Intelligent assessment of the environmental risks of pharmaceuticals
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Facts & Figures
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End date: 31/12/2018
Contributions
IMI funding: 3 000 000 €
EFPIA in kind: 5 689 230 €
Other: 1 599 327 €
Total Cost: 10 297 577 €
Project website: www.i-pie.org
Social media: #ipie

Challenge
There are concerns over the impacts of Active Pharmaceutical Ingredients (APIs) in the aquatic environment.

Of the >1500 APIs currently in use, adequate data to assess their environmental risk is only available for a small proportion.

The challenge is to identify environmental risks of new APIs during early development and prioritise legacy APIs such that intelligent and efficient testing strategies can be defined.

Approach & Methodology
The iPiE project develops new frameworks that utilize information from:

a) ecotoxicological and environmental fate studies,  
b) pharmacological mode of action,  
c) targeted environmental monitoring of APIs, and  
d) in silico models

to support intelligence-based environmental testing of pharmaceuticals.

Results
Key outcomes include:

a) The iPiE Summary Database Search ‘iPiE*Sum’ hosts the physiochemical properties, fate and ecotoxicity of APIs collected during the project,

b) Development of quantitative structure activity relationship (QSAR) models for environmental fate and toxicity and a new catchment-based exposure model for predicting concentrations of APIs in European rivers,

c) Quantification of 41 APIs over 2 years enabling validation of developed exposure models, and

Value of IMI collaboration
The collaboration has supported the formation of a world-leading group of academic, governmental and industry partners. This relationship has enabled more effective delivery of guidance to stakeholders and maximised the value of existing datasets.

Impact & take home message
By accessing the existing data and combining these with predictive models for environmental fate and hazards, it may be possible to establish whether low levels of APIs in the environment constitute a threat to environmental and human health without the need for extensive experimental testing.

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