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# Balancing the health benefits and environmental risks of pharmaceuticals: Diclofenac as an example



V. Acuña <sup>a,\*</sup>, A. Ginebreda <sup>b</sup>, J.R. Mor <sup>a</sup>, M. Petrovic <sup>a,c</sup>, S. Sabater <sup>a,d</sup>, J. Sumpter <sup>e</sup>, D. Barceló <sup>a,b</sup>

- <sup>a</sup> Catalan Institute for Water Research (ICRA), Carrer Emili Grahit 101, 17003 Girona, Spain
- b Department of Environmental Chemistry, Institute of Environmental Assessment and Water Research (IDAEA-CSIC), Carrer Jordi Girona 18-26, 08034 Barcelona, Spain
- <sup>c</sup> ICREA, Passeig Lluís Companys 23, 08010 Barcelona, Spain
- <sup>d</sup> Institute of Aquatic Ecology, University of Girona, Campus Montilivi, 17071 Girona, Spain
- <sup>e</sup> Institute for the Environment, Brunel University, Uxbridge, Middlesex UB8 3PH, United Kingdom

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#### ABSTRACT

Pharmaceuticals are designed to improve human and animal health, but even the most beneficial pharmaceuticals might raise some questions concerning the consequences of exposure to non-target organisms. To illustrate this situation and using diclofenac as a case-study, we analyze global consumption and occurrence data to identify hot spots of consumption without occurrence data, review the scientific literature on the harmful environmental effects to determine whether the observed concentrations in freshwater are of environmental concern, summarize the current pharmaceutical and environmental policies to highlight policy gaps, and suggest a series of research and policy recommendations, which can be summarized as follows: we need to improve the current knowledge on occurrence in freshwaters to properly implement environmental policies (i), diclofenac might pose a risk to non-target organisms in freshwater (ii); the harmful effects that some pharmaceuticals may have on the environment are not always addressed by environmental policies (iii).

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#### 1. Introduction

Our developed, technical society has been able to design and produce a great variety of chemical entities (>300,000 inventoried/ regulated chemicals are currently used in industry, household and agriculture) (Chemical Abstracts Service, n.d.). These chemical include approximately 4000 pharmaceuticals, which are administered worldwide as prescription medicines, over-the-counter therapeutic drugs, and veterinary drugs. Pharmaceuticals are designed to improve human and animal health, but even the most beneficial pharmaceuticals might raise some questions concerning the consequences of exposure to non-target organisms. In fact, it has been claimed that many different pharmaceuticals could be causing harmful effects at environmentally relevant concentrations upon their (voluntary or involuntary) release into the environment (Richardson and Ternes, 2014). The policies necessary to mediate such a delicate balance between these opposite aspects are provided by diverse existing regulations, but there is an increasing public perception that such regulations may not be reflective of the most recent scientific findings and may follow a 'reactive' rather than 'proactive' behavior. In the case of freshwater ecosystems, there is a striking contrast

Abbreviations: EQS, environmental quality standard; LOEC, lowest observed effect concentration; ERA, environmental risk assessment.

Corresponding author.

E-mail address: vicenc.acuna@icra.cat (V. Acuña).

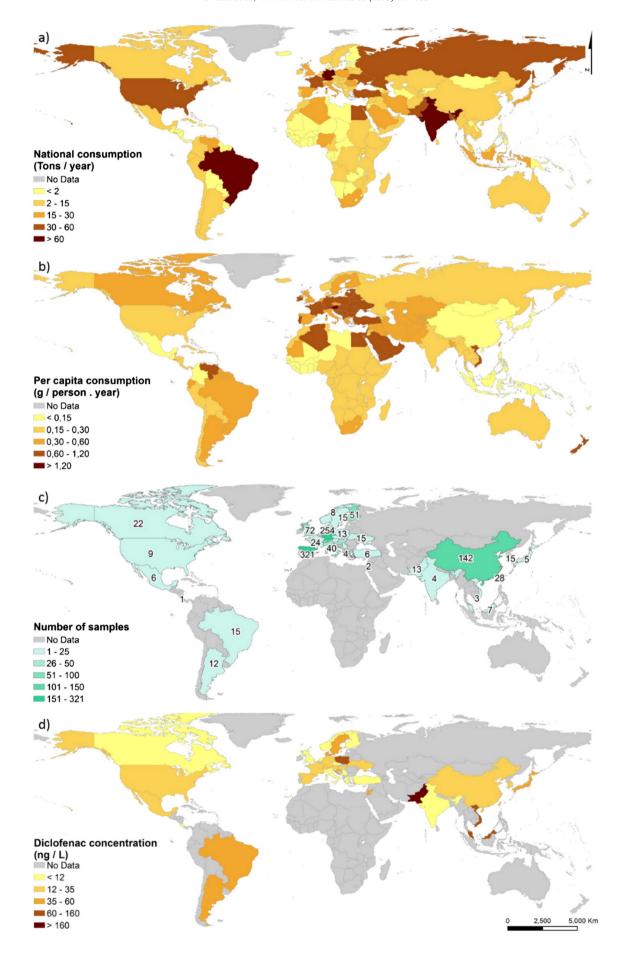
between the number of pharmaceuticals produced and those that have an environmental quality standard (EQS). In fact, none of the currently used pharmaceuticals have an EQS in either the European Union (EU) (Council of the European Communities, 2000) or the United States (US) (United States Environmental Protection Agency, 1999). A switch to a more desirable "proactive" and "preventive" regulatory system should therefore be a priority for policymakers.

The aforesaid situation applies to many pharmaceuticals, and we selected diclofenac as a case study to illustrate the situation of those pharmaceuticals exhibiting both health benefits and environmental risks. We first analyze global consumption and occurrence data to identify hot spots of consumption without occurrence data (Section 3.1), review the scientific literature on the harmful environmental effects of pharmaceuticals to determine whether the observed concentrations in freshwater are of environmental concern (Section 3.2), and summarize the current pharmaceutical and environmental policies to highlight policy gaps (Section 3.3). We conclude the manuscript with a series of research and policy recommendations (Section 4).

#### 2. Material and methods

#### 2.1. Global map of consumption

The IMS-Health dataset, including 2011–2013 national consumption data for 86 nations (expressed as kilograms of consumed compound per



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