

Your Voice In Europe: ROADMAP feedback for Evaluation of Union legislation on blood, tissues and cells

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- Size : select
- Publication : can be published with your personal information

Related document: Evaluation of Union legislation on blood, tissues and cells

Feedback:

I have a few comments on the ROADMAP and more specifically on points 2, 8 and 9 (page 4).

Page 4

Effectiveness:

Point 2. To what extent has the legislation increased the quality and safety of blood and tissues and cells and achieved a high level of human health protection?

Efficiency:

Point 8. How cost-effective has the application of the quality and safety requirements in the legislation been for operators (have the benefits outweighed the costs?)?

Point 9. Are there particular administrative or other burdens for specific groups of operators, including downstream users of blood, tissues and cells as starting materials for medicinal products? 10. To what extent has the legislation resulted in cost implications for hospitals/patients using/receiving blood, tissues and cells?

MY COMMENTS:

By comparing the manipulation of stem cells to that of drugs, stem cell-based products are de facto considered as drugs and regulated by EMA in Europe and medicinal product regulatory authorities in each member state.

In the past 2 years this has led to the marketing authorization of products such as Holoclar by EMA. The development of Holoclar has been led by a pharmaceutical company as the costs

required for achieving such result by non-profit centers would be too great.

The consequence is that many university hospitals and research centers working in this field for years had to stop treating their own patients suffering from limbic stem cell deficiency from being grafted with stem cell preparations that were working (hundreds of peer-reviewed papers are out there to demonstrate this) and will have now to use a licensed product (Holoclar) which costs around 100.000 euros.

The consequences of this are:

- Increased costs (at least 10x) for the national health systems of every member state;*
- A lower percentage of patients being treated, as most of the hospitals/research centers do not have the budget to buy such product or insurance companies might not pay;*
- Loss of expertise by university hospitals/research centers which will eventually lose interest in stem cell-based technologies;*
- Possibility that pharmaceutical companies might eventually drop this technology once they fail to get revenues, thus making these diseases/pathologies orphan again.*

We feel that hospital exemption for clinical application with stem cells should be implemented and not ruled out when a licensed product is on the market. If not this will have tremendous downstream consequences for costs of the national health systems and eventually for the patients who will not have access to a therapy that was available up to a few years before.