

Blood transfusion services and the European Community

The European Commission's proposals need rethinking

The support given by blood transfusion services to health care programmes is unique and essential for modern medical practice. The wellbeing of these services should therefore be jealously guarded by the communities they serve and should reflect the nature of the support of the many thousands of associated voluntary blood donors.

Yet few if any of those donors and few health care personnel may know that a recently issued European Commission directive (89/381) is directed exclusively towards blood transfusion services. Though some of the associated legislation will bring important benefits, its overall effect may be gravely deleterious not only in Britain but also in other parts of the European Community. It seems probable that health ministers in Britain may not recognise the consequences of any associated British legislation because the British negotiating team has, it is understood, been led by the Department of Trade and Industry rather than the Department of Health. This may also explain why, over the years of negotiations in Brussels, our negotiators have at no time consulted senior managers of the British blood transfusion services.

Apparently two concerns have driven the European Commission forward: the nightmare of AIDS, and its association with large pool plasma products that were primarily derived in the 1980s from paid donors, and the concept of the single European market.

The directive seeks to outlaw the paid donor in Europe and to forbid products derived from paid donors from entering Europe. In many European countries, even today, these donors provide over half of the plasma products used. Of no less importance will be the requirement to regard blood and blood products as commodities to be bought and sold throughout the single market. But the directive will also demand higher standards of good manufacturing practice and quality assurance and will require all plasma fractionation facilities to have manufacturing and product licences.

This directive will have a mixed reception. Those who believe that market forces are more fundamental to our survival than gravitational ones will welcome the move to rank blood as a commodity such as cough medicine, but they are likely to be upset at outlawing the paid donor. They regard the unpaid donor's "gift relationship" as an inevitable loser and believe that the supply of large pool plasma products within "Fortress Europe" will collapse without paid donors. But there will be others whose overwhelming concern—sometimes overriding the availability of blood products—is the safety of blood in the 1990s. These experts will rejoice at the demise of the paid donor, who is notorious as being the source of blood products with a higher probability of transmitting

viruses to recipients than those obtained from unpaid donors. This body of opinion may, however, be concerned that the conversion of the unpaid donor's gift into a marketed commodity from which profits can and will be made may give rise to an inexorable disenchantment of the goose that lays the golden egg—the voluntary unpaid blood donor.

Experience suggests that one of the main driving forces sustaining the long term habit of unpaid blood donation is the strong link with the local community. In this context "local" means the community with which the donor easily identifies. The single European market concept will demand that the blood donor identifies with 320 million people—which seems most unlikely. Moreover, the donor (and indeed perhaps most governments) will have no means of knowing whether any transaction within the single market is motivated by humanitarian or by profit motives and will never be sure that contracts to supply products to other countries will not be to the detriment of home supplies. There is little historical support for the notion that not for profit companies are somehow "closer to God" than for profit companies and thus likely to serve the community more effectively and with greater compassion.

Effects of legislative exercises

Ideally, the preparation of this directive should have been started only after consultation with Europe's unpaid blood donors; but there are no truly effective mechanisms to allow this. Legislation that is perceived to disturb this "gift relationship," and in particular to introduce an opportunity for health authorities or their agents to make a profit, may lead to a decline in blood collection programmes throughout the European Community. The European Commission needs to be reminded and the British government advised that it is easy to legislate for products such as cough medicine but that the effects of legislative exercises that may impact on volunteers bearing gifts are not known. Moreover, however attractive it may be to those who dream of a United States of Europe, the concept that European self sufficiency in blood and blood products must override national self sufficiency may prove to be naive and is certainly premature. Had British blood transfusion service managers been consulted they would probably have advised that dreams of single markets and understandable obsessions about paid plasma donors should have been set into the context of the advanced viricidal treatments now available to plasma fractionators. They would also have emphasised that the overriding need is to ensure

the continued availability of products such as red cell concentrates and platelet concentrates—and that this requires a sustained flow of local blood donors every day for the local hospital.

Yet it would be unfortunate for Britain to make (as appears currently fashionable) a wholly negative response to this European Commission initiative. The requirement for our plasma fractionation facilities to have manufacturing and product licences is welcome. For too long these institutions have been protected through various sorts of immunity and have not invested sufficiently in good manufacturing practice and quality assurance. On the other hand, we should be concerned at the apparent exclusion of the need for those institutions responsible for procuring plasma for fractionation (regional blood transfusion centres) to have manufacturing licences, for without the Medicines Control Authority effectively policing good manufacturing practice and quality assurance in the regional centres the safety of blood and blood products may be compromised.

Striving for self sufficiency

Many friends of European health care programmes (particularly in North America) will be concerned and bemused by some of this directive's contents. Large scale plasma fractionation was created as a manufacturing science in the 1940s by Edwin Cohn's Boston team, which was funded by public (government) money. Almost all subsequent advances, however, have come from the commercial fractionation industry—to the benefit of millions of patients. The contributions to scientific advancement by counterparts in the public sector have been disappointing, largely as a consequence of inadequate investment in research and development and wrong systems of management. The pharmaceutical industry invests substantially in research and development at between 10% and 15% of turnover. For over a decade British blood transfusion services have been exhorted by successive ministers to strive for self sufficiency on a research and development budget of less than 1% of turnover and with insufficient central investment in enhanced plasma procurement. The British experience has much in common with other similar public sector institutions throughout the European Community (with the exception of France). So, as we are exhorted by Brussels to drive out these "unclean" commercial enterprises we might reflect that, although they played a tragically key part in bringing AIDS to thousands of unfortunate haemophiliacs, they have contributed substantially to saving the lives of many more thousands over the past 20 years and of millions of other patients requiring albumin or immunoglobulin products. The commercial institutions saw the clinical demand and responded because they were motivated by profit; their public sector counterparts (associated with the unpaid donor) either hid their heads in the sand or did their best—which, it is now clear to all, was not good enough. The European Community directive will place a heavy and frightening burden on the non-profit making or public sector plasma procurement and fractionation institutions. Perhaps with the exception of France, the countries of Europe seem, at the present time, unlikely to be able to cope with the consequences of this legislation in the context of developing new and improved plasma products. The directive may therefore reduce access to new plasma products for the people of the European Community in the 1990s. Moreover, it is also likely to lead to conflicts of interest between these European public sector institutions, which could produce future operational and even political difficulties.

I believe that it cannot be too late to influence the

impending associated British legislation and that the medical profession in Britain should persuade the government to exercise extreme caution as it prepares the relevant parliamentary bill. The appropriate way forward for Europe would, I suggest, be an aggressive European Community commitment to the WHO recommendations of 1975, which seek an evolution towards national self sufficiency in blood and blood products based on the unpaid blood donor. The desirable retreat of the paid donor from Europe would then be more orderly, and the rate would depend on the commitment of individual countries to help themselves and each other. The European Commission could make an important supportive contribution to such national programmes. But overriding all these considerations will be the need to impress the commission and our government that some things in this world should not be bought and sold for profit, and that the blood and associated products of unpaid donors may be one example, as organs for transplantation are another.

If it is too late to halt this legislative march then I suggest that the several European ministers of health should be asked urgently to agree a set of rules for the single market that will protect national blood donor panels. Of no less importance will be the need to see whether it is possible to establish a pan-European Community public sector programme of research and development in plasma fractionation, thus providing for the free movement of intellectual property between European Community countries and ultimately, perhaps, to those other 300 million neighbours in the greater Europe. The European Community could also give assistance and encouragement to collaboration between countries in the manufacturing aspects of plasma fractionation.

Cost-benefit of national self sufficiency

But, closer to home, there is now a most pressing need to target a substantial and coordinated investment in the British blood transfusion services, with particular attention being paid to the enhanced procurement of high quality plasma and plasma product development. Let us hope that the quality of advice received by the Minister of Health will be a little better than that given to a predecessor. Dr David Owen was advised in the late 1970s that British self sufficiency in blood products was achievable in six months with an investment of £0.5m. The investment required is nearer £25-30m a year (increase on base revenue budgets), and the time target, subject to an appropriate input of coordinated management, might be set at three years. It seems certain that the French government would confirm that the political benefits to be derived from such an investment are likely to be considerable over the next decade and that cost-benefit analyses of national self sufficiency in blood and blood products will show high returns.

We may have reason to thank the European Community commissioners in the years to come: though there are some key elements in their proposals that are seriously flawed, they may have assisted some governments to recognise that effective blood transfusion services are a vital and much neglected component of their health care programmes. Perhaps we may also take some comfort from the fact that at present a large number of European Community directives that should by now be national laws across Europe are not. This would suggest that our government has a facility to protect us from this most recent directive.

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