

Editorial

The specificity of labile blood products and plasma derived products

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Labile blood products and plasma-derived products are very sensitive from a social viewpoint. Along with the challenges faced by all medicinal products there is an added challenge due to the lack of raw material and the social problems with regard to their acquisition. Obtaining them depends on blood and plasma donations. Donation patterns are influenced by cultural and educational factors. Heterogeneity of the origin of the raw material is another challenge. Moreover we are dealing with a biological product with a complex composition. It can carry diseases and therefore the risk factor necessitates constant vigilance. As a result, the authorisation holder's responsibilities for the release of these products onto the market are very high. In order to overcome all these serious and multiple difficulties, the use of advanced and safe technology is necessary.

Implementing a whole system that controls the risk management, is one of the authorisation holder's initial premises. With all these important factors, making labile blood products and plasma derived products available to patients is a scientific and social challenge but the benefits are enormous and literally life-saving.

In this special Monograph of Pharmaceuticals Policy and Law, we have sought to cover these complex issues by exploring the different aspects of the development of this unique category of medicinal products. Wide geographical areas that are highly developed such as the EU, are paradigmatic in order to understand the serious social and political contradictions which it faces. The EU is not a society which is exemplified for its solidarity in its donations of human blood, and more even so of human plasma. The donations are insufficient. Europeans as a whole fail to even cover 40 per cent of their needs in plasma for fractionation. Therefore it is not self sufficient in plasma which is required to make a wide range of life-saving medicines. It should however be remembered that Europe may already have enough blood to meet the need for transfusions. An active minority of its politicians have caused laws to be passed ensuring donations are from donors who receive no incentive to donate which is inconsistent with reality and that, if implemented rigidly, would condemn thousands of patients in need of these therapies to a certain death. The aspiration that all donations shall be voluntary, free and unpaid, is an altruistic objective, which reality, unfortunately, contradicts every day. Anybody can support

that objective in order to direct the conduct regarding public health and politics for all policies. However what cannot be confused is a desirable altruistic objective with a legal obligation which would yield results. This would be greatly irresponsible and would cause great political incoherence, which does not resolve every Government's primary responsibility of guaranteeing the right to health for its citizens and making available to them the necessary medicinal products, which science makes possible. If this problem is to be dealt with rationally the Manichean absolutism of political trends must be overcome, which not only fail to resolve anything but also risk the health of thousands of people. What must be clear is that the fundamental rights of the people supersede any school of thought, even if inspired by good intentions. The defence of any so-called ethical principles cannot lead in practice to a total lack of ethics, which would mean depriving patients of the medicinal products that they require.

If this initial political difficulty is overcome, there will have to be a search for essential mechanisms so that society, at the global level, has this rare and precious raw material at its disposal without contravening any objectionable or unacceptable practices.

Governments and all social Agencies should promote to the maximum its actions in order to achieve the greatest number of donations each day. More difficulties cannot be added to this arduous job. Even from a humanitarian or ethical viewpoint nobody can deny a possible donor accepting incentives. Society is socially and ethically obliged to incentive, every citizen, that lends himself to an altruistic action. The citizen shall be able to renounce it or accept it. However if he accepts, his behaviour cannot be ostracised or his generosity and altruistic disposition denied. Incentives cannot be interpreted as a sale. The great gesture of donating one's own blood or plasma cannot be criminalized for the acceptance of an incentive. With only this small social change of appreciating and recognising every person who accepts to be a donor, there would have already been an advance towards the solution to the problem. Blood and plasma are easily renewed tissues, consequently it cannot be compared with the way non-renewable organs or parts of the body are treated judicially or ethically. This is often forgotten. Nevertheless, here a second level of support can be found to strengthen, with guarantees, the steps towards self-sufficiency.

Self-sufficiency has been another concept that has been manipulated and badly interpreted in a nationalistic way. This is another serious problem which we face. Nationalism is a serious illness, the same as ethical Manichaeism. It must be overcome with social "hygiene". If a region or a country, despite all of its efforts, does not obtain the sufficient raw materials (plasma) to produce the medicinal products that it requires, the patients cannot be condemned to a sure death or an inappropriate lack of medication. The United Kingdom is living that awful reality. Due to the existence of bovine spongiform encephalopathy, plasma from donors in that country cannot be used. Moreover that unfortunate health tragedy is having an impact in other countries, due to epizootics spreading to other countries and the prohibition by the American FDA and other regulatory agencies of accepting donations from people

who have resided in the United Kingdom for over six months. Other countries, for different reasons, like the extension of the pandemic of AIDS, find themselves in similar circumstances. These realities shall not be overcome without political fundamentalism. All available funds should be disposable at global level. At least that should be the premise. If one talks about anything it must be about inclining towards and facilitating world sufficiency.

It must not be forgotten either that the raw materials are important but not decisive. If the appropriate technology and an efficient risk control system are not available, the raw materials will have no value.