‘EU blood policy: lessons to be learned from policy-making in relation to Aids contamination of national blood supplies’

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ABSTRACT: This paper examines policy-making with respect to the threat posed by Aids to the blood supply as the epidemic began to emerge in the Western world in the early 1980s. Policy-making will be described on the basis that there were similar patterns of institutional response during this period. Historical developments in EU blood policy are reviewed, with a particular focus on the roles of institutions and organised interests. Lessons learned from policy-making in relation to Aids contamination of the blood supply are considered with a view to assessing both their relevance to current EU blood policy as well as their wider implications for EU policy-making in relation to emerging public health threats. It is contended that the lessons learned from policy-making in relation to Aids contamination of the blood supply in the 1980s, can and should inform the substance and direction of EU blood policy, and in particular decision-making in relation to blood safety. Such lessons are also relevant to wider issues involved in European public health governance. It is suggested that the ability of the EU to respond effectively to emerging public health threats will depend upon the type of institutional arrangements and decision-making structures which are in place in relation to regulation, scientific advice and risk assessment.

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1. Introduction

On the 13th of December 2000, the European Commission adopted a proposed Directive which seeks to promote high quality and safety standards for human blood and blood components. This initiative by the Commission followed on from a specific competency granted in the Amsterdam Treaty to develop such common standards with a view to providing a high level of safety of blood and blood products throughout the European Union for the protection of its citizens. In publishing the proposed Directive, David Byrne, Commissioner for ‘Sanco’, the newly reformed Directorate for Health and Consumer Protection, pointed to the underlying rationale for the proposed Directive:

“Our citizens expect to have access to blood and blood products which have passed through rigorous agreed safety procedures. Those who receive blood are by definition at their most vulnerable…So…wherever they travel in Europe, or wherever their blood is collected, our citizens can be assured that the same safeguards are in place, ensuring the same rigorous standards across the community. We need to learn from the experiences of those whose lives have been devastated by contaminated blood, and we must work together to set high standards and minimise risks for all our citizens.”

The fact that the proposed Directive has been adopted by the Commission is to be welcomed for a number of reasons. Firstly, the course and direction of EU policy-making on this issue to date has been desultory, fragmented and without clear direction. Secondly, the tragic personal and political consequences of widespread Aids contamination of national blood supplies in Member States have emphasised the need for a European-wide approach to regulation in this area. Thirdly, public health threats to the blood supply through communicable diseases, such as Aids, Hepatitis and nvCJD have highlighted the need to take account of the ‘transnational dimension’ not only in blood policy, but also in public health policy generally, at EU level.

The question remains however, whether this recent blood policy initiative by the Commission adequately or comprehensively address key safety issues involved in the collection, manufacture and supply of blood and blood products in the European Union. The consequences of Aids contamination of national blood supplies have resulted in a political and legal ‘after-shocks’ in a number of Member States (Freeman, 2000) leading to significant reform not only of national blood and regulatory institutions, but also the way in which national government decision-making is undertaken in the face
of such public health threats. The findings of Inquiries conducted in a number of countries both within and outside the European Union into the reasons for Aids contamination of national blood supplies in the early 1980s, have emphasised the need for institutional and structural reforms of the national blood system which focus firstly, upon the creation of decision-making structures which are designed to ensure political accountability in the public interest; secondly, a re-organisation of institutional arrangements to broaden the frame of reference and representation in decision-making processes; and finally, the need to develop a strong and independent regulatory agency in respect of blood (biologics), medicinal products and devices. (Leveton et al, 1995) (Krever, 1997), (Bayer & Feldman, 1999) (Steffen, 1999). Such findings at a national level also raise wider issues in relation to the way in which the EU should best approach policy-making in response to public health threats of the kind that was posed by Aids contamination of the blood supply. Developing a suitable and effective approach to such policy-making at EU level has become all the more pressing in light of recent ‘transnational’ public health threats, including BSE, dioxins, and foot-and-mouth disease.

This paper will examine policy-making with respect to the threat posed by Aids to the blood supply as the Aids epidemic began to emerge in the Western world in the early 1980s. Policy-making will be described on the basis that there were similar patterns of response during the initial period of policy-making between 1981 and 1985 when the introduction of HIV testing in Western countries effectively eliminated the risk of transmission of the virus in blood. Such an examination will also involve a consideration of the roles played by key political actors, institutions and interests involved in the policy process. We will then turn to an examination of historical developments in EU blood policy, with a particular focus on the roles of institutions and organised interests. Finally, lessons learned from policy-making in relation to Aids contamination of the blood supply will be considered with a view to assessing both their relevance to current EU blood policy as well as their wider implications for EU policy-making in relation to emerging public health threats.

It will be suggested in this paper that the experience, and consequences, of policy-making in relation to emerging public health threats, such as that which involved Aids contamination of the blood supply in the 1980s, can and should inform the substance and direction of EU blood policy, as well as EU
public health policy generally, in the face of public health threats. It is suggested that the ability of the EU to respond effectively to public health threats will depend upon the type of institutional arrangements and decision-making structures which are developed in the areas of regulation, scientific advice and risk assessment.

2. The Role of Actors, Institutions and Organised Interests in the Policy Process

The theoretical framework which will inform my analysis of the role of actors, institutions and organised interests involved in blood policy at both national and EU level is drawn from two main sources: historical institutionalism and policy network analysis. Historical institutionalists have focused on the need to develop insight into the way in which the ‘rules of the game’ in policy-making have evolved over time which influence the way in which a diverse range of interests and institutions interact in the policy process. (Hall & Taylor, 1996) An examination of the historical development of institutions is considered important in understanding the way in which institutions ‘structure’ political reactions and affect political outcomes (Steinmo & Thelen, 1992) Path dependent patterns of development of institutions are particularly important in understanding the interplay between interests and institutions in the decision-making process and policy outcomes. (Krasner, 1988). Analysis of the historical legacy of such development leads to a greater understanding of both the ‘rules of the game’ operating between interests and institutions in the political system, as well as the way in which institutions advantage certain issues, interests and actors in the policy process. Institutional change in times of crisis is explained through the process of ‘punctuated equilibrium’ (Krasner, 1984) or the presence of ‘veto points’ in political systems Immergut (1992), although perhaps the concept of ‘windows of opportunity’ developed by Kingdon (1995) and used by Cortell & Petersen (1999) is more accurate in explaining institutional change on an incremental basis.

There has been some debate in the academic literature as what is meant by ‘institutions’ (March & Olsen, 1984) (Hall, 1986) (Immergut, 1998). For the purposes of this paper, I would propose to adopt a definition which includes state institutions, executive agencies, the bureaucracy, legislative instruments, the executive, the legislature and the court system. I would define formal and informal
procedures, conventions and standard operating procedures as the ‘rules of the game’ which structure the relationship between interests and institutions in the policy process.

Historical institutionalist tools of analysis will be useful in examining how relevant institutions interacted with organised interests and other political actors in the policy process with respect to safety issues concerning the national blood supply. Firstly, such an approach allows for an examination of the historical development of institutional public health structures and blood establishments in order to establish whether there were any historical legacies in the development of such institutions which would have influenced, not only the type of issues which would have come before policy-makers, but whether certain problems evolved into ‘issues’ which became the subject of policy-making, in the first place. Secondly, such an approach also seeks to examine whether certain interests, institutions or political actors were advantaged in the policy process in the terms of influence upon, and participation in, decision-making with respect to public health policy and the national blood supply. Finally, such an approach would be useful in analysing the ‘the rules of the game’ governing the interaction between institutions and interests operating at both national and EU levels.

In this paper, I also intend to draw upon aspects of the policy network model to explain the role of organised interests and professional groups, particularly at national level. Policy networks have been defined as ‘a cluster or complex of organisations connected to each other by resource dependencies and distinguished from other clusters by breaks in the structure of resource dependencies’. There are a number of key features to this model. It focuses on the structural relations between interests and institutions in the policy process. This focus on structural relations is in line with the approach taken within historical institutionalist analysis. Secondly, it differentiates between different types of groups who participate in policy-making, from established policy communities to issue networks. Thirdly, the model emphasises the role played by dominant coalitions in regulating not only the relationships within the policy network but also the problems that will become the subject of policy-making. Finally, the model seeks to locate and explain the nature and use of power by such dominant coalitions not only in its relationships with other interests and institutions in the policy process but also in seeking to influence the course and outcome of policy-making. (Marsh & Rhodes, 1992) (Rhodes,
The key features of the policy network model provide useful tools of analysis when examining the dominant role played by medical and scientific experts in influencing the course and direction of national policy-making with respect to Aids contamination of national blood supplies in the early 1980s.

The usefulness of using such this model, however, may be questioned when one considers the nature of policy-making in the areas of public health, including blood safety issues, at EU level. Indeed, it has been suggested by Altenstetter (1993) relying on Richardson (1992) that a more appropriate model to use in examining the role of those involved in Aids policy-making generally at EU level is that of ‘epistemic communities’. The model of ‘epistemic communities’ was first developed by Haas (1992) to explain the role and influence of experts in the policy process particularly as it applied in the context of international relations. He defined an epistemic community as a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue area. The characteristics of an epistemic community were that they shared a set of normative and principled beliefs; common causal beliefs; shared notions of validity; and a common policy enterprise. Epistemic communities provided channels through which new ideas could circulate from societies to governments as well as from country to country. (pp. 3, 27) The epistemic communities model is particularly useful in describing the policy style which has developed within the EU scientific advisory system which draws its membership primarily from medical and scientific professionals in Member States who have particular expertise in areas in which the EU require expert advice. One such advisory committee is the Committee for Medicinal Products and Medical Devices which has been influential in recent developments in EU blood policy.

3. Historical Developments in the Blood System

3.1 Introductory Remarks

Before we turn to an examination of policy-making in relation to the risk posed by Aids contamination of national blood supplies in the early 1980s, we will first consider the historical development of both national blood institutions in Western Europe, and the international blood industry following World
War II. The institutional legacies of such historical development have significantly influenced the formulation and implementation of blood policy both at national level, and at EU level. There will also be a particular focus on developments in the blood industry in the United States. This is important for a number of reasons. Prior to, and throughout the period during which Aids contamination of national blood supplies occurred, many Western European countries were heavily reliant on blood products, such as factor concentrates, imported from international pharmaceutical companies specialising in the manufacture of such blood products (‘fractionators’), whose main bases of operation were in the United States. In addition, the United States assumed centre stage in the early years of the Aids epidemic in the Western world. It would end up bearing the greatest burden of Aids cases in the Western world in the period up until 1985 with half of all cases being reported to have occurred amongst residents in three metropolitan areas in the United States. (Bayer & Kirp, 1992) (Glied, 1999) Bayer & Feldman (1999) have pointed to the consequences of the prevalence of background Hiv infection in the United States for Western European countries reliant on factor concentrates manufactured and supplied by fractionators

“60% of the world’s plasma supply was purchased from plasma sellers in the United States, where it was then made into factor concentrate. The fact that the background prevalence of Hiv infection was higher than in any other industrialised nation had fatal consequences.” (p. 3)

In summary, what happened in the United States in relation to Aids and the blood industry mattered. The consequences of United States’ policy-making on these issues would be felt in many Western European countries in the high numbers of haemophiliacs becoming infected with HIV as a result of the use of factor concentrates sourced from American donors, manufactured and supplied by United States-based fractionators. (Krever, 1997) (Starr, 1998) (Bayer & Feldman, 1999)

3.2 National Blood Institutions

Following World War II, many Western European governments formalised arrangements with respect to the collection, organisation and supply of the nation’s blood needs, which included both whole blood and blood products. (Krever, 1997) (Starr, 1998) (Bayer & Feldman, 1999) In some countries, the Red Cross undertook this task, while in other countries, the governments created executive agencies or state institutions to manage the national blood supply. These organisations or institutions
were usually referred to as either ‘blood banks’ or ‘national blood transfusion services’. The medical and scientific staff who ran the blood transfusion services were often referred to as ‘blood bankers’. Such staff normally had scientific expertise in haematology, microbiology or transfusion medicine.

In Western Europe, the two key aims of national blood transfusion services could be described as firstly, to collect blood from ‘volunteer donors’, being individuals who had not sought financial or other reward for their blood donations; and secondly, to achieve national ‘self-sufficiency’, which involved the supply of enough blood and blood products to meet the nation’s needs, thus ensuring that there was no need to import blood and blood products from foreign or other third-party sources. Because of the need to ensure an adequate supply to meet the nation’s blood needs, many national blood transfusion services focused on recruiting, retaining and protecting their donor population. (Krever, 1997) (Bayer & Feldman, 1999)

With scientific advances in blood component research following World War II, blood banks began to expand their range of services to include not only the collection and supply of whole blood, but also specific donor and manufacturing programs in the area of blood components. The ability of blood banks to undertake such programs was dependent upon their ability to recruit and retain sufficient donors. In the case of blood products, such as factor concentrates used in the treatment of blood disorders such as haemophilia, the plasma of 100s of donors was often required to manufacture a single lot. It grew increasingly difficult for national blood transfusion services to meet the growing demand for such blood products. In many cases, Western European national blood transfusion services turned to United States-based fractionators which manufactured these products in order to meet the demand, particularly from the 1970s onwards.

3.3 The Fractionation Industry

As referred to previously, international pharmaceutical companies which specialised in the manufacture and supply of factor concentrates were colloquially known as ‘fractionators’. The four companies which emerged as the major players in the burgeoning fractionation market in the late 1960s in the United States were known as Cutter, Alpha, Armour and Hyland. The fractionators
collected plasma from individuals who had been paid to make their donations. Fractionators collected the plasma they needed from donors through a technique known as ‘plasmapheresis’ which involved separating the blood’s liquid and the proteins it contains from the red and white cells, and then returning the red and white cells to the donor’s body. (Murray, 1991, p. 234) The fractionators needed a continuing and constant source of raw plasma to manufacture blood products, such as factor concentrates, as it was not unusual for the plasma of up to 20,000 donors to be used in the manufacture of a single lot of factor concentrate. (Leveton et al, 1995, p. 30)

Apart from the plasma obtained from blood banks and hospitals with volunteer donors, ‘source plasma’ was usually obtained by the fractionators from a variety of sources which included colleges, prisons and indigent neighbourhoods, usually referred to as ‘Skid Row’. Donors such as prison inmates and gay men were also considered to be a valuable and regular source of plasma. (Leveton, 1995) (Starr, 1998) By the middle of the 1970s, the United States and its fractionators had become the ‘OPEC of plasma’, with Europe being by far their best customer. United States-based fractionators were able to meet well over half of Europe’s needs for fractionated blood products. It proved to be an extremely lucrative market as blood products, such as factor concentrates, sold in Europe at three times the rate at which they were sold in the United States. (Starr, 1998, pp. 240 – 241). By the end of the 1970s, the ‘fractionation’ market supplying much of Western Europe’s needs in relation to blood products, was comprised of a highly integrated networked of resources for the collection, manufacture and supply of such products, which was concentrated in the hands of a few international pharmaceutical companies, with plasma being supplied predominantly by American donors. (Starr, 1998, pp. 258 – 260)

3.4 Ideological Split: Voluntary –v- Paid Blood Donation

With the growth of the fractionation market in the late 1960s in the United States, an ideological and scientific split occurred in the blood industry between those who favoured volunteer as opposed to paid blood donation. The main proponents of the argument in favour of volunteer blood donation were predominantly blood bankers who ran national blood transfusion services, which were based on volunteer blood donation. They argued that, because of the altruistic motive inherent in giving blood
on a volunteer basis, such blood was likely to be free of viral or chronic infections that would harm
the recipient of the blood. As such, blood should not be seen as a commodity, to be bought or sold on
the market to the highest bidder. Richard Titmuss (1971) had contended that the differences in
quality between the blood systems of the United States and the United Kingdom were due to
contamination as a result of the ‘profit motive’. This had resulted in greater costs, more shortages and
waste, and higher hepatitis infection rates in donors in the United States. Titmuss argued that the
importance of volunteer blood donation lay in the fact that not only was it an agency of social
integration, an exemplar of community altruism and morally sound, it was also economically
efficient. Although Titmuss’s conclusions were subsequently criticised as being partially flawed ²,
the scientific evidence in support of his position concerning the higher hepatitis rates of paid donors
was clear. By the early 1970s, there was scientific research available which estimated that it was ten
times more likely that a recipient would contract hepatitis as a result of receiving blood sourced from
paid donors, than if the recipient had received blood sourced from volunteer donors. (Starr, 1998, p.
220)

Despite the concerns expressed by those in charge of national blood transfusion services in Western
European countries concerning paid donation, many of them nevertheless entered into agreements
with fractionators to supply blood products, in particular factor concentrates. The necessity of
entering into such agreements was attributable firstly, to the demands made by doctors and patients for
such products; and secondly, because the national blood transfusion services could not collect enough
plasma from the national volunteer donor pool to meet such demand. (Kramer, 1993) (Berridge, 1996)
(Krever, 1997) (Starr, 1998)

3.5 The Blood System on the eve of the Aids epidemic in Western Europe

During the time in which the Aids epidemic began to emerge in the Western world in the early 1980s,
the blood systems in many Western European countries were bifurcated. Whole blood was collected
from volunteer donors and supplied within national boundaries. Fractionated blood products, such as
factor concentrates, were supplied either wholly through imports from fractionators, or through a
combination of nationally manufactured blood products (sourced from local voluntary blood donors)

Despite aspirations towards national self-sufficiency, many blood transfusion services in Western European countries had been unable to meet their nations’ blood needs. Demands by haemophiliacs for factor concentrates, a lack of a technological expertise, and a weak administrative infrastructure within national blood establishments meant that they were forced to seek out international sources of supply of blood products. As a result, the supply of factor concentrates for use by haemophiliacs had become ‘big business’ in Western Europe by the early 1980s. (Kramer, 1993) (Starr, 1998) Such a system for the manufacture and supply of blood products created a situation whereby the blood of millions of citizens from diverse Western countries became intermingled, creating the potential for widespread viral infection on an international scale. (Starr, 1998) As it stood in the early 1980s, the bifurcated blood system operating in many Western European countries provided a perfect ‘window of opportunity’ for Aids to enter and begin its silent, deadly work.


4.1 Initial Policy Response

Although cases of Aids attributable to the use of blood and blood products first began to appear in the United States in 1982, 7 most Western European countries only began to formulate and implement policy on this issue in the years 1983 to 1984. Many such countries looked towards what policies had already been adopted in the United States as steps had been taken to reduce the risk posed by Aids to the national blood supply early in 1983. Policy initiatives predominantly revolved around the exclusion of donors considered to be at ‘high-risk’ of transmitting Aids, such as gay men, intravenous drug users and those who had previously received blood and blood products. 8

Following a seminal meeting held at the Centers for Disease Control which was attended by all relevant ‘stakeholders’ in the blood industry in early January 1983 (Shilts, 1987), steps were taken by United States-based fractionators to reduce the risk of Aids transmission in their blood products. Such
steps also centred around donor exclusion based on designated high-risk groups although, unlike the voluntary blood banking sector, the fractionators excluded all gay men from donation without qualification. Notwithstanding the issue of such donor exclusion policies in early 1983, several fractionators nevertheless continued to collect plasma from prison inmates, despite evidence of high-risk activities on their part, until the end of 1983. (Leveton et al, 1995) (Krever, 1997) (Starr, 1998) By the beginning of 1984, all fractionators had gained regulatory approval in the United States to market factor concentrates which had been subjected to a heat treatment process to inactivate the Hepatitis B virus and were in a position to supply heat treated factor concentrates on a commercial basis to other Western countries. Policies implemented by most Western countries (as well as the United States-based fractionators) with respect to the risk posed by Aids contamination of the blood supply essentially remained the same until the introduction of large-scale HIV antibody testing on blood donations, which had been implemented in most Western countries by the end of 1985. (Leveton et al, 1995) (Krever, 1997) (Bayer & Feldman, 1999)

4.2 The Consequences of Aids Contamination of National Blood Supplies

There were similar patterns of institutional policy response to the risk posed by Aids contamination of the blood supply in many Western countries in the early 1980s. (Krever, 1997) (Bayer & Feldman, 1999) (Marmor et al, 1999) A number of key factors have been identified as being common to such policy response: firstly, the absence of centralised decision-making structures; secondly, the dominant role played by medical and scientific professionals, in particular blood community elites, in policy-making; thirdly, the dominance of a frame of reference in decision-making which was based on scientific assessments of risk in the face of uncertainty; fourthly, the absence of strong and independent national regulatory agencies; fifthly, the absence of consumer representation in the policy process; and finally, the influential role played by private interests in the policy process.

In pointing to similarities in the policy responses of many Western countries to the risk posed by Aids contamination of the blood supply in the early 1980s, however, the importance of national politics, culture and institutional policy-making processes cannot be ignored (Bayer & Feldman 1999) In reviewing general Aids policy across a number of Western European countries, Steffen (1996)
concluded that the spread and profile of the epidemic, the politics enacted to halt it and to treat its consequences, depended on the existing specificities of a national context’. National ‘filters’ such as national institutions and bureaucracies, political rhetoric, professional forums, and cultural attitudes were important to an understanding of how general principles were translated into specific national contexts. (pp. 145 – 146) In particular, comparative research based on national case studies confirms the particular importance of national political, institutional and socio-cultural factors in determining the extent of the ‘fall-out’ or ‘after-shocks’ arising out of policy-making with respect to the risk posed by Aids contamination of the blood supply in many Western countries in the early 1980s. (Bayer & Feldman, 1999)

4.3 Assessment of institutional policy-making: success or failure?

In assessing success or failure in policy-making with respect to the risk posed by Aids to national blood supplies in Western countries in the early 1980s, one needs to examine firstly whether such policy-making was successful in preventing, or significantly reducing the risk of transmission of the virus to those who used blood products or received blood transfusions. The level of Hiv infection amongst national haemophilia communities is a good indicator of the extent of contamination of the blood supply as many haemophiliacs were regular users of blood products which had been manufactured from blood collected from thousands of donors, whether paid or unpaid. The statistics on Hiv infection of haemophiliacs are chilling. In countries such as the United States which made extensive use of blood products manufactured by the fractionators, it is estimated that between 75% and 85% of the overall haemophilia population became infected with Hiv in the period prior to 1985, although the rate of infection was much higher (of the order of 96%) in relation to severe haemophiliacs who used factor concentrates on a weekly basis. (Bayer, 1999). Although the extent of Hiv infection amongst haemophiliacs in other countries was not been as high as the rate in the United States, it has been estimated that between a third and a half of the haemophilia population in many Western European countries were infected with Hiv as a result of the use of blood products in the treatment of their condition, attributable mainly to the use of factor concentrates manufactured by United States-based fractionators, using plasma sourced from American paid donors. 10
In those countries where national Inquiries have been conducted into the circumstances which led to Aids contamination of the blood supply, there have been a number of common findings, all of which point to an institutional failure to engage in policy-making which adequately addressed the risk posed to the blood supply by the emergence of a new virus, Aids, in the early 1980s. This institutional failure in policy-making has been attributed to a number of factors including the absence of centralised decision-making structures, the lack of a strong, independent regulator, closed policy networks of medical and scientific professionals, and inadequate decision-making processes. (Leveton et al, 1995) (Krever, 1997) (Bayer & Feldman, 1999)

The need for a strong and independent national regulatory agency to properly assess and manage emerging public health threats, such as the one posed by Aids to the blood supply, was emphasised in the findings of a number of national Inquiries. Krever (1997) found that regulatory agencies in many Western countries relied heavily upon information and advice received from other national agencies, in particular the Food and Drug Administration in the United States. Leveton et al, (1995) found that, in the formulation and implementation on policy with respect to Aids and the blood supply, the FDA in turn relied heavily on advice received a closed policy community which involved fractionators as well as medical and scientific professionals involved in the not-for-profit voluntary blood banking sector, with both groups favouring the status quo in the absence of confirmatory scientific proof of Aids transmission through blood and blood products.

In many Western European countries, medical and scientific professionals with expertise in transfusion medicine and haematology, formed the ‘dominant coalition’ within the closed policy networks which influenced the formulation of policy and institutional response. Such policy networks were essentially allowed by many Western governments to make such policy without regulatory oversight or political accountability. The frame of reference for decision-making was guided by a mind-set which required objective scientific data and evidence before decisive action could be taken. Scientific uncertainty and an inability to quantify the risk to the public posed by Aids contamination to the blood supply, contributed to a failure on the part of policy-makers to take decisive action to reduce the risk posed by Aids contamination of the blood supply. They ‘sat on their hands’ and waited for
certainty in the form of a Hiv antibody test which would produce the required objective scientific evidence that Aids had the capacity to infect those who used blood and blood products. (Krever, 1997) (Starr, 1998) (Bayer & Feldman, 1999)

The absence of structures of accountability within the political system, or the failure to make use of what structures were available to hold policy-makers accountable for the decisions they made with respect to the risk posed by Aids to the blood supply, was also a factor contributing to policy failure. Many national blood transfusion services had been created by governments as autonomous legal entities. As autonomous legal entities, they were able to enter into private commercial arrangements with fractionators for the provision of blood and blood products. National blood transfusion services often received little political oversight in the public interest in relation to their institutional and commercial arrangements. In addition, there was no consumer representation in policy-making with respect to national blood supplies. (Krever, 1997, p. 723) The lack of structures of accountability was ‘a guarantee that narrow commercial and institutional interests would prevail on the blood policy agenda’ (Bayer & Feldman, 1999, p. 13)

Our review of policy-making with respect to the risk posed by Aids contamination of national blood supplies in the early 1980s in Western countries reveals that the patterns of institutional response were similar. The findings of subsequent national Inquiries into the circumstances which led to Aids contamination of the blood supply point to a failure on the part of institutions and key decision-makers to engage in policy-making which had, as its guiding objective, the protection of the public interest in the face of an emerging public health threats. Long-standing ideological perspectives within national blood institutions which viewed volunteer blood donation and national self-sufficiency as guarantors of a safe blood supply appeared to produce a form of institutional blindness which ignored the reality of bifurcated national blood systems where blood products were often imported from fractionators, with the plasma used in such blood products having been sourced from American donors who were paid to donate their blood.11 The findings of national Inquiries into the circumstances which led to the Aids contamination of the blood supply have resulted in wide-ranging institutional reform of national
blood transfusion services, regulatory agencies, and decision-making structures. Institutional relationships have been restructured in order to ensure political accountability in the public interest.

Highlighting the similarities in institutional response to policy-making, however, is not to ignore the influence of ‘national’ and socio-cultural factors. Such factors also contributed not only to the ‘mind-set’ of national policy-makers in the early 1980s on this issue, but also to the way in which the consequences of the contamination episode unfolded in many Western countries in the 1990s. We will now turn to an examination of EU blood policy, which has evolved in the context of developments in public health policy generally at EU level, with a view to considering what lessons can be learned from Aids contamination of national blood supplies.

5. EU Blood Policy

5.1 Institutional and Policy Developments prior to Maastricht

It is not intended in this section of the paper to discuss in great detail all of the policy initiatives which have been taken at EU level which may be considered in some way relevant to blood and blood products. Instead, the aim is to highlight key initiatives in this area over the last twenty years with a view to providing insight into the role of institutions, actors and organised interests developments in EU blood policy. In examining developments in EU blood policy, however, one needs to take account of two important factors. Firstly, as discussed previously, the development of a bifurcated blood system in Member States has impacted upon the way in which blood policy has developed at EU level. Up until very recently, there has been a clear demarcation in policy-making with respect to whole blood on the one hand, and fractionated blood products on the other hand. Until recently, policy-making with respect to fractionated blood products has been dealt with as part of policy-making in relation to ‘medicinal products’.

Secondly, the lack of a clear and coherent approach to blood policy at EU level (until very recently) reflects longstanding views amongst Member States that health-related matters are essentially a national issue and should remain so. (Altenstetter, 1992) Organisations charged with meeting the
nation’s blood needs were considered an integral, if somewhat institutionally isolated, part of the national health systems of Member States.

Despite widespread Aids contamination of the blood supply in many Member States in the early 1980s, no major policy initiatives were taken at EU level in response to this public health threat. The lack of action at EU level can be explained by reference to the fact that Aids contamination of the blood supply was seen as national health policy issue. In any case, EU institutions lacked a legal basis upon which to take concerted action on the issue during this period. In the 1980s, EU activity in areas relating to blood policy can be seen primarily in its regulation of the marketing and licensing of medicinal products in furtherance of the completion of the Internal Market. (Weatherill, 1997) (Glocker, 1998) An example of this can be seen in the use of Directives to ensure a harmonisation of laws across Member States to facilitate the supply of such products by pharmaceutical companies, a significant and successful part of the European economy. (Greenwood, 1995).  

The Maastricht Treaty represented a significant step forward in relation to broadening EU involvement in public health policy, which led to a ‘knock-on effect’ in the development of EU blood policy, particularly in relation to safety issues. With the coming into force of the Maastricht Treaty in 1993, specific policy competences were created in the areas of public health and consumer protection. For the first time, EU institutions were given an opportunity to develop a coherent public health strategy. However, the Maastricht Treaty emphasised that any future EU policy initiatives in public health would necessarily have to take account of the principle of subsidiarity no doubt reflecting Member States’ longstanding concerns over EU encroachment into areas touching upon national health policy.

5.2 The Role of the Commission in EU Blood Policy since Maastricht

From 1993 onwards, the basis of subsequent Commission initiatives with respect to blood policy would primarily derive its legal authority from the policy competence in public health granted in the Maastricht Treaty (a pattern which was to continue following the Amsterdam Treaty). With the Maastricht Treaty coming into force, the Commission issued a Communication on the Framework for
**Action in the Field of Public Health** 17 specifying a number of key public health programmes. Although issues relating to blood and blood products were not identified as one of the Framework programmes, the Commission nevertheless committed itself to developing an EU strategy on blood safety and self-sufficiency in the Community. Despite such a commitment, however, there was very little action taken by the Commission, notwithstanding the issue of a Communication by the Commission on the issue in 1994. 18

One explanation for the position adopted by the Commission in relation to blood policy has been attributed to more general problems in the development of EU public health policy. Both Armstrong (1995) and Weatherwill (1997) have argued that the principles of subsidiarity and proportionality served to significantly circumscribe Commission policy initiatives in both public health as well as consumer protection. The introduction of public health policy initiatives was to be seen in the context of ‘adding value’ to the existing national policies of Member States. Randall (2001) has suggested that other explanations may be found in a lack of financial resources to implement framework programmes and the fact that policy responsibility for matters touching upon consumer protection and public health was diffused throughout various Directorates-General within the Commission (until recently) thus contributing to a fragmented and cautious approach to policy-making in these areas. (p. 120).

In 1998, the Commission issued a further *Communication on the Development of Public Health Policy in the European Community*. 19 The Commission acknowledged the need for a fundamental review and reformulation of ‘priorities, structures and methods’ to guide the future direction of EU public health policy. The Commission also acknowledged that the previous two years had seen the ‘emergence of new communicable diseases’, which had ‘contributed to a new and greater awareness of the importance of health policy at Community level.’ With the Amsterdam Treaty coming into force, and in the wake of sustained criticism over its role in the BSE crisis (Randall, 2001), the Commission began to restructure and reshape not only public health policy generally, but also blood policy. There was now a specific legal basis for action at EU level in relation to blood policy which required the adoption of ‘measures setting high standards of quality and safety of organs and
substances of human origin, blood and blood derivatives’ with the proviso that any such measures would not affect ‘national provisions of the donation or medical use of organs and blood’. (see Article 152(4) and (5)).

With the strengthening of the legal basis for public health policy granted through the Amsterdam Treaty, the Commission issued a further Communication on the Health Strategy of the European Commission in May 2000 proposing a Framework for EU public health policy for the years 2001 to 2006. 20 The Communication echoed many of the key points the Commission had made in the 1998 Communication, and identified the three key strands which were to be the basis of any future EU public health policy: improving information for the development of public health; reacting rapidly to threats to health; and tackling health determinants through health promotion and disease prevention. The Commission noted that ‘Members States are faced with cross-border health threats which they cannot properly address on their own, because they do not have the necessary resources, infrastructures and expertise. Examples include nvCJD, HIV and conditions related to pollution. The Community can help Member States to co-ordinate their actions in response to these threats’. The Commission emphasised that there was a need for mechanisms to respond to major health threats. To this end, it would be necessary to develop appropriate systems to assist in surveillance and information transfer in order to facilitate rapid responses to emerging public health threats. In developing such mechanisms, the Commission proposed to take action to underpin policy-making in other ‘key areas of the public health framework, such as securing the safety and quality of blood, organs and substances of human origin and strengthening surveillance and control of communicable diseases.’ Whilst paying due homage to the subsidiarity principle, the Commission nevertheless stressed that the ‘transnational dimension’ to many public health issues meant that the EU could play an important role in ‘adding value’ to Member States’ public health policies. The Commission also confirmed that work was already underway to draft a Directive which would establish an EU-wide framework setting standards of quality and safety in relation to blood and blood derivatives. The Directive would also establish a haemovigilance network which would promote the optimal use of blood and blood derivatives.
In December 2000, the Commission issued a proposal for a Directive to be adopted by the European Parliament and the Council setting standards of quality and safety in relation to blood and blood components. A number of key measures would be taken as a result of the Directive coming into force. Firstly, a scientific advisory committee of blood experts would be established, comprised of representatives from Member States to advise on blood quality and safety issues. Secondly, an adverse monitoring and tracing system in relation to the use of blood and blood components would be established. Thirdly, a system of accreditation would be set up to regulate and monitor blood establishments in Member States to ensure that appropriate quality and safety standards were met as set out in the Directive. Fourthly, earlier Directives which addressed the regulation, quality and safety of both blood and blood components would now be incorporated and covered within the proposed Directive thus creating, for the first time, a coherent legal framework covering the field in relation to blood quality and safety issues. Taking account of the principles of subsidiarity and proportionality, it was noted that the Directive would provide ‘added value’ to Member States’ blood policies because it could address the ‘transnational dimension’ where common approaches were required, especially in the case of communicable diseases. Two of the key aims of the Directive were to create an administrative and regulatory system to facilitate the exchange of blood and blood components in the Community, and to contribute to the attainment of Community self-sufficiency.

5.3 The Role of other EU policy-making institutions: Parliament and Council

The new policy competences relating to public health and consumer protection, which were granted in the Maastricht Treaty, were governed by QMV and the ‘co-decision’ procedure, which allowed for more active participation on the part of European Parliament (as well as the European Council) in generating and promoting key aspects of public health policy at EU level. The European Parliament had long been an advocate of the need to include policy competences in consumer protection and health at EU level. (Glockler, 1998). In relation to blood safety issues, Parliament’s growing interest, and participation, in policy-making in this area can be seen in the number of Resolutions passed between 1993 and 1996 stressing the importance of ensuring blood safety and self-sufficiency throughout the Community through a system of voluntary blood donations. As Randall (2001) has pointed out, however, blood-related issues was but one of a myriad of public health issues which
Parliament has been called upon to address since Maastricht. In this context, Parliament’s interest in blood-related issues needs to be seen in the context of its growing prominence in the area of EU public health policy generally, particularly following the BSE crisis, and the growing influence of the EP Committee for the Environment, Public Health and Consumer Protection (EPHCPC).

An example of the Parliament’s enhanced role in the development of EU health policy generally can be seen in the publication of the Needle Report in 1999 on the future of health policy in the EU. The report was critical of EU institutional arrangements with respect to public health policy-making on a number of levels: diffusion of responsibility within the Commission for public health policy-making DGXXIV and DGV/F; a lack of adequate decision-making structures; a focus on policies dealing with health education and promotion to the exclusion of those dealing with the prevention; and the absence of institutional mechanisms to deal rapidly with emerging public health threats. The European Parliament’s increasing participation in EU public health policy, however, has resulted in continuing disagreements between Parliament, Council and the Commission over both substantive and financial matters. As a result, the conciliation procedure adopted in the event of failure to reach a consensus between the EU institutions (arising out of the co-decision procedure) has become a regular stage along the ‘long and bumpy road’ to the adoption of public-health policies in the EU. (Randall, 2001, 120–121)

From the early 1990s onwards, the Council also began to take a more active role in matters which impacted upon the regulation of blood and blood products. In July 1993, the Council passed a Regulation establishing a European Agency for the Evaluation of Medicinal Products (‘EMEA’). Since Maastricht, the Council has been active in encouraging EU policy-making on blood-related issues, particularly in the areas of blood safety and self-sufficiency within the Community. Following the issue of a Communication by the Commission on these issues in 1994, Council passed a Resolution in 1995 inviting the Commission to submit proposals for the development of an EU blood strategy within the public health Framework programme. Again in 1996, the Council passed a Resolution inviting the Commission to submit proposals as a matter of urgency with a view to developing a co-ordinated approach to the safety of blood and blood products. In a key
development in EU blood policy, the Council passed a Recommendation in 1998 setting standards on the Suitability of Blood and Plasma Donors and the Screening of Blood in the European Community in 1998. The Recommendation reiterated the Community’s commitment to self-sufficiency through voluntary unpaid blood donation in order to prevent the transmission of infectious diseases, such as HIV, Hepatitis and nvCJD. To this end, the Council recommended a number of measures to be adopted by Member States in relation to donor screening, including those referring to distribution of information to increase donor awareness; donor identification and records; donor eligibility; and donor deferral. At the present time, the Council is now considering the adoption of the terms of the proposed Directive on blood quality and safety issued by the Commission in December 2000.

5.4 The Role of Organised Interests in EU Blood Policy

The EU blood policy community is confined to a small number of groups: haemophilia organisations, national blood transfusion services, fractionators, and EU scientific advisory committees. Although there are a number of European-wide consumer groups represented in EU policy-making, their level of influence in policy-making on blood-related issues appears to be limited. The groups most likely to be affected by issues relating to blood quality and safety are those in receipt of blood transfusions and blood products. Users of blood products, such as haemophiliacs, are represented at EU level by the European Haemophilia Consortium which comprises 36 national organisations. The EHC was acknowledged as one of the ‘stakeholders’ in the consultative process which led to the drafting of the proposed Directive on the quality and safety of blood and blood components. No groups representing blood transfusion recipients, however, were listed as ‘stakeholders’ in the consultation process for the Directive.

Despite the presence of groups representing users of blood products within the EU blood policy community, it is clear that the pharmaceutical industry (of which the fractionation industry is but one arm) plays a highly influential in EU blood policy. The pharmaceutical industry has traditionally enjoyed close links with DGIII (Industry), reflecting the importance of the industry in the European economy. (Peterson & Bomberg, 1999) Greenwood (1997) has described the industry’s relationship with the Commission as one of the most influential at EU level, arguing that the relationship places it
in a category apart from what would be commonly understood as a ‘policy community’ into one which could more aptly be described as ‘neo-corporatist at the sectoral level’. (p. 21) The fractionation industry is currently represented at EU level by both the European Association of Plasma Products Industry (EAPPI) and the European Plasma Fractionation Association (EPFA). As part of the international pharmaceutical industry, the EAPPI and the EPFA have adopted a similar approach to representation in blood policy-making at EU level. Such an approach is undermined by two clear strategies: the need to ensure self-regulation of the industry, and the control of medical information concerning their products (Greenwood, 1991).

Lobbying of EU institutions by the pharmaceutical industry has traditionally focused on two key issues: firstly, to promote harmonization of national laws to assist in the free movement of their products; and secondly, to promote the creation of EU structures which will assist in the marketing and supply of their products on an EU-wide basis. (Greenwood, 1997) One of the underlying rationales for the establishment of the European Agency for the Evaluation of Medicinal Products (EMEA) in 1995 was to give the pharmaceutical industry the option of obtaining product authorisations which would have EU-wide recognition, thus avoiding the cumbersome process of having to apply to each Member State for such authorisations. This in line with EU policy to create a single economic market for pharmaceuticals within the Community. (Randall, 2001) With the establishment of the EMEA, the industry also gained representation on the Committee for Proprietary Medicinal Products (CPMP), the key scientific advisory committee within the EMEA. Greenwood (1991) has suggested that another explanation for the industry’s strong support for the establishment of the EMEA to deal with technical mutual recognition issues on the supply of medicinal products in the EU, was that it was preferable to the possible disadvantages of an all powerful centralised agency for medical and biological products, along the lines of the Food and Drug Administration in the United States.

Medical and scientific professionals, or ‘blood bankers’ from national blood transfusion services, form the other influential group involved in EU blood policy community. Their commitment to self-sufficiency derived from voluntary blood donation is clearly in evidence in the development of EU
blood policy, particularly in relation to safety issues. On both an ideological and a practical level, their position is diametrically opposed to that of the fractionators which collect their source plasma used in the manufacture of blood products from paid donations.

The other group which could be considered influential in the development of EU blood policy are those medical and scientific professionals represented on key EU scientific advisory committees, such as the Committee for Proprietary Medicinal Products within the EMEA, and the Scientific Committee for Medicinal Products and Medical Devices. The CMPMD evolved from the re-organisation of the EU scientific advisory system in 1997, following sustained criticism of the system in the wake of the BSE crisis (Randall, 2001). The current influence of the CMPMD is evidenced in their involvement in the drafting of the proposed Directive on blood and blood products. In addition, when the proposed Directive comes into force, it is intended that a Committee of Member States’ representatives be established to provide expert advice on blood quality and safety issues, particularly in relation to emerging public health threats. It is likely that this Committee will play an influential role in developments in EU blood policy in the future.

5.5 Actors, Institutions and Organised Interests in EU Blood Policy

Prior to Maastricht, policy-making which impacted upon blood-related matters was undertaken primarily as part of harmonisation measures in the creation of the Internal Market. Since the granting of policy competences in public health and consumer protection in the Maastricht Treaty, and with the subsequent granting of a specific competence in blood policy in the Amsterdam Treaty, EU institutions have assumed a greater role in promoting the development of a coherent legal and policy framework with respect to blood quality and safety issues. Although the Commission has been the key institutional actor at EU level charged with developing such policy, it was slow to do so following Maastricht, despite the urging of both Parliament and Council.

It is clear that, in legal terms, the granting of a specific competency in blood-related issues in the Amsterdam Treaty has assisted in establishing the legal basis for policy initiatives by the Commission. On a political level, the sustained criticism of the Commission over the BSE crisis, in particular by the
European Parliament also opened a ‘window of opportunity’ (Kingdon, 1995) which could be said to have contributed to an accelerated development of initiatives in blood policy by the Commission. Political fall-out from the BSE crisis led to institutional reform of not only administrative and decision-making structures within the Commission, but a re-organisation of the system for scientific advice. The aim was to achieve greater transparency and accountability in the decision-making processes of the Commission.

The EU blood policy community is small, dominated by commercial, institutional and scientific interests. The inclusion of consumer representation within the policy community in the form of the European Haemophilia Consortium appears to mirror the growing prominence of national haemophilia organisations in blood policy-making at national level in the wake of the political fall-out from contamination of blood supplies from both Aids, as well as Hepatitis. (Bayer & Feldman, 1999). The nature of the historically close relationship between the pharmaceutical industry and EU institutions as described by Greenwood (1997) points to the industry having a highly influential role in policy-making on blood-related issues at EU level.

Developments in blood policy have been influenced not only by current political concerns of EU institutions (such as the BSE crisis), but also by historical developments in national blood systems. The legacy of national institutional arrangements and policy-making resulting in a bifurcated blood system has been mirrored in policy-making at EU level on blood-related issues which to date has created different regulatory approaches to whole blood and fractionated blood products. The commitment by blood bankers in Member States to national self-sufficiency through voluntary unpaid blood donation is also mirrored in EU blood policy.

EU Scientific Committees which have played a role in developments in blood policy, such as the Scientific Committee for Medicinal Products and Medical Devices, exhibit a policy style reflected in Haas’s model of ‘epistemic communities’. It is be expected that the establishment of the Committee (comprised of representatives from Member States) to advise on blood quality and safety issues if and
or when the proposed Directive comes into force in the near future, will no doubt also reflect a similar policy style.

6. EU blood policy: lessons to be learned from AIDS contamination of national blood supplies

There have been significant developments in EU blood policy since the Maastricht Treaty granted specific policy competences in public health and consumer protection. Such policy competences have been broadened and deepened with the Amsterdam Treaty, where a specific policy competence was granted in blood-related matters. If the substantive contents of the proposed Directive recently issued by the Commission on blood quality and safety are adopted by Member States, there is likely to be a coherent and comprehensive EU-wide legal and regulatory framework in place with respect to blood and blood products in the very near future. The impact of such an EU-wide framework will be significant in terms of quality assurance and safety, with the establishment of monitoring systems to track adverse reactions, and a Member State scientific advisory committee to deal with blood quality and safety issues, particularly in the area of emerging public health threats to the Community blood supply.

Communicable diseases, such as HIV, Hepatitis and nvCJD know no national boundaries, and the creation of such a legal and regulatory framework in blood quality and safety at EU level, recognises the need for a transnational approach to policy-making in the face of emerging public health threats. Notwithstanding such recent initiatives in EU blood policy, however, the question remains as to whether effective institutional arrangements and decision-making structures are in place at EU level to effectively respond to future threats to the safety of the Community blood supply.

Lessons learned from an examination of institutional policy response to Aids contamination of national blood supplies suggests a number of structural shortcomings in current EU blood policy, particularly in the area of blood safety. As discussed previously, in Western countries, the findings of national Inquiries into the circumstances which led to the Aids contamination episode have led to wide-ranging institutional reform of national blood transfusion services, regulatory agencies, and
decision-making processes. Reforms within the national blood system have predominantly focused on restructuring institutional relationships and decision-making structures in order to ensure political accountability in the public interest. Such Inquiries also acknowledged that an ideological perspective on the part of national blood institutions which viewed volunteer blood donation and national self-sufficiency as guarantors of a safe blood supply contributed to a failure to act upon concerns regarding the safety of blood products imported from United States-based fractionators.

In order to develop effective institutional arrangements at EU level to ensure blood safety, the lessons from Aids contamination of national blood supplies are clear. Firstly, policy-making in relation to blood quality and safety issues must take account of bifurcated national blood systems which may involve the supply of blood products from private commercial interests, such as fractionators, where the disease prevalence in the source donor population may be unknown. Fractionators’ commercial interests in the international supply of blood products may be at odds with the interests of national blood institutions in ensuring self-sufficiency in blood and blood products through voluntary donation by national citizens. The clash of such interests may present problems in ensuring blood safety at EU level. There is need to ensure that, in the formulation and implementation of policy at EU level, decision-makers are guided primarily by the need to ensure the safety of European citizens, regardless of commercial and institutional interests. It is not clear from recent initiatives in blood policy, however, that EU institutions have created consultative and advisory processes which seek to strike a balance between commercial and institutional interests, particularly in light of the dominant influence of the pharmaceutical industry at EU level.

Secondly, centralised and accountable decision-making structures need to be developed to ensure appropriate institutional responses to emerging threats to safety of the Community blood supply. In developing such structures, thought needs to be given to the composition of such decision-making structures, as well as the types of groups which have representation within such structures. Findings from Inquiries conducted into the circumstances which led to Aids contamination of national blood supplies have emphasised the need for consumer representation as a counter to the influence of commercial and institutional interests. In addition, it has been emphasised that decision-making
structures need to be centralised with accountability extending to the highest levels of government to ensure blood safety in the public interest. (Leveton et al, 1995) (Krever, 1997) It is not clear that appropriate structures are in place at EU level in relation to blood policy to ensure that decision-makers are held accountable for decisions taken in relation to blood safety. This is particularly so given the heavy reliance placed on the scientific advisory system in the formulation of blood policy, a system which has been criticised as lacking in accountability.  

Thirdly, there needs to be a paradigmatic shift in the frame of reference for decision-making with respect to the assessment of risk in the face of emerging public health threats. No longer can such decision-making be dominated by a frame of reference which demands an assessment of risk based on scientific notions of certainty, with strategies based on ‘zero-risk’ solutions. (Leveton, et al, 1995) Assessment of risk needs to be associated with danger to the public. Scientific advisers need to take account of the fact that what is an acceptable risk to the public will essentially always be a political question, and one where it will be necessary to exercise political judgement. Decision-makers must take account of potential political outcomes in risk assessment. (Douglas, 1992)

Despite a reorganisation of the scientific advice system at EU level in 1997, 35 there has been no significant reform to date of institutional decision-making structures at EU level which recognises either the complex nature of risk assessment in relation to transnational public health threats, or addresses issues of accountability in relation to decision-making by scientific advisers. Such structures are crucial given the reliance placed by EU institutions upon scientific advice to formulate policy responses to emerging public health threats. In December 1999, a group of eminent scientists prepared a report at the request of DG XXIV on issues relating to the future of scientific advice at EU level. The Report suggested that mechanisms needed to be created to ensure that the system of scientific advice was politically accountable in the public interest, acknowledging that scientific advisory committees had been subjected to industrial pressures which had resulted in a perceived bias towards political and industrial, rather than consumer, interests. The Report also stressed the need to create institutions at EU level which could develop expertise in risk assessment, management and communication to respond appropriately to emerging public health threats. 36
The Report also proposed that a supranational regulatory institution be created at EU level to deal with scientific advice, surveillance, and risk assessment, to be known as the ‘European Food and Public Health Authority’. The creation of such an institution was suggested as the best way to approach the increasingly complex and difficult issues involved in responding to public health threats which have a ‘transnational dimension’. The Report emphasised that mechanisms needed to be developed to ensure that the Authority and its scientific advisory committees would be held politically accountable for decision-making in the public interest.

Majone (1994) has suggested that, in the case of supranational regulation, mechanisms to ensure accountability should include legislative and executive oversight, strict procedural requirements, public participation, and judicial review. The findings of Inquiries into the circumstances which led to Aids contamination of national blood supplies have suggested that the existence of a strong and independent regulatory institution is crucial to the effective management of responses to emerging public health threats. (Leveton et al, 1995) (Krever, 1997). The recent announcement by the Commission that a European Food Authority will be established is indicative of a policy shift by Member States in support of greater supranational regulation in the areas of food safety, no doubt accelerated by the political fallout from the BSE crisis. In making such announcement, however, no reference was made to the inclusion of public health within the remit of this new Authority. Given the likelihood of future transnational public health threats, the absence of institutional arrangements and decision-making structures which facilitate accountability in the areas of scientific advice, regulation and risk assessment will continue to hamper the EU’s ability to effectively respond to emerging public health threats.

7. Conclusion

In this paper, we have examined policy-making arising out of Aids contamination of national blood supplies which revealed similar patterns in institutional response to the emergence of a new public health threat. National Inquiries conducted in a number of Western countries in the wake of widespread Hiv infection amongst users of blood and blood products revealed institutional failure to
deal with the risk posed by the virus to national blood supplies. Whilst acknowledging that national and socio-cultural factors were important, institutional factors were the predominant causes leading to policy failure. Institutional reform following the findings of such inquiries have included a reorganisation of national blood institutions and regulatory agencies; a restructuring of decision-making processes; and the development of centralised decision-making structures to ensure political accountability in the public interest.

An examination of developments in EU blood policy over the last twenty years revealed that prior to Maastricht, EU activity in matters relating to blood issues was seen primarily in the regulation, marketing and licensing of medicinal products (such as ‘blood products) in furtherance of the creation of the Internal Market. Health policy, including blood policy, was seen as a national issue by Member States. Following Maastricht and the granting of specific policy competences in public health and consumer protection, EU blood policy remained fragmented and no major blood policy initiatives were taken by the Commission, despite calls by the Parliament and the Council to do so. The political fall-out from the BSE crisis, and the granting of a specific policy competence in blood-related issues in the Amsterdam Treaty, has recently led to significant developments in EU blood policy, with the Commission issuing a proposed Directive in relation to blood quality and safety. The adoption of the Directive by Member States will, for the first time, create a coherent and comprehensive legal and regulatory framework in relation to blood and blood products which will hopefully contribute to a safer blood supply for citizens throughout the Community.

The creation of this legal and regulatory framework is, however, only one of the issues that needs to be addressed if the EU is to respond effectively to threats to the safety of the Community blood supply, especially from new communicable diseases. The lessons learned from Aids contamination of national blood supplies suggest that there are a number of particular institutional arrangements and decision-making structures need to be in place to ensure an effective institutional response to threats to the safety of the Community blood supply. Firstly, in the formulation and implementation of policy at EU level, decision-makers need to be guided primarily by the need to ensure the safety of European citizens, regardless of the influence of commercial and institutional interests. Secondly, centralised
and accountable decision-making structures need to be developed to ensure appropriate institutional responses to emerging threats to the blood supply. In developing such structures, thought needs to be given to the composition of such decision-making structures, as well as the types of groups which have representation within such structures. Findings from Inquiries conducted into the circumstances which led to Aids contamination of national blood supplies have emphasised the need for consumer representation as a counter to commercial and institutional interests. Thirdly, the frame of reference for decision-making by policy-makers in the face of emerging public health threats needs to be based on an assessment of risk which takes account of public perceptions of danger. Scientific advisers need to accept responsibility for the political outcomes of such assessment. Structures need to be created to ensure accountability on the part of scientific advisers in the formulation of blood policy at EU level.

Finally, the creation of an independent EU agency which would deal with scientific advice, risk assessment and regulation of public health, would address many of the shortcomings in institutional arrangements and decision-making structures which currently prevent the EU from responding effectively to a range of transnational public health issues, including blood safety. Its independence and regulatory powers would create more of a level-playing field between the various interests represented across a range of public health issues at EU level. It would also become a repository for information, expertise and evaluation of matters relating to public health. The recent announcement by the Commission that a European Food Authority is to be established represents a welcome development in food safety, although it is not clear what the responsibilities of the new Authority will be. Clearly, the inclusion of public health within the remit of this new Authority was a ‘bridge too far’ for Member States at the present time.
NOTES

1 Article 151(4)(a) Treaty on European Union (as amended by the Amsterdam Treaty): the Council will adopt measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent measures.”


3 This view is supported by the findings of the Honourable Mr. Justice Horace Krever (1997) in Volume 3 of his Final Report where he reviews blood policies adopted in the period 1981 – 1987 in seven Western industrialised democracies, including those of EU Member States, such as France, the United Kingdom, Germany and the Netherlands; see also Bayer & Feldman (1999) for national case studies of policy-making in relation to HIV/AIDS Contamination of the blood supply, which includes case studies from a number of EU Member States.

4 Factor concentrates contain a concentrated form of clotting factors which are deficient in persons with haemophilia, and are manufactured from the plasma of 1000s of donors. Factor concentrates are contained in small vials of white powder which contain the clotting factor. The white powder is mixed with sterilised water and injected into the haemophiliac to prevent or arrest internal bleeding. (Leveton et al, 1995) (Krever, 1997)

5 Haemophilia is a genetic disorder transmitted by females and predominantly affecting males. Persons with haemophilia lack the necessary clotting factors to arrest spontaneous internal bleeding, mainly into joints and organs. There are two types of haemophilia. Haemophilia A is the most common form of haemophilia and results in a deficiency in clotting factor VIII. Haemophilia B (or Christmas Disease as it is known) is less common, affecting only 15% of the haemophilia population. Haemophilia B results in a deficiency of clotting factor IX. In relation to each type of haemophilia, there are recognised medical gradations referring to the level of clotting factor, ranging from severe (less than 1%), moderate (between 2% and 6%) and mild (between 6% and 25%). Those with severe haemophilia tend to suffer from frequent bleeds (sometimes up to once a week) whereas those with mild haemophilia tend to suffer from intermittent bleeds, usually precipitated by trauma or surgery. (Krever, 1997, pp. 26 – 27)

6 Starr (1998, p. 228) and Bayer (1999, p. 20) point out that Titmuss ignored the fact that over 40% of blood collected in the United States during the period which he studied, was through volunteer donation.

7 In July 1982, the Centers for Disease Control, the leading government institution in the United States for the monitoring of infectious diseases reported for the first time in the Western world a link between Aids and use of blood products. (see CDC.16/7/82. ‘Pneumocystis Carinii Pneumonia among Persons with Hemophilia A’ MMWR. Atlanta: United States: 31:27: 365 – 367) In December 1982, the CDC reported for the first time in the Western world a link between Aids and blood transfusion (see CDC. 10/12/82. ‘Report on a possible case of transfusion associated Aids in a 20 month old infant’. MMWR. Atlanta. United States. 31:48: 652 – 653.)
Many national blood transfusion services preferred to only exclude gay men ‘with multiple partners’ for fear of stigmatising the whole of the gay community. Donor Leaflets were prepared by many national blood transfusion services setting out details of ‘high-risk’ groups and describing Aids-related symptoms. Decisions were made in some instances to examine donors for Aids-related symptoms and/or to question them about their possible ‘high-risk’ status. In some cases, ‘surrogate testing’ was introduced to identify and exclude those donors who showed evidence of past Hepatitis B infection or had other immunological abnormalities. (Leveton et al, 1995) (Krever, 1997) (Bayer & Feldman, 1999)

It was established by the middle of 1984 that the heat treatment process would also eliminate the Aids virus in factor concentrates. (Leveton et al, 1995) (Krever, 1997)

Kroner et al (1994) provides a review of Hiv infection of haemophiliacs taken from statistics provided by 16 haemophilia treatment centres in the both the United States and Europe. The authors of the article estimate that the median Hiv seroconversion rates in Europe ranged from September 1981 to March 1983 reflecting the use of products manufactured from American plasma.

Bayer & Feldman (1999) have observed that the ideological perspective which favoured voluntary blood donation and national self-sufficiency has achieved the ‘status of international orthodoxy’. Aids contamination of national blood supplies revealed that the citizenship of the donor ought not to be the key factor in determining the safety of the blood supply, but rather whether there was a low prevalence of communicable diseases in the donor population. (pp. 7, 9)

It has been forcefully argued that the way in which Aids was ‘socially constructed’ in the Western world in the early 1980s also contributed to a failure on the part of policy-makers to take decisive action to reduce the risk posed by Aids to national blood supplies. The fact that those affected in the early years of the epidemic in Western countries were gay men and intravenous drug users impact upon the way in which governments approached policy-making. This was particularly so in an era where there were a number of strongly conservative governments, such as those in the United Kingdom and the United States. The policy responses of these governments during this period has been characterised as one of indifference to a disease that was considered a ‘gay plague’ and therefore not worthy of serious attention by government policy-makers. (Altman, 1986) (Brandt, 1987) (Shilts, 1987) and (Weeks, 1989)

A detailed summary of action taken at EU level in relation to the regulation of blood and blood products, and safety issues is provided by the Commission in its proposal for a Directive on blood quality and safety (see COM (2000) 816 final (13.12.200).

A clear example of this can be found in the 1989 Directive which dealt with the licensing and authorisation of medicinal products in Members States, which also included special provisions for medicinal products from human blood and plasma. (see OJ L 181, 28.6.1989, p. 44).

Article 129 of the Maastricht Treaty introduced policy competences in the areas of public health and consumer protection. New elements which were included in the area of public health were ‘contributing to a high level of health’; ‘encouraging co-operation among Member States’; ‘prevention of diseases’; ‘incentive measures’. No harmonisation of laws and regulations was included.

Bulmer (1994) describes the principle of subsidiarity as requiring that action must be achieved better by joint action than by the member States individually if an issue was to be introduced into the domain of supranational governance. (p. 426)

COM (93) 559 (final).

COM (94) 652 (final) 21.12.94.

COM (98) 230 (final) 15.4.98.

24 OJ EC L 214 24.8.1993. The EMEA was formally established in 1995 and was designed to regulate and evaluate medicinal products for human and veterinary use throughout the EU. The EMEA is assisted in its work by a number of scientific advisory committees. It also plays a vital role in ‘pharmacovigilance’ co-ordinating information on medicinal products. (see also Randall, 2001).

25 OJ C 15 18.1.1994, p. 6

26 OJ C 164 30.6.1995 p. 1


29 In the proposal for the Directive on quality and safety issues in relation to blood and blood components issued on the 13th of December 2000, the Commission identified a number of groups as ‘stakeholders’ who were consulted in the drafting of the Directive: European Haemophilia Consortium, European Association of the Plasma Products Industry (EAPPI); European Plasma Fractionators Association (EPFA); International Federation of Blood Donor Organisations (IFBDO/FIODS) (see (see COM (2000) 816 (final) 13.12.2000. 2000/0323 (COD).

30 It is not possible in this Paper to discuss in detail patterns of consumer representation at EU level in the area of public health. The most senior advisory Committee on consumer matters to date at EU level has been the Consumer Committee which is comprised of five key European consumer organisations, together with representation by 15 national consumer groups. In 1994, the European Consumer Forum was also created as a platform for dialogue between industry and consumer groups. (Glockler, 1998, p. 243) In its most recent Communication on the future of EU public health policy published in 2000, the Commission stated that it intended to set up a new mechanism, the European Health Forum to give the public health community at large an opportunity to play a greater role in the development of health policy.

31 The EHC has adopted a common blood policy on the supply, safety and quality of factor concentrates in light of the fact that 70% of factor concentrates used in Europe derives from human plasma. (See EHC policy document at http://www.wfh.org/EHC/ehc5.htm)

32 It is noted in paragraph 11 of the proposed Directive that ‘in elaborating the provisions of this Directive account has been taken of the opinion of the Scientific Committee for Medicinal Products and Medical Devices as well as international experience in the field.’ (see COM (2000) 816 (final) 13.12.2000. 2000/0323 (COD)

34 see endnote 36.

35 In 1997, the Commission undertook reorganised the system of scientific advice at EU level, establishing a Scientific Steering Committee with overall responsibility for the EU scientific committee system and convened 8 new Scientific Committees. The advice and opinions of these new Scientific Committees were to be ‘based on the principles of excellence, independence and transparency.’ (see Commission Decision No. 97/404/EC 10.6.1997 (OJ L 169 27.6.1997); and Commission Decision No. 97/579/Ec 23.7.1997 (OJ L 237 28.9.1997).


REFERENCES


