

# EEBA STATEMENT ON EUROPEAN GOOD PRACTICE GUIDELINES FOR CORNEAL DONATION

Venice, 31 December 2016

For many corneal diseases the transplantation of corneal tissue using human donor tissue is the only option to visually rehabilitate patients.

In 2004 DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells was agreed upon by EU Member States. The directive states "As there is a need to ensure the availability of tissues and cells for medical treatments, Member States should promote the donation of tissues and cells, including haematopoietic progenitors, of high quality and safety, thereby also increasing self-sufficiency in the Community."

It is now more than 10 years ago since the directive was adopted. In Europe, however, there is still a relative shortage of corneal donor tissue, and many European countries still import corneal donor tissue, primarily from the United States.

The *European Eye Bank Association* (EEBA) was formed for the advancement of eye banking. Its Mission is to help provide tissues and cells of optimum quality and safety for transplantation and the treatment of eye diseases, according to the highest medical and scientific standards, and making them available to as many patients in need as possible.

In order to learn and evaluate to what extent individual European States have promoted the donation of corneal tissue, EEBA undertook in 2014 a survey of legislation and initiatives related to corneal donation among the Member States. The National Competent Authorities for Tissues and Cells in 35 European countries were approached and were asked to respond to the following short questionnaire:

1. *Has your country implemented a national legislation explicitly describing how corneal donation should be promoted?*
2. *Do you have regional guidelines explicitly describing how corneal donation is promoted?*
3. *Have your collaborating hospitals implemented guidelines explicitly describing how corneal donation is promoted?*
4. *Is the effective corneal donation rate in collaborating hospital departments monitored regularly?*
5. *Do you have private or patient organisations actively involved in promotion of corneal donation in your area?*

Official response were received from the following 15 countries:

Belgium, Bulgaria, Estonia, Germany, Ireland, Italy, Latvia, Lithuania, Luxembourg, Portugal, the Republic of Moldova, Romania, Slovenia, Switzerland and the UK

In addition, based on information received from individual eye banks in a further 6 countries (Denmark, Finland, The Netherlands, Norway, Serbia and Sweden) it has been possible to summarise a European position.

Overall, only 4 of the 21 countries surveyed had implemented national legislation explicitly describing how corneal donation should be promoted, 4 countries had national or regional guidelines explicitly describing how corneal donation is promoted, 11 countries monitored the effectiveness of corneal donation rates, and in 8 countries private or patients organisations were actively involved in promotion of corneal donation.

*The European Eye Bank Association (EEBA) is a technical-scientific organization comprising individual members from 88 eye-banks from 25 European countries. Founded with the simple objective of sharing information regarding eye-banking, the Association is today the leading pan-national association in Europe dedicated to the advancement of eye-banking and an authoritative reference point for eye banks wishing to work according to quality standards.*



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It seems, therefore, that there is a real need to promote corneal donation in many European countries. As a result, the Committee of the *European Eye Bank Association* therefore states that:

- For many corneal diseases the transplantation of corneal donor tissue is still the only treatment option to visually rehabilitate patients.
- There continues to be a shortage of corneal donor tissue within many European Member States,
- In order to ensure self-sufficiency of corneal donor tissue each European Member State
  - should implement national legislations and/or guidelines in order to promote corneal tissue donation.
  - should promote development of guidelines for promotion of corneal tissue donation at national and local levels
  - should regularly monitor the effective corneal donation rate, and establish routines for further intervention and promotion if donation rates are insufficient or decrease



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