IMI consultation on advanced therapies

Response from Patricia Vella Bonanno

Innovative Medicines Initiative consultation

Facilitating the translation of advanced therapies to patients in Europe

Patient access and unmet medical need

The introduction of new treatment approaches to meet unmet medical needs is plausible and should be applied prioritising the good of patients. Thus as long as different treatment modalities meet the respective applicable regulatory framework and achieve the desired or claimed level of effectiveness expected with the specific product, the different treatment modalities should be allowed to co-exist and the decision on which product to be used will rest with the empowered patients and the healthcare professionals prescribing and applying the treatment.

One major determinant of access to ATMPs by patients will be the pricing and affordability of these products.

For ATMPs with a centralised marketing authorisation it is important that these therapies are available on all markets where these products are needed to be used and that Marketing Authorisation Holders do not restrict marketing of products on certain markets.

Classification and regulation

The regulatory framework applied should be commensurate and applicable to the specific therapeutic product and the level of risk associated with the use of the product for the patient. There should be no moves to change or interpret the legislation in a way to push products into being classified as ATMPs.

The regulatory requirements set by the EMA to obtain marketing authorisation for ATMPs are very high. The level of regulation and the risk governance framework applied should be commensurate with the level of risk involved.

The hospital exemption should remain and be applied at discretion/interpretation of the stakeholders directly involved in its application. There should be no attempts to restrict the hospital exemption to give advantage to the industry over the hospitals. The industry can still manufacture the products concerned to sell them to those facilities which do not have the ability to access these products through the hospital exemption. Competition will help to increase and widen the access and affordability of these products for patients.

Dr Patricia Vella Bonanno

Pharmaceutical Expert

pvellabonanno@gmail.com