




Short communication

## Sustainability of medicines and biocides. A One Health approach

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## ABSTRACT

Intelligent use of medicines and biocides is essential for ensuring human and animal health including the control of zoonosis (infectious animal diseases transferable to humans) and animal welfare. Current marketing authorization and pharmacovigilance approaches however don't address sustainability. An integrated methodology is vital to address their global impact. A One Health concept is proposed which integrates social, economic and environmental considerations into a single trusted assessment of sustainability based on benefits and risks for humans, animals and ecosystems health.

## 1. Introduction

Sustainable biological communities and ecosystems rely on a balance and cooperation between multiple species for their maintenance. Increasing urbanisation has disrupted ecosystems functions and mankind no longer recognises the vital importance of the need to live in harmony with the ecosystems on which it depends for its own long-term survival. Global coordinated action is needed urgently if the quality of human life is to be sustained.

The principal, interrelated causes of this decline are:

- Climate change impacts
- Progressive reduction in habitats and species diversity in many ecosystems
- Growing scarcity and unequal distribution of natural resources
- Unsustainable disposal of waste products of human activity, including chemical pollutants.

To date the politically favoured priority is to address climate change by restricting fossil fuel combustion to achieve carbon emission neutrality. Scant attention has been paid to the likelihood that these measures will increase the other causes of the decline in sustainability.

Since the 1960 s, chemical pollution has been identified as major

global concern for Public Health and environmental protection, leading to actions at national and international level, including several United Nations (UN) initiatives. Decision making on medicines (human and veterinary uses) and biocides (used to control unwanted organisms) requires specific considerations due to their societal benefits (Willmott et al. 2024).

Sustainability should be a key consideration in a development of any chemical (Sudheshwar et al. 2024) and drug (Wynendaele et al. 2021). The EU published its 'Chemicals: Strategy for Sustainability' as part of the European Green Deal. However they fail to address the key considerations (Bridges et al. 2023). The EU is leading sustainability integration for pharmaceuticals, but there are conflicting policy objectives requiring trade-offs among the three pillars (De Spiegeleer and Wynendaele 2025).

Pre-marketing assessments are still conducted for each product and use. For human medicines, the safety for the patient is being complemented with environmental risks, including ecosystems and humans exposed through the environment, which would support strategies for promoting sustainable use (Jairoun et al. 2025). For veterinary medicines parallel risk considerations cover the safety of the target animal species, the user, pet owners in case of domestic animals, consumers of animal-derived food commodities, and the environmental risks linked to animal waste management practices. For biocides, the coverage is based

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on the use patterns, assessing environmental risks when emissions are anticipated.

Integrating the results from substance-by-substance assessments and balancing the overall risks benefits is a greater challenge. The direct benefits are typically for a particular group of the population, the patients or users, while the risks as outlined above are far broader. A sustainability assessment requires a sub-framework for each pillar, with conclusions translated into common units and a weighting approach linked to societal expectations. Monetization has been suggested as the common unit, but in our view, financial units are not the best indicator for societal needs. In the case of medicines and biocides, improving health is the societal aim and should lead the integration of sustainability pillars. This short communication analyzes the limitations of the current EU regulatory approach; proposing a “One Health” based sustainability framework for integrating and weighting the results from each pillar. Our aim is to trigger a discussion among researchers, regulators, health care professionals and other stakeholders, that could lead the development of new frameworks covering the market authorisation, and also, the development of guidance for selecting the most sustainable products in daily practice considering health and environmental needs.

## 2. Methods

This short communication is the result of the integration of independent extensive reviews by the co-authors as part of a set of conferences at the Instituto de Salud Carlos III and the Royal Academy of Veterinary Medicines of Spain (RACVE); followed by a dialogue and critical analysis reviewing EU policies, strategic approaches and risk assessment processes, focused on the EU Green Deal and the guidance documents on pharmaceuticals and biocides, published by the EU Agencies EMA ([www.ema.europa.eu](http://www.ema.europa.eu), accessed on 23/06/2025)) and ECHA (<https://www.echa.europa.eu>, accessed on 23/06/2025). The critical assessment was based on the personal experience of the co-authors in scientific committees and panels dealing with regulatory assessments, supported by a focused literature search using PubMed, Web of Science and Scopus databases.

## 3. Proposal

An integrated multidisciplinary sustainability assessment appears as the best suited option for providing science-based support to decision makers. A main difference for medicines and biocides *versus* other chemicals is that the benefits are also health related. This is implicit in sustainability assessment for antimicrobial resistance for biocides (OECD 2021); but has not been sufficiently expanded to other environmental impacts.

It has been recognised that sustainability should be integrated as a key element through the life cycle of pharmaceuticals, starting already at the initial steps of drug discovery (De Spiegeleer et al. 2024; De Spiegeleer and Wynendaele 2025). Our proposal is to link three sustainability pillars through a One Health approach (Fig. 1). The social pillar is driven by Public Health policies, encompassing veterinary public health and addressing specifically vulnerable human and animal groups; this pillar can be quantified through impacts on specific health indicators. This approach has been applied to air pollution (WHO 2021) and should be extended to other chemicals. The environmental pillar covers impacts on biodiversity and ecosystem functions. Ecosystem services (Hernández-Blanco et al. 2022) are defined as the benefits that humans get from healthy ecosystems, such as provision of food and water, regulation of water resources, water/air/soil quality, or recreation. Translating ecosystem impacts into perturbations of these services connects environmental risk assessments with the social pillar, including health, wellbeing, or food safety. The economic pillar involves the analysis of cost, benefits and overall impacts of the different alternatives, and should consider impacts on ecosystem services linked to water and food security, erosion control, etc. The combination of the three pillars enables the overall sustainability of each option, and the selection of those best featured in terms of minimum policy targets and best use of available resources. For medicines the social and economic pillars have usually been considered albeit in an unintegrated form. For biocides the environmental pillar is also often partially addressed.

The challenge from a regulatory perspective is in implementing this approach is that the current risk assessment paradigm has not evolved significantly in the past 50 or so years. The focus is still on risk quotients linked to individual acceptable risk level established by regulatory bodies. We propose a new risk assessment paradigm, where decisions are

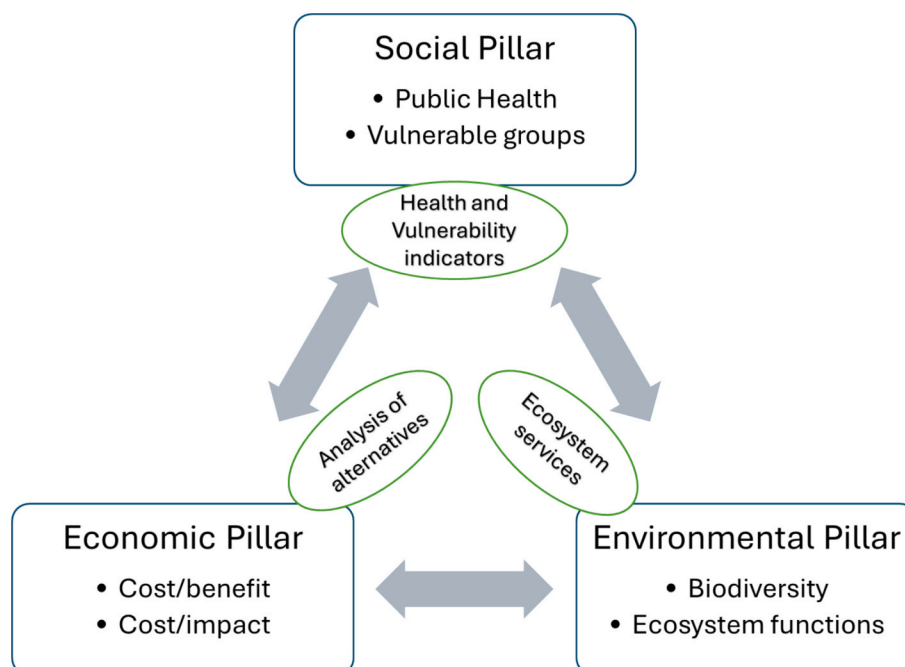


Fig. 1. A One Health based sustainability assessment for medicines and biocides.

based on a more informative assessment of the expected effects on human, animal and environmental health; allowing the integration of individual substance risks into overall impacts and the likelihood of undesired consequences. As demonstrated by some proof-of-concept studies and frameworks (Bopp et al. 2018; Cattaneo et al. 2023; Tyack et al. 2022), this integration is possible. For human health, the proposal is to use health impact pathways (Pallarés Porcar et al. 2024); to be extended to animal health including welfare, as the concept of “health status” at individual and population level are harmonized.

The integration of the environmental impacts of the chemical substances used in an area requires spatially and temporally explicit assessments, considering the agricultural landscapes, i.e. distributions of crops, pastures and livestock, sludge/manure applications, transfer to water bodies and non-crop areas, as well as wildlife habitats. A conceptual framework has been recently developed for pesticides (Tarazona et al. 2024) and can be adapted for assessing the combined risk of medicines and biocides. The main difficulty when moving from risk to impacts is the lack of a harmonized concept for “environmental health”. Biodiversity lost and disruption of ecosystem functions are proposed as “health indicators” for quantifying the impact on ecosystem services. Risk/benefit balances address direct impacts, and ecosystem services linked to the sustainability pillars cover address the indirect health consequences of environmental risks (Fig. 2).

#### 4. Discussion

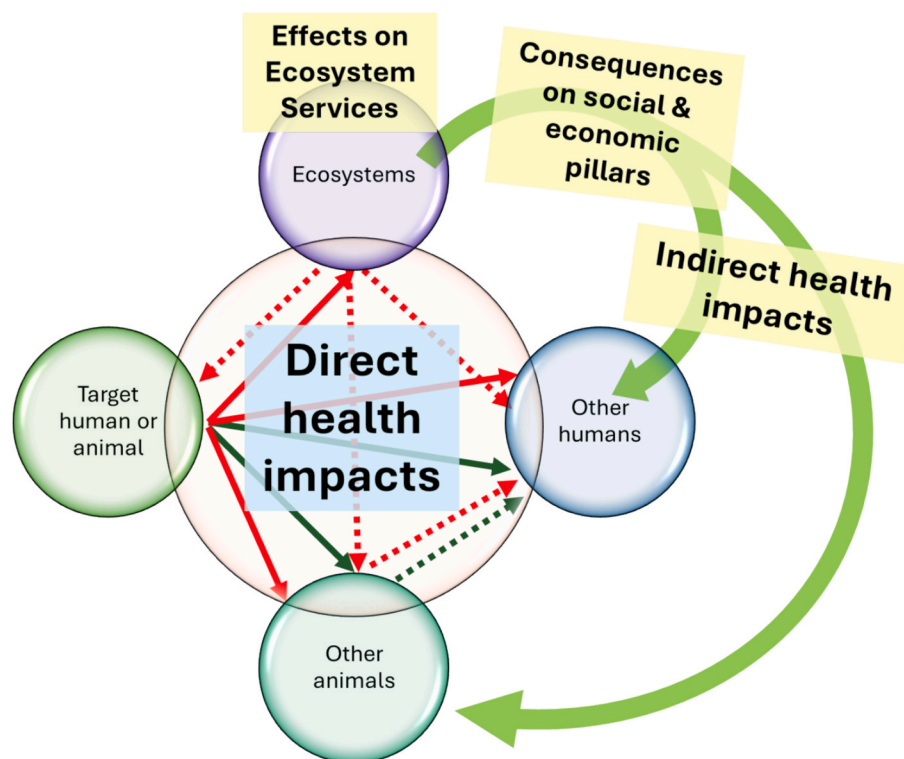
Why is a One Health sustainability paradigm much needed? Monitoring programmes have confirmed the widespread presence of residues of active substances and metabolites of pharmaceuticals and biocides in the environment. Human pharmaceuticals levels are usually low but widespread (Sumpter et al. 2024) triggering concerns about their overall combined impact. Regarding veterinary medicines and biocides, their impact can be mitigated through proper management strategies (Nightingale et al. 2023), and actions have been implemented in recent decades, including restrictions on agrochemicals and increasing the

complexity and cost of waste management. There is a clear need to reduce the environmental impact of various farm management practices, however the oversimplified evaluation approaches coupled with a lack of comprehension of what is truly needed have prompted a very negative reaction. For example, many European countries have witnessed farmers protests against their governments plans for ‘greening agricultural practices and setting aside some of their land as nature reserves. It is very evident that a major rethink is necessary what sustainability means and how it is to be achieved.

It is vital that health professionals, practitioners and other scientists are proactive in both charting and enabling a road map of appropriate widely accepted assessment procedures to ensure prompt progress to a more sustainable environment; health managers play a key role for ensuring the sustainability of health services (EHMA 2022), but require training (Wieërs et al. 2024) and practical tools for integrating sustainability in their daily practice. The One Health concept has a crucial role to play in facilitating progress because of its understanding of appropriate animal husbandry practices and of the roles of animals in the wild in sustaining the ecosystems they inhabit.

Implementation of sustainable food production has become a priority. Worldwide, the human population is under exponential increase moreover the progressive movement of humans from rural to urban living shows no sign of abating. One important consequence of this has been a major expansion in factory scale rearing and maintaining of an ever-increasing range of animals as a food source. Climate change has extended the habitat of infectious diseases vectors, and zoonotic and tropical diseases are emerging in temperate areas.

The combination of all these factors has resulted a great increase in the use of medicines and biocides. The massive use of antibiotics by humans, animals and plants has resulted in the emergence and spread of antibiotic-resistant bacteria, which is of major concern (Willmott et al. 2024). Antibiotic resistance may be just the point of the iceberg regarding the global health and environmental challenges linked to the use and misuse of medicines and biocides. Wastewater effluents and sludge from wastewater treatment plants that are intended to manage



**Fig. 2.** Under a One Health approach, direct risk and benefits are integrated as health impacts, while perturbations on the services to humans and animals provided by ecosystems are translated into indirect health effects.

excreta containing human and pet medicines and biocides, frequently result in environmental release as do manure and slurry management for those used in farmed animals. This results in the combined co-emission of many chemical substances and their metabolites. These are issues rarely considered in considering regulatory approval of medicines and biocides. This highlights the need for integrating approaches, as set out above. It needs to be recognised as a priority if our society is to progress to sustainability.

### Declaration of generative AI and AI-assisted technologies in the writing process

No AI tools have been used in this manuscript.

### CRedit authorship contribution statement

**Arturo Anadón:** Writing – review & editing, Writing – original draft, Conceptualization. **James Bridges:** Writing – review & editing, Writing – original draft, Conceptualization. **Jose V Tarazona:** Writing – review & editing, Writing – original draft, Conceptualization.

### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

### Data availability

No data was used for the research described in the article.

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