IHI PREMIER – Prioritisation and Risk Evaluation of Medicines in the EnviRonment

Update relevant to GPL revision

There are a number of issues in the new pharmaceutical legislation for which the PREMIER project is already working on providing solutions. The PREMIER project is a public-private research consortium with industry, academia, and two governmental institutes, amongst which the European Medicines Agency. The Commission is leveraging tax payers money with industry in direct partnership.

One of the most important issues is the environmental risk assessment of 1000+ untested legacy pharmaceuticals that have been authorised before 2006. This will be time consuming, very costly and would require intensive animal testing. The gap to backfill is decades and perhaps a billion euros.

Within the PREMIER project we have developed a framework to prioritise the environmental assessment of existing medicines. Combined with a database, we also design a novel information and assessment system for identifying and addressing environmental risks of medicines, especially for those with limited data availability.

Based on our prioritisation, environmental data for up to 25 existing medicines are actually generated! With this work, we don't only fill data gaps but we can also validate the prioritisation framework. Moreover, with the development of - we call it - "Fish Decision Tree", it could be shown that experimental testing on fish is not required for about a third of the substances. If we accept this one aspect of PREMIER it translates to sparing more than a quarter of a million vertebrates in regulatory testing, a cost in excess of 40M Euro avoided and a saving in excess of 100 years of laboratory time. In addition to this, we develop innovative tools that do not require animal testing, so we can identify and predict potential environmental impacts associated with the use of human medicines.

As mentioned, we are also developing a centralised, transparent, public and easily accessible database, the need for which is also mentioned in the draft legislation. All information from past environmental risk assessments will be part of this database, and a sustainability plan for this database is discussed with EMA, being a partner of this project. The database will be IUCLID compatible and we plan to be live to the public before ECHA and EFSA release their versions of the One Substance – One Assessment approach.

And finally, the quest for greener drugs is further explored, using the innovative non-animal testing approaches we developed, and in collaboration with industry's R&D experts. We defined guiding principles, which have been discussed with the medicinal chemists of the involved EFPIA companies. The ultimate aim is to provide tools and guidance to assess environmental hazards and risks in an early stage of the development process.

In conclusion, within the PREMIER project, leading academia, regulators and industry are already working together to solve a number of the issues in the draft pharmaceutical legislation, and we are open to further information exchange.