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Mapping the Contours of European Union Health Law and Policy

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Introduction

This paper explores the new field within European social policy of European Union (EU) 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,[1] this area has as yet been the subject of little attention from the legal perspective.[2] 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.

Traditionally, 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 [3] 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 medicinal 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'. [4] 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, Community law, in its various forms[5]) in the determination and execution of health policy.

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,[6] although there is now also an increasing interest in social security law.[7] 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, [8] this may also be the case within health care law, as a component part of social welfare law in general.

National social welfare provision within Member States of the EU is undergoing a period of retrenchment, in response to various forces, including globalisation processes and demographic changes, such as ageing populations (particularly important for national health services). One role for the EU in this respect could be to preserve a distinctively 'European social model' in social welfare provision, including the provision of health care. If the EU is to be successful in this respect, its legal system must be such that the basic values and norms underpinning 'European' health policies can be maintained in the emerging new economic, social and political climate. A secondary aim of this paper is thus to ask to what extent the current Community law relating to public health and health care is responsive to such a 'European social model'.

What is the 'European social model'?[9] There are, of course, many social models among the Member States of the EU.[10] A distinctively 'European' model is discernible only at a high level of abstraction. However, this does not mean that the values encapsulated in the phrase the 'European social model' are not worthy of protection. At the very least, those values involve the recognition that the economic imperatives of a free market must in certain circumstances be constrained in order to attain social goals such as equality of access to goods or benefits in society, solidarity within and between generations, sustainability of development and so on. In the context of health policy, such values may include equality of access to health care and the determinants of good health, solidarity in health care financing, and regulation of economic activity as is necessary to protect and promote public health. Promoting the European social model is thus a fundamentally normative activity As the European Union emerges as a 'non-state post-national polity', its actions having effects in ever increasing areas of economic, social and political life, the issue of what model of social regulation is chosen within the EU's legal order is of crucial significance in terms of the values that post-national polity seeks to uphold Therefore, an underlying implication of this paper is that European social law – and all its constituent parts, including health law – is *not* a fringe area, but should be a focus for concerned discourse on the future direction of the EU itself

Article 152 EC

The starting point for a legal analysis of EU health law and policy is Article 152 EC. Article 152 EC began life as Article 129 EC, introduced into the Treaty of Rome at Maastricht, as the first formal recognition of a specific legal basis for EU-level health policy action. In fact, this grant of formal competence to take such action post-dated health-related policies effected at EU-level.[11] Article 129 EC represented a compromise between those governments of Member States who did not want any EU mandate in health, and those who wanted to go further The provision was seen by some as setting limits to the expansion of EU-level activities in the public health field, which had occurred in the past without any specific legal basis. For others, it was a mere formalisation of what was already taking place,[12] the implication being that such action could lawfully be taken further. Article 152 EC thus constitutes a legal reification of public health policy within the Treaty, within which it is unclear which of these positions is its underlying aim. This may have implications for its legal construction.[13]

Article 152 EC confirms that the Community is under an obligation to take action in the field of public health Such action is mainly to complement national health policies. The EU institutions are to encourage 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 liaise with the Commission and to coordinate policies and programmes in the relevant areas. Thus it is implicit 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, unlike the old Article 129 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,[14] and delimits the types of measures that may be enacted. According to Article 152 (4) (c), the EU institutions shall adopt 'incentive measures designed to protect and improve human health, excluding any harmonisation of the laws 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 direct objective the protection of public health' (Article 152 (4) (a) and (b)).

Thus two types of legislation are envisaged: the 'measures' of (a) and (b) may presumably include re-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 latter provisions are an extension of (or rather a derogation from) the powers given to the EU institutions in Article 37 EC to effect the common agricultural policy (CAP).

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[1] Geyer, *Exploring European Social Policy* (Cambridge: Polity, 2000), Normand and Vaughan, eds, *Europe without Frontiers: Implications for Health* (Chichester. Wiley, 1993); Hermans, Caspane and Paelinck, eds, *Health Care in Europe after 1992* (Aldershot Dartmouth, 1992); contrast Freeman, *The Politics of Health in Europe* (Manchester: Manchester University Press: 2000)

[2] For exceptions, see Van der Mei and Waddington, 'Public Health and the Treaty of Amsterdam' 5 *European Jo of Health Law* (1998) 129-154; McKee, Mossialos and Belcher, 'The Influence of European Law on National Health Policy' 6 JESP (1996) 263-286; Montgomery, *Health Care Law* (Oxford: OUP, 1997) also contains many references to EU level norms.

[3] Spicker, *Social Policy: Themes and Approaches* (London: Prentice Hall/Harvester Wheatsheaf, 1995), p 3.

[4] Montgomery, *Health Care Law* (Oxford: OUP, 1997), p 4, see also McHale and Fox, *Health Care Law: text and materials* (London: Sweet and Maxwell, 1997).

[5] The subject of enquiry thus includes the obvious 'hard law' measures of Community law, such as regulations, directives, decisions and so on, but also 'soft law' measures, such as recommendations, declarations and so on: Such soft law measures may be significant in a number of ways, including forging a direction for future measures of hard law, and informing interpretation of measures of hard law by courts.

[6] Barnard, *EC Employment Law* (Oxford: OUP, 2000); Bercusson, *European Labour Law* (London: Butterworths, 1996); Burrows and Mair, *European Social Law* (London: Wiley, 1996); Nielsen and Szyszczak, *The Social Dimension of the EU* (Copenhagen: Handelshojskolens Forlag, *); ****

[7] Luckhaus, 'European Social Security Law' in Ogus and Wikeley, eds, *The Law of Social Security* (London: Butterworths, 1995) is an early example. See also Hervey, *European Social Law and Policy* (London: Longman, 1998); Hervey, 'Social Security: The EU Dimension' in Harris, ed, *Social Security Law in Context* (Oxford: OUP, 2000); Barnard and Hervey, 'Survey on Employment and Social Law' 17 YEL (1997) 435-490; 18 YEL (1998) 613-657; 20 YEL (2000) (forthcoming).

[8] Leibfried and Pierson, *European Social Policy: Between Fragmentation and Integration* (Washington, Brookings, 1995); Leibfried and Pierson, 'Social Policy' in Wallace and Wallace, eds, *Policy-Making in the European Union* (Oxford, OUP, 1996)

[9] Defined by Commissioner Flynn in a speech for the conference *Visions for European Governance*, Harvard University, 2 March 1999, as follows. 'The European social model spans many policy areas. Education and training. Health and welfare. Social protection. Dialogue between independent trades unions and employers Health and safety at work. The pursuit of equality. The fight against racism and discrimination It takes many forms - welfare systems, collective arrangements, delivery mechanisms. It has been conceived, and is still applied, in many different ways. By different agents. Under different public, private and third sector arrangements in different parts of Europe. It is a system steeped in plurality and diversity - reflecting our richness of culture, tradition and political development. All the variants reflect and respect two common and balancing principles. One is competition - the driving force behind economic progress - the other is solidarity between citizens.'

[10] See Hervey, *European Social Law and Policy* (London: Longman, 1998), p 57-61; Esping-Andersen, *The Three Worlds of Welfare Capitalism* (Cambridge: Policy, 1990), Ginsburg, *Divisions of Welfare* (London: Sage, 1992); Cochrane, 'Comparative Approaches to Social Policy' and 'Looking for a European Welfare State' in Cochrane and Clarke, eds, *Comparing Welfare States: Britain in International Context* (London: Open University Press, 1993); Gomà, 'The social dimension of the European Union: a new type of welfare system?' 3 JEPP (1996) 209-230; Rhodes and Mény, 'Europe's Social Contract Under Stress' in Rhodes and Mény, *The Future of European Welfare* (Basingstoke: Macmillan, 1998); Maurizio Ferrera 'The Four 'Social Europes: Between Universalism and Selectivity' in Rhodes and Mény, supra.

[11] Chief among these were the 'Europe against Cancer' programme (Decision 88/351/EEC of the Council and Representatives of the Governments of the Member States meeting within Council OJ 1988 L 160/52) and the 'Europe against AIDS' programme (Decision 91/317/EEC of the Council and Ministers of Health of the Member States adopting a plan of action in the framework of the 'Europe against AIDS' programme OJ 1991 L 175/26

[12] McKee, Mossialos and Belcher, supra n *, p 267.

[13] Ultimately, of course, from a legal point of view, the proper construction of Article 152 EC is a matter for the European Court of Justice; see Article 230 EC, Article 234 EC.

[14] But see below, on activities in other fields with implications for health policy.

Their inclusion in the Treaty is apparently due to the BSE/CJD crisis. The provision removes from the scope of the CAP veterinary and phytosanitary measures which are primarily concerned with human or public health [15] Significantly, a different legislative procedure (codecision, rather than the basic procedure of Article 37 EC) is to be used [16]

The provisions in Article 152 (4) (a) are more obviously an extension of the power of the EU institutions. Their presence in the Treaty may be explained by various health scandals concerning blood and human organs, such as the distribution and transfusion of HIV-infected blood and blood products.[17] It may also be relevant that an embryonic 'market' in human blood, organs and other substances is emerging in the EU. Using the ordinary internal market provisions, including those on free movement of goods and consumer protection, to regulate this 'market' is politically and ethically sensitive in many Member States, as these substances are neither conceptualised as 'goods' nor the object of ordinary commerce or consumption However, 'consumers' of these 'goods' do need to be protected within the EU's legal order Article 152 EC gives power to Council to enact the necessary protective regulations as public health measures, although the measures may well be modelled on existing internal market consumer protection regulation. Community requirements will set only a 'minimum floor' of regulatory protection, and Member States are free to enact higher standards if they wish. There is a specific exclusion in sub paragraph 5 for 'national provisions on the donation or medical use of organs and blood' This refers to the differences in national legal systems concerning donor consent.[18]

According to Article 152 EC, Community action in the field of public health is to be directed towards 'improving public health, preventing human illness and diseases and obviating sources of danger to human health'. Clearly to carry out such a broad remit in full would be beyond the budgetary allocation made to the Commission in respect of public health, and therefore policy choices have to be made within this broad category The direction of the EU's public health policy is indicated in Article 152 EC itself, and has been elaborated by secondary legislation Action of the EU institutions in the health field is to be directed towards a number of particular areas, in particular 'major health scourges' (such as cancer, AIDS or BSE/CJD), research into the causes and transmission of these diseases, 'drugs-related health damage, including information and prevention', health information and education. These reflect pre-Maastricht Commission activity, which was focused upon areas of activity that the Commission judged would not be politically contentious.[19]

The areas of activity for the EU in the health field are also based on a notion of EU-level 'value added' within EU health policy. The 1993 Council Resolution on Public Health[20] provides that the aim of the Community action must be such that it cannot be sufficiently achieved by Member States acting alone This is a specific application of the general principle of Community law of 'subsidiarity' [21] In the health field, criteria to test proposed activities for compliance with subsidiarity might include a clear need for coordination of activity or for enabling Member States to learn from each other's experience in health care reform or innovation; functions which might be performed more cheaply for the EU as a whole (for instance, research into rare or 'orphan' diseases which would be too expensive for one Member State acting alone), issues which cross national boundaries (for instance, epidemics, the environment or the consequences of free movement of persons), and action to make exchange of information beneficial (for instance, standardisation of definitions).[22]

The 1993 Council Resolution was fleshed out by a number of official Commission action programmes. The public health programmes proposed on AIDS, cancer, drug dependence and health promotion were implemented in 1996;[23] the fifth programme on health monitoring was implemented in 1997 [24] The final three programmes – on injury prevention, rare diseases; and pollution-related diseases were adopted in 1999 [25] These programmes support a number of projects covering, for instance, exchange of information and personnel, training, pilot projects, information campaigns, and networking of organisations and experts. In 1998, however, the Commission proposed a single integrated public health strategy.[26] The Council and the European Parliament (and also the Economic and Social Committee, and the Committee of the Regions) responded positively to the Commission's 1998 proposals,[27] taking the view that a single overall framework programme would be the best way forward The Commission has put forward a proposal for a decision adopting the new public health framework [28] The proposed new programme will repeal the existing eight public health programmes [29] The three priorities of the 1998 consultation – improving health information and knowledge; responding rapidly to health threats; and addressing health determinants – are to be maintained. The rationale for EU-level intervention, in the context of a field in which the main responsibilities for organisation and delivery of health care rest with the Member States, remains that of 'added value'. Pursuant to the new Amsterdam competencies, in addition to the public health programme, the new framework encompasses other potential legislative measures, including measures of harmonisation in the veterinary and phytosanitary fields, on standards of quality and safety of human organs, and on quality and safety of human blood and blood derivatives.

The EU has developed its own contribution to the development of European health policies in a number of essentially non-contentious areas, with restricted budgets. Such activities may be built upon in the future These policies have been presented by the Commission in its White Paper on Social Policy as part of the European social model,[30] and there seems to be no reason to refute this for such essentially uncontroversial activity.

'Mainstreaming' of public health in EU policies

Article 152 EC thus provides the legal basis for a relatively modest role for the EU in the formation of health policy within the EU's multi-level system of governance. However, many of the EU's other policies – some very well established and for which the EU institutions have competence – may have significant impacts on the protection and promotion of public health and of health care provision in the Member States These would include the common agricultural policy,[31] the internal market,[32] environmental policy,[33] consumer protection,[34] competition policy,[35] and even some elements of the employment strand of social policy [36] Of these, the internal market is crucially important, because of its 'constitutional' position in the EU's legal order The question then arises of the extent to which the EU institutions are obliged, or indeed are even competent, to include health protection or promotion motivations in their instrumentalisation of measures in these related policy fields Again, a legal perspective will be taken on this question.

The relationship between public health and other Community policies probably first came to the fore during the Delors' Commission and the promulgation of the 1992 programme for the completion of the internal market Any social policy regime within the EU must now take its place within the 'constitutional' construct of the internal market, the law of which has been one of the fundamental drivers of the integration process. The relationships between the EU's internal market law and social regulation in general are already well explored in the literature [37] The dynamic imperative of the EU's internal market and competition law, as interpreted by the European Court of Justice, orders the relationship between social regulation and free trade Membership of the European Union requires Member States to comply with Community law [38] The EU's internal market and competition law may be an inhospitable environment for measures of national social welfare policies, in particular because internal market law is enforceable by individuals within the Member States. Individual litigation concerning national social welfare policies, including health policies, may have the effect of revealing some national laws and policies as inconsistent with Community law, which precludes national governments from pursuing those policies or maintaining those laws in place.[39] In addition, the dynamic of the impact and application of internal market law, through individual litigation, may render some aspects of national social regulation not formally unlawful, but in practice politically undesirable [40]

Thus the reach of Community internal market law – as determined by the European Court of Justice and by national judicial authorities – may have profound implications for social welfare policies (including health policy) within the EU The fear that this dynamic will undermine provisions of social regulation within the EU is often expressed as a fear of social or welfare dumping, or 'the race to the bottom'. [41] In the health context, this would mean that Member States with lower health standards would undermine those with higher standards.

Put very simply, two types of responses[42] to this problem have been articulated. The first type of response is an argument for a 'repatriation' of social welfare competencies to national authorities, and a clearer demarcation of boundaries between national and EU competencies. Those adopting this position often point to the 'democratic deficit' of the EU institutions. They

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[15] Van der Mei and Waddington, supra n *, p 137

[16] Although Council is to act by qualified majority under Article 37 EC, the role of the European Parliament is consultative only, rather than the codecision role envisaged in Article 152 EC.

[17] See Abraham and Lewis, *Regulating Medicines in Europe* (London and New York: Routledge, 2000), p 73-74; Van der Mei and Waddington, supra n *, p 137.

[18] See Roscam Abbing, 'European Community and the Right to Health Care', in Hermans, Casparie and Paelinck, supra n *, p 172.

[19] See Geyer, supra n *, p 173.

[20] OJ 1993 C 174/1

[21] Article 5 EC The principle of subsidiarity requires that proposed activities and functions of the EU institutions are demonstrably better performed at European, rather than national, level.

[22] See Abel-Smith, Figueras, Holland, McKee and Mossialos (eds), *Choices in Health Policy: An Agenda for the European Union* (Dartmouth, 1995), p 126

[23] Decision 646/96/EC OJ 1996 L 95/9; Decision 647/96/EC OJ 1996 L 95/16; Decision 102/97/EC OJ 1997 L 19/25; Decision 645/96/EC OJ 1996 L 95/1.

[24] Decision 1400/97/EC OJ 1997 L 193/1

[25] Decision 372/99/EC OJ 1999 L 46/1

[26] See COM(98) 230 final

[27] Council conclusions of 26 November 1998 on the future framework for Community action in the field of public health OJ 1998 C 390/1, Council resolution of 8 June 1999 OJ 1999 C 200/1; European Parliament Resolution A4-0082/99 of 12 March 1999 OJ 1999 C 175/35; Opinion of the ECOSOC of 9 September 1998 OJ 1998 C 407/26; Opinion of the Committee of the Regions of 19 November 1998 OJ 1998 C 51/53

[28] COM(2000) 285 final

[29] COM(2000) 285 Proposal for a Decision of Council and Parliament, Article 12. In order to ensure continuity, the existing programmes are to be continued until 31 December 2002, Decision 521/2000/EC OJ 2001 L 79/1

[3030] Commission, *European Social Policy A Way forward for the Union* (White Paper on Social Policy) COM(94) 333 *** check

[31] The CAP has implications for food safety, a major determinant of public health, and cause of illness.

[32] The free movement of goods includes free movement of medicinal goods, which must be regulated to ensure safety, quality and efficacy of pharmaceuticals. The movement of goods potentially hazardous to human health, such as dangerous consumer items, also needs regulation. Free movement of persons includes movement of patients and of medical professionals, who may also move freely to provide or receive services

[33] Matters such as air and water quality are major determinants of public health, as may be the presence of substances hazardous to human health in the environment

[34] Food law would be a major component of health related consumer protection law, but other areas, such as cosmetics, could also be included.

[35] The use of competition law to attack anti-competitive agreements such as those granting intellectual property rights to subsidiaries, or the enforcement of intellectual property rights by dominant firms, applied to the pharmaceuticals industry, may have implications for the pricing of pharmaceuticals and other medical goods within the Member States, thus affecting health care provision

[36] Legislation protecting workers from workplace hazards and occupational illness and accidents make a contribution to health protection.

[37] See, for instance, Maduro, *We the Court* (Oxford: Hart, 1998); Maduro, 'Striking the Elusive Balance between Economic Freedom and Social Rights in the EU' in Alston, ed *The EU and Human Rights* (Oxford: OUP, 1999), Weatherill, *Law and Integration in the European Union* (Oxford. Clarendon, 1995), Weiler?, *****

[38] Article 10 (ex 5) EC

[39] For example, in Case C-120/95 *Decker* [1998] ECR I-** and Case C-158/96 *Kohll* [1998] ECR I-**, it was held that Luxembourg was not permitted to require prior authorisation for reimbursement from the social security fund for medical goods or services purchased outside its territory, when no such prior authorisation was required when the goods or services were purchased within Luxembourg.

[40] This may arise for instance from the financial drain placed on national policies by virtue of the requirement of non-discrimination on grounds of nationality, for instance requiring non-discriminatory treatment of all migrant EU citizen workers and their families (or possibly all EU citizens see Case C-85/96 *Martinez Sala* [1998] ECR I-**).

[41] See Barnard, 'Regulating Competitive Federalism in the EU? The Case of European Social Policy'. in Shaw, ed, *Social Law and Policy in an evolving European Union* (Oxford: Hart, 2000); Barnard, 'Social Dumping and the Race to the Bottom Some Lessons for the EU from Delaware?' 25 ELRev (2000) 57. See also Mosley, 'The social dimension of European integration' 129 *International Labour Review* (1990) 147-63; Kleinman and Piachaud, 'European Social Policy: Conceptions and Choices' 3 JESP (1993) 1-19; Deakin, 'Labour Law as Market Regulation' in Davies et al, *European Community Labour Law: Principles and Perspectives* (London: Clarendon, 1996)

[42] There is, of course, a third type of response, which is a different sort of argument altogether. This is the argument from neo-liberalism to the effect that social regulation should be limited in any case to the barest minimum Those adopting this position may disagree as to what is required to ensure the efficient operation of the market. Economists may express this equation in terms of market externalities According to these commentators, the dynamic of internal market and competition law is to be encouraged, as preventing state intervention in the efficient operation of the market. Where the competence to adopt measures of social regulation is removed from the states by internal market and competition law, this should not be reallocated to EU institutions, but left to the free market. ***

seek a narrow definition of the material and personal scope of internal market law. However, this response is impoverished by its conceptualisation of the social welfare field as being *either* an EU *or* a national responsibility As noted above, certainly in terms of social policy in general, the European Union may be better described as an area of 'multi-level governance' Although in general, social welfare mainly 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 interactions between institutional actors at both levels.[43] Within that construct, national or sub-national social welfare measures must take their place within the EU's system of governance and vice versa. Thus, the 'repatriation' argument is unsatisfactory as it ignores the multi-level nature of the EU's polity, 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 competencies to bring it into effect as applicable law within all Member States. In its extreme form, this response calls for the creation of a 'European social superstate'.[44] At least at present, this would be impossible for political reasons, even if it were desirable [45] However, a modified form of this response recognises the multi-level nature of social policy making, and seeks to articulate a uniquely 'European' social model within all Community policies. The 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 and promoting the social values inherent in the European social model.

This is the approach promoted first by the Delors Commission, in 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 118a EC provided a legal basis for adoption of directives improving the workplace environment, especially the health and safety of workers. The European Court of Justice has taken a broad view of the notion of 'health and safety' in this context,[46] referring to the WHO's definition of health, as 'a state of complete psychic, mental and social well-being'. Thus Article 118a (now 137) 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.[47] Article 130r (now 174) EC provided that the Community's environmental policy is to include among its objectives the protection of public health Most significant was the new Article 100a (now 95) (3) EC, which specifically provides that the Commission, in proposing harmonisation measures 'which have as their object the establishment and functioning of the internal market', shall 'take as a base a high level of protection' in measures concerning 'health, safety, environmental protection and consumer protection'. This is an explicit Treaty recognition 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 'mainstreaming' of health into Community policies was brought even more firmly into focus by the Maastricht and Amsterdam amendments to the Treaty Article 3 (p) EC[48] 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 Community competencies in the field. Old 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 this was transformed to its 'strong' form in Article 152 (1) EC: 'a high level of health protection shall be ensured in the definition and implementation of all Community policies and activities' 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.[49]

The beefing up[50] of the mainstreaming element in Article 152 EC is said to be[51] in response to the arguments of the UK government in Case C-180/96-R *UK* v *Commission*,[52] 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 feed or human food chain, or materials destined for use in pharmaceuticals or cosmetics) were adopted on the basis of economic measures and the need to reassure consumers and protect the beef market. The UK sought an interim suspension of the ban with respect to various products for which the risk of BSE was not established or had been eliminated by national measures. Essentially, the UK argued that the ban was not justified for such products. The Court took the view that the potentially[53] serious harm to public health posed by BSE did justify the measures. Implicit in the Court's reasoning was the position 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.[54] This implicit position was made more explicit by the 'strong mainstreaming' of public health protection in all Community policies, effected 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 enacted 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 within the Member States 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 section is to organise according to the definition of health policy developed in the introduction, rather than according to the traditional divisions of Community law. The focus remains on the role of law in determining the content of such policy, and the extent to which the values of the 'European social model' are upheld in its provisions.

Health policy, as noted above, is concerned with all aspects of the provision of healthcare. It includes individual entitlements to medical treatment, the regulation of health professionals, the regulation of production and marketing of medicinal products, the administration of health care services, the protection of public health and the promotion of health generally. Each of these is now considered in turn

(i) Individual entitlements to medical treatment

In general, entitlements to medical treatment and health care are determined according to the provisions of national law. All the Member States have a national health system ensuring near universal access to comprehensive service, although the details and mechanisms of provision vary considerably.[55] However, the rights of patients to health care within the Member States of the EU are affected by a number of EU-level measures.

Migrant workers, who are nationals of a Member State ('citizens of the EU'[56] (EUCs)),[57] and their families (irrespective of nationality) enjoy health care entitlements in the host state under Regulation 1612/68/EEC and Regulation 1408/71/EEC. These measures aim to promote the free movement of (EUC) workers within the EU, but each utilises a different model with which to do so. Regulation 1612/68 is a measure of regulatory EU-level harmonisation, based on the principle of non-discrimination for migrant workers. Thus according to Regulation 1612/68, Article 7, EUC migrant workers and their families are entitled to 'the same social ... advantages as national workers'. This would clearly include access to national health service provision, on the same basis as national workers [58]

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 detriment in respect of their social security entitlements as a consequence of having exercised their rights to move freely to work within the EU. The Regulation does not apply to 'social and medical assistance', but only to 'social security' [59] However, this concept includes various health benefits: Title III, chapter 1 of the Regulation[60] covers the coordination of sickness and invalidity 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 basis as for nationals of that state.

Regulation 1408/71, Article 22 covers the entitlements of insured persons falling within the scope of the Directive[61] to sickness benefits Where insured persons are staying in the territory of another Member State,[62] and their condition necessitates immediate treatment, they are entitled to receive health care or medical treatment from the health care institutions of the state in which they are staying, on the same terms as those insured within that state, as if they were insured with it.[63] These 'benefits in kind' are provided on behalf of the competent Member State; in other words the financial burden falls on the competent Member State. Article 22 also makes provision for the competent Member State to authorise receipt of medical treatment in another Member State [64] Authorisation may not be refused 'where the treatment in question is among the benefits provided for by the legislation of the Member State on whose territory the person

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[43] Indeed, the hierarchical metaphor of 'levels' is perhaps inappropriate here. Better, descriptively, would be the idea of a matrix, network or web of regulatory actors. See Armstrong, 'Governance and the Single Market' in Craig and de Búrca, eds *The Evolution of EU Law* (Oxford· OUP, 1999).

[44] See, for instance, Simpson and Walker, eds, *Europe for richer or poorer?* (London: CPAG, 1993), Check Mancini's 'case for statehood' article ***

[45] Check Weiler's response *** Ref to the constitutionalism literature that escapes from the 'statehood'/nation model, and reconceptualises EU as post-national polity.

[46] Case C-84/94 *UK* v *Council (Working Time)* [1996] ECR I-5755 See Barnard, *The ECJ's Working Time Judgment: The Social Market Vindicated* CELS Occasional Paper No 2, 1997.

[47] This is significant as Article 95 (2) (ex 100a) EC provides for unanimous voting in Council (under Article 94 EC) on internal market measures concerning 'the rights and interests of employed persons', whereas Article 137 (ex 118a) provides for qualified majority voting.

[48] Ex Article 3 (o) EC added at Maastricht

[49] See Case C-376/98 *Germany* v *Parliament and Council (Tobacco Advertising)* and Case C-74/99 *R* v *Secretary of State for Health and others ex parte Imperial Tobacco and others*, 5 October 2000. See Hervey, 'Up in Smoke· Community (anti) tobacco law and policy' 26 ELRev (2001) 101-125.

[50] Perhaps an unfortunate metaphor, in the context of the very serious nature of BSE/CJD.

[51] Geyer, *supra n* *, p 175

[52] [1996] ECR I-3903.

[53] At the relevant time, the link between BSE and CJD was not clear.

[54] See para 63.

[55] See Freeman, supra n *; Saltman et al, eds, *Critical Challenges for Health Care Reform in* Europe (Buckingham, Open University Press, 1998); McCarthy and Rees, *Health Systems and Public Health Medicine in the EC* (London. Royal College of Physicians, 1992); Elola et al, 'Health indicators and the organization of health care systems in Europe' 85 *American Journal of Public Health* (1995) 1397

[56] Article 17 EC

[57] The position of migrant workers from other states (third country nationals) is less privileged in Community law.

[58] The Court adopted a broad approach to 'social advantages' in Case 207/78 *Even* [1979] ECR 2019. In the context of benefits related to health, see, for example, Case 63/76 *Inzirillo* [1976] ECR 2057 concerning a disability allowance and Case 65/81 *Reina* [1982] ECR 33 concerning a childbirth loan.

[59] This term is not defined by the Regulation. The Court's jurisprudence focuses on whether the benefit accrues as of right, after a period of employment of affiliation to a social insurance scheme, on the occurrence of a specific risk, of whether there is an element of discretion or means testing. See e g. Case 139/82 *Piscitello* [1983] ECR 1427; Barnard, supra *n* *.

[60] Articles 18-36

[61] 'An employed or self-employed person who satisfies the conditions of the legislation of the competent state for entitlement to benefits' (Article 22 (1)). The personal scope of the Regulation is thus a matter for national law.

[62] This need not be for the purposes of employment or business, so includes travel for tourism.

[63] The 'E111 scheme' Regulation 1408/71, Article 22 (1)(a).

[64] Regulation 1408/71, Article 22 (1)(c) This scheme is much used by Luxembourg, whose size precludes maintaining all necessary health care facilities, see Lonbay, 'Free movement of health care professionals' in Goldberg and Lonbay, eds, *Pharmaceutical Medicine, Biotechnology and European Law* (Cambridge. CUP, 2000)

concerned resides and where he cannot be given such treatment within the time normally necessary for obtaining the treatment in question in the Member State of residence taking account of his current state of health and the probable course of the disease' [65] Thus there is no general duty on Member States to authorise the receipt of medical treatment, save in the unusual situation in which the treatment sought is not available in the competent Member State.[66]

In general, the system set up by Regulations 1612/68 and 1408/71 is relatively uncontentious, as the state providing the health service is usually also the state receiving contributions from the patient (either in the form of taxation or of social security contribution or both) who is working within that Member State, or at least can claim compensation from that state, through the complex system of financial transfers between Member States set up by Regulation 1408/71. The idea that a Member State should not be required to pay for health care in circumstances in which that state has received no (tax or social security) contributions in respect of the patient is also reflected in the 'residence directives',[67] which explicitly provide that non-workers who take up residence rights in a Member State other than that of which they are a national must have sufficient resources to avoid becoming a burden on the medical assistance schemes of the host state. Thus, for instance, the increasing numbers of retired northern Europeans resident in the warmer climes of Mediterranean Member States must have private medical insurance. This is significant, as it may prevent a 'race to the bottom' in welfare provision in 'sunshine states'.[68] Indeed, there is evidence that such free movers are returning to utilise the health care systems of their home states when their health deteriorates to the point at which the cost of private insurance becomes prohibitive [69]

In addition to the measures applicable to migrant *workers*, the European Court of Justice has developed the Treaty provisions on freedom to provide and receive *services* in the health care field, in effect creating a freedom of movement for patients The Court has explicitly held that privately remunerated medical services fall within the Treaty provisions on freedom to provide services [70] The Community law rights to provide and receive medical services across borders have proved particularly controversial in the field of human reproduction Although the fact pattern of *Grogan*[71] was such that Community law was not applicable, the implication was that abortion, though unconstitutional in Ireland, falls within the definition of 'service' in Community internal market law. This prompted some commentators to call for a clear demarcation between national and EU-level norms in this field [72] A happier story was that of Diane Blood, who successfully relied on her Community law rights before national courts,[73] in order to seek private IVF treatment in Belgium, in circumstances in which it would have been unlawful in her home state of the UK.[74]

The Court has adopted a relatively wide concept of 'privately remunerated' medical treatment, in the context of the freedom to provide and receive services, holding that, in certain circumstances, treatment reimbursed under a national social security scheme may be included In the *Kohll* case, a Luxembourg national challenged the refusal of authorisation from the social security medical supervisors for his daughter to receive dental treatment in Trier, Germany. The Court of Justice found that the fact that the national rules at issue fell within Regulation 1408/71 did not exclude the application of the Treaty provisions on freedom to provide and receive services. Treatment was to be provided on a private basis, 'outside any hospital [i.e public] infrastructure'.[75] The need for prior authorisation for cross border receipt of services, where no such authorisation was needed for receipt of the same services within Luxembourg, was thus discriminatory, contrary to Articles 59 and 60 EC Luxembourg argued that the national rules were justified by the need to control health expenditure. However, Kohll was seeking remuneration only at the flat rate provided for within the Luxembourg system Thus, according to the Court, the application of the free movement rules presented no threat to the financial stability of the relevant social security scheme Justification was not established

Thus *Kohll* establishes that, provided that no direct threat is posed to the financial stability of the social security funds, individuals may receive health services from providers in another Member State, and require that their national social security funds meet the cost, at least at the rate at which the services would be reimbursed if the benefit were received in the home Member State Of course, this principle applies only in the case of health services provided through the mechanism of cash benefits to be spent in the market of social service providers [76] Two distinct pressures on national health systems may arise from the rulings. Difficulties experienced by those Member States whose nationals go elsewhere to receive medical treatment[77] are unlikely to affect Member States where health services are not, in the main, financed through a mechanism of cash benefits. However, a Member State in which professionals have both national health service and privately funded patients[78] might find itself becoming a 'host state', to which patients go to receive medical goods or services. Such host states may experience an unpredictable influx of patients This may have an impact on health care provision for nationals, for instance longer waiting lists. Nothing in the *Kohll* judgment[79] appears to provide a mechanism by which such host states may protect the stability of their health service systems, as they may not lawfully refuse treatment to non-nationals as to do so would be discriminatory, contrary to Articles 49 (ex 59) and 12 (ex 6) EC Moreover, a Member State that provides a higher standard of service, better value for money, or a greater choice for medical 'consumers' is likely to attract more free movers to receive these services Member States whose medical profession enjoys a high reputation may attract free movers seeking treatment. As a worst case scenario, if such pressures reached extreme levels, there might be a temptation on the part of the national authorities of those states to reduce the quality of service provided, in order to discourage such 'medical tourism' - a classic 'race to the bottom' Thus, in terms of *Kohll*, the Court seems to have paid insufficient attention to upholding the values implicit in the 'European social model' [80]

Finally, Community law has had an impact on the entitlement to medical treatment and health care for men and women in the Member States of the EU through its measures concerning sex equality in social security, in particular, Directive 79/7/EEC [81] Directive 79/7/EEC applies to workers and the self-employed, those who are unable to work due to illness, accident or involuntary unemployment, work-seekers and retired workers [82] Its material scope covers statutory social security schemes protecting against *inter alia* sickness, invalidity, accidents at work and occupational diseases The Directive also covers 'social assistance', in so far as it is intended to supplement or replace those schemes.[83] Social assistance schemes are covered if they are 'directly and effectively linked' to one of the enumerated risks.[84] For instance, in *Richardson*,[85] the Court held that the Directive applies to UK national health service prescription charges, as protecting against the risk of sickness. The UK's argument, to the effect that the exemption with respect to 'the determination of pensionable age for the purposes of granting old-age and retirement pensions, and the possible consequences thereof for other benefits'[86] applied, was rejected. The removal of the discrimination between men and women would produce no consequences for the financial equilibrium of the social security scheme, as persons claiming free prescriptions would no longer be liable for national insurance contributions. Thus equal treatment of men and women is required, according to Community law, in the provision of health care services falling within the scope of the Directive. Equality of treatment is itself a value implicit in the 'European social model' The Court has also paid attention to the potential for EU-level norms to undermine the coherence and therefore the financial viability of national social security provision, in its jurisprudence on the application of the exemption provisions,[87] of which *Richardson* is one example. The Court has developed a principled balance between non-discrimination and financial viability of schemes Thus it might be said that the application of the sex equality provisions is sensitive to the European social model

(ii) Regulation of health professionals

All Member States of the EU regulate the practice of health care by professionals. Professional regulation is undertaken by quasi-public bodies, which grant entitlements to utilise medical professional titles and to practice branches of the medical profession. These entitlements are usually based on the qualifications required to carry out a medical professional activity. Regulation of health professionals fulfils two key health policy goals: to ensure that such professionals are competent and appropriately trained, so as to safeguard patient safety; and for reasons of cost containment. Professional regulation is thus a key component of national health policies.

In principle, health professionals within the EU[88] enjoy the freedom of movement to work and the right of establishment in a Member State other than that of their nationality in accordance with Community law The basic Treaty provisions of Articles 39, 43, 49 and 50 EC apply The exemption provided in Article 39 allowing restrictions on the grounds of public policy, security and health applies only to individuals, and may not be used by Member States to restrict access to the medical profession, or branches of the medical profession, as a whole.[89]

However, there are considerable differences in practice between national regulatory regimes for medical professionals in the Member States.[90] To facilitate the movement of health professionals, the EU institutions have enacted a number of directives on the mutual recognition of qualifications in the health field [91] These directives set out an agreed core of requirements for professional training in each profession, and abolish restrictions on freedom of establishment based on the fact that a professional qualification was obtained in a Member State other than

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[65] Regulation 1408/71, Article 22 (2)

[66] See Case 117/77 *Pierek No 1* [1978] ECR 825 and Case 182/78 *Pierek No 2* [1979] ECR 1977. See further Van der Mei, 'Cross-border access to medical care within the EU' 5 MJ (1998) 277-97, Hervey, 'Buy Baby: The European Union and the Regulation of Human Reproduction' 18 OJLS (1998) 207-33, at 215-6

[67] Directive 90/366/EEC OJ 1990 L 180/30 (replaced by Directive 93/96/EC OJ 1993 L 317/59); Directive 90/365/EEC OJ 1990 L 180/28; Directive 90/364/EEC OJ 1990 L 180/26.

[68] Havinghurst claims that this took place in the United States, with respect to the 'sunshine states' of California and Florida downsizing welfare benefits in an attempt to avoid an influx of poor people, see Havinghurst, 'American Federalism and American Health Care. Lessons for the European Community' in Hermans, Caspane and Paelinck, supra n *, p 42.

[69] Dwyer, 'Retired EU Migrants, Healthcare Rights And European Social Citizenship' * JSWFL (2001) (forthcoming).

[70] Cases 286/82 and 26/83 *Luisi and Carbone*. [1984] ECR 377, para 16 This ruling was confirmed in respect of the medical treatment of abortion in Case C-159/90 *SPUC* v *Grogan* [1991] ECR I-4685

[71] Case C-159/90 *SPUC* v *Grogan* [1991] ECR I-4685

[72] See in particular Phelan, 'Right to Life of the Unborn versus Protection of Trade in Services The European Court of Justice and the Normative Shaping of the EU' 55 MLRev (1992) 670-89

[73] *R* v *HFEA ex parte Diane Blood* [1997] 2 All ER 687 (Court of Appeal).

[74] See further Hervey, supra n *

[75] Para 29.

[76] It would not apply where a Member State makes provision through publicly funded services and health services are free at the point of receipt.

[77] In particular, loss of control over supply as a cost containment measure.

[78] As is the case, for instance, with dental professionals in the UK

[79] Or in its companion case, Case C-120/95 *Decker* [1998] ECR I-**, concerning free movement of 'medical goods', in this case prescription spectacles.

[80] However, in other cases involving potential jeopardy to national social systems, the Court has utilised the notion of 'social solidarity' to protection such values. This concept could be applicable in future cases concerning the application of internal market law to medical services. See further Hervey, 'Social Solidarity. A buttress against internal market law' in Shaw, ed *Social Law and Policy in an Evolving European Union* (Oxford. Hart, 2000) 31-47

[81] OJ 1979 L 6/24

[82] Directive 79/7/EEC, Article 2

[83] Directive 79/7/EEC, Article 3

[84] Case C-243/90 *Smithson* [1992] ECR I-467

[85] Case C-137/94 [1995] ECR I-3407.

[86] Directive 79/7, Article 7 (1)(a).

[87] See for instance Case C-92/94 *Graham* [1995] ECR I-2521

[88] The discussion below applies to health professionals who are citizens of the EU; the position of third country nationals is less clear.

[89] Case 131/85 *Gül* [1986] ECR 1573, Case 307/84 *Commission* v *France* [1986] ECR 1725, see ter Kuile, du Pré and Sevinga, 'Health Care in Europe after 1992. the European dimension' in Hermans, Caspane and Paelinck, eds, *Health Care in Europe after 1992* (Aldershot Dartmouth, 1992), p 12

[90] Lonbay, supra n *, p 46-47

[91] Doctors. Directive 75/362/EEC and 75/363/EEC OJ 1975 L 167, as amended by Directive 93/16/EEC OJ 1993 L */*. See, in general, Finch, 'Professional Recognition and Training of Doctors' 2 *European Journal of Health Law* (1995) 163-174, Dentists· Directives 78/686/EEC and 78/687/EEC OJ 1978 L 233; Pharmacists: Directives 85/432/EEC and 85/433/EEC OJ 1985 L 253; pharmacists do not, however, have an automatic right to establish a pharmacy in another Member State, as some Member States control the geographic distribution of pharmacies for social and cost containment reasons.; Nurses: Directives 77/452/EEC and 77/453/EEC OJ 1977 L 176, Midwives· Directives 80/154/EEC and 80/155/EEC OJ 1980 L 33

that in which the professional wishes to practice. National authorities giving authorisation to health professionals practising within their territory are obliged to recognise qualifications obtained in another Member State [92] Other health professionals, for instance those whose work is not regulated in all Member States,[93] may rely on the general 'new approach' Directive 89/48/EEC on the recognition of higher education diplomas.[94]

In practice, the level of migration of health professionals remains fairly low, with the exception of movement between Member States with a shared language,[95] and movement at the borders of Member States [96] However, the Directives have increased mobility, with the UK as the most popular destination for migrant doctors.[97] 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 recognised in one, but not other EU states.[98] The Court of Justice has confirmed that the adoption of the mutual recognition directives does not render the basic Treaty provisions on freedom of movement inapplicable.[99] Thus health professionals may enforce their rights to move freely to exercise their professions within the EU. This may have implications for capacity building and for cost containment in national health policies Capacity building problems need not undermine the European social model, so long as sufficient numbers of medical professionals are being trained across the EU as a whole. However, if internal market law 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.[100]

(iii) Regulation of production and marketing of medicinal products

The law relating to medicines or pharmaceuticals is a component of health law.[101] In all Member States of the EU, the law regulates the development, manufacture, licensing, importation, distribution, marketing and retail of pharmaceuticals and other medical products However, such regulation is not simply a matter of national law. A significant body of EU-level norms, dating back to the 1960s, concerns pharmaceuticals. Moreover, to the extent that national regulations governing pharmaceuticals may impede the 'establishment and functioning of the internal market', they may be subject to Community internal 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 authorisation for new medicinal products;[102] measures on the authorisation of manufacture of medicinal products;[103] measures on surveillance of safety of pharmaceuticals during their life on the market ('pharmacovigilance');[104] measures concerning labelling and packaging of pharmaceuticals;[105] and measures on advertising of pharmaceuticals.[106] Directive 65/65/EEC[107] is the earliest EU-level measure with the aim of harmonising safety and efficacy standards for medical products. Enacted in response to the thalidomide tragedies of the early 1960s,[108] the Directive required Member States to enact laws to ensure that new medical products may not be marketed on their territories without the approval of a competent regulatory body

More detailed harmonisation provisions for the criteria and procedures according to which approval may be given by national regulatory bodies for new medical products followed. A large number of detailed provisions of secondary legislation now cover all industrially produced medicines.[109] The Commission, in accordance with power delegated for this purpose by the Council, regularly updates technical requirements governing testing of new medicinal products.[110] In addition to criteria relating to quality, safety and efficacy, rules relating to procedures for marketing authorisation (time limits, giving of reasons, publication),[111] to manufacture (quality control, inspections),[112] to labelling (packaging to include information relating to dose, ingredients, side effects)[113] and to advertising of medical products (advertisement to the general public of prescription drugs is prohibited)[114] have been harmonised. These provisions are consolidated in the Commission's multi-volume publication 'The Rules governing Medicinal Products in the European Community'.[115] Rules protecting consumers from defective medicinal products in situations where these safeguards fail are found in the Product Liability Directive.[116]

Other provisions appear to be aimed 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, was established by Directive 93/39/EC.[117] A 'centralised procedure', according to which EU-level approval may be given to certain medicinal products by a new EU-level administrative agency, the European Medicines Evaluation Agency (EMEA), was set up by Regulation 2309/93/EC.[118] EMEA authorisation is compulsory for all new medicinal products derived from biotechnology, and is optional for other 'innovative' products.[119]

The cross-border marketing of medicinal products has also been affected by Community internal market and competition law. Prices obtaining for pharmaceutical products vary widely between Member States [120] This 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 on the matter [121] In many circumstances, the Court has upheld the Member States' discretion to protect public health in holding the restriction on parallel trade justified.[122] However in others, the Court has favoured the parallel trade, holding that neither the exemption in Article 30 EC, nor the 'mandatory requirements' of *Cassis de Dijon*,[123] nor the protection of intellectual property rights[124] justifies the non-application of Community internal market or competition law.[125] The Court has taken the view that measures in effect constraining parallel trade are not necessarily

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[92] The system is overseen by a comitology procedure, within which information on national training systems is exchanged; Decision 75/364/EEC OJ 1975 L 167/17; Decision 75/365/EEC OJ 1975 L 167/19.
[93] For instance, physiotherapists, see McKee, Mossialos and Belcher, 'The Influence of European Law on National Health Policy' 6 *Journal of European Social Policy* (1996) 263-86.
[94] OJ 1989 L 19/16.
[95] For example, the UK and Ireland, Belgium and France; Germany and Austria.
[96] For example, Dutch dentists providing services on German territory because the Netherlands restricts the numbers of dentists to one for every so many inhabitants, whereas German law has no such restriction, see Pierson and Leibfried, 'Semisovereign Welfare States: Social policy in a multitiered Europe' in Leibfried and Pierson, eds *European Social Policy* (Washington: Brookings, 1995).
[97] Lonbay, supra n *, p 66-67.
[98] See for instance Case C-16/99 *Erpelding* [2000] ECR I-*, Case C-238/98 *Hocsman* [2000] ECR I-*; Case C-371/97 *Gozza* [2000] ECR I-*.
[99] Case C-340/89 *Vlassopoulou* [1991] ECR I-2357 *** check
[100] Consider pharmacists provisions here? ***
[101] See Montgomery, *Health Care Law* (Oxford. OUP, 1997), chapter 9; McHale and Fox, *Health Care Law: Text and Materials* (London: Sweet and Maxwell, 1997), p 188-193.
[102] The 'hub and lynchpin' of Community pharmaceuticals law, see the Opinion of AG Lenz in Case */* *Upjohn* [1991] ECR I-1702, para 14. Directive 65/65/EEC, as amended
[103] Directive 75/319/EEC OJ 1975 L */*, Directive 91/356/EEC OJ 1991 L 193/30.
[104] Directive 75/319/EEC OJ 1975 L */*; Directive 93/39/EC OJ 1993 L */*; Regulation 2309/93/EC OJ 1993 L */*; Regulation 540/95/EC OJ 1995 L 55/5.
[105] Directive 92/27/EC OJ 1992 L */*
[106] Directive 92/28/EC OJ 1992 L 113/13; see also Directive 84/450/EEC on misleading advertising OJ 1984 L 250/17 and Directive 89/552/EEC 'TV without frontiers' OJ 1989 L 298/23.
[107] OJ 1965 L 369/65; OJ Sp Ed p 20. Now amended and consolidated by Directive 93/39/EC OJ 1993 L 214/22.
[108] White, 'Whither the Pharmaceutical Trade Mark? 8 *European Intellectual Property Review* (1996) 441-445, p 441; Gardner, 'The European Agency for the Evaluation of Medicines and European Regulation of Pharmaceuticals' 2 ELJ (1996) 48-82, p 52, Kaufer, 'The Regulation of New Product Development in the Drug Industry', in Majone ed *Deregulation or Re-regulation? Regulatory Reform in Europe and the United States* (Pinter, 1990) p 157.
[109] Including vaccines, toxins or serums and allergens: Directive 89/342/EEC OJ 1989 L 142/14; blood products. Directive 89/381/EEC OJ 1989 L 189/44, radiopharmaceuticals: Directive 89/343/EEC OJ 1989 L 142/16; and medical devices Directive 90/385/EC on active implantable medical devices OJ 1990 L 189/17; Directive 93/42/EC on medical devices OJ 1993 L 169/1.
[110] Council Recommendations 83/571 and 87/176 concerning tests relating to the placing on the market of proprietary medicinal products OJ 1983 L 332/11 and OJ 1987 L 71/1 ** New rules agreed Jan 2001 See Watson, 'EU Harmonises rules for trials' BMJ 2001;322 68 See Sauer, 'The European Community's Pharmaceutical Policy' in Hermans, Casparie and Paelinck eds *Health Care in Europe After 1992* (Dartmouth, 1992) p 133 Amendments are made according to the 'regulatory committee procedure', under which the Committee must support the Commission proposal by a qualified majority in order for the amendment to be adopted.
[111] Directive 93/39/EC amending Directive 65/65/EEC and Directives 75/318/EEC, 75/319/EEC OJ 1975 L 147/1
[112] Directives 75/318 and 75/319/EEC; Directive 87/18 on harmonisation concerning the application of principles of good laboratory practice and the verification of their application for tests on chemical substances OJ 1987 L 15/29; Directive 88/320 on inspection and verification of good laboratory practice OJ 1988 L 145/35.
[113] Directive 92/27 OJ 1992 L 113.
[114] Directive 92/28 OJ 1992 L 113. Officially supported vaccination campaigns are exempted (Article 3 (5)). See also Directives 92/25 and 92/26 OJ 1992 L 113.
[115] http://dg3 eudra.org/eudralex/index.htm
[116] Directive 85/373/EEC OJ 1985 L 210/29. However, the Directive includes the 'development risks defence' according to which if at the time of manufacture of the product, the state of scientific and technical knowledge was such that the risk of harm was not foreseeable, the producer will not be liable under the Directive, Article 7 (e). In the case of medicinal products, a classic development risk is a side effect that has a long latency period, and therefore only materialises some years after the product is marketed.
[117] OJ 1993 L 214/22. However, it appears that the mutual recognition of national authorisations works more in theory than in practice. Many national authorities 'exhibit an extreme reluctance to accept the assessment of the Reference Member State', see Commission, Enterprise DG, *Evaluation of the operation of Community procedures for the authorisation of medicinal products* (Brussels: Commission, 2000), prepared by Cameron McKenna/Andersen Consulting.
[118] OJ 1993 L 214 For further information on these procedures see Gardner, 'The European Agency for the Evaluation of Medicines and European Regulation of Pharmaceuticals' 2 ELJ (1996) 48-82; Abraham and Lewis, supra n *; Cuvillier, 'The role of the European Medicines Evaluation Agency in the harmonisation of pharmaceutical regulation' in Goldberg and Lonbay, eds, supra n *.
[119] Regulation 2309/93/EC, Article 3 (1) and (2); Annex Parts A and B. 'Innovation' is to be defined in accordance with the opinion of the EMEA. These provisions supersede the earlier Directive 87/22/EEC OJ 1987 L */*. The number of centralised marketing authorisations (compulsory and optional) has grown steadily since 1995. In 2000, some 122 medicinal products had received authorisation through the centralised procedure.
[120] The reasons for this included exchange rate movements, but also the special features of both the supply and demand sides of the pharmaceuticals market. On the supply side, pharmaceuticals companies, in an industry of innovation, depend heavily on research and development, and their profitability is based on patent protection for a few successful products over relatively short periods of time. On the demand side, the ultimate consumer of the product (the patient) pays at most only part of the price of the product. (In fact, many consumers are exempt from any co-payment at all, see Noyce et al, 'The cost of prescription medicines to patients' 52 *Health Policy* (2000) 129-145.) The remainder of the cost is met either by the government, from taxation, or, in systems where health protection is paid for by (compulsory) insurance, by the insurer. Further, neither the patient nor the government or insurer determines which product is bought, or how much is bought: this is a matter for the medical professional prescribing the medication. Finally, access by patients whose diseases or disorders require treatment, to many of the products produced by the pharmaceutical industry, is perceived to be a matter of 'life and death', or at least of 'quality of life'. Medicines – like other public goods or services such as energy, water or transport – are seen as essential in ways that most other goods are not. See Mossialos and Abel-Smith, 'The Regulation of the European Pharmaceutical Industry' in Stavridis, Mossialos, Morgan and Machlin, eds, *New Challenges to the EU. Policies and Policy-Making* (Aldershot: Dartmouth, 1997); Thompson, *The Single Market for Pharmaceuticals* (London: Butterworths, 1994) p 8; Hancher, 'EC Competition Law, Pharmaceuticals and Intellectual Property: recent developments' in Goldberg and Lonbay, eds, supra n *, p 77.
[121] For discussion of the relevant jurisprudence, see Thompson, supra n *; Hancher, 'The European Pharmaceuticals Market: problems of partial harmonisation' 15 ELRev (1990) 9-33; Hancher, 'Creating the Internal Market for Pharmaceutical Medicines. An Echternach Jumping Process' 28 CMLRev (1991), 821-853; Oliver, *Free Movement of Goods in the European Community* (Sweet and Maxwell, 1996), p 215; Kon and Schaeffer, 'Parallel Imports of Pharmaceutical Products: A New Realism or Back to Basics' 18 ELRev (1997) 123-144; Hancher, in Goldberg and Lonbay, supra n *.
[122] Case 32/80 *Kortmann* [1981] ECR 251, Cases 266 & 267/87 *R* v *Royal Pharmaceutical Society of Great Britain, ex parte Association of Pharmaceutical Importers and others* [1989] ECR 1295; Case C-369/88 *Delattre* [1991] ECR I-1487; Case C-60/89 *Monteil and Samanni* [1991] ECR I-1547; Case C- 94/98 *Rhone-Poulenc Rorer* [1999] ECR I-8789; Case C-55/99 *Commission* v *France* [2000] ECR I-**.
[123] See Case 104/75 *De Peijper* [1976] ECR 613, Case 181/82 *Roussel* [1983] ECR 3849; Case 56/87 *Commission* v *Italy* [1988] ECR 2919, Case 215/87 *Schumacher* [1989] ECR 617; Case C-347/89 *Freistaat Bayern* v *Eurim-Pharm* [1991] ECR I-1747; Case C-249/88 *Commission* v *Belgium* [1991] ECR I-1275; Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575
[124] Case 15/74 *Centrafarm* v *Sterling Drug* [1974] ECR 1147; Case 16/74 *Centrafarm* v *Winthrop* [1974] ECR 1183; Case 187/80 *Merck* v *Stephar* [1981] ECR 2063; Cases C-267 & 268/95 *Merck* v *Primecrown* [1996] ECR I-6285
[125] See Case IV/M 555 *Organon* OJ 1995 C 65/4; *** check Glaxo in Spain case; Commission Decision concerning Adalat OJ 1996 L 201/1 ** check progress of case before ECJ.

justified on grounds of consumer protection, as consumer interests are also met by the availability of cheaper pharmaceuticals. In fact, in *Duphar*,[126] the Court explicitly held that an Article 30 EC justification would not be available where the national cost containment rules[127] had an 'economic', rather than specifically public health protection, basis. The Court's approach may therefore be seen as giving little support for a longer term public health interest in maintaining and supporting national pharmaceuticals 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 national regulatory regimes, in setting up EU-level institutional fora (committees) in which disputes between national authorities may (and in some cases must) be resolved and in requiring minimum standards of consumer protection where medicinal products cause harm. Community law therefore has a significant effect on this aspect of national health policies It is difficult to provide a general assessment of the extent to which the EU-level measures in this field underpin a European social model. To the extent that EU-level re-regulatory harmonisation has taken place, and also to the extent that exceptions apply to the internal market rules, this suggests a recognition that the free play of the market must be tempered in order to protect public health However, Abraham and Lewis[128] make a convincing case to the effect that the new marketing authorisation procedures have had the effect of suppressing genuine medical or scientific concerns about the safety and clinical efficacy of new medicines[129] in the name of EU-level 'efficiency'. Moreover, 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 genuinely *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 expected through harmonisation 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 for 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 such aspect: the pricing of pharmaceuticals.[130] Since around the beginning of the 1970s, health policies in all advanced capitalist states, including the Member States of the EU, have been concerned with searching 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 [131] One regulatory measure of cost containment is the regulation of pricing of pharmaceuticals.

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 methods are utilised to achieve this end [132] These fall into three main types: volume controls, indirect price controls and profit controls Volume controls limit either by 'positive lists' or 'negative lists' the type of products that may be reimbursed under the national health system.[133] The market for those 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 for which reimbursement is available are competitively priced, for instance by using generic rather than proprietary products where possible. Indirect price controls operate in various ways. The level of reimbursement 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 pharmacists 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, Portugal, Greece).[134] This division goes some way to explaining the division between 'high price' Member States such as Germany, and 'lower price' Member States.

All of these measures restrain the application of normal market rules to the sale and supply of pharmaceuticals Consequently, as noted above, there is no single internal market in pharmaceuticals in the EU [135] 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 measures of public health law concerning 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 *Schumacher*[136] 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 his personal use from a French pharmacy, a medicinal product 'Chophytol', used to treat dyspepsia and as a diuretic Chophytol 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 provisions on the free movement of goods.

The German government argued that the measure was justified on public health grounds.[137] 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 authorisation for pharmaceuticals, contained in Directive 65/65/EEC, as amended.

The Court gave this argument 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 directives.[138]

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*,[139] 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 private importation of pharmaceuticals by post. Again the German government posited a public health justification, this time on the grounds that the labelling and packaging of the product would be in a different language, and this would constitute a danger to human health The Court took the view that 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 packaging issue had already arisen before the Court in *Eurim-Pharm*.[140] This did not concern private imports of pharmaceuticals, but parallel imports by a company, Eurim-Pharm Eurim-Pharm imported into Germany pharmaceuticals authorised for marketing in other Member States, and repackaged them in order to comply with German law on packaging of medicinal products. The German law required an import certificate, authorising import, which Eurim-Pharm argued was not necessary, on the grounds that only 'finished medicinal products' needed such an authorisation, and that, as Eurim-Pharm had to repackage the goods, they were not 'finished'. The German court held that the goods were 'finished medicinal products', but that the certificate could not be issued, as the goods, at the time of import, did not comply with the marketing requirements in respect of packaging Thus the combined effect of the relevant measures of German law was to preclude all parallel imports of pharmaceutical products authorised for marketing in other Member States, where such products would have to be repackaged for the German market (in practice, effectively all parallel imports of pharmaceuticals).

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*.[141] That permit ensures that the parallel imports have an identical composition to products already on the German market 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.[142]

The position of mass parallel imports of pharmaceuticals, undertaken by companies rather than private individuals, was considered further in *Lucien Ortscheit*,[143] 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 the country of origin, if the products were ordered by pharmacies in limited quantities on the basis of a prescription from a 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

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[126] Case 238/82 *Duphar* [1984] ECR 523

[127] 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 Mossialos and Abel-Smith, in Stavridos, supra n *, p 375

[128] Supra n *.

[129] Or, to put it another way, the 'therapeutic need' for new pharmaceuticals There are thousands of pharmaceuticals on the European market. The World Health Organisation estimates that only about 250 are necessary to meet basic health needs Norway actually abolished its 'therapeutic needs' clause for marketing authorisation in preparation for (proposed) EU membership, Sweden was forced to abandon its 'second choice' classification for approval of new pharmaceuticals that are no more clinically effective than products already on the market, in order to comply with Community law. See Abraham and Lewis, supra n *, p 210-211.

[130] Other potential impacts might include the impact of Community law on health insurance provision, see for instance Case C-67/96 *Albany International*.[1999] ECR I-5751, discussed in Hervey, in Shaw, supra n *.

[131] See Moran, 'Explaining the rise of the market in health care' in Renade, ed, *Markets and Health Care: A Comparative Analysis* (London: Longman, 1998), p 17-18.

[132] [see e.g. Kon and Schaeffer, 1997. 126, Hancher, 1990: 11; Mossialos and Abel-Smith, in Stavridos et al, 1997 375-383]

[133] [Table re MS lists on p 375 of Mossialos and Abel-Smith, in Stavridos et al, 1997]

[134] Hancher, 1990, supra n *

[135] The Commission has attempted several times to introduce harmonising legislation in this area, but, save Directive 89/105/EEC on the transparency of measures regulating the pricing of medical products for human use and their inclusion in the scope of national health insurance schemes OJ 1989 L 40/8, no significant progress has been made to this effect. Indeed it has been suggested that the Transparency Directive is not effectively enforced, at least in the UK, see Earl-Slater, 'Regulating the price of the UK's drugs: second thoughts after the government's first report' 314 BMJ (1997) 365-8

[136] Case 215/87 [1989] ECR 617.

[137] On the basis of Article 36 (now 30) EC

[138] See above

[139] Case C-62/90 [1992] ECR I-2575

[140] Case C-347/89 *Freistaat Bayern* v *Eurim-Pharm* [1991] ECR I-1747

[141] Case 104/75 *De Peijper* [1976] ECR 613

[142] Para 35

[143] Case C-320/93 [1994] ECR I-5243.

Eurim-Pharm imported such products into Germany, and advertised the products in publications aimed at German health professionals. Lucien Ortscheit, another importer of pharmaceuticals into Germany, sought an order restraining Eurim-Pharm from its advertising activities. The Court found that the prohibition on advertising was contrary to Article 28 EC, as it applied only to 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 a procedure for Community authorisation or mutual recognition of national authorisations, Member States are entitled to prohibit the marketing in their territory of medicinal products not authorised for marketing in that territory, even if authorisation 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 the rules justified. It would be interesting to see whether, given the new procedures on marketing authorisation at Community level, the Court would reach the same decision today 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 in place measures that underpin pricing of pharmaceuticals. The impact of Community law is, of course, limited. However, the administration of national health policies must take place within its context The main thrust of Community law appears to be towards creating a single market in pharmaceuticals It is significant that the issue of the protection of pharmaceuticals prices is not explicitly mentioned in any of the rulings, although the effect of the decisions is to remove various measures from the menu of price control mechanisms available to the German government. Thus it might be said that broader social aims of the national legislation do not appear to have been taken into account

(v) Protection of public health

Historically, the protection of public health through control of diseases was a key component of national health policies, and it remains so today.[144] The EU has also played a role in this respect, in particular as the control of disease is a matter for which clear EU-level 'value added' can be distinguished, as disease does not respect the boundaries of nation states. The EU has supported programmes of action concerning control of communicable diseases for a number of years, even pre-dating the inclusion of (old) Article 129 EC at Maastricht.[145] Where the EU continues to finance worthwhile projects[146] concerning disease control, the EU institutions may be said to be taking on some of the public health role of the Member States, thus again providing an example of multilevel governance in this field. There may also be a significant force for convergence between national health policies, enhanced by the Commission support of such programmes as the AIDS programme, because of the high intensity of inter-country exchanges, agreement on methods, achievement of a uniform and enhanced quality, and the production of common documents and statements prompted by such programmes.[147]

Public health protection is also effected in a number of other areas of public life, including protection of health at the workplace, regulation of dangerous goods and environmental regulation Again the EU has had an impact in these areas, with, for instance, measures of employment law covering health and safety in the workplace,[148] liability for dangerous or defective products[149] and measures on matters such as air and water quality[150] that have an effect on public health. Again space precludes detailed discussion of all such measures The discussion here will concentrate on two high-profile public health concerns, both concerning food law, in which the EU has played a role. the BSE/CJD crisis and the regulation of genetically modified foodstuffs.

The regulation of food – its production, processing, distribution and retail – is an established part of European societies Food is a very densely regulated sector in Community law, with over 80 separate pieces of EU-level legislation on the subject. One key reason[151] for the regulation of food is the protection of public health. Hazards to human health passed on through the food chain, such as bovine spongiform encephalophy (BSE) (but also, for instance, e-coli, salmonella and listeria) justify regulatory responses In the EU context, the internal market requires that such regulation emanates from the EU-level, as, in principle, foodstuffs lawfully produced and marketed in one Member State must be accepted in all other Member States.[152]

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 as being caused by an agent similar to that which causes the sheep disease scrapie. It appears that there is no evidence that BSE can be transmitted other than through the eating of contaminated animal feed Further public concern was generated through the identification of Creutzfeldt 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 does BSE in cattle. In 1996 there were indications that a new form of CJD (vCJD) that had emerged could be linked to consumption of BSE-infected meat. Thus the EU had within its borders, on an undetermined scale, a new, and fatal, human disease, the spread of which had not been contained at the appropriate time, and about which consumers had been misinformed.[153] Little wonder, then, that the ensuing consumer concern (indeed panic) raised fundamental questions about the effectiveness of the regime for regulation of food in the EU

The BSE/CJD crisis had the effect of undermining the trust – on which mutual recognition is based – between governments and consumers in different Member States. It appears that anti-BSE procedures were agreed in 1986, but the UK Ministry of Agriculture Fisheries and Food was unable[154] to enforce them.[155] Moreover, the European Parliament Committee of Inquiry[156] found that the EU institutions, in particular the Commission and Council, had failed to carry out their duties in a number of respects. It appears that, in the balance between deregulation and re-regulation reached with the internal market/mutual recognition approach to food law, a political vacuum had developed, with national governments and Community officials unsure which actions they should and could take at the height of the BSE crisis.[157] In the wake of this, there is now a distinct movement back towards the EU-level imposition of detailed and principled regulatory standards for food These will have a clear impact on public health protection within the Member States.

Other, less crisis-laden, 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 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 organisms in foodstuffs. These in turn have raised health questions and consumer concerns for the safety of such foods. Possible health risks arising from genetically modified foods might include the transfer of carcinogens,[158] or allergens Most food allergies are associated with proteins, with some common foodstuffs containing several allergenic proteins.[159] 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.[160] This does not allay consumer fears to the effect that that genetic modification may exacerbate the problems of food allergies. Another significant health concern arises from the use of 'marker' genes to identify certain plants by their resistance to antibiotics.[161] The consumption of such genetically modified organisms might lead to antibiotic resistance further down the food-chain,[162] and is therefore of concern where the genetically modified product is to be used as food or feed, and where the antibiotic to which it is resistant is one in common use, for instance ampicillin.[163]

The marketing of genetically modified food in the EU is now covered by Regulation 258/97/EC, the 'Novel Foods Regulation' [164] A marketing authorisation must be granted for all genetically modified foodstuffs and foodstuffs with genetically modified ingredients to be sold within the EU Authorisation is granted at EU level, consequent upon a committee procedure, on the basis of a risk assessment of the product In addition, and more significantly from the point of view of consumers, the Regulation requires that genetically modified foods be labelled [165]

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[144] For an historical account, and details on current provision, see Donaldson and Donaldson, *Essential Public Health* (Plymouth Petroc Press, 2000).

[145] See for instance, Decision 91/317/EEC of Council and Ministers of Health of the Member States adopting a plan of action in the framework of the 'Europe against AIDS' programme 1992-1995 OJ 1991 L 175/26; Decision 647/96/EC of European Parliament and Council adopting a programme of Community action on the prevention of AIDS and certain other communicable diseases within the framework for action in the field of public health 1996-2000 OJ 1996 L 95/16, Regulation 550/97/EC on HIV/AIDS related operations in developing countries OJ 1997 L 85/1.

[146] Many of the projects funded under the EU programmes are pilot projects, the implication being that if they are successful, national authorities will take over responsibility for promoting their methodologies

[147] See further Interim Report from Commission to European Parliament, et al, on the implementation of the programmes of Community action on the prevention of cancer, AIDS and certain other communicable diseases, and drug dependence, within the framework for action in the field of public health (1996-2000) COM(99) 463 final. For further discussion, see Hervey, 'The European Union dimension' in Brazier and McHale, eds, *AIDS, Europe and Human Rights* (forthcoming).

[148] See the Framework Directive on health and safety at work Directive 89/391/EEC OJ 1989 L 183/1, and its many 'daughter directives'. For further discussion, see Barnard, supra n *, chapter 6.

[149] See the Product Liability Directive 85/374/EEC OJ 1985 L 210/29. For further discussion, see Weatherill, *EC Consumer Law and Policy* (London. Longman, **)

[150] See e g. Framework Directive 96/62/EC on ambient air quality assessment and management OJ 1996 L 296/55; Bathing water directive 76/160/EEC OJ 1976 L */*; Drinking water Directive 80/778/EEC OJ 1980 L */*; Municipal waste water treatment Directive 91/271/EEC OJ 1991 L 135/40. For further discussion, see Scott, *EC Environmental Law* (London: Longman, **), Koeman, *Environmental Law in Europe* (The Hague: Kluwer, 1999).

[151] Other reasons include the wish to protect certain lifestyles in the agricultural domain; to guard against unemployment among certain social groups; to promote animal welfare; and ecological or environmental reasons, such as the protection of natural areas or biodiversity. See, Rippe, 2000, p 72

[152] The principle of 'mutual recognition' – see Case 120/78 *Cassis de Dijon* [1979] ECR 649.

[153] Famously, the then UK Minister of Agriculture. John Gummer, appeared before television cameras eating a beefburger with his daughter. See also the UK Tyrrell Committee Report, 12 July 1990, and the European Parliament Temporary Committee of Inquiry into BSE, 'Report on alleged contraventions or maladministration in the implementation of Community law in relation to BSE' 7 February 1997 A4-0020/97, http://www.europarl.eu.int/conferences/bse/a4002097_en.htm, which outlines the failures of the UK government to take account of scientific warnings of health risk.

[154] Or possibly unwilling

[155] See the Report of the European Parliament Committee of Inquiry, supra n *.

[156] See also Report on the European Commission's follow up of the recommendations made by the Committee of Inquiry into BSE, 14 November 1997, A4-0362/97, http://www.europarl.eu.int/conferences/bse/a4036297_en.htm.

[157] O'Rourke, *European Food Law* (Bembridge: Palladian,1999), p 99

[158] Economist, 'Who's afraid?' 19 June 1999, p 15-16; Economist, 'Genetically Modified Food' 19 June 1999, p 19-21, cited Runge and Jackson, 'Labelling, Trade and Genetically Modified Organisms' 34 *Journal of World Trade* (2000) 111-122, at 112.

[159] For instance, wheat and milk contain approximately 20 different allergenic proteins.

[160] O'Rourke, supra n *, p 123

[161] For instance, Plant Genetic Systems' GM oilseed rape (MS1, RF1), which contains a marker gene conferring resistance to kanamycin.

[162] Runge and Jackson, supra n *, p112, O'Rourke, supra n *, p 123.

[163] Ciba-Geigy's (now Novartis) herbicide resistant corn, which includes a marker gene making it resistant to ampicillin, was the first genetically modified product to be rejected under the authorisation procedure in Directive 90/220/EEC OJ 1990 L 117/15; see ENDS report. 'UK helps block EC approval of GM corn' 255 (1996) p 45 The current provision regulating genetically modified organisms in the EU (Directive 2001/18/EC OJ 2001 L 106/1) provides, in Article 4 (2), that the use of antibiotic resistant marker genes is to be phased out in the EU. This proposal was originally put forward by the European Parliament, see COM(98) 85; COM(99) 139

[164] OJ 1997 L 258/1 The impetus for the Novel Foods Regulation was the approval, under the authorisation procedure of Directive 90/220/EEC (now repealed and replaced by Directive 2001/18/EC), the general environmental measure of Community law covering genetically modified organisms, of two genetically modified food products for marketing within the EU. These were Monsanto's soya and Ciba-Giegy's (now Novartis) maize A number of consumer lobby groups expressed their concerns about the potential risks to human health arising from these products. The risk assessment under Directive 90/220 was focussed on the environmental impact of the authorisation of particular genetically modified organisms, and it was felt that a more explicit human health risk assessment would be appropriate for genetically modified food products. The Novel Foods Regulation was enacted in response to these concerns

[165] Regulation 258/97/EC, Article 8. This 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 sectors of the population, or which gives rise to ethical concerns, or the presence of a genetically modified organism in the sense of Directive 90/220/EEC, Annex I A, Part I. Annex I A, Part I covers 'recombinant DNA techniques using vector systems ...; techniques involving the direct introduction into an organism of heritable material prepared outside the

However, Article 8 of Regulation 258/97 requires labelling of genetically modified foods only where the composition, nutritional value, appearance and use, are no longer 'substantially equivalent' to a traditional foodstuff Therefore, so long as there are no 'substantial' changes to the food, there is no duty to label the product as being a product of biotechnology Moreover, a drawback of the Novel Foods Regulation from the point of view of consumer health protection and provision of consumer information is the exclusion in Article 1 (2) This provides that the Regulation applies only to foods and food ingredients that have not hitherto been used for human consumption to a significant degree in the EU. However, marketing authorisations for genetically modified food products[166] had already been granted under Directive 90/220/EEC. These products were therefore not covered by the new labelling requirements of Regulation 258/97, and products containing these ingredients were required only to meet the general food labelling requirements of Directive 79/112/EEC [167] In order to fill this loophole, a new regulation covering soya and maize was adopted in Regulation 1813/97/EC.[168]

These and other health concerns relating to food law[169] have prompted the European Commission to propose a new strategy and reform of EU food law,[170] based on the so-called 'farm to fork' approach The proposal comprises three elements: a major programme of legislative reform to achieve high standards of food safety in the EU; a Community framework of national systems of control for food regulation; and the establishment of a 'European Food Authority' whose task would be to establish risk assessments through scientific advice, to gather and disseminate information and analysis and to provide a rapid alert system for health risks posed by foodstuffs. This proposal, if adopted, would constitute a major refocusing of EU food law, altering its main concern from the completion of the internal market in food towards a position much more concerned with public health protection Thus this important determinant of public health would be largely regulated by measures and principles emanating from the EU-level, enforced by the EU institutions in cooperation with national authorities The 'social' (public health) elements of food law would thus be asserted above the interests of completing the internal market in food. It remains to be seen how the proposed new system will work in practice

(vi) Health promotion

Finally, national health policies are concerned with health promotion, the attempt to encourage lifestyle decisions that will promote health and avoid disease. This may encompass health education in matters such as nutrition, exercise, prevention of accidental injury, and other lifestyle choices such as the consumption of alcohol and nicotine [171] The promotion of health may offer an illustration of the limits of mainstreaming health within Community policies. The EU institutions have a duty to bring health considerations into the determination of other policies. However, this does not translate into a competence to use powers and procedures applicable in other policy fields in order to bring about what is predominantly a health-promotion based objective This is illustrated by the Court's ruling in the *Tobacco Advertising Directive* case.[172]

The link between tobacco smoking and health problems, in particular cancers, is well established. Anti-tobacco campaigns are an established part of national health policies, aimed at reducing the burden on public health systems imposed by smoking-related illness Anti-tobacco campaigns are also an established part of EU-level activity. The 'Europe against Cancer' campaigns include public information and education strands, aimed at identifying and disseminating best practice in campaigns to change people's life styles by persuading them to give up smoking. Moreover, some evidence shows that there is a link between advertising of tobacco products and take-up of smoking.[173] Because of this, many Member States have adopted legislation restricting tobacco advertising.[174] The European Union also adopted such legislation, first in 1989, in the TV Without Frontiers Directive,[175] which banned TV advertising or teleshopping for cigarettes and other tobacco products. Subsequently, the EU adopted the Tobacco Advertising Directive 98/443/EC,[176] which provided that all forms of advertising and sponsorship of tobacco products were to be banned within the Community.[177]

The legality of this directive was challenged before the European Court of Justice The basis of the challenge was that the institutions were not competent to enact the directive, and even if they were so, the wrong legal basis was used The Court began its analysis by pointing out that the national measures affected by the Directive are to a large extent inspired by public health policy objectives [178] This appeared to imply that the Directive itself had a public health policy objective The Court went on to point out that Article 129 (4) EC explicitly excluded any harmonisation of national laws designed to protect and improve public health [179] Other articles of the Treaty could not be used as a legal basis to circumvent that restriction on Community competence [180] After examining the objectives and the effects of the Directive, the Court concluded that the Directive was not properly enacted on the basis of Articles 100a, 57 (2) and 66 EC It was not an internal market, but a health promotion, measure The Directive was therefore annulled.[181]

This ruling confirms that the 'mainstreaming' obligation of Article 152 EC does not extend to the use of Community competencies in other areas, in particular the power to adopt harmonisation measures concerning the establishment and functioning of the internal market, for health promotion objectives. The internal market legal basis provisions do not amount to a general Community regulatory power [182] The implication of the ruling appears to be that the EU institutions may not use their internal market competencies to promote a model of socio-economic regulation that prizes health promotion above internal market objectives. Such health promotion measures remain within the competencies of national authorities Thus Article 152 EC precludes the use of Article 95 EC to promote the European social model in this respect

Conclusion

This paper aimed to set out the contours of an emerging European health policy, and to consider the role of law in its development and instrumentalisation. A broad approach to health policy has been taken, combined with an understanding of the EU as a multilevel system of governance or a non-state polity within which law and policy is made in interactions within and between institutions at different levels. This reveals a number of areas in which Community law has had an impact on the development of national health law and policy. Space precluded detailed discussion of all 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, free movement of goods, free movement of persons, consumer protection, environmental law, employment law and so on Such a 'cross-sectional' approach to Community 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 distinctively European social model in its proposals, and the Council and European Parliament appear to be broadly in favour. Of course, differences in the detail emerge. Occasionally, the institutions of the EU have over-reached their competencies in attempting to promote public health objectives, as in the case of *Tobacco Advertising* But, overall, the EU seems to be mustering its legal resources towards protecting a European health policy based on the values of the European social model· equality of access to health care and the determinants of good health, solidarity in health care financing, and regulation of economic activity as is necessary to protect and promote public health

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organism including micro-injection, macro-injection and micro-encapsulation; cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally'. This would require, for instance, information about possible allergens in GM foods. For the purposes of labelling, the substantially similar test is to be on the basis of scientific assessment of whether the characteristics of the food are different, in comparison with a conventional food, having regard to the accepted limits of natural variations for such charactenstics The relevant characteristics include composition, nutritional value or nutritional effects, and intended use. Where there is no existing equivalent to the novel food, appropriate provisions must be adopted to adequately inform the consumer of the nature of the novel food. Genetically modified additives and flavourings are covered by Regulation 50/2000/EC OJ 2000 L 6/15. The Regulation applies to additives (within the scope of Directive 89/107/EEC OJ 1989 L 40/27) and flavourings (within the scope of Directive 88/388/EEC OJ 1988 L 184/61) which are, contain or are produced from genetically modified organisms, as defined by Directive 90/220/EEC. The Regulation imposes a labelling requirement identical to that of the Novel Foods Regulation, based on the substantially equivalent test. The definition of substantially equivalent is provided in Article 3, which explicitly provides that a GM additive or flavouring is not substantially similar where it contains protein and/or DNA resulting from genetic modification. This is a tightening of the definition in Regulation 258/97/EC

[166] Such as Novartis' *Bt* maize (Decision 97/98/EC) and Monsanto's soya (Decision 96/281/EC) **check**

[167] OJ 1979 L 33/1, now consolidated in Directive 2000/13/EC OJ 2000 L 109/29

[168] OJ 1997 L 257/7, amended by Regulation 1139/98 OJ 1998 L 159/4, and by Regulation 49/2000/EC OJ 2000 L */* This is based on the provision in Article 4 (2) of Directive 79/112, which provides that Community provisions applicable to specified foodstuffs and not to foodstuffs in general may provide that other particulars than those required by Directive 79/112 must appear on food labelling. Regulation 1813/97/EC applies the labelling requirements of Article 8 of the Novel Food Regulation to the GM soya and maize products noted above

[169] For instance, dioxin contamination of animal food products from feed produced in Belgium

[170] See Commission, *Green Paper on Food Law* COM(97) 176; Commission, *Consumer Health and Food Safety* COM(97) 183 final; Commission, *Communication on Food, Veterinary and Plant Health Control and Inspection* COM(89) **; Commission, *White Paper on Food Safety* COM(2000) **, 12 January 2000; Proposal for Regulation on EU food law COM(2000) 716.

[171] See Donaldson and Donaldson, *Essential Public Health* (Plymouth. Petroc Press, 2000), p 113-134

[172] Joined cases Case C-376/98 *Germany* v *Council and Parliament* and C-74/99 *R* v *Secretary of State for Health and others ex p Imperial Tobacco* [2000] ECR I-**.

[173] COM(91) 111 final, International Union against Cancer research, cited Watson 315 BMJ (1997) 1559-64.

[174] Italy, Portugal, Belgium, Ireland, Luxembourg, Denmark, Spain, the Netherlands, the UK; see Commission MEMO/00/60, 5 October 2000.

[175] OJ 1989 L 298/23

[176] OJ 1998 L 213/9.

[177] Directive 98/43/EC, Article 4.

[178] Para 76

[179] Para 77

[180] Para 79

[181] For further discussion, see Hervey, supra n *.

[182] Opinion of AG, para 83, see also para 89