Draft paper: not for citation but comments and criticisms most welcome.

Introduction

This paper explores the new field within European social policy of European Union health policy. My principal aim is simply to identify the main constituent parts of this emerging new policy field. Although a number of social and political scientists have drawn attention to an emerging European Union health policy, this has as yet been the subject of little attention from the legal perspective. Therefore, this paper will focus on the legal construction of the EU’s health policy, paying particular attention to the ways in which legal concepts and mechanisms are contributing to the contours of this new field of EU activity.

At national level, health policy and health care systems are viewed as a central plank of social policy. Health, along with social security, housing, social work and education, is one of the ‘big five’ social services. Health policy may be broadly defined as concerned with all aspects of provision of health care – irrespective of the mechanism by which this is financed – including matters such as regulation of health professionals and producers of medical products, individual entitlements to provision of medical treatment, and protection of public health and health promotion generally. Of course, the determinants of health go beyond the formal provision made for care of the unwell, and include matters such as consumer protection, workplace hazards and general environmental factors. To some extent, these matters can be included within a broad notion of public health protection and promotion.

Health care law is a relatively new discipline, embracing ‘the practice of medicine, but also that of the non-medical health care professions, the administration of health services and the law’s role in maintaining public health’. This definition takes health care law beyond the traditional confines of medical law, which tends to focus upon the doctor-patient relationship. Thus the subject of enquiry is the role of law here.

Social policy in general is increasingly becoming an area in which competencies of institutions at EU and national level overlap. Thus far, the focus of European lawyers interested in the social policy field has tended to be on employment law, although there is now also an increasing interest in social security law. If social welfare law in general is becoming an area of multi-level governance, in which EU-level and national norms combine and interact to create a multi-level policy, then this may also be the case within health care law, as a component part of social welfare law in general. Social welfare provision within Member States of the EU is undergoing a period of reformation, in response to various forces, including globalisation processes and demographic changes. In the 1990s, agency representatives stressed the importance of formal competence to take such actions. Post-1980s health-related policies affected at EU-level, in which EU-level and national norms interact and restructure to create a multi-level policy. This may also be the case within health care law, as a component part of social welfare law in general.

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Article 152 EC

The starting point for an analysis of EU health law and policy is Article 152 EC. Article 152 EC began life in Article 129 EC, introduced into the Treaty of Rome at Maastricht, as the first formal recognition of a specific legal basis authorising the EU to take action within the confines of formal competence to take such actions. Post-1980s health-related policies affected at EU-level, in which EU-level and national norms interact and restructure to create a multi-level policy. This may also be the case within health care law, as a component part of social welfare law in general.

Article 152 EC represents a compromise between those governments of Member States who did not want to establish an effective mechanism for promoting the health service, and those who wanted to go further. The provision was only set as being subject to varying levels of delegation within the overall competence of the 1980s. Article 152 EC thus constitutes a legal representation of such an obligation to take action within the field of public health. Such an obligation is mainly to complement national health policies. The obligations are to continue cooperation between Member States and lend support to their action. However, in accordance with Article 152 EC, Member States are placed under an obligation to facilitate the promotion of respective initiatives and programmes in the relevant areas. It is thus in principle in Article 152 EC that national health policy in those matters covered by the Treaty may not lawfully develop along totally separate national lines, but that some elements of multi-level coordination are required.

Moreover, the obligations in Article 152 EC, Article 152 EC makes provision for EU-level action beyond mere coordination of national policies. Article 152 (4) sets out the procedures by which the EU institutions may act in the health field, and delimit the types of measures that may be enacted. According to Article 152 (4) (a), the EU institutions shall adopt ‘incentive measures designed to protect and improve human health, extending any applicable rules of the law and regulations of the Member States’. However, additional powers to adopt ‘measures’ by implication including harmonising regulations, directives or other acts – in two further areas is added to the pre-Amsterdam wording. These are ‘measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives’ and ‘measures in the veterinary and phytosanitary fields which have as their objective the protection of public health’. Annex II to the Treaty, however, Article 152 (4) (b), however, Article 152 (4) (b), (c), (d) and (e) do not then lay down conditions for the adoption of such measures. These provisions thus lay down the specific conditions for the adoption of such measures. These measures are envisaged: the ‘measures’ of (a) and (b) may potentially include trans-regulatory harmonisation provisions, the ‘incentive measures’ of (c) explicitly preclude such harmonisation. In one sense, these provisions, especially those in Article 152 (4) (b), are not an extension of Community competence, as they refer to areas of well-established EU policy these provisions are extensive (or rather a derogation from) the powers given to the EU institutions in Article 152 EC to effect the common agricultural policy (CAP).
Their inclusion in the Treaty is apparently due to the BSE/CGID crisis. The provision removes from the scope of the CAP veterinary and phytosanitary measures which are primarily concerned with animal health and disease. It is, however, a significant departure from the traditional approach of the Community, which has previously sought to ensure food safety and health protection by means of comprehensive rules and regulations.

The provisions in Article 152 (a) are no longer an extension of the use of the CAP in food safety and health protection. They are intended to prohibit the use of certain measures, such as the application of specific sanitary or phytosanitary measures to the exclusion of other measures, and to clarify the limits of the power of the Commission to adopt measures in this field.

The provisions in Article 152 (b) are also an extension of the use of the CAP in food safety and health protection. They are intended to provide for the Commission to adopt measures to protect human health and animal health, and to clarify the limits of the power of the Commission to adopt such measures, and to provide for the right of the Commission to adopt such measures in the absence of a proposal from the Member States.
seek a narrow definition of the material and personal scope of national law. However, this response is impoverished by its conceptualisation of the social welfare field as being either an EU national field, on the one hand, or a national field within an EU context, on the other. The European Union may be better described as an area of 'multi-level governance'. Although in general, social welfare remains within the competence of national governments, the institutions of the European Union are responsible for some elements of social policy (and, as we have seen, a few elements of health policy).

In practice, therefore, the determination of social welfare policy takes place in cooperation and interaction between institutional actors at both levels.

With regard to national or sub-national social welfare measures, such measures must take place within the EU's system of governance and vice versa. Thus, the 'repetition' argument is unsubstantiated, as it ignores the multi-level nature of the EU's policy, and the practice of policy determination and regulation within and between actors at both levels.

A second type of response appears to be the mirror image of the first. It argues for the EU to develop its own harmonised model of social welfare provision, with the necessary competences to bring it into effect as legislation within all Member States. In its extreme form, this response calls for the creation of a 'European social superstate'.

"At least at present, this may not be feasible for political reasons, or even if it were desirable." However, a modified form of this response recognises the multi-level nature of social policy making, and seeks to articulate a unique 'European' social model within all Community policies. This implication is that this model would underpin social welfare policies emanating from both EU and national levels, thus creating a sufficiently level playing field of competition and scope for free movement of the factors of production to comply with the integration imperatives of the Treaty, while at the same time protecting social rights resulting in the social model in the European social model.

This is the approach promoted firstly by the Delors Commission, then the Treaty amendments to the Single European Act. A number of social policy protections were introduced into the Treaty, as a response to the fears of social dumping, raised by the prospect of the completion of the internal market. Several of these have implications for health care policy. Article 118 EC provided a legal basis for actions targeting illegal dumping of the workplace environment, especially the health and safety of workers. The European Court of Justice has taken a broad view in the application of Article 118 EC, referring to the WHO's definition of health, as 'a state of complete physical, mental and social well-being'. Thus Article 118 (now 173) EC may be used as a legal basis for measures whose principal aim is to protect the health of workers in this broad sense, even where the measure concerned has effects on the establishment and functioning of the internal market.

Article 130 (now 174) EC provided that the Community's environmental policy is to include among its objectives the protection of public health. Most significantly, the new Article 100a (now 95) (3) (E) which specifically provides that the Commission, in proposing harmonisation measures 'which have as their object the establishment and functioning of the internal market, shall act as a base of high level protection in measures concerning health, safety, environmental protection and consumer protection'. Thus, the Treaty also recognises that internal market measures may have an impact on health protection in the Member States, and that the EU's response to this is to preserve the 'European social model' in promoting high levels of protection in these matters.

The strengthening of health into Community policy was brought even more firmly into focus by the Maastricht and Amsterdam amendments to the Treaty Article 3 (p) EEC provides that the activities of the Community shall include 'a contribution to the attainment of a high level of health protection'. This is the first explicit recognition in this part of the Treaty of the Community competences in the field. Article 129 EC included a 'weak mainstreaming' provision to the effect that health protection requirements were to form a constituent part of the Community's other policies, and the second stage of implementing the social model in the European social model.

The implication is that public health interests must now be taken into account when pursuing potentially competing goals in other policy areas. However, the mainstreaming requirement does not extend to a power to use other legal bases in the Treaty to promote public health aims.

In practice, the strengthening element in the development of health protection in the EU is its inclusion in Article 130 (now 174) EC in the UK v Commission, concerning the emergency measures taken against BSE. The UK argued that the measures (banning the export of bovines, meat from bovines and products obtained from bovines liable to enter the animal food or human food chain, or materials destined for use in pharmaceticals or cosmetics) were adopted on the basis of economic measures and the need to reassure consumers and protect the beef market. The Court accepted an inspection of the ban with respect to various products for which the risk of BSE was not established or had been eliminated by national measures. Employment of health protection as a non-economic measure was not acceptable. The Court took the view that the potential serious harm to public health posed by BSE did justify the measures.

In principle, the reasoning was that the protection of public health is a fundamental duty of the EU institutions, which cannot be disregarded in the pursuit of the common agricultural policy. This implicit position was made more explicit by the 'strong mainstreaming' of public health protection in all Community policies, affected at Amsterdam.

### Health protection within Community policies

Thus the EU institutions are obliged to 'mainstream' health considerations in the instrumentalisation of their other policies. Measures with a health objective enounced by the EU institutions, pursuant to these policies, and based on the relevant legal basis provisions of the Treaty, thus have an impact on the determinants of public health and the provision of health care services. If the system is conceptualised as a multi-level system of governance, and approached from the point of view of a multi-level health policy, these measures, though regarded as components of other policies within the construct of Community law, may therefore also be regarded as forming part of the EU's health policy. For this reason, the approach taken in this chapter is to regard health protection as a non-economic measure of non-discrimination for migrant workers. Thus according to Regulation 130 (now 174) EC's concern is to provide health protection against 'social and health mistreatment', but only to 'social security'.

However, this concept includes various health benefits. Title III, chapter I of the Regulations covers the coordination of sickness and external medical benefits. The 'competent Member State' (usually the Member State in which the worker resides) is required to provide health care, medical treatment and welfare services for migrant workers 'on the same terms and conditions as those which are enjoyed by nationals of the same State'.

Regulation 130 (now 174) EC's concern is to protect migrant workers against 'social and health mistreatment' and to ensure that they are treated 'on the same terms and conditions as those which are enjoyed by nationals of the same State'. An 'individual entitlement to medical treatment' is provided for the competent Member State to authorise receipt of medical treatment in another Member State. This provision is made to ensure that the transfer of migrant workers between EU Member States is not restricted by the Member States' medical treatment systems. These rights are given to all workers and their families and are provided for by the competent Member State, and are to be treated as the residents of that State.

### Individual entitlements to medical treatment

In general, entitlements to medical care and health care are determined according to the regulations of national law. All the Member States have a national health system ensuring universal access to comprehensive service, although the details and mechanisms of provision vary considerably. However, the rights of patients to health care within the Member States of the EU are affected by a number of EU-level measures: first, measures taken in response to the adoption by the Commission of the EU's 'health care sector reform', and then in response to the establishment of the EU's social model in the European social model.

Migrant workers, who are nationals of a Member State ('citizens of the EU') and their families (irrespective of nationality) enjoy health care entitlements in the host state under Regulation 1621/85 and Regulation 1408/71/EEC. These measures are intended to promote the free movement of (EU) workers within the EU, but each utilises a different model with which to do so. Regulation 1621/85 is a measure of regulatory EU-level harmonisation and applies to all Union citizens and their families are entitled to the 'same social and health advantages as workers'. This would clearly include access to national health service provision, on the basis as national workers.

Regulation 1408/71 aims to coordinate national social security schemes in order to prevent persons who move from one Member State to another for the purposes of employment from suffering detrimental in respect of their social security entitlements. There is a consequence that, by ensuring non-discrimination for migrant workers. Thus according to Regulation 1408/71, workers are entitled to the same social and health advantages as workers in the host state.

Regulation 1408/71, Article 22 covers the entitlements of insured persons falling within the scope of the Directive to sickness benefits. Where insured persons are staying in the territory of another Member State, their condition and their medical care is determined according to the medical care institutions of the state in which they are staying, on the same terms and conditions as those which are enjoyed by nationals of the same State, as if they were insured in it.

These 'benefits in kind' are provided on behalf of the competent Member State, in all other words the financial burden falls on the competent Member State. Article 22 also provides for the competent Member State to authorise receipt of medical treatment in another Member State. Migrant workers are not, however, entitled to the same medical treatment as those who are nationals of the same State. The person's medical status is determined by the competent Member State, and the medical care is provided by the competent Member State. These rights are given to all workers and their families and are provided for by the competent Member State, and are to be treated as the residents of that State.
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that in the professional wishes to practise. National authorities governing authorization to health professionals widely so that they are not regulated in all Member States, or may rely on the general approval Directive 89/48/EEC on the recognition of higher education diplomas. 85

In practice, the level of migration of health professionals remains fairly low, with the exception of movement between Member States with a shared language, and movement at the border between the various countries within the EU, 86 Thus, there are no significant barriers for migration in the context of established medical professions. This means there remains (at least circumstantial) evidence of administrative or bureaucratic factors limiting migration. Here the role of Community law, and especially rulings of the European Court of Justice, in removing these barriers to free movement may prove to be increasingly significant. Litigation has occurred in particular in respect of the issue of recognition of specialist medical qualifications, and on the position of third country nationals, with qualifications from non-EU States that are recognized in one, but not other EU States. The Court of Justice has confirmed that the adoption of the mutual recognition principle, as provided for by Directive 90/489/EEC on the recognition of qualifications provided for the purpose of exercising a profession, is to be respected in the EU regulatory framework within the EU. This may have implications for capacity building and for cost containment in national health policies. Capacity building programs need not undermine the European medical model, so long as sufficient numbers of medical professionals are being trained across the EU as a whole. However, if internal market undermines the regulation of medical professionals as a mechanism for cost containment, this may have implications for European social values. Thus far, the Court has not been given an opportunity to consider the relevant issues. 86

(ii) Regulation of production and marketing of medicinal products

The law relating to medicines or pharmaceuticals is a component of health law. 88 In all Member States of the EU, the law regulates the development, manufacture, licensing, importation, distribution, marketing and retail of pharmaceuticals and other medicinal products. However, such regulations is not a matter of national law. A significant body of EU-level norms, dating back to 1965, have resulted in the establishment of the European Economic Community (EEC) or the European Union (EU). To the extent that these rules must be applied to the production, distribution and supply of medicines in the EU, they are subject to Community international market or competition law.

EU level-action concerning regulation of pharmaceuticals includes measures aimed (broadly) at protection of the consumers of pharmaceuticals (patients), covering for instance the requirement for national systems granting marketing authorization (MA) to place information about the risks and benefits of medicines on the life of the market ("pharmaceutical vigilance"), 89 measures concerning labelling and packaging of pharmaceuticals, 90 and measures on advertising of pharmaceuticals. 91 Directive 65/65/ECE is the earliest EU-level measure with the aim of harmonising safety and efficacy standards for medicinal products. Enacted in response to the thalidomide tragedy of the early 1960s, 92 the Directive required Member States to enact laws to ensure that new medicinal products may not be marketed on their territories without the approval of a competent regulatory body.

More detailed harmonisation provisions for the critics and procedures according to which approval may be given by national regulatory bodies for new medicinal products followed. A large number of detailed provisions of secondary legislation now cover all industrially produced medicines. 93 The Commission, in accordance with power delegated for this purpose by the Council, has on several occasions updated these regulations to ensure the safety and quality of medicines, and ensure the protection of patients. The main body of rules concerning procedures for marketing approval ("marketing authorization") and the giving of reasons, publication, 94 to manufacture (quality control, inspections), 95 to labelling (including to include information relating to dose, ingredients, side effects) 96 and to advertising of medicinal products (advertisement to the general public of prescription drugs is prohibited) 97 have been harmonised. These provisions are consolidated in the Commission's multi-volume publication: 'The Rules governing Medicinal Products in the European Community'. 98 Rules protecting consumers from defective medicinal products in situations where these safeguards fail are found in the consumer protection Directive 85/577/EEC. 99

Further provisions are applicable more at creating an "internal market" in pharmaceuticals, for instance rules on the mutual recognition of national authorisations, and EU-level procedures facilitating such mutual recognition. The "decentralised procedure" for approval of a new medicinal product in other Member States, once approval has been granted by one Member State, is an option for all other Member States. 100 The European Medicines Evaluation Agency (EMEA) was set up by Regulation 2003/93/EC 101 and the agency is compulsory for all new medicinal products derived from biotechnology, and is optional for other "innovative" products. 102

The cross-border marketing of medicines and pharmaceuticals has also been affected by Community international market or competition law. Prices obtained for pharmaceuticals vary widely between Member States. The Court has led to the development of a considerable parallel trade in pharmaceuticals. It is difficult to discern a simple trend in the Court's jurisprudence. 103 In many cases, the Court has upheld the Members States' discretion to protect public health in holding the restriction on parallel trade justified. 104 However in other matters, the Court's issued parallel trade is subject to competition by European market as the competition law. 105 It is very difficult to translate the Court's decision in to practice. 106

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justified on grounds of consumer protection, as consumer interests are also met by the availability of cheaper pharmaceuticals. In fact, in Duphar,136 the Court explicitly held that its Article 30 EC statement would not be available where the national cost containment rules137 had an "economic", rather than specifically public health protection, basis. The Court’s approach may therefore be seen as giving little support for a long term public health interest in maintaining and supporting national pharmaceutical industries.

Thus, the complex law and regulatory system concerning pharmaceuticals in the EU is formed through the interplay of national and EU level norms, principles and practices. Community law has played a significant role in the development of this regulatory order, for instance in determining the competence of the various EU institutions to act, in providing procedures to enable the mutual recognition of the quality of medicinal products and in the setting up of EU-level institutional fora (committees) in which decisions between national authorities may (and in some cases must) be reached.138 It is clear that the current regulatory regime is fragmented, as the EU market (the "internal market") is an emerging concept. The same holds true for the regulatory framework139 for the pharmaceutical industry, as the EU system gives little attention to the essential issue, which is how to provide a regulatory regime that promotes the supply of new pharmaceuticals that are generally needed, as opposed to bringing profits to the producers. If this is accepted, then the new system may be said to place the efficiency gains for the industry explored through harmonization and mutual recognition above the values of the European social model.

(iv) Administration of health services

Again, in general, the administration of health services is a matter of national law. However, Community law has had a limited impact on some aspects of the administration of health services.

Discussion here will focus on one aspect: the pricing of pharmaceuticals.140 Since around the beginning of the 1970s, health policies in all advanced capitalist states, including the Member States of the EU, have been focused on the search for means of cost containment, in response to the end of the 'long boom' after the end of World War II and the rise of universalism in welfare provision. Many states have resorted to various mechanisms (including imposition of 'market' models on health care provision) as an attempt to impose restraints on demand for health care from citizens.141 One regulatory measure of cost containment is the regulation of pharmaceutical prices.

National governments retain a special position as the main purchasers of pharmaceuticals within a state, and therefore justify measures to keep this expenditure low. Within the EU, various different national systems of regulating health care provision exist, and in particular, the type of reimbursement that may be reimbursed under the national health system. The market for pharmaceutical products is thereby more or less guaranteed within a particular Member State, and conversely, it is almost impossible for products not on a positive list to be successfully marketed within a particular state. Governments aim to ensure that the products that are reimbursable for all products in a particular class may be fixed in order to encourage the use of cheaper generic products. Use of generics may also be encouraged by permitting pharmacies to keep a proportion of savings on products supplied (Netherlands) or by making prescribing doctors responsible for the cost in some way (UK). Cost-sharing between patient and provider may also operate as an indirect price control. Profit controls may be laid down by legislation or administrative action, or may be the result of negotiations between the national government and the pharmaceutical industry. These limit the levels of profit that may be made on sales of pharmaceutical products to national health services. Where a state is concerned also to support its internal pharmaceutical industry, and to promote its research and development and export capacity, the former two methods are favoured (e.g. Germany, UK). Where there is less of a concern for the home-grown pharmaceutical sector, stricter profit or price controls are more likely to be used (e.g. Belgium, Spain, Greece, Portugal).142 This division gives some way to explaining the division between high-purchasing power countries, and lower purchasing power countries.

All of these measures constrain the application of normal market rules to the sale and supply of pharmaceuticals. Consequently, as noted above, there is no effective competition in pharmaceuticals in the EU.143 The question arises therefore to what extent Community internal market law may affect national cost containment provisions. As space precludes discussion of all the relevant case law, the focus here will be on the impact of Community law on the regulation of pharmaceutical prices and on the pricing of pharmaceuticals in one 'high price' Member State, Germany. A number of German measures of health law, aimed in part at protecting the high prices for pharmaceuticals in that Member State, or at least having that effect, have been the subject of challenges before the European Court of Justice.

Challenges to the German measures came first from litigants effecting private imports. In Schumacher144 the Court found that the prohibition of private imports of pharmaceuticals, for personal use, was incompatible with Community law. Schumacher, a German resident, ordered, for personal use from a French pharmacy, a medicinal product 'Chophytop', used to treat depression and as a diuretic. Chophytop was authorised to be marketed in both France and Germany, and was available over-the-counter in both Member States. However, the price for the product was higher in Germany than in France. As German law prohibited the private importation of pharmaceuticals, the customs authorities refused entry to the product. Schumacher challenged this as contrary to the Community law, and to the freedom of goods.

The German government argued that the measure was justified on public health grounds.145 Consumer protection was guaranteed by restricting the sale of pharmaceuticals only to authorised retailers within Germany. It was argued that the entire system of consumer and health protection would be jeopardised, if private individuals were free to import medicinal products. That freedom might give rise to abuses which it would be impossible to control, and to the misuse of medicinal products. Further, it would also facilitate evasion of the rules on national autorisation for pharmaceuticals, as it would encourage direct sales in the Community.

The Court argued this claim about short shrift. The Court pointed out that the purchase of a medicinal product in a pharmacy in another Member State provides a guarantee equivalent to that provided by the German rules. This is all the more the case, given that pharmacists' professional qualifications within the EU have been the subject of harmonisation in the mutual recognition of diplomas.

The impact of the Schumacher ruling was relatively modest, as it concerned only imports by private individuals, carried out by those individuals themselves. The issue was taken further in Commission v Germany,146 in which the Commission challenged German regulations prohibiting the importation of prescription-only medicinal products, prescribed or purchased in another Member State, in quantities not exceeding normal personal needs (save in exceptional circumstances). The effect of the prohibition was to prevent the importation of prescription-only medicinal products from another Member State, on the grounds that the importation of such products would be in a different language, and would constitute a danger to human health. The Court took the view that the distance itself does not preclude adequate protection for consumers, and that the language problem could be overcome by the medical professional prescribing or supplying the product.

The Court held that such a system was not compatible with Community law. In order to assess whether Germany's claimed justification - the protection of health - could be established, a proportionality test was to be applied. The importer has a permit, as required under Directive 75/319, Article 16 (2), for repackaging. The importer is thus subject to checks under this Directive, and the German law procedures bringing it into effect. The importer must also have a marketing permit, that is, a simplified authorisation, taking into account the ruling in De Peijper.147 That permit ensures that the parallel imports have an identical composition to products already on the market for Germany for which marketing authorisation has, of course, been granted. Therefore, the prohibition on the importation of the medicinal products arising from the application of the German rules on repackaging was not necessary for the effective protection of human health.148

The position of mass imports of pharmaceuticals, undertaken by companies rather than private individuals, was considered further in Luxemburg, concerning German law restricting the advertising of medicinal products. The relevant national law permitted importation of pharmaceuticals from other Member States, where those pharmaceuticals are authorised for marketing in those other Member States, for personal use. In the absence of a prescription of a medicinal product outside its medical professional. However, advertisements for such products were prohibited. This had the practical effect of limiting parallel imports, as, without such advertising medical professionals remained unaware of sources for pharmaceuticals in other Member States.

137 Here, cost containment measures taking the form of positive and negative lists, which control costs by limiting the volume of pharmaceuticals on which public health authorities may spend, see Mosenthal and Abel-Smith, supra note 1, p. 371. 
138 Supra n. 2.
139 Supra n. 9.
140 See, e.g., Eekelaar here, the "beneficiary/not needy" test for pharmaceuticals.
141 There are thousands of pharmaceuticals on the European market. The World Health Organisation estimates that only about 150 are necessary to meet the needs of the world's population. In practice, however, the need for new medicines is high, and actual utilization does not reach 5% of the potential.
142 See A. F. West, supra note 141, p. 71-75.
144 Case 261/76 Schumacher v Germany (1979) ECR 561. 
145 See above.
146 Case C-42/90 EEC Commission v Germany (1992) ECR 1-575. 
149 Case C-103/88 Parke-Davis v Netherlands (1989) ECR 385. 
Recent Pharm imported its products into Germany, and advertised the products in publications aimed at German health professionals. Lucien Orkatz, another importer of pharmaceuticals into Germany, bought an order restraining EuroPharm from its advertising activities. The Court found that the prohibition on advertising was contrary to Article 28 EC, as it is only foreign medicinal products. A prohibition on advertising may restrict the volume of imports, as it deprives medical professionals of a source of information concerning the availability of these products.

The Court then applied a proportionality test to see whether the restriction on free movement of goods was justified. The Court pointed out that, at the present stage of harmonisation and in the absence of expressions of the European Commission, the Court is entitled to declare the restriction to be null. The restriction of medicinal products not authorised for marketing in that territory, even if authorised has been successfully obtained for marketing in other Member States. The prohibition of advertising, the Court felt, was a logical corollary of that position, as it aimed to ensure that the individual importation of unauthorised medicinal products was exceptional, and to prevent the systematic circumvention of the need to obtain a German marketing authorisation. Thus the Court found that the conditions justified. It would be interesting to see whether, given the new procedures on marketing authorisation at Community level, the Court would reconsider this issue.

Also, the provisions of Directive 92/28 on advertising of medicinal products did not apply to the facts of this case, as they arose before the Directive was to be implemented by the Member States.

These examples, concerning only one Member State, give a flavour of the impact of internal market law on the free movement of pharmaceuticals on the ability of Member States to maintain a high level of public health. The impact of Community law is clearly high priced in the field of public health. If the protection of public health is not so clearly stated by such Member States, this is because in the context of the internal market requires that such regulation emanates from the EU level, as, in principle, those laws, having been produced in the EU, are accepted by all Member States.

BSE is a disease of cattle first recognised in Great Britain during the mid-1980s, and subsequently in other European countries such as France, Portugal and Switzerland. The disease was identified among cattle on a farm in the UK, which was in the same herd as other BSE cases that had been reported in the area through the routine testing of aged cattle. Further public concern was generated through the identification of Cretzfeldt Jacob disease (CJD). This is a rare neurological disorder, which has occurred worldwide over a number of years and provides similar spongiform changes to the brain as BSE does in cattle. In those years there were indications that a new form of CJD (vCJD) that had emerged could be linked to consumption of BSE-infected meat. In response to this concern, the UK government introduced immediate measures on an unprecedented scale.

Other, less cross-border, reasons for changes in EU food regulation include the fact that the past few decades have seen significant changes in the food industry in Europe. These arose as European consumers (particularly those in the north of the UK and Europe) have increased their use of convenience foods. Food production has changed as a result of new technology, in particular biotechnology, and the use of genetically modified foods has increased, as well as the use of chemicals in food production. New modes of production, foodstuffs and genetically modified foods might include the transfer of carcinogens, or allergens. Most food allergens are associated with proteins, with some common foods containing several allergens. The United States Food and Drug Administration has admitted that there is insufficient knowledge about food allergies generally to predict whether any genetically modified food will cause an allergic reaction. This does not apply to consumer fears to the effect that this genetic modification may exacerbate the symptoms of food allergies. Another significant health concern arises from the use of 'marker genes' to identify certain plants by their resistance to antibiotics. The consumption of such genetically modified organisms might lead to antibiotic resistance further down the food chain, and is therefore of concern where the genetically modified product is to be used as food or feed, and where the components are most likely to be resistant in common use, for instance aspirimycin.

This is covered by Regulation 258/97/EC, the "Novel Foods Regulation". A marketing authorisation must be granted for all genetically modified foodstuffs and foods with genetically modified ingredients to be sold in the EU. Authorisation is granted at EU level, consequent upon a committee basis, on the basis of a point of view of consumers, the Regulation requires that genetically modified foods be labelled.


The principle of 'mutual recognition' – see Case 120/87 Caenese di Dijon [1979] ECR 649. The Commission, for example, the UK Minister of Agriculture, Jim Churton, appeared before television cameras eating a beefburger with his daughter. See also the UK Treasury Committee of Inquiry, 12 July 1999, and the European Parliament Committee of Inquiry of the European Parliament investigating the marketing of the product in the EU. These were Mesterton's views and C-J's views on CJD.

The main criterion of the novel food is that it has not yet been demonstrated to be safe under existing conditions of use. The new food is a food not already authorised by competent national authorities as safe for consumption.

The novel food was a genetically modified organism (GMO) that had been specifically engineered to be resistant to herbicides. The novel food was a food not already authorised by competent national authorities of other Member States as safe for consumption. The novel food was a genetically modified organism (GMO) that had been specifically engineered to be resistant to herbicides. The novel food was a food not already authorised by competent national authorities of other Member States as safe for consumption. It was therefore a novel food as it had not been demonstrated that it was safe for consumption.

Regulation 258/97/EC, Article 8 requires consumer information on any characteristic of the food which renders it no longer equivalent to an existing food; the presence of material not present in an existing equivalent food which may have implications for the health of certain segments of the population, or which gives rise to ethical concerns, or the presence of a genetically modified organism in the sense of Directive 90/219/EEC, Annex I A, Part I, Annex A, Part I, covers "novel" substances, and those by water systems; techniques involving the direct introduction into an organism of heritable material prepared outside the


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organism including micro-injection, micro-injection and micro-encapsulation, cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritably genetic material are produced through the fusion of two or more cells by means of methods that do not occur naturally. This would require, for instance, information about potential allergies in GM foods. For the purpose of labelling, the term 'genetically modified' or 'genetically engineered' cover all such insertions and at least at this level. This reveals a number of areas in which Community law has had an impact on the development of national health law and policy. This precluded detailed discussion of these areas, but examples in each area were chosen as illustrations.

One of the challenges EU health law and policy poses for European lawyers is that, as a subject of enquiry, it goes beyond the traditional constructs of Community law. In order to have a satisfactory view of the field, it is necessary to look beyond notions of EU health law as defined by the Treaty or by the European Commission. As we have seen, EU health law cuts across a number of traditional areas of Community law including agriculture, freedom of movement of goods, movement of persons, consumer protection, environmental law, employment law and so on. Such a cross-sectional approach to EU law may reveal policy linkages and interactions between institutions and legal norms in unexpected places, and may suggest future research agendas.

Finally, the paper aimed to consider the extent to which a 'European social model' is being promulgated within the emerging European health policy. Taking into account the various different types of legal action considered, the overall conclusion is that this is, in general, being effected. The propensity for directly effective Community law to undermine national provisions upholding a European social model is present, but in many cases this has been recognised by the European Court of Justice. As far as EU-level norms are concerned, the Commission seems keen to promote a distinctive European social model in its proposals, and the Council and European Parliament appear to be broadly in favour. As a result, differences in the detail emerge (within the scope of Directive 89/107/EEC of 30 March 1989) and (within the scope of Directive 88/389/EEC of 18 June 1989) which are, in some cases, produced from genetically modified organisms, as defined by Directive 90/219/EEC. The Directive specified a requirement on the labelling of foods that are derived from the Novel Food Regulation, based on the substantially different test. The definition of substantially different is provided as Article 1 of Directive 90/219/EEC, which explicitly provides that a GM additive or substance is not substantially similar where it contains protein and/or DNA resulting from genetic modification. This is a tightening of the definition in Regulation 2589/97.

### Conclusion

This paper aimed to set out the contours of an emerging European heath policy, and to consider the role of law in its development and instrumentalisation. A broad approach to health policy, which includes an understanding of the EU as a multilevel system of governance or a non-state policy within which law and policy is made in interactions between and within institutions at all levels. This reveals a number of areas in which Community law has had an impact on the development of national health law and policy. This precluded detailed discussion of these areas, but examples in each area were chosen as illustrations.

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