

Gesundheit!

Stockholm Network Health and Welfare Newsletter

Volume 1: Issue 6

Commentary

Crisis Management in Healthcare Policymaking by Helen Disney

Topic of the Month

Financial Crisis and Healthcare in Central and Eastern Europe by Paul Healy

Briefing

Devolved healthcare – the Spanish way by Cristina Palomares

Review

Health Consumer Powerhouse's *Euro Health Consumer Index 2009* by Adrienne Cernigoi

Stockholm Network publications

Biogenerics or Biosimilars? Discussing the Present, Considering the Future

Keeping Medicines Safe – A Study of the Regulations Guiding the Approval of Medicines in Emerging Markets

Commentary

Crisis Management in Healthcare Policymaking by Helen Disney¹

Healthcare policymaking is always a complex process but it might be less so if it were not for the constant need to revise expectations and change plans according to the external environment. “Events, dear boy, events” as Harold Macmillan would have put it. Doctors and nurses are trained to deal with crisis and to think and act quickly in emergencies but what about healthcare policymakers and managers?

The past couple of years have brought more crises than usual, with the most obvious of course being the global financial crisis which is now hitting hard, forcing a slowdown of reform. Governments are now starting to make tough cuts to the public purse and consumers who have lost their jobs or seen their savings fall in value feel less able to pay out of pocket for private treatment as well. Health budgets are feeling the pressure and the winners will be those who manage to find clever ways to innovate or save money. Nevertheless, sacrifices will almost certainly have to come be it job cuts, further rationing or longer waits for treatment.

In this issue Paul Healy looks at the impact of the crisis on Central and Eastern Europe which once held out the hope of becoming a reform

model for other parts of the world but which is now suffering some serious setbacks as a result of the downturn.

Moving southwards, Cristina Palomares describes and summarises the workings of Spain’s healthcare system and its experiment with devolution of healthcare to the regions. While the experience of local healthcare appears to be popular with some, Spain, like the UK, has as yet failed to grasp the nettle of funding reform – so do healthcare vouchers provide the key to the future?

For consumers, mostly unused to using any healthcare system other than their own, it is hard to find out or assess whether other countries’ systems are really any better. Adrienne Cernigoï takes a peek at the findings of the latest *Euro Health Consumer Index* to find out some answers.

Ultimately the success of healthcare policymakers has to be judged on the healthiness of the populations they serve – but as we wait for an improvement in our financial health, learning to react to and manage crisis may come to be the most important skill of all.

¹ Helen Disney is chief executive officer of the Stockholm Network.

Topic of the Month

The Financial Crisis and Healthcare in Central and Eastern Europe by Paul Healy ¹

Almost two years ago, the Stockholm Network launched a new initiative which focuses on healthcare reforms in Central and Eastern Europe (CEE). The CEE Ahead project aims to identify examples of best practice in healthcare reform, while monitoring the progress that has been made, and which could be made in the long-term towards modern and financially sustainable healthcare systems.

Certainly, significant progress has been made by CEE countries, and patients in the region now benefit from greater choice and empowerment, as well as notably improved health outcomes. The Soviet Semashko system was supposed to create justice and equality, by allowing every person to have the same healthcare rights, whilst imposing an obligation upon the state to provide decent services to every citizen.

However, in practice, this was never the case. Instead the system was too rigid, unable to control rising expenditure and powerless to prevent the inevitable, growing gap between demand and supply.

Ultimately, healthcare became unequal as higher quality services were reserved and accessed unjustly by a privileged few. In particular, the Semashko system in the CEE region could not deal with complex conditions such as cancer and cardiovascular diseases, and the inequality of services led to large waiting lists and an environment of corruption and informal payments.

Reform

The speed at which CEE countries reformed their healthcare systems following the fall of the Soviet Union showed how unsatisfied people had become with the Semashko system. Instead, policymakers were calling for a move towards Bismarckian healthcare reforms which had succeeded in improving health conditions for many Western European countries.

Up until the start of the financial crisis, healthcare reform in the CEE region, whilst undertaken in different ways and with different emphases, had succeeded in bringing about a new mindset, attitude and resolve among CEE policymakers with regard to the design of modern, patient-centric and sustainable healthcare systems. The improvement in health outcomes and increased public satisfaction had encouraged policymakers to be bold and it was

hoped that CEE systems could eventually seek to compete with, and perhaps even surpass, the healthcare systems of the more established European economies.

Financial Crisis

Unfortunately, the global financial crisis has caught many policymakers by surprise and in the CEE region the disturbance is acute. Many CEE countries had become confident reformers, encouraged by significant improvements and considerable investments. Large current account deficits had been tolerated because of high foreign investment, which gave rise to public spending sprees that have been described as a “released prisoner having access to a limitless credit card”². Dried up investments mean the CEE region is less able to maintain such spending levels and their degree of indebtedness looms over their ability to face future healthcare challenges.

CEE health systems are under severe financial pressure and unable to sustain services within the current context of funding. Systems are heavily indebted and governments are struggling to find additional funding revenues. Inevitably, this is leading to citizens paying more for their healthcare, whether it is through informal payments, formal payments, higher premiums, or an increase in general taxation, whilst

services in the future will probably deteriorate regardless.

If CEE governments expect their healthcare systems to perform better with less funding, they will be asking a great deal of a healthcare workforce that is largely unhappy and resistant to further rounds of cost cutting. Furthermore, demands for higher pay are likely either to place a greater strain on the country’s fiscal budgets, if submitted to, or to place a greater strain on the government’s political standing if resisted. For patients, the likely consequence is that they will have to bear the brunt of an unhappy and underpaid workforce that is refusing to work, working to rule, or trying to supplement its wages with informal payments.

Whilst the financial crisis will not have a dramatic effect on long-term demographic shifts in the CEE region, it will certainly place CEE governments trying to tackle this shift under significant pressure. The CEE region is ageing and will continue to age incrementally over time. Each year that passes sees a greater pressure being placed on the working population to fund the current healthcare needs of the elderly. It is vital therefore that each CEE country maximises the number of people in work.

Overall, it is clear that the major healthcare challenges in CEE countries are made harder and more daunting within the context of the financial crisis, especially since health systems in the CEE region are still connected, either directly or indirectly, to the government budget. The cost of healthcare has certainly risen gradually over the last 19 years, yet there has not been a particularly dramatic rise in the last few years because of the financial crisis. Rather than there is now less of a tolerance for it because the government has less money to spend.

Up until recently, governments have allowed healthcare spending in the CEE region to spiral and are only now facing the financial reality of attempting to provide healthcare to all of their citizens. The financial crisis is raining down on the public purses of CEE countries and governments are struggling to provide adequate shelter for their citizen. New ways of providing healthcare in the region need to be considered to allow it to “weather the storm”.

Weathering the Storm

Although private healthcare industries are more widespread in the CEE region now, there is still a dominant government presence in both the funding and provision of health services. There is also still resistance to the concept of using the

private sector, highlighted by Poland’s President Lech Kaczynski’s recent veto of proposals, which would have allowed hospitals to operate on a more commercial basis by taking loans to improve their facilities and services, because they were too “free-market”³.

President Kaczynski’s argument was that privatisation in Poland’s health system would harm the poor and elderly. Yet this fails to appreciate that allowing more private services can help to alleviate pressures on public spending that should be dedicated more specifically to vulnerable people, such as the poor and elderly. Broad health spending cuts hurt everybody’s health services and it will be the more vulnerable people that will find it harder to deal with these cut backs, rather than those with greater access to their own finance.

More public-private partnerships in the CEE region would allow for greater patient choice and empowerment, whilst maintaining a role for the state in healthcare services. Public-private partnerships are in effect business arrangements between the government and a private sector provider. These arrangements not only contractually obligate the private company to provide a service, but also force public providers to be clear on their objectives within the partnership, thus creating a new level of discipline for all providers.

In 2003, Romania underwent a private-public partnership in order to deal with an increase in demand for outpatient dialysis services. In doing so, the National Health Insurance Fund (NHIF) awarded service contracts for eight separate dialysis centres that provided outpatient services for patients in eight different public hospitals. The contracts were granted through a public tendering process and the private operators were also made responsible for renewing all the equipment and renovating the facilities as part of the agreement. By 2006, €12.4 million had been invested by the private partners and the NHIF had saved an estimated €4 million per year. Overall, the quality of service had improved at a lower cost to the public purse⁴.

The argument that healthcare is too important an industry to be provided by the private sector does not wash, as it is precisely because healthcare is so vital that it should no longer be provided purely by governments in such a one-size-fits-all way. The health of people is something personal to them and will depend on a variety of genealogical, environmental and behavioural factors, yet so many healthcare systems meet this diversity with uniformity.

Providing patients with choices empowers them to direct how their health services are supplied and causes the providers of such services to fit

around these choices, and thus around the patients needs. One of the most effective ways of doing this is to institute an enhanced health insurance system that further empowers its users. Such a system should provide for a greater degree of competition, not least between healthcare providers from both the public and private sectors.

The CEE region provides an opportunity for these reforms to develop and the financial crisis could very well be the best juncture at which to begin. The problem will be finding the political will to do so as such a move is likely to be strongly resisted by voters.

¹ Paul Healy is a policy analyst at the Stockholm Network.

² David Roche in "Eastern Europe and the Financial Crisis" in *the Wall Street Journal* (28/03/09). See <http://online.wsj.com/article/SB123819932316462089.html> (Accessed on 01 Jul. 09).

³ "Polish president vetoes health reform plan" in *Reuters* (26/11/2008). See <http://www.alertnet.org/thenews/newsdesk/LQ231766.htm> (Accessed on 19 Aug. 09).

⁴ Health, Nutrition and Population. *Public-Private Partnerships and Collaboration in the Health Sector* (2006). See <http://siteresources.worldbank.org/INTECAREGTOPHEANUT/Resources/HNPDiscussionSeriesPPPPaper.pdf> (Accessed on 23 Nov. 09).

Briefing

Devolved healthcare – the Spanish way by Cristina Palomares¹

Background

The right of the Spanish people to have access to healthcare was dictated by the Spanish Constitution of 1978 and later articulated in the General Health Bill of 1986. Since the approval of the Bill, Spanish citizens have enjoyed universal and free (at the point of use) access to healthcare².

The Spanish health system, which is financed through taxation, includes foreign residents who are registered in the Spanish social security system and covers 60 per cent of the cost of medicine (the remaining 40 per cent is paid by the patient) in most cases. However, medicines prescribed by doctors working for the national health system are free of charge for pensioners.

As a nation, Spain is made up of 17 Autonomous Regions or Communities (AC), all of which enjoy a large number of devolved powers, including that of healthcare. From 1981 until 2002, different central governments

administered the transfer of health responsibilities to seven of the 17 Spanish AC.

Of the first seven, five became politically accountable for healthcare services (Catalonia, Galicia, Valencian Community, Canary Islands and Andalusia) but only two (Basque Country and Navarre) also became fiscally accountable. The remaining 10 regions (Madrid, Castilla-Leon, Castilla-La Mancha, Murcia, Extremadura, La Rioja, Aragon, Balearic Islands, Asturias and Cantabria) were dependent on the *Instituto Nacional de la Salud* (INSALUD) based in Madrid, until 2001, when devolution was finally completed. From then on, the INSALUD became the *Instituto Nacional de Gestión Sanitaria*, an administrative centre within the National Health Service, also in charge of the health services in the autonomous cities of Ceuta and Melilla.

From 2002 onwards, the Spanish health system therefore became a decentralised system; in fact, Spain is now a country with 17 different health systems. The State, however, has retained the powers of (i) overseas-related healthcare activities³, (ii) basis and general coordination of healthcare, and (iii) legislation on pharmaceutical products⁴. The management of the health budget is the direct responsibility of the AC, although their fiscal capacity varies from region to region.

Health problems are now dealt with at regional level, making the system more efficient, and each AC is now free to implement the system they consider most appropriate for their population and their needs. Yet, the system is not short of criticism.

Some find that devolution has multiplied the amount of regulation and management of services (including 17 regional agencies for the evaluation of health technology) and has diminished economies of scale⁵.

From some patients' point of view, devolution has also brought inequalities into the system. The last 10 AC to become responsible for the administration of their healthcare systems have found it hard to catch up with the efficiency and level of service of the other five regions which have had much more experience in the area.

Resources for funds are also different in each AC. After devolution in 2002, bargaining for funds lay in the negotiations between regional and national finance ministers, as the main source of funding⁶.

Public, Private or both?

In 2007, Spain's total health expenditure represented 8.5 per cent of GDP, below the

OECD average of 8.9 per cent - of which 71.8 per cent corresponded to public expenditure⁷.

According to OECD data, despite the low level of expenditure, Spain has a higher than average number of doctors (3.7 practising physicians per 1,000 inhabitants in comparison to the OECD average of 3.1) but less qualified nurses (7.5 per 1,000 inhabitants in comparison to the OECD average of 9.6) and a lower number of hospital beds (2.5 per 1,000 inhabitants in comparison to the OECD average of 3.8)⁸.

In total, the Spanish public healthcare sector has an extensive network of 804 hospitals and 160,981 beds; 2,879 *Centros de Salud* or Polyclinics; and 8,311 *Consultorios Locales* or Local Surgeries⁹. In total, the public sector owns two-thirds of the total hospital beds in the country. The rest are part of the private sector which is made up of the Church, the Spanish Red Cross, and private charities as well as for-profit organizations¹⁰.

Many AC have signed agreements with private providers such as local hospitals, specialised clinics, etc. in order to alleviate the long waiting lists found in the public sector and to provide a more efficient service to patients, especially those with urgent and/or special needs. In Madrid and Valencia, for example – both currently run by centre-right governments -

some public hospitals have a combination of public and private administration, while other public hospitals are entirely privately managed. In general, the result has been more efficiently run hospitals.

Private healthcare in Spain is used by one sixth of Spaniards¹¹ either as a complement or as an alternative to the public healthcare. This system is funded either by personal insurance, direct payment from patients or agreements with individual AC and the central administration. In the latter case, 2.5 million out of more than 9 million private healthcare users are civil servants¹².

Some departments of the public administration have signed agreements with various insurance providers enabling them to offer their employees (civil servants) the option to choose either a public or private healthcare plan; an overwhelming proportion – between 83 and 87 per cent - choose the private system¹³. This privilege has raised complaints among other public sector workers who would prefer to opt for a private healthcare plan if they were also given the option.

Privately insured patients seek to reduce their waiting time to see a family doctor or a consultant and also to have a test or an operation done. Unlike countries such as the

UK, access to a private general practitioner (GP) or even a consultant is direct – there is no “gatekeeper” function. Privately-insured patients do not have to go through their assigned public family doctor to be referred to a private service. This system reduces the administrative burden on already overwhelmed GPs working in local surgeries.

New challenges

For both the government and the opposition an institutional consensus on health among the seventeen Spanish regions – the so-called *Pacto por la Sanidad* or Health Pact – seems to be essential to guarantee equality, quality, innovation, cohesion and sustainability in the system for the entire population. For the opposition People’s Party, especially, the place of residence should not define the quality of healthcare patients receive¹⁴.

Despite the financial crisis and the budget cuts in the administration, the Socialist government has recently declared that the departments of education and health will not be affected¹⁵. But it is not so much about not cutting the budget.

According to experts asked for their opinions by the daily *El Mundo*, Spain’s healthcare system is in need of deep structural reforms especially in areas such as sources of funding, the role of

consultants in health management and the incorporation of new technologies. Also, the financial crisis urges policy makers to think about whether the current system will be sustainable in the near future. In that respect, experts demand an analysis of the Spanish health system from two perspectives: demand for services and distribution of funding¹⁶.

Indeed, an increase in demand for services is mainly due to the staggering increase of the Spanish population: from 39,852,651 in 1998 to 46,157,822 in 2008¹⁷, and also to a growing ageing population, which in itself requires more money and new services.

Furthermore, according to the European Union, the Spanish are among the Europeans who visit their doctors most often: an average of 9.5 times per patient per annum. Financial measures, such as a co-payment system for some services, have been regarded by some experts as a possible solution to that problem¹⁸.

The director of the Instituto de Estudios Economicos, Juan Iranzo, however, does not support this solution. Iranzo supports instead the idea of a “health cheque”, or health voucher because “it is not profit-oriented but it aims to make better use of the resources”. Unlike co-payments, a health cheque would “introduce

competence [in the service] and the capacity of choice for the patients”.

Iranzo also declared during the recent meeting of the World Forum Soria 21, that the Spanish health system is “unsustainable”. Although he believes that the current system “cannot be financed with the existing structural debt” in Spain, he believes that it is the universalisation and the cost of health-related services which makes it unsustainable. Iranzo argues in favour of a clear definition of what public health can cover and also for the introduction of private management¹⁹.

Conclusion

The Spanish healthcare system is a puzzle made up of seventeen different systems accessible to all citizens at no direct cost (at the point of access). Changes in the demographic and social patterns as well as a critical financial situation, however, mean that the system as it stands is not sustainable. It is great news that the Spanish population is growing and also living longer but the current system therefore cannot deliver quality of service and must adapt to recent developments.

Structural reforms are urgently required to address the problem of greater demand for services and distribution of funding. Proposals

like the introduction of the health cheque and of private management are food for thought for Spanish decision-makers concerned with the future health of the nation.

¹⁹ “El actual sistema sanitario español es “insostenible”, según expertos reunidos en el Foro Soria 21”, in *Europa Press*, 26 October 2009. See, <http://www.europapress.es/epsocial/rsc/noticia-actual-sistema-sanitario-espanol-insostenible-expertos-reunidos-foro-soria-21-20091026145205.html> (accessed 29 October 2009).

¹ Cristina Palomares is chief operating officer of the Stockholm Network.

² Excluding simple extractions, dental services or plastic surgery for cosmetic purposes are some of the few services not covered by the public healthcare system.

³ Overseas-related healthcare activities are all those related to monitoring and controlling potential health risks arising from the importation, exportation or transit of goods, and international travel.

⁴ For a definition of the State duties in health issues, see:

<http://www.msps.es/en/organizacion/consejoInterterri/introduccion.htm> (accessed 26 October 2009).

⁵ Beatriz Gonzalez Lopez-Valcarcel and Patricia Barber Perez, “Beneficios, costes y riesgos de la descentralización sanitaria en España”, in *Referent No.3*. 2008. See www.uch.cat/index.php?md=documents&id=1928&lg=esp p. 7. (accessed 27 October 2009).

⁶ Costa-i-Font, Joan and Lopez-Casasnovas, G. and Planas, I. “Diversity and regional inequalities in the Spanish system of health care services”. *Health economics*, 14 (S1) 2005, p. 11.

⁷ OECD. *How does Spain Compare*. .OCED Health Data 2009. See <http://www.oecd.org/dataoecd/46/7/38980294.pdf> (accessed 27 October 2009).

⁸ Ibid.

⁹ Spanish Ministry of Health. See <http://www.msps.es/ciudadanos/prestaciones/centrosServiciosSNS/hospitales/busquedaCA/frmBusquedaCA.jsp> (accessed 13 October 2009)

¹⁰ Eunice Rodriguez, Pedro Gallo de Puelles and Albert Jovell, “The Spanish health care system: lessons for newly industrialized countries”, in *Health and Policy Planning*; 14 (2), 1999, p. 168. See <http://heapol.oxfordjournals.org/cgi/reprint/14/2/164.pdf> (accessed 26 October 2009).

¹¹ Costa-i-Font and Lopez-Casasnovas, 2005, op.cit. p. 6.

¹² Figures for 2005. See http://www.consumer.es/web/es/salud/atencion_sanitaria/2006/04/21/151171.php (accessed 13 October 2009).

¹³ Gabriel Calzada, Sanidad nacionalsocialista, Libertad Digital, 1 Febrero 2009. See, <http://www.libertaddigital.com/opinion/gabriel-calzada/sanidad-nacionalsocialista-47573/> (accessed 27 October 2009).

¹⁴ *Presupuestos generales del Estado, 2009*. Ministerio de Economía y Hacienda, Gobierno de España, p. 11. See http://www.sggp.pap.meh.es/Presup/PGE2009Ley/MaestroDocumentos/PGE-ROM/doc/1/3/23/3/1/N_09_E_R_31_126_1_2_D_1.PDF. See also the health policy of the opposition People’s Party in their webpage, http://www.pp.es/nuestras-ideas/sanidad_54.html (accessed 26 October 2009).

¹⁵ *El Mundo*, 08/10/2009. See <http://www.elmundo.es/elmundo/2009/10/08/paisvasco/1254996658.html>.

¹⁶ “Radiografía al sistema nacional de salud. La sanidad necesita cuidados intensivos” in *El Mundo*, 08/10/2009. See <http://www.elmundo.es/elmundosalud/2009/10/07/medicina/1254936007.html>.

¹⁷ Instituto Nacional de Estadística. See data in <http://www.ine.es/jaxiBD/tabla.do?per=12&type=db&divi=DPOP&idtab=2> (accessed 26 October 2009).

¹⁸ “Radiografía al sistema nacional de salud”, op.cit.

Review

Health Consumer Powerhouse's *Euro Health Consumer Index 2009* by Adrienne Cernigoi¹

Turning patients into consumers is at the heart of the 2009 *Euro Health Consumer Index* (EHCI), which compares 33 national healthcare systems in Europe. The index measures the most “consumer friendly” healthcare systems that engage patients using the twin instruments of choice and information. This reflects the growing trend in European healthcare towards patient empowerment, giving status to the patient in the system, for example by expressing legislation in terms of patients’ rights. The idea has gained particular traction in the context of EU proposals for cross-border healthcare legislation, which would allow patients to seek treatment anywhere in the EU and be reimbursed by their home country. So, if patients could choose where to receive treatment, where would they go?

By the EHCI’s assessment, the Netherlands should be the first choice. The Dutch system tops the table for the second year, with 863 out of a possible 1,000 points, scoring highly in each category. As the authors of the report state, while excellence in user-friendly healthcare does

not always denote the best healthcare, the indicators used to measure consumer-friendliness are important in judging healthcare service quality.

This explains why the Netherlands (1st) outranks Sweden (9th); although the latter has consistently won the best treatment category, it is hampered by poor waiting times. According to the report, the key to Dutch success is the separation of healthcare financing from healthcare provision; in addition, increased competition among health insurers and competition among health professionals leads to better choice and quality for patients.

While the Netherlands scores well overall, for patients looking for excellence in a particular area the report examines which country performed best in each of six categories: patients’ rights and information (Denmark), e-Health (Portugal), waiting times for treatment (a tie between Albania, Belgium, Germany and Switzerland), outcomes (Sweden), range of services offered (Belgium, Luxembourg and Sweden), and access to medicines (Denmark and the Netherlands).

In the bottom half of the rankings, it seems unlikely that patients would opt for Central and Eastern European (CEE) countries. Bulgaria comes in last, while only Slovenia manages to

slip into the top half of the draw. The report notes that the loss of rank by most CEE countries in this year's index "might be a very real manifestation of the financial crisis", with Estonia a visible victim, as it slips down seven places from its 2008 position.

More worryingly, the index illustrates how the financial crisis has aggravated healthcare inequalities across Europe. Scores from the Czech Republic, Estonia and Hungary have fallen in the waiting time category, compared to the performance of non-CEE countries which was generally better in 2009 than the year before. What is more, the range and reach of services scores for Hungary, Latvia and Slovakia slipped in 2009 while Bulgaria and Lithuania did not perform well in the access to medicines category.

The rather gloomy assessment of the state of CEE healthcare systems taken from overall rankings alone, however, masks more positive progress in the EHCI's headline criterion: consumer empowerment. Despite the parlous state of government coffers, CEE countries such as Estonia, Hungary and Lithuania have managed to prove that it is still possible to improve patients' rights as policies that benefit consumers do not always depend on GDP or involve large increases in health spending.

The report attributes good scores in the sub-categories "healthcare law based on patients' rights", "patient organisations involved in decision making" and "access to register of legitimate doctors" to the more responsive healthcare systems in CEE countries. Here, the CEE region has benefitted from not having a well-established medical system, where the primary loyalty of bureaucrats and medics may end up becoming the organisation they created rather than their patients. In terms of patient rights and information, the CEE outperforms systems in Greece, Spain and the UK.

Patient choice becomes especially important when considering EU cross-border health plans. Proposals adopted by the European Parliament, and subject to member states' negotiations, put patient empowerment at the heart of legislation to allow treatments such as non-hospital care to be received anywhere in the EU without prior authorisation from the home country.

Member states have, however, been wrangling over the detail; such as the power of states to control the flow of patients to their health services. If patients can see that cancer waiting times are much better in Germany than in the Czech Republic, how can the German authorities stop their service becoming overwhelmed? Health tourism can also work in reverse: if Croatia joins the EU, why pay the EU

average of €7,000 for a state-of-the-art hip operation, when equally excellent Croatian hip replacements cost €3,000? Smaller member states are also concerned that this will exacerbate the problem of large outflows of patients and medical specialists to other countries.

The EHCI report concludes that if cross-border healthcare becomes a reality, much more attention should be paid to free choice, equal and direct access and reducing the information handicap of the consumer. Arne Bjornberg, research director of Health Consumer Powerhouse, said the league table serves as “a reality check” for governments to benchmark their healthcare against Europe’s best performing health systems. If consumers can start looking beyond their borders, then countries should also look across to their neighbours to make changes that bring them closer to the top score.

¹ Adrienne Cernigoi was formerly a research intern at the Stockholm Network.

Stockholm Network publications

Biogenerics or Biosimilars? Discussing the Present, Considering the Future

The Stockholm Network's health and welfare programme examines healthcare policymaking from the perspective of the consumer, aiming to identify policies which can create a world in which the patient has greater information and choice.

The study of healthcare policy is particularly demanding because the pace of scientific change is now so rapid. Policymakers constantly struggle to make sure they are keeping up with the ever changing developments and that the current legislative and regulatory framework is in line with new thinking.

The development of biological drugs poses one such challenge – a completely new form of medicinal treatment arrives into the marketplace which upsets expectations, changes business models and requires a different mindset to its more straightforward predecessors.

How can patient safety be maximised while not causing undue delays in getting new medicines and treatments to the market? What balance

should be struck between rewarding innovators and allowing competition? How do different jurisdictions handle this problem and is any kind of best practice starting to emerge?

Very few policy papers have yet been written by think tanks on the issue of biosimilars and even less about their impact on healthcare policymaking. This study attempts to explain the background and open the debate to a wider audience as well as to make a series of policy recommendations which we believe are in the best interest of both patients and innovators.

Biogenerics or Biosimilars? examines the various challenges that the advent of biosimilars raises, particularly with regard to the regulatory framework, market opportunities, IPRs and most importantly of all, with regard to public safety.

The paper also takes four of the most relevant pathways as case studies, namely the EU, WHO, Canada and the US (where legislation is still under way), and evaluates in particular whether these pathways have resolved the safety and IP dilemmas.

In summary, the paper presents the following policy considerations for future biosimilar frameworks:

1) Legislation should require a baseline scientific comparison of the biosimilar with the original drug.

2) Based on the differences identified in the scientific comparison with the original biologic, the legislation should identify the level of clinical data that will be needed to evaluate and approve the biosimilar.

3) Legislation should call for post-marketing safety studies in order to monitor any potential differences in safety and efficacy between the biosimilar and original drug that become apparent once a biosimilar enters the market.

4) Legislation should define the standard and criteria for interchangeability of the biosimilar with the original drug.

5) Finally, legislation should provide sufficient incentives to research-based companies via IP protection. It should ensure that patent protection is not eroded with the entry of biosimilars. If appropriate, the term of data exclusivity may be extended. Furthermore, authorities will need to consider the incentives for biosimilar companies and evaluate whether some amount of data exclusivity for biosimilars will be necessary to attract investment, especially given that the cost will probably be higher than with generic drugs.

The above recommendations should allow more clarity and predictability for those wishing to enter the market as well as providing enhanced scientific rigour, in the interests of patients.

Keeping Medicines Safe – A Study of the Regulations Guiding the Approval of Medicines in Emerging Markets

Keeping Medicines Safe attempts to show, firstly, just how serious a threat substandard and counterfeited medicines are to public health and, secondly, to discuss how the regulations of the production, sale and use of medicines can have an impact on the availability of these dangerous drugs.

The paper begins by examining the very nature of medical and pharmaceutical regulations: Why are they necessary? What are the concepts and ideas drug regulations are based on? And what are some of the essential best practices? It moves on then to examine how drug regulations have been designed in a number of countries (China, India, Brazil, Argentina and Turkey) which have experienced problems with substandard and counterfeited drugs. By examining each country separately it finds that because they all faced different sets of challenges, drug regulators and policymakers had responded to them differently. In some cases this had led to positive results; in other

instances the results were less encouraging. The paper's final section provides some concrete examples of the lethal effects counterfeiting and substandard drugs can have on public health and how bad, non-existent or un-enforced regulations can play a serious part in this process.

The evidence from the paper's sample of China, India, Brazil, Argentina and Turkey shows that while the problems of substandard medicines and counterfeiting are widespread they also affects countries differently. The specific problems each individual country has to grapple with, depends on the legislative, regulatory, cultural, and socio-economic policies and make-up of that country. As such there are no easy or quick fixes. Some problems can be addressed relatively easily, while others require hard thinking, large resources, and national – or even international – coordination.

The paper makes the following policy recommendations which are divided into two categories: general recommendations valid for all countries, and some country-specific recommendations.

General Policy Recommendations

Recognise the problem. Governments in all countries (and across the world) must

acknowledge the extent to which the production of substandard drugs and counterfeiting is a real threat to public health and safety. This is the first step towards action.

There must be a better understanding at the regulatory, policy and public level of the differences between substandard and counterfeited drugs. While the effects of the two are often similar – detrimental and sometimes lethal health outcomes to patients – their causes are not always the same. Counterfeiting is the deliberate production of illegal, unsanctioned and mostly harmful medicines. Substandard drugs, by contrast, can be produced, sold and distributed by completely legitimate and authorised entities who are often unaware of their product being (or becoming) substandard.

Country-Specific Policy Recommendations

China: China must do better at implementing its existing regulatory framework. While resources for the SFDA have been increased and there is improvement in national and international coordination, Chinese regulators and policymakers must make enforcement a greater priority.

India: Indian drug regulations are highly disparate, inefficient and not well-enforced.

Regulations should be streamlined and a clear regulatory framework and source of authority should be established. The current split between central and provincial functions does not foster efficiency or effectiveness. The resulting provincial and regional differences of rules, regulations and enforcement are at the heart of India's difficulties with substandard and counterfeited medicines.

Brazil: Like China, Brazil's enforcement mechanisms and authorities need to be strengthened. Legislation introduced in 2003 to effectively outlaw similars by 2015 is a step in the right direction, but the long time frame leaves many potentially dangerous drugs in circulation.

Argentina: Unlike Brazil, Argentina has not addressed the existence of non-bioequivalence tested similars and should do so. ANMAT should also introduce a more comprehensive system of pharmacovigilance which increases the burden of reporting onto health professionals.

Turkey: Regulations of pharmacists and pharmacovigilance must be improved and implemented more effectively on the ground.