International Survey on Manufacturing and Use of Serum Eye Drops

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Purpose
Since more than 40 years Serum Eye Drops (SED) are used as treatment for severe forms of dry eye. Therapeutic efficiency is documented with growing evidence; still large, randomized trials are required. In contrast to other substances prepared from blood, manufacturing of SED is not very standardized. The guidelines for substances of human origin (SoHO) in Europe, coming into action in 2027, underline the necessity for evaluation and standardization.

Method
In a standardized online questionnaire data on size and regulatory structure of manufacturing, strategies used for validation and manufacturing, details on delivery, documentation of efficiency and occurrence of side effects were surveyed.

Results
Evaluation of 24 completed questionnaires included answers from Europe, East Mediterranean and Asia. Participants who did not complete the questionnaire or did not report the name of the responsible person had been excluded before. As source of SED 23 used serum, one platelet (plt) lysate; one participant serum or plt lysate and plt-rich plasma, another one plt-rich plasma from apheresis.
In 2024 almost 4000 autologous donations were processed to more than 140,000 single daily doses in closed systems (Biomed Device or Meise System), and more than 40,000 in eye drop bottles. In the allogeneic directed setting, 399 donations resulted in > 19,000 daily doses in closed systems and over 6000 in eye drop bottles. More than 7000 allogeneic undirected donations provided over 584,000 daily doses in closed systems and over 65,000 in eye drop bottles.
As active substance for validations albumin, EGF, FGF, PDGF, VEGF, and total protein were reported. 23 centers deliver the eye drops frozen (dry ice, cooling packs), whereas one institution transports them thawed, refrigerated to the patient. For details like selection of donors, dilutions, validation or bacterial safety, a large variety was observed in the answers.

Conclusion

This first large, international survey on manufacturing eye drops from human blood showed a large variety in almost all details. A study group was initiated to evaluate possibilities for improvement and standardization of donation, manufacturing and delivery in the context of the SoHO regulations.

Acknowledgement:
We thank all participants of this survey, their respective patients and donors.