be persuaded to stay, while a career in nursing can once again become attractive for young people.

Measures are required that will improve the situation of specialist nurses in the short, medium and long term. In the short term, it is essential to settle primarily the issue of wages and fringe benefits, and clarify areas of competence and training issues.

In the medium and longer term, the primary requirement is to integrate nurse training into the Bologna-compliant training system, which would thus guarantee mobility between training levels as well as in career opportunities. Furthermore, this would create the basic conditions for lifelong learning. Infrastructure development would also do much to popularise the career. Payment of rent and the cost of everyday living also impose a significant financial burden on nurses, who find this difficult to accept. This is why the construction of new and modern nurse hostels, the formation of independent bedsits and the provision of service flats would go some way towards offsetting their financial problems and as a result fewer might consider quitting or changing their career path.

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What do we really know about reference pricing for pharmaceuticals?

Evidence from a systematic review of the literature

Matteo Maria Galizzi, Simone Ghislandi and Marisa Miraldo

Summary: Health policy-makers worldwide have adopted different Reference Pricing (RP) systems for pharmaceuticals. Systems may differ concerning their effects on pharmaceutical prices, firms' strategies, market structure, public and private expenditure, health outcomes and Research and Development (R&D) investments. We present evidence from a recent systematic review of the effects of RP across different systems. Evidence suggests RP successfully decreases drug prices and expenditures in the short-run. Prices drop more where generics have more market power. There is no evidence of negative health effects associated with patients switching between drugs. More research is needed on the long-term effects of RP and its impact on R&D.

Key Words: Reference Pricing, Pharmaceutical Markets, Evidence-based Policy, Generics Competition.

Introduction

Expenditure on pharmaceuticals has been increasing at a faster rate than total health spending: per capita spending on pharmaceuticals rose by >50% between 1995 and 2005.[1] This trend poses serious concerns about the financial sustainability of public health systems and has motivated a series of cost-control policies.

In this context, many countries have adopted Reference Pricing (RP) as a reimbursement system for pharmaceuticals. RP policy consists of clustering drugs according to some equivalence criteria and defining a reference price for each cluster. Drugs can be clustered according to chemical (identical products with same active principal), pharmacological (chemically different but pharmacologically related drugs) or therapeutic equivalence (all drugs used to treat a particular condition). The combination of these options gives rise to several variants of RP schemes. For example, a so-called generic RP (GRP) applies only to products with expired patents and generic competition, and clusters drugs according to chemical equivalence (same form and active compound), while therapeutic RP (TRP) applies to clusters of drugs that are therapeutically equivalent.

Under all RP systems, the third-party payer will reimburse no more than the reference price for each drug in that cluster. If a consumer buys a drug at a price that is lower or equal to the RP of that cluster, then the drug is reimbursed up to the RP value. In contrast, if the purchased drug is priced higher than the RP, the consumer will pay the difference between the RP value and the actual drug price. In fact, in many countries, RP can interact with other forms of out-of-pocket expenditure, such as the co-payment, whereby patients have to pay a share of the drug price. RP is generally seen as an effective mechanism for the reduction of drug prices, as it is believed to encourage self-restraint and to promote appropriate drug use and therefore control the demand for expensive drugs. However, the effectiveness of RP ultimately depends on its ability to promote the financial responsibility of consumers and to enhance competition in pharmaceutical markets.

In the last decade a number of countries have introduced RP schemes (Belgium, Hungary, Italy, Norway, South Africa and

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Spain) following the experiences of Canada, Germany and New Zealand, where RP has been operating for nearly twenty years.[2] The time is thus ripe for an assessment of the overall effects of RP:

– What are the effects of RP on the pharmaceutical market?
– How do firms react to this policy mechanism?
– Which RP scheme seems to work best?

In order to answer these and other questions we systematically reviewed the existing literature on RP.[3]

In what follows, we start by describing the selection criteria of the studies included in the review, and then present the main findings of the literature. The final discussion is intended to summarise the existing evidence on the effects of RP and to suggest some ideas for future research on the topic.

Objectives of the systematic review and selection criteria

A number of articles exist which, directly or indirectly, refer to the RP and to its effect on pharmaceutical markets. Most of them, however, either consist of comments on existing evidence, or mainly provide qualitative and descriptive policy analyses. In our review, we aimed to only include studies which provide either original theoretical insights or new and robust quantitative evidence to evaluate the impact of RP on health and economic outcomes.

To be eligible for our review, the studies had to be published in a peer reviewed journal, written in English and accepted before September 2009. Studies could be either theoretical or empirical. A theoretical contribution was considered original when it presented new analytical insights and original suggestions guiding and motivating empirical investigation. An empirical study was considered original when it presented new data.

Given the inherent differences, the selection of theoretical and empirical papers was based on different criteria. In order to be included, theoretical papers had to present: (i) original insights motivating and qualifying results from empirical investigation and (ii) strong analytical rigour. On the other hand, in order to be included, empirical studies had to adopt a robust identification strategy, and in particular to employ either a Before-and-After (relevant variables are compared before and after the introduction of the RP) or a Difference-in-Difference (variables are compared in time, but with a control group of drugs to which the RP does not apply) approach.

The initial search (on PubMed and EconLit) provided 468 articles. After applying the above mentioned selection criteria, five theoretical and 30 empirical studies remained. A total of ten countries are represented in the empirical literature: Belgium, Canada, Germany, Hungary, Italy, New Zealand, Norway, South Africa, Spain and Sweden. Most of these countries applied a GRP, with the notable exception of Canada, Germany, Hungary and New Zealand, where products were clustered according to therapeutic similarities. The function linking prices to the reimbursement level is different from country to country, as is the market power of the generic producers. All these details make the country-specific analysis difficult to generalise. However, it is a worthwhile to emphasise some common results emerging from the analysis of the 35 included papers.

Results: theoretical studies

The theoretical studies focus on different aspects of RP regulation, and it is thus difficult to sum up their results in few lines. In particular, the evaluation of the RP crucially depends on the policy used as a comparison, on the assumed characteristics of the market, and on the details of the policy design used in the theoretical model. However, some results seem robust to all specifications:

1. RP works well in reducing prices above the reimbursement level.
2. There are no strong incentives for generic firms to reduce prices once the Reference Price has been set. Hence, RP might not be effective in the long run.
3. RP can trigger price increases on therapeutic substitutes not covered by the policy. Again, this phenomenon might jeopardise the long-run effectiveness of the RP, especially if RP is applied to narrow clusters of products no longer covered by patents.
4. Firms can react to RP by setting prices strategically. In this sense, despite using market forces to regulate reimbursement prices, RP might not completely achieve the envisaged goal of perfectly competitive prices. This partial failure is due to the strategic interactions that RP itself is likely to trigger.
5. RP can discourage Research and Development (R&D) efforts by lowering the profitability of the drugs included in the clusters. At the same time, it can encourage a reallocation of R&D towards more innovative and breakthrough drugs to increase expected profits. Hence, the overall effect on R&D is ambiguous.

Results: empirical studies

Concerning the evidence on prices, virtually any country that implemented generic RP experienced a significant price reduction for drugs under RP. Price reductions are larger for prices originally higher than the Reference Price (as predicted by theory) and for markets where generic competition is stronger. Prices of substitute products not under RP can also be affected. However, the empirical results here are ambiguous and no robust conclusion can be drawn. Finally, the empirical literature does not provide sound evidence on the pricing behaviour of the firms producing generic drugs. It is not clear, for example, how prices of generics react once the Reference Price is introduced and how the RP changes as a consequence of generics competition. Further empirical research on this topic is needed.

The main reason why RP is introduced is to control expenditure. Regarding this issue, the empirical literature points to significant short-run savings due to the introduction of RP. Most of the studies conducted in Canada, Germany, Belgium, South Africa, Italy, Spain and Sweden confirm this prediction. For example, RP induced a one year saving of $Can6.7 million (€4.8 million) for ACE inhibitors in Canada, corresponding to 6% of annual expenditure. Although these savings are statistically and economically significant, often they are not large enough to translate into significant reductions in overall pharmaceutical expenditure. Moreover, once again the long-run effects of RP have not been properly investigated.

Other important variables can be affected by the RP. First, the quantities sold of active compounds; in principle, demand for a compound might be reallocated to other close substitutes in order to avoid low prices due to RP. The empirical evidence suggests that under TRP demand switches to cheaper active compounds. In GRP, the literature shows a slow but systematic reallocation of the demand towards products still under patent protection. However, empirical results here are not

robust and further research is needed.

Second, by switching to the least expensive drug, patients might visit their physicians more often and/or consume more health care services. Moreover, switching between drugs might be associated with changes in health status. Regarding health care consumption, studies in Canada show that initially patients do actually consume more non-drug health services. However, a few months after the implementation of RP, generally there was a return to the previous pattern of health care consumption. Even more importantly, the existing evidence does not confirm the existence of negative significant health effects associated with patients switching between drugs.

Finally, concerning industry profitability, the main issue is whether prematurely forcing chemicals still under patent protection into the competitive arena, by clustering them together under RP, might lower pharmaceutical innovation by decreasing profitability. In theory, this is possible. Empirically, this still seems to represent only a remote possibility as we found only one study analysing the link between R&D and RP.[4] Data for this study refer to Canada (TRP), and the results suggest that the R&D expenditure in the pharmaceutical industry did not change significantly when RP policies were adopted.

Discussion

The variety of analyses of RP reflects the heterogeneity of countries and regulatory contexts to which this regulatory tool is applied. A systematic review of the existing literature helps to identify the effects which seem robust across all experiences. Looking at the evidence from articles published in scientific, peer-reviewed journals, what can we claim to know about the effects of RP after more than twenty years of application around the world? According to our results, some evidence is very robust, while some is less robust and needs to be further researched.

There are three robust conclusions. First, we can now accurately predict the theoretical effects of RP on prices, quantities and R&D. Even though the intensity of the effects depends on the precise analytical framework, prices of brand-name products should decrease, while there is no reason why prices of generic drugs should be affected; demand should be reallocated towards cheaper products or drugs not under RP; and firms can react to the RP by setting prices strategically. Second, empirical short-run effects on prices and expenditure are clear cut. Prices drop more where generics have more market power and under GRP, while expenditure after one year reduces consistently in all countries. Third, the impact of the GRP on the market for generics is such that demand within the chemical compound under RP reallocates toward cheaper versions, mostly generic drugs.

Besides these robust findings, some other effects have been shown to hold in certain contexts but are not generalisable to all contexts. The most important is related to the (lack of) health effects related to the TRP due to patients' switching to cheaper active compounds. On this issue, the strongest evidence comes from Canada, where no significant impact on patient health after the introduction of RP was found. Two studies found negative health effects from switching. However, their sample size was relatively small and patients were selected non-randomly. Furthermore, the results have been open to criticism. In any case, more evidence is certainly required on this topic.

Finally, we found that two key issues are widely under-investigated in the existing literature. First, the long-run effects of RP have not been sufficiently considered, neither under a theoretical nor an empirical approach. Theoretical analysis has mainly focused on static models. The dynamic deriving from the link between firms' strategies and reimbursement levels has not been fully explored. Empirically, no analysis has described the dynamic of the RP and the link between prices and reimbursement levels. The second key topic which should receive more attention is the empirical relationship between RP and pharmaceutical R&D. Although theoretical results are clear in this sense, the question of whether more competitive after-patent markets discourage investments in R&D or reallocate R&D towards more innovative projects is of crucial importance.

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Mythbusters

Myth: The ageing population is to blame for uncontrollable health care costs

FACT: The proportion of Canadians 65 years of age and older is increasing as the baby-boom generation reaches retirement age.

FACT: Older adults need more medical services than younger people.

Taken together, these snippets of reality can conjure a frightening image, in which the health care costs of the ageing population balloon until the system becomes unsustainable, necessitating cuts to services and/or tax increases. But, health care costs don't inflate uncontrollably just because there are more seniors. 'Boomerangst', as it has been cleverly dubbed, isn't based in reality, so say the experts.

The cost of ageing

Health care costs generally increase with age. When the Canadian Health Services Research Foundation first busted this myth in 2002, Canada was spending $8,208 per year per senior versus $1,428 (in 2008 dollars) per person under the age of 65. By 2008, these figures had grown to $10,742 and $2,097, respectively. Among older seniors, the data are even more telling. Seniors 80 years of age and older cost the system $18,160 per capita, more than three times the cost of seniors aged 65 to 69.[1]

Estimates of how the ageing population will affect health care costs vary considerably, with some predicting doom and gloom and others a minor blip on the radar.[2] Only time will tell the true story, but developing credible predictions is a core component of responsible health systems planning.

Some of the best research shows that, although health care costs will begin to rise as baby-boomers age, the impact will be modest in comparison to that of other cost drivers, such as inflation and technological innovation.[3,4] Economic models suggest that growth in health care costs due to population ageing will be about 1% per year between 2010 and 2036[5] (although it has been argued that the assumptions used in these models make for rosy predictions). These low figures can be reassuring, but with the public share of health care spending topping $120 billion as it did in 2008,[1] even growth of 1% translates into a lot of money.

Ageing and sustainability

There are two issues at play when it comes to age and health care delivery. First, the older we are the more health care we use. While the overall population is using more care than ever, seniors are using proportionally more care than younger age groups, which is why seniors cost the system more. They are more likely than younger people to have chronic conditions (and more of them) such as heart disease, dementia and diabetes, which require longer hospital stays and more physician visits.[6] Having multiple chronic conditions may also involve the use of many different drugs to treat each condition separately. Research has shown that such treatment regimens are often not managed properly, leading to adverse drug reactions and further hospitalisation.[7]

With respect to sustainability, it's the more rapid growth in age-specific health care utilisation for seniors that may be cause for concern. Studies have shown that per capita use of medical, surgical and diagnostic specialists is increasing more for seniors than for younger people, and services provided to seniors are altogether more costly.[8] An 80-year-old today is twice as likely to have cataract surgery, a knee replacement, and/or a coronary bypass as in 1990.[9]

Some of these increases in utilisation relate to medical and technological advances (for example, equipment for new surgical techniques or increased use of medical imaging technology).[10] Others relate to age-specific

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Mythbusters are prepared by Knowledge Transfer and Exchange staff at the Canadian Health Services Research Foundation and published only after review by a researcher expert on the topic.

The full series is available at http://www.chsrf.ca/publicationsandresources/Mythbusters.aspx

A series of essays by the Canadian Health Services Research Foundation on the evidence behind healthcare debates

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health care needs, which will increase in tandem with the ageing population (for example, the number of seniors with dementia is expected to double by 2038).[11] Without changes in policy, care delivery, prevention or treatment for those with dementia, the economic implications of this greater utilisation could be considerable.

Second, dying is expensive. Research shows that we cost the health care system the most in our final years of life – and, obviously, our likelihood of dying increases as we age.[12] In fact, the high (and rising) service use by older people is in many ways a reflection of their greater probability of dying.

Restructuring care for seniors

Ensuring that age-specific increases in utilisation do not spiral out of control will require tough decisions, which may include disinvesting from some services and investing more in others. It will also mean designing systems that make sense for the care of seniors. Arguably, there are too many seniors in acute care settings because community supports (whether residential care, assisted living or home care) are not available. Our reliance on alternate level of care (ALC) beds (i.e., non-acute patients residing in acute care beds waiting for admission elsewhere)[13] demonstrates the need for stronger continuing care supports.

A move toward integrated continuing care delivery can produce sizeable cost savings, create efficiencies, and improve the quality of care and caregiver satisfaction.[6,14,15] Supporting the education, recruitment and retention of caregivers to help with home support is an essential element of a broader labour strategy to meet seniors' care needs while controlling costs.

Conclusion

While the impact of the ageing population alone won't bankrupt the health care system, there is still a need to get age-specific cost increases under control, especially those related to death and dying. The good news is that problems expected to arise from population ageing can be managed with smart changes to care delivery for the elderly. It's the other issues – such as the growing cost of health care services and the increased costs arising from technological innovation—that are causing expenditures to escalate. These are the cost drivers that require our foremost attention.

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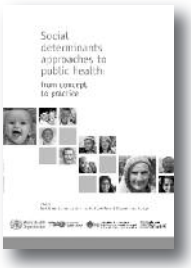
NEW PUBLICATIONS

Eurohealth aims to provide information on new publications that may be of interest to readers. Contact Azusa Sato at a.sato@lse.ac.uk if you wish to submit a publication for potential inclusion in a future issue.

Social Determinants Approaches to Public Health: From Concept to Practice

Edited by Erik Blas, Johannes Sommerfeld, Anand Sivasankara Kurup



Geneva: World Health Organization, 2011

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224 pages

Freely available online at: http://whqlibdoc.who.int/publications/2011/9789241564137_eng.pdf

The thirteen case studies contained in this publication were commissioned by the research node of the Knowledge Network on Priority Public Health Conditions, a WHO-based interdepartmental working group associated with the WHO Commission on Social Determinants of Health. The publication is a joint product of four departments within WHO, and is intended to complement the previous publication by the Department of Ethics, Equity, Trade and Human Rights entitled *Equity, Social Determinants and Public Health Programmes*.

The WHO has long upheld that achieving equity in health is a goal in itself, and has commissioned a variety of projects to tackle avoidable and unfair inequities. In diverse case studies, authors describe how programmes have failed or succeeded and analyse how they have addressed the challenges to five types of processes of implementation: going to scale (how pilot studies can be adapted to large scale interventions; managing policy change (the influence of the policy environment); managing intersectoral processes (how to work with other sectors); adjusting design (flexibility towards changing needs and priorities); and ensuring sustainability (both financial and institutional).

Using this framework, each chapter addresses different topics, including: a menstrual regulation programme in Bangladesh; a suicide prevention programme in Canada; food and vegetable promotion in Chile; delivery centres for migrants in China and an immunisation programme in Nigeria. Together, they describe a wealth of experiences and document the real-life challenges faced by policy-makers, and suggest a way forward for future projects.

Contents: Introduction and methods of work (background, rationale, process and methods, case study themes, summary references); Chapters 2–15; Annexes.

Global Status Report on Alcohol and Health 2011

World Health Organization

Geneva: World Health Organization, 2011

ISBN: 978 92 4 156415 1

286 pages

Freely available online at: *www.who.int/substance_abuse/publications/global_alcohol_report/en/index.html* (as whole document or in country profile sections)

This publication from WHO evaluates available evidence on alcohol consumption, consequences and policy interventions at global, regional and national levels. With nearly 4% of all deaths related to alcohol (by way of injuries, cancer, cardiovascular diseases and liver cirrhosis), and especially affecting men and young people, it has been recognised that too few countries have effective policies to address the harmful use of alcohol.

WHO reports that 34 countries have adopted formal policies, but there are no clear trends on most preventive measures. The report follows the Global Strategy, endorsed by WHO's Member States in May 2010, which promotes a range of proven effective measures for reducing alcohol-related harm. These include taxation on alcohol to reduce harmful drinking; reducing availability through allowing fewer outlets to sell alcohol; and raising age limits for those buying and using effective drink-driving measures.

The Global Status report outlines adult alcohol consumption, patterns of drinking, health consequences (morbidity and mortality) and existing policies in member states. This information is available by region and subsequently country name. It shows that worldwide consumption in 2005 was equal to 6.13 litres of pure alcohol consumed per person aged 15 years or older and marked increases were seen in consumption levels within Africa and South-East Asia during 2001–2005. It also finds that almost half of all men and two-thirds of women did not consume alcohol in 2005, with lower abstention rates in high-income countries, and higher rates in North African and South Asian countries. The report provides information to raise awareness on the problems of harmful alcohol use and helps countries to better prevent and reduce such harm.

Contents: Foreword; Acknowledgements; Abbreviations; Introduction; Consumption; Consequences; Policies and interventions; References; Appendices.

WEBwatch

Please contact Azusa Sato at a.sato@lse.ac.uk to suggest web sites for potential inclusion in future issues.

European Federation of Nurses Associations (EFN)

www.efnweb.org/version1/en/index.html

The EFN was founded in 1971 to represent the nursing profession and its interest to European Institutions, based on the nursing education and free movement directives of the European Union. The website outlines the role of the EFN, its core networks and involvement in EU projects. Visitors to the site are able to download articles and press releases, and an exclusive members section allows for perusal of detailed meeting notes. On the homepage a monthly update and forthcoming agenda are highlighted. In addition useful links and a search tool are accessible. The website is available in English and French.

Royal Pharmaceutical Society (RPS)

www.rpharms.com/home/home.asp

The RPS is the professional body for pharmacists and pharmacy in England, Scotland and Wales. The RPS actively supports and represents the professional interest of its members, and serves to promote their specific needs. The website contains information about pharmacy and latest pharmaceutical news, as well as sections dedicated to the support and development of pharmacists. Users can sign up to online groups, search for jobs and download documents on key topics. A search box, contact information and other user friendly tools allow for ease of access.

International Pharmaceutical Excipients Council Europe (IPEC Europe)

www.ipec-europe.org

IPEC Europe is an association that serves the interests of producers, distributors and users of pharmaceutical excipients (pharmacologically inactive substances used as carriers for the active ingredients of a medication) and represents the views of its members to appropriate regulatory bodies (European Commission, European Medicines Agency, European Pharmacopoeia). A full list of members is available online, alongside details of specialised committees, downloadable publications and guidelines and a list of events. The site allows users to sign up to a newsletter and access a dedicated members only section. A search box and contact information are found online. The site is in English only.

Nursing and Midwifery Council (NMC)

www.nmc-uk.org

The NMC is a nursing and midwifery regulator for the UK, Channel Islands and the Isle of Man, existing to safeguard the health and well being of the general public and serves to cover over 650,000 health care professionals. The site provides a wealth of information about nursing and the role of the NMC with pages devoted to the general public, nurses and midwives, employers and managers, educators and students. Each section outlines upcoming events, relevant programmes and search boxes for ease of access. Publications are downloadable and users can sign up for the NMC news to be sent by email. The site is available in 14 languages including Asian, African and European languages.

Pharmaceutical Care Network Europe (PCNE)

www.pcne.org/about-us.php

The PCNE was established in 1994 by a number of European pharmaceutical care researchers and became an official association (under Dutch law) in 2004. PCNE's aim is to help to develop pharmacy along the lines of pharmaceutical care in European countries through stimulation of research, implementing projects , as well as the organisation of networking and dissemination conferences. The website allows users to browse through news items, search for publications and information about its members and projects, and participate in an online forum. A dedicated members only section and details of upcoming events are accessible. The website is available in English only.

Association of British Pharmaceutical Industry (ABPI)

www.abpi.org.uk/Pages/default.aspx

The ABPI represents 150 members including the large majority of the research-based pharmaceutical companies operating in the UK, both large and small. Combined, APBI members research, develop, manufacture and supply more than 80% of the medicines prescribed through the UK National Health Service. The site outlines their vision, information about the industry and projects across a range of disciplines and with a diverse set of stakeholders. The ABPI library allows users to select and read documents including the annual review, medical and disease information and guidelines, in addition to accessing a media centre which provides the latest news releases and fast facts. Contact information and links to related sites (including ABPI Wales, Scotland and Northern Ireland), upcoming events and twitter feeds, are all found on the homepage. The site is available in English only.

News

Press releases and other suggested information for future inclusion can be emailed to the editor David McDaid d.mcdaid@lse.ac.uk

NEWS FROM THE INSTITUTIONS

Employment, Social Policy, Health and Consumer Affairs Council meeting conclusions

Health Ministers of EU member states gathered in Luxembourg on 6 June 2011 for the 3095th Employment, Social Policy, Health and Consumer Affairs Council meeting. They exchanged views on childhood immunisation and on modern, responsive and sustainable health systems and adopted conclusions on both items. They also adopted conclusions on the European Pact for Mental Health and Well-being, as well as on innovation in the medical device sector.

European Pact for Mental Health and Well-being

Poor mental health affects one in four individuals at least once during their lifetimes and can be found in more than 10% of the EU population during any given year. A *Eurobarometer* survey in October 2010 revealed that 15% of Europeans had sought professional help in the past year because of psychological problems. According to Eurostat, suicide remains a significant cause of premature death in Europe, with over 50,000 deaths a year in the EU.

The Council adopted conclusions entitled *the European Pact for Mental Health and Well-being: results and future action*. The conclusions acknowledge the work that has been done under the European Pact since June 2008 and invite member states and the Commission to continue their engagement in the treatment and prevention in the area of mental health and wellbeing.

More specifically, they invite the member states and the Commission to set up a "joint action" on mental health and well-being under the EU public health programme 2008–2013 providing a platform for exchange of views, cooperation and coordination between member states.

The Commission is also called upon to submit a report on the outcomes of the joint action and consider which future policy actions could be taken as a follow-up to the European Pact for Mental Health and Well-being. The member states are urged to make mental health and well-being a priority of their health policies and to develop strategies and/or action plans on mental health. The conclusions also summarise the outcome of five thematic conferences on different aspects of mental health organised under the European Pact for Mental Health and Well-being in different European capitals from 2009 to 2011.

Innovation in the medical device sector

The medical device sector in Europe comprises around 18,000 small and medium-sized enterprises and the Council adopted conclusions on innovation in the sector. The conclusions were prepared as a follow-up to the high level health conference on innovation in medical technology held in Brussels on 22 March 2011.

The conclusions call upon member states and the Commission to take initiatives to promote innovative and user-friendly medical devices that focus on improving the health of patients and the well-being of themselves and their relatives. The Council stressed that innovation should be based on a holistic approach (i.e. it should take into account the whole health care process and all patients' needs - physical, social and psychological). It should also focus on public health priorities and health care needs in order to improve cost-effectiveness.

The Council has also discussed the forthcoming review of the legislative framework for medical devices and has prepared a list of considerations that the Commission is invited to bear in mind when reviewing the three directives on medical devices. These include considering how clinical data from pre-marketing studies and post-marketing experience (vigilance reports, post-marketing clinical follow-up, European registers) must be collected in a transparent way and to a greater extent in order to provide the clinical evidence which fulfils regulatory purposes and can, where appropriate, assist health technology assessment, whilst fully recognising and respecting national competences for the latter. Consideration should also be given to methods for ensuring that notified bodies are better equipped with the appropriate expertise to analyse such data in a meaningful way. The Council also noted that the vigilance system for medical devices must be further developed in order to allow a coordinated analysis and a rapid and coherent EU-wide response to safety issues, if needed.

Childhood immunisation

Ministers also adopted conclusions on childhood immunisation and exchanged views on the re-emergence of measles in Europe. They expressed concern about the continuing outbreaks of measles in the EU and agreed that vaccination was the best and most effective means of combating this and other infectious diseases. Some also stressed the need to organise catch-up vaccination programmes for young adults and adolescents who have not been vaccinated during their childhood.

Ministers considered that information campaigns could contribute to strengthening public confidence in vaccination and improving the measles vaccination coverage. This measure could be supplemented at EU level by an exchange of experience and of good practice. They highlighted the fact that the under-vaccinated populations are often found among some belief groups, marginalised people and Roma, and that it was particularly difficult to convince such people of the vaccines' benefits.

Prior to the exchange of views Marc Sprenger, Director of the European Centre for Disease Prevention and Control (ECDC), gave a short presentation on

measles and vaccination. According to Mr Sprenger the vaccines were victims of their own success; at a time when, thanks to vaccination, some important infectious diseases such as smallpox had been eradicated in the EU, some European citizens were more aware of the vaccines' side effects than of the diseases themselves. Due to a smaller than necessary vaccination coverage the target to eradicate measles and rubella by 2010 had been missed and postponed to 2015. Mr Sprenger stressed that measles was far from harmless, with around 20% of the infected people needing hospital care and some facing long-term disabilities or even death. He expressed the view that additional efforts were needed to meet this target.

In their conclusions ministers recalled that vaccination is the most effective and economical way of preventing infectious diseases and that vaccines have led to the control, lower incidence and even elimination of diseases in Europe that in the past resulted in death or disability for millions of people. The global eradication of smallpox and the elimination of poliomyelitis from most countries were cited as examples of successful vaccination programmes.

The conclusions also invite member states and the Commission, among others, to take steps to strengthen member states' vaccination programmes, exchange information, increase vaccination coverage and promote children's vaccination programmes, and to establish, with support from the ECDC and the European Medicines Agency, a non-exhaustive list of elements suggested for inclusion in national, sub-national immunisation cards or health booklets.

The conclusions are based on the outcomes of the expert conference *For a Healthy Future of Our Children – Childhood Immunisation*, held in Budapest on 3–4 March 2011. On 16 September 2010 the World Health Organization (WHO) also adopted a resolution on renewed commitment to the elimination of measles and rubella and prevention of congenital rubella syndrome by 2015 and sustained support for polio-free status in the WHO European region.

Towards modern, responsive and sustainable health systems

In their conclusions Ministers considered that health constitutes an important precondition for a prosperous economy and should therefore be considered as an investment rather than solely as an expenditure item. They also expressed the view that despite tightening resources, equitable access to high quality health services should be maintained. Measures which have been taken, or are currently considered in the member states in order to reach this target, include the regulation of the pharmaceuticals sector, incentives for buying generic medicines, e-health-prescriptions and prevention.

Ministers concurred that the EU wide reflection process initiated by the conclusions could assist member states to meet the challenges of the health systems by providing a basis for the exchange of information and best practices. Several ministers considered that the working party on public health at senior level was the right forum for this exchange.

In their conclusions ministers invited the member states and the Commission to initiate a reflection process under the auspices of the working party on public health at senior level to identify effective ways of investing in health, so as to pursue modern, sustainable and effective health systems. The Commission was urged to support the reflection process, to stress the major economic role of the health sector, aiming to shift health from being regarded as just an expenditure item to being acknowledged as a contributor to economic growth. The Commission should also provide effective tools and methodologies to member states for assessing the performance of health systems. Furthermore, ministers called upon the Commission to present regular reports to the Council to contribute to the reflection process; the first report should be submitted by the end of 2012.

More information at www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/122430.pdf

Digital Agenda: EU Task Force to advise how to promote eHealth to help patients and health care systems in Europe

A new EU eHealth Task Force to assess the role of information and communications technologies (ICT) in health and social care and to suggest ways for ICT to speed up innovation in health care to the benefit of patients, carers and the health care sector met for the first time in Budapest on 10 May, chaired by Estonia's President Toomas Hendrik Ilves.

The high level advisory group, which met on the fringe of eHealth week in Hungary, comprises health care professionals, representatives of patients and of the medical, pharmaceutical and ICT industries, legal experts and policy makers. ICT applications already help to empower patients and address challenges faced by EU health care systems like an ageing population, a rise in chronic diseases, a shortage in health professionals and budget constraints by, for example, enabling remote diagnosis and treatment and secure sharing of patient records. However, there is considerable potential to develop eHealth much further in the future: allowing health care workers to dedicate more time to be with patients; enhancing self-help and independence of patients and older people; and also to develop new modelling-based diagnostic techniques.

It will advise the Commission on how to unlock the potential of eHealth for safer, better and more efficient health care in Europe as regards diagnostics, prevention and treatment. It will look carefully at how to achieve inter-operability of eHealth services and technologies across the EU. It will also explore the relationships between eHealth, telemedicine, and social policy, initiatives.

The Task Force will also take into account current policy developments at EU level, including the Digital Agenda for Europe, the European Innovation Partnership on Active and Healthy Ageing and the recently adopted Directive on patient rights for cross border care, but its focus will be on the future, and how innovation can benefit health care systems and society at large.

Digital Agenda: Council Presidency eHealth Declaration on delivering better health care

The deployment of eHealth technologies in Europe, with a view to improving the quality of health care, reducing medical costs (expected to reach 16% of EU countries' GDP by 2020) and fostering independent living for those needing care, is a key objective of the Digital Agenda for Europe.

In Budapest on 10 May a Hungarian Presidency Declaration urging Member States to deploy eHealth services to the benefit of patients, health care workers and national health care systems was welcomed by European Commission Vice-President for the Digital Agenda Neelie Kroes and Health Commissioner John Dalli.

The Declaration outlines a common, forward-looking vision and sets out a

series of policy priorities. It stresses the need for, and benefits of, investment in eHealth and telemedicine and of strengthened coordination of all policies related to eHealth. It will also support the work of an eHealth task force.

In particular it urges Member States to implement Directive 2011/24/EU on patients' rights in cross-border health care and urges both Member States and relevant stakeholders to support and facilitate the deployment of telemedicine systems and services, in particular in the area of remote disease management where strong evidence on efficiency and clinical benefits exists.

It also calls for measures to develop and adopt guidelines for health professionals, for implementing innovative tools aiming at enabling integrated health services, for example, chronic disease management services (e.g. for diabetes and chronic heart failure), tools for better use of human resources and capacities in the health sector and access to appropriate, safe and quality health care.

The Declaration also refers to the need to agree and implement common measures to achieve interoperability of eHealth systems; take steps to enable data analysis for research and public health purposes while ensuring respect for protection of personal data privacy; and agree on a minimum common set of data to be collected and exchanged across Member States on chronic diseases.

For more than two decades, the European Commission has been supporting EU research in eHealth through the funding of more than 450 projects worth some €1 billion to enable Europe to take the leadership in research and innovation in this field. Commissioner Kroes, noted that "the evidence shows that eHealth pays off in terms of efficiency gains, health and welfare improvements and increased care worker productivity." An eHealth Action Plan 2012–2020 is due to be presented by the Commission before the end of 2011.

More information at
http://ec.europa.eu/information_society/digital-agenda/index_en.htm

Traditional herbal medicines: more safety for products put on EU market

'Traditional' herbal medicinal products are a sub-group of herbal medicinal products that have been in use for at least 30 years, including at least 15 years in the EU, and that are intended to be used without the supervision of a medical practitioner and are not administered by injection. This category is not limited to European traditional herbal medicinal products; it can also include Chinese and Ayurdevic medicinal products.

In order to protect public health, all medicinal products, including traditional herbal medicinal products, need a marketing authorisation to be placed on the EU market.

The 2004 Herbals Directive (2004/24/EC) updated the 2001 Directive on the Community code for medicinal products for human use (Directive 2001/83/EC) by introducing a simplified procedure specifically for traditional herbal medicinal products, allowed these products to be registered without the safety tests and clinical trials that a full marketing authorisation procedure would involve. At the same time, the Directive provides the necessary guarantees of their quality, safety and efficacy.

The Directive gave an exceptionally long transition period for manufacturers to register their traditional herbal products already on the EU market when the Directive entered into force. Applicants have had seven years to apply to the competent authority in the Member States(s) where they wanted to market their product. The expiry of this transition period means that only medicinal products which have been registered or authorised could remain on the EU market after 1 May 2011.

An applicant who wishes to register a traditional herbal medicinal product must provide documentation showing that the product in question is not harmful in the specified conditions of use. They must also provide evidence that the product has a proven track record, i.e. that it has been used safely for at least 30 years – 15 of these in the EU.

John Dalli, European Commissioner for Health and Consumer Policy, said, "we have now reached the end of a long transition period which has given producers and importers of traditional herbal medicinal products the necessary time to show that their products have an acceptable level of safety and efficacy. Patients can now be confident about the traditional herbal medicinal products they buy in the EU."

More information at
http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm

Commission proposes to revamp rules to protect EU workers from harmful electromagnetic fields

Current rules are intended to protect workers like doctors and nurses giving patients magnetic resonance imaging scans (MRI), people working with radar, welders and workers repairing power lines.

The proposal takes account of the 2004 Directive on minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields. It would update the current exposure limits to take on board new scientific evidence – particularly in relation to exposure limits of MRI in hospitals. It would also include a number of provisions to help employers in their efforts to carry out the risk assessments required by EU law.

The aim of the proposal is to balance the protection of workers' health and safety with appropriate flexibility and proportionality so as not to unduly hamper the use and development of industrial and medical activities. The proposal will be sent to the European Parliament and the EU's Council of Ministers for adoption. The new directive's deadline for implementation will be set by the Parliament and the Council.

The proposal can be accessed at
http://ec.europa.eu/commission_2010-2014/andor/documents/proposal_dir_electfields_en.pdf

New Directive on falsified medicine

On 27 May 2011 the Council of the European Union formally adopted the Directive on Falsified Medicines. This had been approved by the European Parliament in February. The proposal was passed without debate and with just one abstention. In a statement, the Council said that it has taken action "against the alarming increase of falsified medicines detected in the EU and the public health risk which that poses."

Falsified medicines (the term 'falsified' is used to distinguish the issue from intellectual property violations, so-called 'counterfeits') are a major threat to public health and safety. As falsifications become more sophisticated, the risk that falsified medicines reach patients in the EU increases every year. Falsified medicines represent a serious threat to global health and call for a comprehensive strategy both at European and international level.

The new directive includes a number of provisions to address falsified medicines,

including the addition of safety features for prescription medicines to allow verification of authenticity and identification - down to the individual pack level, as well as tamper-evident seals.

Outside of the safety features provision, the Directive also tightens controls over the upstream supply chain, with registration requirements for importers, manufacturers and distributors of active pharmaceutical ingredients (API), with marketing authorisation holders responsible for verifying that APIs are made in accordance with Good Manufacturing Practice (GMP) and distributed according to Good Distribution Practice (GDP).

The Directive adds obligations for manufacturers to inform authorities about cases of falsification, while a legal basis is created for customs – in cooperation with other authorities – to "prevent medicinal products suspected of being falsified entering into circulation." Greater oversight of internet sales is called for, including an official logo for certified online pharmacies to allow members of the public to buy medicines online – in member states that allow the practice – with greater security. Finally, more stringent sanctions against those who manufacture, distribute, import and export falsified medicines must be imposed by member states.

Member states have until 2 January 2013 to transpose the Directive into their national legislations, a process which will take place via the recently introduced 'delegated acts' procedure.

More information at
http://ec.europa.eu/health/human-use/quality/fake-medicines/index_en.htm

Specialised food products: Commission initiative to provide better information to consumers

After more than thirty years of application, and given the evolution of food products and the evolution of EU food legislation, a review of dietetic food legislation became necessary. Specialised 'normal' foods have increasingly been targeting sub-groups of the general population (for example, protein bar supporting muscle building for sportspeople, food supplements for pregnant women, fortified food in calcium and vitamin D suitable for older adults, slimming products etc).

Consequently, the difference between 'dietetic foods' for specific groups of the population and 'specialised foods' for the general population or sub-groups is no longer clear for citizens, stakeholders and enforcement authorities. Therefore, it became clear that the existence of a specific EU framework for 'dietetic foods' existing in parallel with other, more recent, pieces of legislation was no longer justified.

Thus on 20 June 2011 the European Commission adopted a draft regulation that it claims will better inform consumers across the EU and achieve the aim of better and clearer legislation. Food companies may no longer be able to register normal food products as 'dietetic', as the European Commission is proposing to abolish the concept from EU legislation altogether. Dietary foods will be solely covered by other already existing legislation, such as one on nutrition and health claims (Regulation 1924/2006) and/or the regulation on the addition of vitamins, minerals and other substances to foods.

No products will have to be withdrawn from the market as a result of the new rules. Those covered by the dietetic food legislation will be legislated fully by other pieces of existing food legislation. In order to facilitate the adaptation of products and reduce costs for operators, mainly in terms of re-labelling, a two-year transitional period is foreseen.

The draft regulation also strengthens and clarifies provisions for foods intended for vulnerable groups of the population who need particular protection – namely infants and children up to three years old, and people with specific medical conditions, such as cancer patients or individuals with metabolism disorders.

It does so by maintaining the existing compositional and labelling rules applicable to infant and follow-on formulae, processed cereal-based foods and other baby foods and foods for special medical purposes. Further, the proposal establishes a single EU list of substances, instead of the existing three, that can be added to these foods. The substances covered in the list include, among others, minerals and vitamins.

In response to the proposal, Ferdinand Haschke, President of the Association of the Food Industries for Particular Nutrition Uses of the European Union (IDACE) stated that "there is no justification for dismantling the existing legislation. General food law alone is not adequate to provide food safety and health protection for the vulnerable and fragile part of the EU population. Many of our consumers have very special and unique nutritional needs."

Meantime European consumers' organisation BEUC encouraged the Commission to act "in order to ensure that the right foods were being marketed as dietetic products". It warned European consumers over "borderline products" and "unclear labelling on suitability" of dietetic foods.

The proposal will be now submitted to the European Parliament and the Council. If these institutions reach an agreement on the proposal the new regulation should be in force by the end of 2012.

More information at
http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm

Inadequate housing causes more than 100,000 annual deaths in Europe

Inadequate housing accounts for over 100,000 deaths per year in the World Health Organization European Region and causes or contributes to many preventable diseases and injuries, including respiratory, nervous system and cardiovascular diseases and cancer. This is the main conclusion of a report, *Environmental burden of disease associated with inadequate housing*, released on 23 June by the WHO Regional Office for Europe.

The new publication presents the results of an international study that was coordinated by WHO/Europe's European Centre for Environment and Health, in Bonn, Germany and implemented in collaboration with WHO headquarters and experts and institutions in Europe and elsewhere. The report reviews the evidence on exposure to housing-related hazards and associated health effects and provides guidance on how to quantify the health effects of inadequate housing for selected housing risk factors. The report estimates the environmental burden of disease caused by inadequate housing for eleven housing hazards. Better surveillance and data collection are needed in south-eastern Europe and central Asia, where a lack of exposure data inhibits good estimates.

Much of the housing stock in the European Union (EU) still had many health hazards in 2009, such as excessive noise exposure (22%), dampness (16%), overcrowding (18%), problems keeping the dwelling warm in winter (9%) and a lack of hygiene equipment such as an indoor flush toilet (3%) or a bath or shower (3%). Comparable statistical data for the countries in the European Region outside the EU are not easily available, but

evidence indicates that the housing situation is worse, especially among people with low income.

"Home should be a safe place. Yet for many it is not, especially for vulnerable people who spend most of their time at home such as young children, older people and people with disabilities," said Zsuzsanna Jakab, WHO Regional Director for Europe. "Inadequate housing conditions represent a serious environmental health threat that is preventable. We hope that this new evidence will prompt governments and local authorities to review housing policies to protect the health of Europeans and reduce social inequities in long-term exposure to environmental risk."

The report addresses in one document many of the risk factors associated with housing – such as noise, damp, indoor air quality, cold and home safety – each chapter presenting statistical analysis based on sound data and scientific evidence. The lack of home safety measures such as smoke detectors is associated with 0.9 deaths per 100,000 population annually, equivalent to more than 7,000 entirely preventable deaths each year across the Region. People die of cold at home: low indoor temperatures cause 12.8 deaths per 100,000 population per year; and exposure to radon causes 2–3 deaths per 100,000 population for selected countries. Exposure to second-hand smoke causes 7.3 deaths; and the use of solid fuels as a household energy source without proper ventilation is associated with 16.7 deaths per 100,000 children and 1.1 deaths per 100,000 adults annually.

Poor housing is also strongly linked with ill health, including disease. In the whole WHO European Region, using solid fuels as a household energy source results in the loss of 577 annual disability-adjusted life-years (DALYs) per 100,000 children younger than five years, and housing-related exposure to lead causes an annual loss of 79 DALYs per 100,000 population. Data for 45 countries indicate that mould in homes results in the loss of 40 DALYs per 100,000 children each year. Further, exposure to noise from road traffic in Germany alone causes a loss of 31 DALYs per 100,000 population annually. Lack of smoke detectors causes an annual loss of 22 DALYs per 100,000 population in the whole European Region.

The report is available at http://tinyurl.com/6kph3mk

World Health Assembly closes with European priorities on action agenda

The Sixty-fourth World Health Assembly closed on 24 May, after working for eight days through a broad agenda that yielded 28 resolutions on global health matters, many of which have high priority in the European Region.

The policy work of the Health Assembly began with the Review Committee's report that the International Health Regulations helped the world prepare to cope with the influenza A(H1N1) 2009 pandemic, although global public health emergencies needed to be handled better. The Committee also declared that the pandemic had been real, and that its one-year investigation found no evidence that the pharmaceutical industry influenced WHO's decision-making.

Pandemic influenza preparedness

The World Health Assembly approved a framework for pandemic influenza preparedness, the culmination of four years' negotiation between WHO Member States. The framework will improve the sharing of tools and knowledge on the influenza virus, improve access to vaccines and bring other benefits. The next phase is to ensure the implementation of the agreement.

New strategy to combat HIV

A new, comprehensive strategy to combat HIV was adopted. The Global Health Sector Strategy for HIV/AIDS (2011–2015) will guide action by WHO and countries around the world. If implemented, WHO's recommendations could save at least two million lives and prevent at least 4.2 million new HIV infections. In addition, the draft European action plan on HIV/AIDS was presented to delegates, and will be submitted for adoption by the WHO Regional Committee for Europe in September.

Non-communicable diseases

Delegates and partners in global health discussed non-communicable diseases (NCDs), such as diabetes, heart disease, stroke, cancer and chronic respiratory diseases. NCDs pose one of the greatest challenges to health and development, contributing to more than 60% of deaths worldwide. Delegates urged heads of state and government to attend the United Nations General Assembly high-level meeting on NCD prevention and control, to be held in September.

Protecting health from climate change

Member States welcomed the priority that WHO has given to protecting health from climate change, and reinforced their own commitment, citing new initiatives ranging from regional ministerial meetings to implementation projects.

More information on the World Health Assembly at http://apps.who.int/gb/

ECJ NEWS

Potentially far reaching implications of stem cell patents case for European research

According to Advocate General Yves Bot (*Opinion of the Advocate General in Case C-34/10 Brüstle v Greenpeace eV*), totipotent cells carrying within them the capacity to evolve into a complete human being must be legally classified as human embryos and must therefore be excluded from patentability. Nor can a procedure using other embryonic stem cells, known as pluripotent cells, be patented where it first requires the destruction or modification of the embryo.

The case refers to Oliver Brüstle who holds a patent, filed in December 1997, which concerns isolated and purified neural precursor cells, produced from human embryonic stem cells used for the treatment of neural defects. According to Mr Brüstle, the first clinical applications have already been developed, in particular for patients with Parkinson's disease.

On the application of Greenpeace eV, the Bundespatentgericht (Federal Patent Court, Germany) declared Mr Brüstle's patent invalid, in so far as it related to procedures allowing precursor cells to be obtained from human embryonic stem cells. The Bundesgerichtshof (Federal Court of Justice, Germany), to which Mr Brüstle had appealed, decided to stay proceedings and refer questions to the Court of Justice on the interpretation, in particular, of the term 'human embryo', which is left undefined by European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. The questions concern, essentially, whether the exclusion of the human embryo from patentability concerns all stages of life from the fertilisation of the ovum or whether other conditions must be satisfied, such as the attainment of a certain stage of development.

The Advocate General, in coming to his opinion first made the point that the Court was being called upon for the first time to consider the concept of 'use of embryos for industrial or commercial purposes' contained in Directive 98/44. Having stated at the outset his awareness of the extreme sensitivity of that question and the importance of the philosophical, moral, human, economic and financial issues at stake, the Advocate General began his legal analysis by stating that, since the directive pursues the objective of establishing effective and harmonised legal protection of biotechnological inventions, the embryo needs to be given an autonomous definition in EU law. That analysis is supported by the first interpretations by the Court in its case-law concerning that directive.

After pointing out the major divergences existing between the legislation of the Member States and the impossibility, in the current state of scientific knowledge, of using a criterion of that nature capable of being recognised by all the Member States, the Advocate General fixed upon the wording of the directive, which, in Article 5(1), protects 'the human body, at the various stages of its formation and development'.

He then observed that totipotent cells, appearing after fusion of the gametes and existing in that form only for the first days of development, have the essential characteristic of carrying within each of them the capacity to develop into a complete human being. Since these cells represent the first stage of the human body they will become they must be legally classified as embryos, the patentability of which must be excluded. Similarly, the blastocyst stage of development, reached around five days after fertilisation, must also be classified as an embryo, since, according to the Advocate General, the principle of human dignity, to which the directive refers, is a principle which must be applied not only to an existing human person, to a child who has been born, but also to the human body from the first stage in its development, i.e. from fertilisation.

By contrast, pluripotent embryonic stem cells, taken in isolation, do not fall within the definition of an embryo, since, individually, they are no longer capable of developing into a complete human being. They can 'only' differentiate themselves into various organs forming parts of the human body. These cells are relevant to Mr Brüstle's patent, their removal from the embryo taking place at the blastocyst stage. However, it is not possible to ignore the origin of these embryonic stem cells. The fact that they come from some stage in the development of the human body is not in itself a problem, provided only that their removal does not result in the destruction of that human body at the stage of its development at which the removal is carried out. In the opinion of the Advocate General, it must therefore be agreed that inventions relating to pluripotent stem cells can be patentable only if they are not obtained to the detriment of an embryo, be that it's destruction or its modification. To make an industrial application of an invention using embryonic stem cells would amount to using human embryos as a simple base material, which would be contrary to ethics and public policy.

In conclusion, the Advocate General considered that an invention cannot be patentable where the application of the technical process for which the patent is filed necessitates the prior destruction of human embryos or their use as base material, even if the description of that process does not contain any reference to the use of human embryos. The Advocate General observed, however, that the patentability of uses of human embryos for industrial or commercial purposes is not prohibited under the directive where it concerns only inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it – for example to correct a malformation and improve its chances of survival.

Implications of the Opinion

The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

The regulation of embryonic stem cell research is a national competence, under the EU's research framework programme, and funding may be given for research taking place in countries which allow embryonic stem cell-based research. Embryonic stem cell line production is forbidden in Austria, Denmark, France, Germany and Ireland, but permitted in Finland, Greece, the Netherlands, Sweden and the United Kingdom.

A spokesman for the Commission's Research Commissioner, Maire-Geoghegan Quinn, said that all funding projects are "subject to ethical review and EU funds may not be used for the derivation of new embryonic stem cell lines". However, that does not preclude the use of funds within member states on embryonic stem cell research, which could then be patented overseas.

In response to the Opinion, leaders of major stem cell projects in Europe published an open letter in the journal Nature on 28th April (Nature, 472, 418; 2011). The authors, representing both embryonic and adult stem cell research, pointed to a potential wide-ranging impact on the entire stem cell field if the European Court chooses to uphold Bot's opinion in a final and legally binding ruling. They state that the Advocate-General's opinion undermines years of funding from the European Commission and individual EU member states for research aimed at developing human embryonic stem cell based therapies. They suggest that citizens may find that new therapies are developed elsewhere and will not be available in Europe, or will be prohibitively expensive.

More information at
http://curia.europa.eu/jcms/upload/docs/application/pdf/2011-03/cp110018en.pdf

COUNTRY NEWS

E. coli: Germany says worst of illness is over

As of 30 June 2011, there had been 33 deaths since the outbreak of the E.coli infection in Germany. A further 100 patients are thought to need kidney transplants or long-term renal dialysis. The daily numbers of reported new cases have steadily decreased since they peaked on 22 May. Investigations by the German authorities indicate that the vehicle of the bacterium responsible for the outbreak, enteroaggregative verocytotoxin-producing E. coli is sprouted beans and sprouted seeds. German authorities have stated that they had identified the contamination source as being vegetable sprouts from an organic farm in Lower Saxony, northern Germany. The farm cultivated sprouts from a variety of products including lettuce, azuki beans, mung beans, fenugreek, alfalfa and lentils. It has been closed and all its products recalled. The Robert Koch Institute has warned people in Germany not to eat raw sprouts of any origin. The last known date of illness onset

in a patient with confirmed E. coli O104:H4 infection was 18 June 2011.

Germany plans to tighten its checks on fresh vegetables and there are calls to speed up laboratory reporting procedures. Consumer Affairs Minister, Ilse Aigner, said she had asked regional authorities across Germany to prioritise checks on growers and importers of bean sprouts, including handlers of imported seeds. Germany has now lifted its warning against eating raw cucumbers, tomatoes and lettuce, but kept it in place for sprouts. The European Commission has offered €210m to European farmers who have seen a dramatic loss of income since the outbreak started in early May. Initially, Germany mistakenly blamed Spanish cucumbers – a move which brought some Spanish vegetable exporters to a standstill.

The latest information on the outbreak can be found at http://tinyurl.com/65dfzss

England: Government backs major changes to plans for NHS reform

Prime Minister David Cameron has agreed to make major concessions on plans for NHS reform in England, but insisted the government had not made a 'U-turn' on policy.

In response to mounting criticism over aspects of the planned Health and Social Care Bill, a comprehensive overhaul of the NHS, the government launched a listening exercise to obtain more views and insight on the reforms on 6 April 2011. At the same time an NHS Future Forum – a panel of experts, set up to "pause, listen and reflect" – was launched. Subsequently, its 45 members attended around 200 events and met more than 6,700 people face to face around England. More than 25,000 people sent their views to the Forum by email, while a further 4,000 sent private comments, completed questionnaires or website responses.

On 13 June the Forum published its recommendations to the Government on the modernisation of health and social care. It made sixteen key recommendations, including that the pace of the proposed changes should be varied so that the NHS implements them only where it is ready to do so, while the Secretary of State for Health should remain ultimately accountable for the NHS. They also recommended that nurses, specialist doctors and other clinicians be involved in making local decisions about the commissioning of care – not just general practitioners (GPs) – but in doing this the NHS should avoid tokenism, or the creation of a new bureaucracy. Competition, they said, should be used to secure greater choice and better value for patients – it should be used not as an end in itself, but to improve quality, promote integration and increase citizens' rights. All organisations involved in NHS care and spending NHS money (regardless of whether public or private sector bodies) should be subject to the same high standards of public openness and accountability.

Ministers have accepted changes suggested by the NHS Future Forum, including more controls on competition and a slower pace of change. The independent health policy think tank, the King's Fund, in their analysis have stated that "the amendments proposed by the government will significantly improve the Bill and it now offers a more promising approach to addressing the challenges of the future." They cautioned however that "despite the headlines generated by the reforms, the key priority facing the NHS remains the need to find £20 billion in productivity improvements to maintain quality and avoid significant cuts to services. The uncertainty of the past few months has caused instability within the NHS at a time when it faces significant financial and operational difficulties. The government must now provide the direction and stability the NHS desperately needs to navigate the challenging times ahead".

Commenting on the government's planned changes to the Health and Social Care Bill for England, Dr Hamish Meldrum, Chairman of Council at the British Medical Association (BMA) was cautious, stating that "we are pleased that the government has accepted the Future Forum's core recommendations, and that there will be significant revisions to the Health and Social Care Bill. We will need to look carefully at the details of the changes, but it seems clear that what we are likely to see is a very different Bill, and one which puts the reforms on a better track. There is much in the government's response that addresses the BMA's concerns, and many of the principles outlined reflect changes we have called for. The success of the reforms will very much depend on how the various elements link together and work on a practical level, and on how much they engage clinicians and patients locally." He also noted that "hanging over all [the reform process], however, is the fact that the NHS is facing unprecedented financial pressures. The focus on structural reform must not distract us from the task of minimising the impact of funding cuts on care."

The NHS bill will now go back to the committee stage in the House of Commons to be scrutinised again by MPs before going through its House of Lords stages. The NHS Future Forum will continue to lead on listening in the NHS. Among other areas they will focus on education and training; patients' rights; and public health.

The report of the NHS Future Forum is available at http://healthandcare.dh.gov.uk/future-forum-report/

The Government's response to the Forum is available at http://healthandcare.dh.gov.uk/government-response-to-nhs-future-forum/

Russia: Health warnings on abortion advertisements to be introduced

State Duma deputies, worried about a falling birth rate, passed in a third and final reading on 1 July 2011 a bill which introduces health warnings for all abortion advertisements. The amendment to the law on advertising says 10% of the space used in abortion ads must carry a list of possible negative consequences for women, including infertility.

"Advertising of medical services for abortion should not contain a statement about the safety of such medical services," the bill said. Speaking of current advertisements, Deputy Viktor Zvagelsky, a United Russia member of Duma's Economic Policy and Entrepreneurship Committee, said, "these ads make young girls believe they won't have any problems interrupting a pregnancy," RIA-Novosti reported. He said the bill was drawn up because "the situation with abortions in Russia was depressing."

Russia's abortion rates are still among the world's highest, contributing to a fertility rate of only 1.4 children per woman – far below the 2.1 needed to maintain the existing population. A total of 1.5 million abortions were carried out in 2007, similar to the number of children born that year, according to the Duma's web site. The rate has become a serious concern for Russia as it fights to stem a steep population decline.

The United Nations predicts that by 2050 Russia's population will have dropped by almost a fifth from today to 116 million. It has said overcoming racism and taking in

more migrants could help Russia boost its population. Health experts say key factors in the decline are poor diet leading to heart disease, heavy drinking by men, an HIV/AIDS epidemic spurred by heroin abuse and a high number of violent deaths.

The bill is expected to pass the Federation Council and be signed into law by President Dmitry Medvedev without problem.

Meantime in a move supported by the Russian Orthodox church, conservative parliamentarians have announced plans to submit to the Duma draft legislation proposing that the publicly funded health service stop offering abortions altogether, forcing women who want an abortion to pay for one at a private clinic. Such legislation would ban free abortions at government-run clinics and prohibit the sale of the morning-after pill without a prescription, said Duma Deputy Yelena Mizulina, who heads a parliamentary committee on families, women and children. Controversially abortion for a married woman would then also require the permission of her spouse, while teenage girls would need their parents' consent. If the legislation is passed, a week's waiting period would also be introduced so women could consider their decision.

Mizulina said she wants to see public debate on abortions before the bill is submitted to the Duma, an apparent attempt to build support after similar legislation stalled last year. A bill proposed in late 2010 called for the criminal prosecution of doctors who end late-term pregnancies, but it faced government opposition and was never put up for a vote. It was unclear how much support the anti-abortion measures would receive in the Duma.

Spain referred to European Court over reduced VAT rate for medical equipment

On 19 May 2011 the European Commission decided to refer Spain to the EU's Court of Justice concerning its illegal application of a reduced rate of value added tax (VAT) to general medical equipment, appliances to alleviate animals' physical disabilities and substances used in the production of medicines. These goods do not qualify for a reduced VAT according to the rules laid down in the VAT Directive, and the application of a reduced VAT rate may distort competition within the EU.

The VAT Directive (2006/112/EC) allows member states to apply a reduced VAT rate to medical equipment, aids and other appliances which are "normally intended to alleviate or treat disability", and which are "for the exclusive personal use of the disabled". However, Spain applies a reduced rate of VAT to medical equipment for general use and for equipment used for disabled animals and so goes beyond the scope of what is allowed under the EU rules.

Furthermore, although the VAT Directive allows a reduced rate to be applied to pharmaceutical products 'normally used' for health care, prevention of illnesses and as treatment for medical and veterinary purposes, it does not allow a reduced rate for substances used in the production of medicines.

EU legislation on reduced VAT rates must be strictly interpreted and applied in order to avoid competitive distortions within member states and between member states. If a product is not specifically listed in Annex III of the VAT Directive, member states cannot apply a reduced rate to this product (unless they benefit from a particular derogation, which is not the case for Spain).

The Commission sent a reasoned opinion (second step of an infringement proceeding) to Spain on 24 November 2010 requiring the reduced VAT rates in question to be withdrawn. However, as the Spanish authorities have not done so, the Commission has referred the case to the EU's Court of Justice.

Northern Ireland: Suicide prevention funding ring-fenced

On 5 July Health Minister, Edwin Poots, pledged that funding for suicide prevention programmes in Northern Ireland would be ring-fenced. The Department of Health, Social Services and Public Safety currently provides £3.2 million funding per annum to support the implementation of the Northern Ireland Suicide Prevention Plan *Protect Life*. Over £2 million of this budget is allocated to the support of local communities in the development of suicide prevention initiatives. A further £3.5 million per annum is also provided to support the delivery of the *Lifeline 24/7* crisis response helpline.

Speaking during a visit to the Suicide Awareness and Support Group in West Belfast, the Minister said "suicide is an issue that is not going to go away. It presents a complex and deeply concerning challenge for all sectors of our society… I know that there has been a steady upward trend in these tragic deaths despite strenuous suicide prevention efforts by statutory, community and voluntary sector organisations such as the Suicide Awareness and Support Group. This is highlighted in the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness. A report that I launched last week, which aims to improve mental health services in Northern Ireland and help reduce the risk of suicide or homicide by people with mental illness."

Suicide is inextricably linked with deprivation. Rates are twice as high in deprived areas and the gap continues to widen. Eleven of the twenty most deprived wards in Northern Ireland are situated in the North and West Belfast Parliamentary Constituencies.

The report of the Confidential Inquiry into Suicide and Homicide is available at http://www.dhsspsni.gov.uk/suicideandhomicideni.pdf

The Suicide Prevention Strategy 'Protect Life' is available at http://www.dhsspsni.gov.uk/phnisuicidepreventionstrategy_action_plan-3.pdf

Netherlands: Ministry of Health to scrap most translation services

In May Health Minister, Edith Schippers, announced that funding for translation services would be scrapped from 1 January 2012, generating cost savings of €19m per annum. In a letter she stated that patients (or their representatives) should be responsible for their own command of the Dutch language. Government subsidies for interpretation and translation services in health are incompatible with this principle. She suggests that a patient/client can bring someone with them or hire a professional interpreter at their own expense. One exception to the new position is made for health care of female refugees.

An open letter to the minister, signed by 46 international experts on health and migration, urged the government to reconsider this 'backward step', arguing that it would restrict access to health care for many migrants. Poor communication may also be costly, leading to misdiagnosis, non-adherence and drop-outs from treatment. A number of Dutch professional bodies, including the Dutch Medical Association and the Association for Psychiatry have warned that safety, quality and effectiveness of care may be compromised.

The open letter to the Minister of Health, Welfare and Sport is available at http://mighealth.net/nl/index.php/Letter

News in Brief

EU population older and more diverse – new demography report says

The *European Demography Report 2010* reveals Europeans are living longer and healthier lives. Fertility continues to rise slowly, increasing from below 1.45 to 1.6 children per woman. Life expectancy has also been increasing at the rate of 2–3 months every year. It is the main driver of population ageing. However, in four member states (Bulgaria, Lithuania, Latvia and Romania) the population is decreasing rapidly due to more deaths than births and outward-migration.

More information at http://ec.europa.eu/social/main.jsp?catId=502&langId=en

England: Report on health inequalities in London

The London Health Commission has published a report providing an overview of current health inequalities in London, both in terms of health outcomes and key indicators of the wider social determinants of health. It is intended to illustrate the current situation and to stimulate/inform discussion on the focus for future action across London. The emphasis in the report on indicators of the social determinants of health reflects the priority given to the "causes of the causes" in *Fair Society, Healthy Lives*, the report of the strategic review of health inequalities in England post-2010, undertaken by Professor Sir Michael Marmot.

The LHC report is available at http://tinyurl.com/6ddlk6z

New European report on preventing elder maltreatment

Elder maltreatment is pervasive throughout the WHO European Region: at least four million older people are estimated to experience maltreatment in any one year and 2,500 of them will die each year. Most countries have an ageing population, putting increasing numbers of people at risk. A new report from the WHO Regional Office for Europe report highlights the biological, social, cultural, economic and environmental factors that influence the risk of being a victim or perpetrator of elder maltreatment, as well as the protective factors that can help prevent it.

The report is available at http://www.euro.who.int/__data/assets/pdf_file/0010/144676/e95110.pdf

European mortality database updated

The European Detailed Mortality Database (DMDB) has been updated with the latest available data on causes of death. It allows flexible and user-friendly access to mortality data at the three-character ICD (International Classification of Diseases) code level and supplements the European Mortality Database (MDB), which provides mortality data only for predefined, broader and selected aggregates of causes of death. Fifty three country-years of detailed mortality information have been added to the DMDB since the last update, including figures from Montenegro for the first time. The updated database will allow in-depth analysis of more than 185 million deaths occurring in 47 Member States in the WHO European Region over a 20-year period.

The database can be accessed at http://data.euro.who.int/dmdb/

Most hospitals online but telemedicine services not fully deployed

More than 90% of European hospitals are connected to broadband, 80% have electronic patient record systems, but only 4% of hospitals grant patients online access to their electronic records, according to the results of a survey conducted for the European Commission. The deployment of eHealth services in acute hospitals in 30 European countries was examined. Chief Information Officers were asked about the availability of eHealth infrastructure and applications in their hospitals, whereas Medical Directors were asked about priority areas for investment, impacts and perceived barriers to the further deployment of eHealth.

The survey found that European hospitals are more advanced than US hospitals in terms of external medical exchange, but lag behind in using eHealth to view laboratory reports or radiology images. The survey provides useful data for the work of the EU eHealth Task Force on assessing the role of information and communications technologies (ICT) in health and social care, which is due to suggest ways for ICT to speed up innovation in health care to the benefit of patients, carers and the health care sector.

The survey is available at: http://ec.europa.eu/information_society/newsroom/cf/item-detail-dae.cfm?item_id=6952

Help Wanted? Providing and paying for long-term care

Spending on long-term care in OECD countries is set to double, even triple, by 2050, driven by ageing populations. Governments need to make their long-term care policies more affordable and provide better support for family carers and professionals, according to a new OECD report. *Help Wanted? Providing and Paying for Long-Term Care* says that half of those who need long-term care are over 80 years old. The share of the population in this age group in OECD countries will reach nearly one in ten by 2050, up sharply from one in 25 in 2010. This percentage will reach 17% in Japan and 15% in Germany by 2050. Spending on long-term care, which now accounts for 1.5% of GDP on average across the OECD will also rise. Sweden (3.5%) and the Netherlands (3.6%) today spend the most, while Portugal (0.1%), the Czech Republic (0.2%) and the Slovak Republic (0.2%) spend the least.

More information at www.oecd.org/health/longtermcare/helpwanted

Shaping the future of health care in Greece

The global financial crisis has created unprecedented economic and social conditions in many countries, including Greece. Despite the challenges, the health care reforms that Greece is currently undertaking offer an opportunity to achieve short- and long-term improvements in the efficiency, quality, organisation and effectiveness of health care. A conference, "Shaping the Future of Health Care in Greece", took place on 21 June 2011 in Athens. It aimed to evaluate the state of the health care system, health policy and health care reforms, in light of the experience and knowledge obtained from reforms and successful models evolved in European and other health care systems.

Presentations from speakers are available at http://healthcareconference.boussias conferences.gr/default.asp?pid=1&la=2

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