

Case-study 8.2.1

The health impact of European single market legislation

Mike Joffe and Sofie De Broe

Aim

To investigate the possible health impact of internal market legislation in the European Union

Objectives

- To investigate the health impact of European Community policies that are relevant to the free movement of goods
- To develop the methodology of health impact assessment in this context
- To establish a European network of relevant expertise

Specific topic areas for work

- Pharmaceutical products
- Medical devices
- Dangerous substances and preparations
- Foodstuffs
- Fiscal policy

Background

In preparation for the completion of the single market, much of the work was motivated by considerations of health.

Underlying concept

The health impact of internal market policies depends on the minimum standard that each European Directive is intended to establish.

The reason for this is that market forces can have a "levelling down" effect. For example, if food hygiene standards were originally higher in one Member State than in the others, it is likely that these higher standards are associated with higher costs. The consequences of liberalising trade in these circumstances are that domestic production will be replaced by cheaper imports produced using lower standards, and producers in the high-standard Member State will be penalised. There will also be negative implications for the balance of trade. However, these consequences could be prevented if a "floor" is set through the specification of a high level of health protection. In addition, the specification of a high level of health protection would ensure that the standards would rise in those Member States that had previously had a lower level of health protection.

Project hypothesis

After the initiation of the internal market on 1 January 1993, standards have risen and become more uniform (except in cases where national derogations have been agreed).

Methodology

1. Analysis of the regulatory systems for each specific topic area
2. Critical review of the existing evidence.

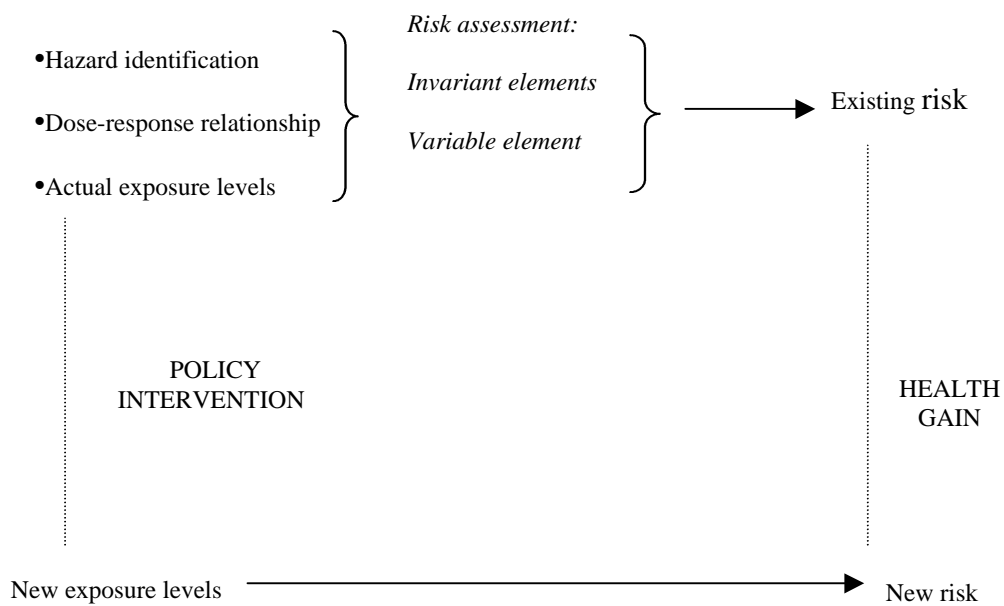
The ideal would have been to assess whether the degree of regulation arising from the policy conferred an appropriate level of health protection according to the evidence. However, the evidence base is slight: little material has been published in peer-reviewed journals. Although there is more information available in the grey literature, this is an under-researched area.

3. Developing a model to assist in assessing health impact

A model was developed to relate pre-existing risks to policy interventions (*see Figure J1*). When working on the specific topic areas, it was found that there are three different approaches that can be taken, which correspond to different points of entry to the model, as follows:

- research-driven approach - that is, working from good-quality data on both the invariant elements of risk assessment (i.e. hazard identification and dose-response relationship), and the variable element of risk assessment (i.e. actual exposure levels), for a particular hazard both before and after policy intervention, it is possible to assess the health gain (i.e. decrease in risk) as a result of policy intervention;
- intervention-driven approach - that is, identifying hazards for which the legal status had changed as a result of EU legislation (i.e. policy intervention), and then relating the change in status to the scientific evidence, it is possible to assess the health gain as a result of policy intervention;
- incident-driven approach - that is, inferring an increase in risk of harm attributable to a particular hazard from a knowledge of incidents that have already occurred, it is possible to assess health gain after policy intervention by monitoring the decrease (if any) in the number of incidents as a result of the reduction in risk.

Fig. J1: Policy/Risk Assessment Model (PRAM)



Results

Pharmaceutical products

It is not clear whether standards will rise or fall as a result of harmonisation. At present regulatory authorities are based at a national level; owing to competition between them for contracts, it is expected that this situation will change and only about five will survive. Moreover, the requirement is for the rapid evaluation of applications for new products (time-frame of typically 210 days), and there is concern about whether it will be possible to maintain a high quality of product review under these circumstances. The consequence is that there is a relation of co-operation between the pharmaceutical industry and the regulatory agencies, which places a heavy responsibility on the peer review process. Furthermore, there are two additional concerns about: (i) the level of secrecy the companies feel they need to impose on the regulatory agencies to maintain commercial confidentiality about new products; and (ii) the lack of attention to need for the product, within the current EU pharmaceutical product regulatory system (essentially an economic-based system). There is now a case for moving to a system that has the rational use of pharmaceutical agents as its basic aim, i.e. the production of new drugs that have a therapeutic advantage over drugs that are already available.

Medical devices

A progressive raising of standards is likely to be the result of harmonisation. In fact, many medical devices have been removed from the market. The resulting benefit of the policy intervention may be quite large, but it is not possible to quantify it because data on previous harm from medical devices is inadequate, a consequence of the previous haphazard system of categorising medical devices. In addition, there does not appear to have been any work done that could be used to assess the public health impact of changes in legislation and practice.

Dangerous substances and preparations

The main aim of the regulatory system is to prevent the occurrence of adverse outcomes. Thus, for this topic area, it is difficult to assess health impact because serious health consequences known to result from exposure to dangerous substances are uncommon, with few specific instances, e.g. asbestos. Nevertheless, it was possible to identify an instance where specific policy intervention has made a difference. In 1997, Germany and Austria reported approximately 1000 cases of children who had been poisoned as a result of drinking the coloured oil from decorative oil lamps. There was one fatality, and many suffered from serious respiratory problems that could be long-lasting. An urgent Directive was issued to ban the use of coloured oil in lamps, together with other measures to prevent further cases of poisoning.

Foodstuffs

In general, the level of protection with respect to food additives has been unchanged or increased in most Member States. It is not possible to define the "best" level of protection because: (i) this judgement involves a trade-off between the benefits of restricting the use of a potentially harmful substance and the benefits of using it, which is indeterminate as they are not measured by a common metric; (ii) the evidence on which to base such judgements is typically incomplete. However, it is possible to detect trends in the use of certain substances as the scientific evidence has evolved, e.g. boric acid has now been restricted in use to sturgeon's eggs, and nisin has been phased out apart from use in mascarpone. With respect to food hygiene, the EU has adopted a comprehensive regulatory regime, by instituting a good infrastructure and good practices throughout the food chain underpinned by the **Hazard Analysis Critical Control Point (HACCP)**. This has changed the orientation of regulation towards consumers rather than producers. There is general agreement that this system is an improvement on previous methods. The underlying intentions are: (i) to make standards similar for trade purposes; (ii) to improve food hygiene throughout the EU. With respect to nutrition, a general view is taken that the consumer can and should decide on dietary composition. Nutritional labelling is compulsory only when a health claim for the product is made. However, it is likely that price and availability affect consumer behaviour more than labelling, especially among those groups in the population who have relatively few resources or low incomes. It would appear that the Single European Act does not provide a suitable basis for policy initiatives in this area, but the health compliance clauses of the Maastricht and Amsterdam Treaties provide an opportunity due to their insistence that all EU policies should ensure health protection.

Fiscal policy

The EU has weaker legal powers in the area of fiscal policy. In the late 1980s, the Community encouraged an increase in the level of taxation on cigarettes, especially in those Member States of southern Europe where tax has previously been low. Data for the years 1988-97 were analysed. It was found that the level of excise duty had greatly increased in the low-tax countries (e.g. Greece, Spain and Portugal), whereas most of the high-tax countries had stable levels with some exceptions, notably the UK. In terms of assessing the impact on health, an increase in tax is not the same as an increase in price. However, if it is assumed that the tax rise is passed on to consumers, the economics literature suggests that for every 1% increase in price there will be a decrease in consumption of 0.3-0.6%, arising in part from some smokers quitting and some cutting down. It is also to be expected that fewer smokers would be recruited from childhood. In a population of about 35 million of whom 28% are smokers, a 5% increase in price (adjusted for inflation) would mean that 1% of smokers would give up, that is, almost 100,000 people would become ex-smokers. A comparable magnitude of reduction would be expected in cutting down, and a fall in recruitment. The benefit to health, after a lag corresponding to the latent period of the various smoking-related diseases, is therefore likely to be large from a price rise of this magnitude. However, there are three adverse consequences from such a price rise. First, as increases in price disproportionately affect people who are unable to quit (who tend to be on low incomes or disadvantaged in some other way), there is a decrease in equity. Second, excise duties have not been raised on other forms of tobacco, which may mean that some smokers switch from manufactured to hand-rolled cigarettes which are more harmful. Third, the loss of market sales in the EU has led to the tobacco industry expanding sales in developing countries. Overall, however, the findings in the area of fiscal policy support the hypothesis that standards have risen, and become more uniform (if standard in this case is taken to mean "those conditions which most effectively promote health", and therefore corresponds to a high price of tobacco).

Project duration

15 months

Source of funding

European Commission

Reference

1. Joffe, M. And De Broe, S. (2000) The health impact of European single market legislation. Eurohealth 5(4); 21-7.

Contact:

Dr Mike Joffe, Imperial College School of Medicine, Department of Epidemiology and Public Health, St Mary's Campus, Norfolk Place, London W2 1PG.

e-mail: m.joffe@ic.ac.uk

© Mike Joffe and Sofie De Broe

Copyright for each case-study belongs to the author(s) or, where appropriate, the health authority or local authority concerned. Permission to quote from this work must be obtained from the authors. Moreover, each author or, where appropriate, the health authority or local authority retains the intellectual property rights (IPR) to the work.