Innovative Medicines Initiative

EcoRisk prediction

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Need for public-private collaboration

- Issue requires involvement of many different stakeholders
- Data sharing between public and private organizations needed
- Regulatory acceptance and scientific integrity
- High transparency for stakeholders
- Opportunity for an objective consensus approach

Objectives of the full project

- Develop experimentally validated methodology based on scientific information on specific properties of pharmaceutical compounds in order to predict a response in environmental organisms
- Establish an ecotoxicological database for pharmaceuticals to identify predictive elements for ecotoxicological hazards and exposures in close collaboration with other EU (co-)funded projects developing large databases for (eco)toxicological information
- Develop recommendations for the use of the results of the project for prioritizing legacy products for experimental testing and in early development programmes for new compounds
- Develop recommendations for closing knowledge gaps and evaluating the questions about risks of pharmaceuticals in the environment

Pre-competitive nature

- Develop common strategies to assess and prioritize environmental hazards and risks of pharmaceuticals
- Collaboration in providing a basis of further investigations and regulatory activitiesthrough a robust and agreed process
- Develop new methodologies which can be used in research and development by industry and other organizations

Expected impact on the R&D process

- Support predictions of the potential environmental risks of un-tested APIs during early development or on the market
- Focus experimental research on ecotoxicological effects on specifically sensitive organisms, life-stages and specific test designs for critical endpoints (intelligent testing)
- Use knowledge-based models to predict environmental exposure and fate scenarios
- Identification of potential environmental issues at an early stage of research and development in order to take into account mitigation strategies

Suggested architecture of the project

- Workpackages with mixed contributions from applicants and EFPIA participants
- Coordination by steering committee (work package leaders and deputies, project coordinator and deputies, project manager)
- Stakeholder advisory group (academia, regulatory bodies, trade associations)

Expected contributions of the applicants

- Expertise in environmental assessment of pharmaceuticals
- Work in multidisciplary teams - pharmacology, ecotoxicology, physiology, bio-informatics, statistics, database development, QA/QC and data curation
- Expertise in statistical approaches for data mining
- Collection and evaluation of environmental and pharmacologically related information
- Evaluation of information with regard to validity and quality
- Being able to link adverse molecular events to ecological risk or adverse outcomes at the population level or above
- Expertise in developing and performance of data management systems in order to generate structures for data base input
- Laboratory expertise in molecular, cell based and ecotoxicological whole organism testing

Expected contributions of the applicants

- Expertise in exposure modelling, develop criteria for use of exposure models including the sensitivity and specificity
- Evaluate results of in silico and experimental research in order to come up with recommendations
- Identification of meaningful concepts for the evaluation of correlation patterns useful for prediction of ecotoxicological hazards and risks
- Management of the consortia along with the ability to manage all administrative and coordination activities and to provide the best possible interaction of the applicant consortium with the EFPIA consortium

Expected (in kind) contributions of EFPIA members

- Provide unpublished industry information and unpublished environmental exposure assessment data on human pharmaceuticals
- Provide toxicological and pharmacological data and expertise to be used in data mining
- Provide expertise in exposure models such as PhATE
- Provide alligned testing in cooperation with the applicants
- Cooperate on the selection process for parameters/endpoints
- Support the development of extraction and combination methods
- Develop proposal for experimental validation of identified correlations and similarities

Expected (in kind) contributions of EFPIA members

- Coordinate with the eTOX project (IMI) to determine needs for further adaptation of the eTOX data management system
- Cooperate with applicant consortium partners and stakeholder advisory group in developing recommendations, illustrate realistic scenarios in API research and development
- Cooperation in project coordination

What's in it for you?

- Benefits of this particular project for:
  - Academic researchers:
    Availability of data not yet accessable, development of new and innovative prediction methodology, use of interdisciplinary information
  - SMEs:
    Cooperation in large public-private research project, experience in new data evaluation tools and methodology, provide expertise in experimental testing methods
  - Regulators:
    Availability of new scientifically validated methodology to prioritize pharma substances for environmental risk assessments,
    support regulatory initiatives to analyze the risk of pharmaceuticals in the environment.

Key deliverables of the full project

- Literature evaluation of concepts for mode-of-action based approaches to environmental risk assessment
- A data management system filled with literature, industry owned and possibly regulatory data, focussing on links between environmental information and specific properties of APIs in cooperation with other projects (such as IMI eTOX, Mistrapharma)
- Delivery of predictive tools for early screening of hazardous environmental properties and validation of the tools through experimental research projects
- Guidance on how the tools can be used to develop a prioritization process for existing APIs (legacy products)
- Guidance on how the tools can be used in early development programmes for new APIs
- Discuss the outcome of this programme with stakeholders, evaluation of the overall situation on PiE

Questions?

- Contact the **IMI Executive Office**

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