Perspectives on pharmaceutical policy

Reforming EU health competence: framing the discussion

Sustainable development
Health Impact Assessment in Sweden
The politics of waiting lists
Patient-physician communication in the Czech Republic
Europe at the crossroads

In this issue of Eurohealth perspectives on two important issues affecting European health policy are presented. The first of these concerns potential Treaty reform, as well as examining ways in which to improve existing arrangements. Current discussions on reform of the Treaty are taking place in a very different context to those faced in Amsterdam in 1997. The existing Treaty contains a commitment to contribute towards attaining a high level of health protection, but the impact of the EU health policies can now be felt far beyond the confines of public health. Often however these impacts are unforeseen and not taken into account when drafting Directives. Furthermore increasingly judgements at the European Court of Justice, applying existing Treaty principles on the operation of a single market, are influencing the ways in which health care systems across Europe operate, regardless of the long standing principle that responsibility for health care rests with the Member States.

Paul Belcher et al suggest a number of potential areas to explore in addition to Treaty revision in order to move towards developing an appropriate framework for health policy in Europe. This includes the increased use of the open coordination method. They also discuss the balance between the internal market and social objectives such as health. Philip Berman in his article reflecting on potential Treaty revisions refers to the need to consider the guiding principles underlying all European health care systems: universality, solidarity and equity, and argues that given the two divergent objectives of improving the operations of the internal market and ensuring social protection, it may be an appropriate time to reintegrate the Health and Social Affairs DGs.

In this issue there are also a series of different perspectives reflecting on developments in pharmaceutical policy across Europe. Recently the European Parliament debated the Pharmaceutical Review, notably voting against one key aspect allowing for very limited direct to consumer advertising of prescription medicines in a small number of disease areas. A separate development has been the first report of the European Commission’s High Level Group on the Innovation and Provision of Medicines (G10). The group put forward 14 recommendations intended to help improve the competitiveness of the European pharmaceutical industry and foster innovation, whilst being mindful of the need for industry to meet public and social objectives. The group is scheduled to meet again in April to review progress. Contrasting perspectives from the pharmaceutical industry, consumers, the European Parliament, health care policymaking and academia on aspects of both these initiatives are presented.

Finally this issue of Eurohealth contains two new features: a web watch providing information on useful web sites, and secondly a new publications page. I hope that you will find this information of interest, and will submit suggestions for web sites and new publications that may feature in future issues.

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Health Impact Assessment (HIA) is a method for predicting the potential health consequences of political decisions. The main purpose of HIA is two-fold: to increase awareness of what determines health for sectors outside the health sector and also to provide policy-makers with a more efficient way to make informed decisions. Many countries are already looking at the potential health consequences before making decisions, but HIA provides a systematic approach to predict and estimate the potential impact. This approach usually involves developing a tool and checklist, to screen and analyse potential health impacts in an organised fashion.

The aim of this study is to present current developments of HIA at a national level in Sweden and to introduce preliminary results from a screening process of governmental inquiries (directions to green papers) for all ministries during 2001 and 2002. Screening these inquiries provides a good opportunity to access the decision making process at an early stage long before any proposals and white papers are produced. A full report from this process will be published during 2003.

Many organisations and countries have emphasised the need to develop and use HIA. In the international arena, organisations like the EU and WHO have explicitly promoted HIA as a method of estimating the potential health impacts of different policies and many countries are in the process of implementing HIA at the national and regional level. From 2003 impact assessments are gradually being introduced to policy areas covered by the EU’s competence, among them the area of public health. A variety of implementation methodologies have been developed such as Environmental Impact Assessment (EIA), Strategic Impact Assessment (SIA), Human Impact Assessment and the Integrated Impact Assessment (IIA). Several countries have combined HIA with EIA, mainly because EIA is a well-known concept with established methodology for predicting the environmental impact of different policies.

HIA as a method and process
Generally, HIA methodology can be divided into two parts; first considering how a document (policy, project, program etc) will impact on the determinants of health and second how these determinants, in turn, will affect population health. To conduct a HIA, it is thus necessary to possess knowledge on health determinants and their relationship with health outcomes, as well as data on the distribution of the determinants in the population. Ideally, the results of the HIA should therefore be estimated for the whole population as well as by gender or vulnerable groups.

Conducting a HIA entails four distinctive steps: screening, scoping, appraisal and evaluation. The first step is concerned with document selection and the screening process. A checklist has to be developed based on certain criteria considering possible changes in health outcomes as a consequence of a proposed policy. These criteria are often based on health determinants and take different population group characteristics into consideration. Scoping deals with issues such as when in the policy process HIA should be conducted, by whom and how this should be performed. The appraisal phase constitutes the actual assessment, which can be performed at different levels of depth (a rapid assessment or more in-depth analysis), and the evaluation process should appraise the process itself, i.e. how well the assessment worked and if it has led to any changes in policy or the policy proposal.

HIA in Sweden
In Sweden, a systematic HIA approach at the local and regional level has been developed and occasionally implemented. The Swedish Federation of County Councils and the Association of Local Authorities
started to develop a tool for HIA in the mid 1990s. The tool is divided into three parts; “the health question”, “the health matrix” and “the health impact analysis.” Half of all county councils and one sixth of local authorities are using or are in the process of introducing HIA, and a recent evaluation of this HIA approach found that both civil servants and politicians were pleased with the way the process was working.

The first HIA at a national level was conducted in 1995 when Sweden joined the European Union. The HIA assessed potential public health impacts in Sweden of the introduction of EU regulations concerning trade in alcoholic beverages. A second major HIA concerned the health impacts of the EU Common Agriculture Policy. Since then several HIAs have been performed at the national level, e.g. the effects of an age limit on the sale of tobacco. However, these HIAs were not performed in a systematic way, and the outcomes were not always expressed in quantitative terms.

An initial investigation in 2001 to study the implications of using HIA at this level led to the conclusion that the HIA implementation process requires more evaluation in practice.

The screening process

The first step towards implementation of HIA as an integrated part of policy making has recently been taken in Sweden. This obligation is further emphasised in the recent white paper on public health, presented to Parliament in December 2002, and currently passing through the legislative process. The aim of the present study at the National Institute of Public Health (NIPH) is to develop the screening element of the HIA process; to create a checklist followed by screening of governmental inquiries (from January 2001–August 2002) in the ten principle Ministries (finance; defence; health and social affairs; foreign affairs; environment; communication, industry and employment; education; justice; culture and agriculture). The reason for choosing governmental inquiries was to try to enter the decision making process at an early stage. Preferably, HIA should be conducted during the process of proposal development in order to have a fair chance of impacting on the policy maker and policy development. The criteria for governmental inquiries are publicly available at www.regeringen.se and are thus appropriate for systematic screening.

The principle aspects of screening were first to determine the main criteria (based on determinants of health and differential characteristics of population groups) to efficiently screen potential health consequences. Second, to decide how best to use the criteria regarding equity and gender issues.

It was important to look at the determinants of health and health outcomes, as well as how different population groups could be affected by a change in the proposed policy. The proposed national public health goals are based on the major health determinants and were identified by a parliamentary committee (1997–2000) (Table 1). To estimate the potential health impacts on the population, screening examined the whole population as well as looking at gender and vulnerable groups (Table 1).

Preliminary results

Preliminary results of the present study indicate that approximately one third of all governmental investigations ought to include a HIA. This is based on the
assumption that if one or more health determinants were affected by an inquiry then HIA should be conducted. Most governmental inquiries were undertaken in the Ministry of Industry, Employment and Communication, Agriculture, Environment, and Finance. However, resource constraints mean that it will not always be possible to conduct a HIA, and therefore it will be necessary to prioritise inquiries. At a later stage of the HIA, it will be useful to use the additional criteria disregarded earlier in the checklist such as “type of policy?” “are the effects of the policy direct or indirect?” and “are there short or long run health consequences?” Use of these criteria will help select inquiries with the largest potential health impact.

Using health targets as the main criteria on the checklist proved to be very useful, as these goals are based on the main determinants of health. The most frequently used targets in the screening process were participation in and influence on society, economic and social security, and healthy working life. These three goals are very broad and consist of several sub-targets and therefore are often affected by policy proposals. Moreover by including such health targets in a screening tool their use can be evaluated. This use of targets in a HIA can provide information about if and how the targets are regarded in policy proposals, and in which Ministries.

The screening process was not considered to be difficult, but tricky. A necessary requirement for the screening process was the formation of a HIA core group. This consisted of a number of experts from the NIPH with different backgrounds. The core group screened some of the inquiries, making it possible to discuss general aspects of the process and suggest improvements. It was important to reach consensus when there were doubts as to whether certain inquiries necessitated HIA. A core group such as this appears to be essential for a successful HIA process.

Conclusion

HIA is not a discipline or a subject of in its own right, but more of a systematic process for predicting changes in population health status as a result of a specific policy proposal. The aim is to place health on the political agenda of all governmental departments and provide policy-makers with better information. The development of a more regular and systematic HIA has just begun in Sweden and elsewhere, and it is important to continue analysing this process. The next step as mentioned earlier is to set the conditions on how to prioritise among inquiries that led to a HIA, and with this knowledge, move on to the scoping and appraisal stage. In 2003 the NIPH will present the study to the Ministry of Health in Sweden, and working together to set the direction for the future work of HIA in Sweden.

REFERENCES


“Approximately one third of all governmental investigations ought to include a HIA”