The EMA’s and National Competent Authorities' perspective

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² The Repurposing Observatory Group is an ad hoc group composed by representatives of the EMA, National Competent Authorities, and the European Commission, plus patient’s representatives (Eurordis and Anticancer Fund) and industry associations (EUCOPE, EFPIA and Medicines for Europe)

Abstract

The perspective for repurposing is quite different when one considers finding a new use for i) an active substance that has never been authorized, ii) a medicine that is still within intellectual property or regulatory data protection or iii) a well-known medicine that is out of any protection period. While pharmaceutical companies may find a commercial interest in pursuing a non-clinical and clinical development in the first two cases, they are less likely to carry out such development for out-of-protection medicines. In the third case, the current environment (regulatory and market access) does not encourage pharmaceutical companies to further explore existing opportunities in repurposing. Other parties, including academic institutions and learned societies, are more willing in general to explore repurposing options when medicines are out of these protection periods. However, this academic research rarely has an impact in terms of regulatory recognition of a new use and indication. Academic sponsors usually do not intend to become marketing authorisation holders, and may have a vague notion about regulatory requirements. In support, the EU Commission has initiated a regulatory science curriculum project called STARS. In addition, the current regulatory pathways do not foresee submission of data by parties that are not intending to be a marketing authorisation holder. This can mean that medicines are used outside their authorised uses (off-label) and official clinical guidelines might recommend their use based on available evidence, despite not being formally authorized. Under the umbrella of the Pharmaceutical Committee and as a result of the discussions at the European Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) a virtual Repurposing Observatory Group (RepOG) was set up in 2019 to define and test the practical aspects of a pilot project thought to provide support to ‘not-for-profit’ stakeholders generating or gathering data for a new therapeutic use for an authorised medicine.

Keywords

Drug repurposing, Off patent authorised medicines, Patients access, Regulatory support, Repurposing Observatory group, Pilot launch

References

None