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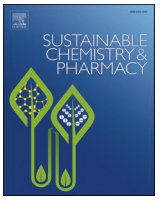

Environmental Pharmaceutical Index - a practical information, classification and dissemination system for medication in Germany

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ABSTRACT

Residues of pharmaceuticals in the environment can cause significant ecotoxicological issues but they also pose an imminent risk for human health e.g. by pollution of water resources used for food and drinking water production. Many active substances of pharmaceuticals for human use and their metabolites have been identified in the environment worldwide. To maintain water quality a variety of approaches during a pharmaceutical lifecycle are urgently needed, spanning actions from development, production over dispensing to *end-of-pipe* advanced wastewater treatments. In this paper, we report about a recently developed eco-directed pharmaceutical prescribing concept for Germany capable to trigger a significant *beginning-of-the-pipe* effect. The proposed system aims to balance therapeutical needs and environmental impacts by including ecotoxicological information and classification into pharmaceutical and medical decision making within the praxis of prescribing and dispensing medicines. We reviewed relevant existing eco-directed classification systems from Sweden, Finland, and Scotland. Based on these three different systems, we propose a practical environmental information, classification and dissemination system tailored to the German healthcare system, which combines positions from stakeholders including those responsible for regulation and health related data. Our results can be highly relevant to approaches aiming to establish similar systems in further countries. We identified the database *ChemInfo* hosted by the German Environment Agency as the central information system, for collecting environmental information from market authorisation processes. Our novel traffic light classification system is based on the hazard and risk outcomes of the environmental risk assessment and presents for the first time a European wide applicable environmental classification, capable of ranking pharmaceuticals within an indication group and identifying substances of concern to support decision making.

The classification system will label all pharmaceuticals, recently added to the EU list of priority substances within the Water Framework Directive, in red. Finally, we identified eight

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dissemination systems through which this information and classification can be included into decision making.

1. Introduction

Pharmaceuticals play an indispensable role in public healthcare, especially in the context of an ageing society with increasing therapeutic needs. In 2022, there are about 1300 active pharmaceutical ingredients (API), for which an Environmental Risk Assessment (ERA) is necessary according to the European Medicine Agency (EMA). These were consumed in quantities exceeding 10,000 tonnes in Germany (Balzer, 2025). Due to demographical changes alongside increasing rates of polymorbidity and polymedication, medical treatments are expected to significantly increase in Germany and in many other countries over the next decades (Editorial, The Lancet Healthy Longevity, 2021; Schoffer et al., 2023; Civity Management Consultants, 2017). It is thus expected that the current issues related to pharmaceutical residues in the environment will become even more relevant including immediate or latent environmental effects and the pollution of human drinking water and food production resources (Wilkinson et al., 2022; Khan et al., 2023; Muambo et al., 2024; Pérez-Lucas and Navarro, 2024).

Besides their target affinity API must meet pharmacokinetic requirements such as suitable half-live values. Therefore, they are chemically designed to resist e.g. against metabolism or further factors such as different pH values and reach surface waters mainly through excretion after use (Wang and Urban, 2004). However, a significant part also comes from improper disposal of medicines (Caban and Stepnowski, 2021; Rogowska and Zimmermann, 2022). When entering a water body, pharmacologically active residues of human origin may cause negative effects on non-target organisms (Sehonova et al., 2018; Wang et al., 2021). Significant examples include span from feminization of male fish to failure of an ecosystem by xenoestrogens like ethinylestradiol. The most prominent example not happening in water organisms was the near extinction of vultures in India and Pakistan through fatal renal failure caused by diclofenac (Nash et al., 2004; Kidd et al., 2014; Swan et al., 2006).

Regarding the options to address water pollution by drug and metabolite residues, different actions along the pharmaceutical lifecycle can be considered. However, tackling potential ecotoxicological problems of drug residues already at the source is considered to be the most effective approach (Caban and Stepnowski, 2021; Helwig et al., 2024). This paper presents an Environmental Pharmaceutical Index for Germany, which is in line with Caban and Stepnowski's *beginning-of- pipe* concept. The proposed system aims to help healthcare actors include information on environmental impacts into their pharmaceutical and medical decision-making process when prescribing and dispensing medicines. The proposed system has parallels with approaches implemented in Sweden over the last two decades as well as approaches from Finland and Scotland (Fass and Janusinfo databases, (Ågerstrand et al., 2009; Ramström et al., 2020; Linder et al., 2023b); the Wise List, (Gustafsson et al., 2011).

2. Methods

2.1. Concept development workflow

The conceptualisation of an environmental information and classification system for pharmaceuticals in Germany was carried out from November 2023 to June 2025. The project included the evaluation of case studies in countries with similar existing or planned systems. We aimed to gather knowledge about their implementation, workflow and effectiveness through literature reviews and qualitative interviews with key stakeholders involved in the implementation process (Fig. 1). To increase the buy-in of German stakeholders for such a system, their perspectives were mapped using interviews, expert meetings and a workshop as well as a literature review. In a final step, the feasibility of the developed concept from a technical, organisational, financial, political and legal perspective was analysed in a stakeholder workshop and using data collected within the project.

2.2. Literature review peer-reviewed literature and policy letter/presentations

A scoping literature review through scientific and grey literature was carried out to capture information on two established environmental information and classification systems (Sweden and Finland), and one such system under development (Scotland). Details on search terms are presented in supplemental material chapter 2. The aim of the literature review was to understand 1) how these systems are designed; 2) how effective they are regarding lowering the entry of pharmaceutical residues into the environment, and 3) how pronounced the adherence to these individual systems is. Specific attention was paid to legal framework, data sources, algorithms for classification, and presentation of information at the user interface. Results were summarized to identify existing data as well as knowledge gaps (see supplemental material chapter 3). A second literature review was carried out focusing on Germany to identify positions of key stakeholders and previous work on such a system (see supplemental material chapter 4). The literature was also used to identify key stakeholders as potential interview partners, see chapter 1.4. Both literature reviews were summarized using principles from Younas and Ali (2021).

2.3. Stakeholder mapping

A key stakeholder mapping was carried out for Germany. As the environmental information and classification system is conceived

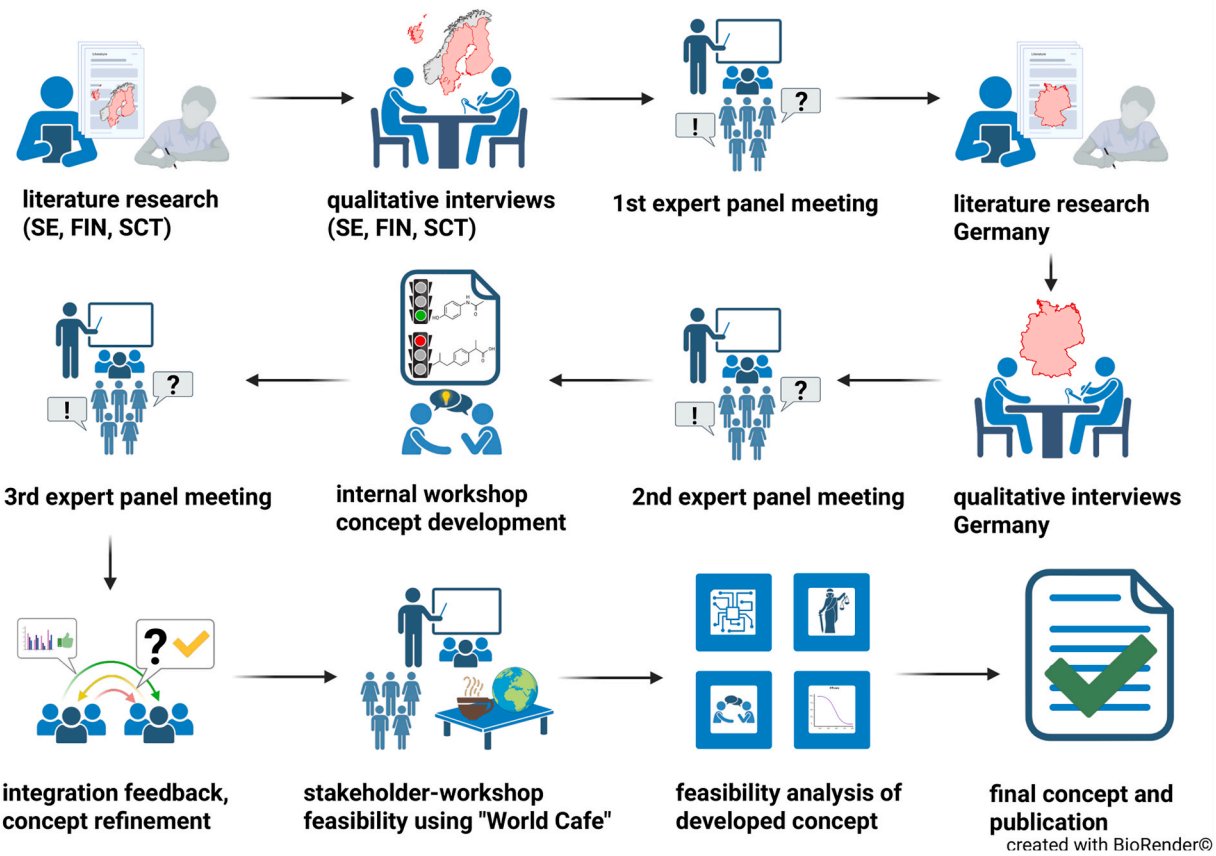

Fig. 1. Project workflow from case studies to German literature review, concept development and feasibility check. Countries for case studies were identified through initial literature review. SE = Sweden, FIN = Finland, SCT = Scotland.

to be used by health professionals involved in prescribing, dispensing, using, teaching, or in charge of reimbursement decisions, we focused on relevant individuals working within the German healthcare system as well as health insurance companies and universities (German Federal Ministry of Health 02.2025). Next, the stakeholders were ranked by their position within parts of decision-making processes during the pharmaceutical lifecycle. Additionally, we implemented a colour code based on the future relationship to the information and classification system, e.g. if the stakeholder will primarily use data from the system or will contribute data to it. If a stakeholder agreed to participate in the expert panel meetings or stakeholder workshop, suggestions for further stakeholder that could be contacted were requested and recommended people were again contacted.

2.4. Stakeholder interviews: international stakeholders from case studies and German stakeholders

During this project, a case study is defined as the combination of literature review and qualitative interviews from countries with existing environmental information and classification systems until data saturation, based on duplication of statements and information, was achieved. Prior to each interview, a question guide was sent to the interviewees (see question guides in supplemental material chapter 5-8). As data and knowledge gaps differed between the examined countries of the case studies, questions were designed individually for each country and type of person to be interviewed following an abductive stile. Interviews were semi-structured allowing individual responses depending on the specific background. The question guide consisted of inductive elements regarding data and knowledge gaps on how the specific systems were developed and established. It also contained deductive elements to reinsure critical findings from literature search. Data saturation was reached in international and national interviews for the related questions. Question guide and overview on interviews (country, profession of interviewee, interview-code and duration) can be found in supplemental material (chapters 1 and 5-8).

For international stakeholders, professions are not presented as experts for interviews were chosen based on their respective participation in the development of their national environmental information and classification systems. Although Norway and the Netherlands are no case study countries, interviews were conducted as the Norwegian Felleskatalogen presents a key connecting factor between the Swedish and the Finnish systems and within the Netherlands a specific classification approach for pain killers was developed which we included into our concept. For the German participants, professions are given as they were chosen to represent important stakeholder groups within the German healthcare system and important dissemination systems (see Fig. 2).

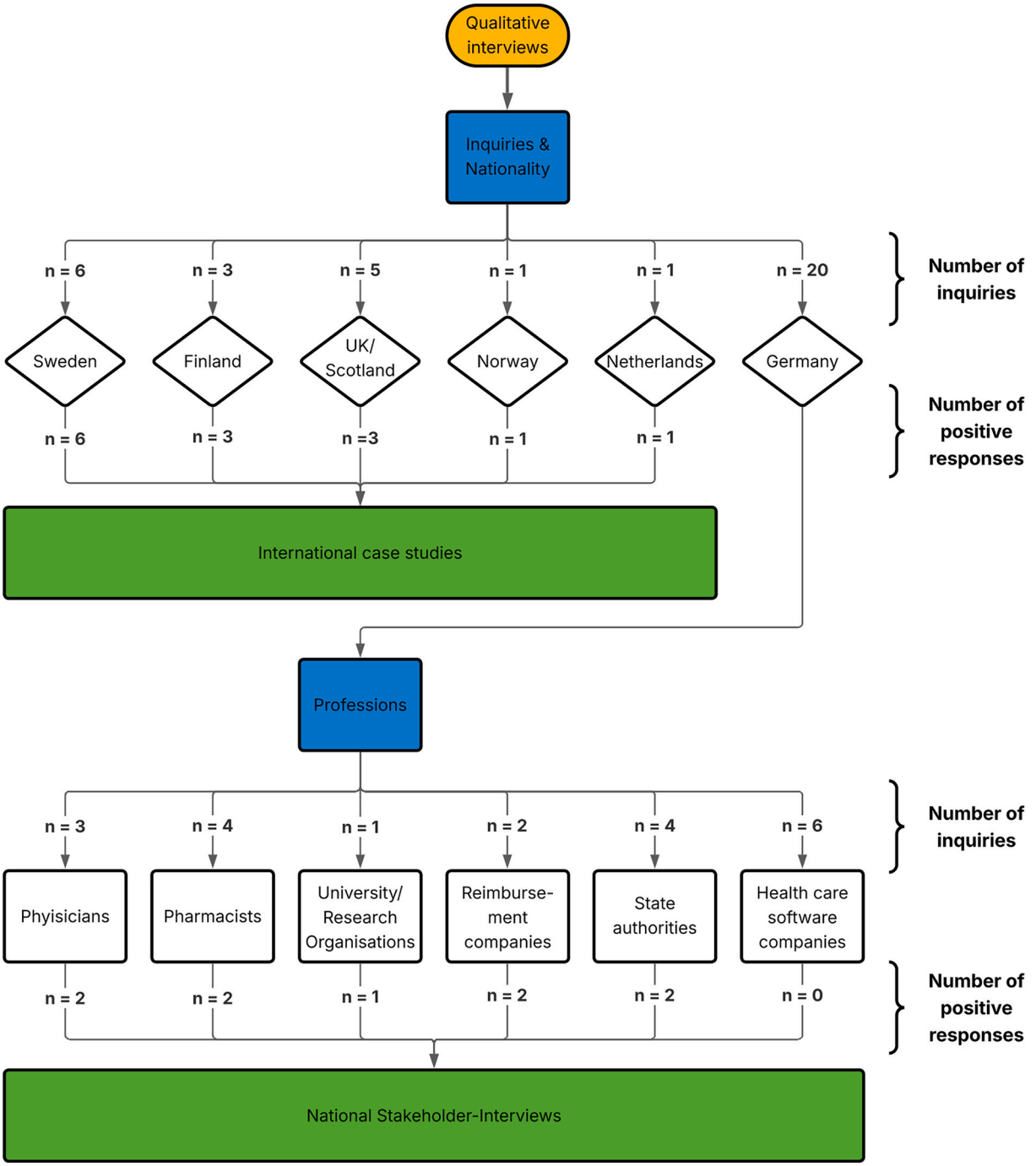

Fig. 2. International and national qualitative stakeholder interviews. Number of inquiries and positive responses are presented on the right. International stakeholder interviews are divided following the country of the case study or corresponding identified stakeholders of classification systems. National stakeholder interviews are divided following professions working in the German healthcare sector.

2.5. Project development in Germany: expert panel - Nominal Group Technique

For collecting qualitative data and feedback we used online expert panels (Bailey et al., 2019). The meetings were organized at regular intervals throughout the two-year project for the Germany-related part of the project, with experts working within the German healthcare sector including health insurance companies, physicians and pharmacists as well as their representing professional associations, academia, environmental researchers from research organisations and non-governmental organisations (NGOs). For every

meeting, the Nominal Group Technique (NGT) was used to collect ideas and prioritize common decisions and perspectives within the expert panel (Harvey and Holmes, 2012). Specific unsolved questions were collected by using MURAL software (https://www.mural.co/). The prepared MURAL boards were also sent to the participants prior to each meeting to collect their ideas. Following each meeting, an anonymised protocol was shared showing the final results. The protocols were then sent to the participants allowing for checking if everything was understood and logged in a correct way.

2.6. German stakeholder workshop - World Café

A comprehensive Stakeholder Online-Workshop was carried out (Participants' overview in supplemental material chapter 1.2), where the case study results along with the views of German stakeholders and the concept were presented. In the second part several aspects of the concept were discussed and feedback on remaining questions was collected using the *World Café* method (Löhr et al., 2020). Participants were free to choose which breakout room (e.g. *World Café* table) they want to visit (switching to other breakout rooms enabled). Discussions and chats in the first part of the workshop and during the *World Café* were logged and included into the question feedback and *World Café* tables following the event. While the expert panel consisted of the same group of experts accompanying the project and giving feedback during its whole runtime, the stakeholder workshop introduced a bigger group of stakeholders from the healthcare sector to gather feedback from people *not* being part of the project during its development.

3. Results

At the beginning of the project, existing literature was reviewed to identify existing environmental information and classification systems and databases for pharmaceuticals. This process resulted in five countries with different approaches. First, Sweden was identified as the country with the oldest and two databases (Fass.se and Janusinfo.se) as well as a therapeutic dissemination system (the Wise List) including environmental aspects into decision making. Next, Fass.se shares information to the Norwegian database Felleskatalogen.no and to the Finnish Pharmaca Fennica compendium. As the Felleskatalogen presents a database highly similar to Fass.se, it was decided to analyse the Finnish system more detailed as it is a different way of presenting and including information into therapeutic information systems. The Scottish initiative was the latest approach of developing a system able to include environmental information into therapeutic decision making following a significantly different approach compared to the Scandinavian countries. Last, a Dutch report on classifying pain killers based on their potential environmental harmfulness was published. Following this initial review, the Swedish databases and systems Fass.se, Janusinfo.se as well as the Wise List, the Finnish Pharmaca Fennica compendium and the Scottish initiative were chosen to be analysed in detail as they present existing systems with different approaches and ways of presenting their information. All further steps are presented in Fig. 1 in methods chapter 1.1.

Relevant background information for the next sections of this paper is the fact that most environmental information generated for pharmaceuticals is related to the ERA procedure. An ERA must be carried out for drug market authorisation within the European Union since 2006 following the requirements of the Guideline on the environmental risk assessment of medicinal products for human use (EMEA/CHMP/SWP/4447/00 Rev. 1-Corr). All conducted studies for the ERA dossier following OECD guidelines are peer reviewed by EU authorities and offer various parameters that are highly suitable to be included into an environmental classification. The following national systems make use, in different ways, of this main source of data regarding the environmental behaviour of pharmaceuticals.

3.1. Review of international case studies and stakeholder interviews

3.1.1. Case study Sweden

3.1.1.1. Background and political aspirations towards a rational and sustainable use of APIs. Sweden's environmental classification activities began in 2001, when the Stockholm County Council and Apoteket AB (a state-owned pharmaceutical retailer) started collecting environmental information on pharmaceuticals (Ramström et al., 2020; Linder et al., 2023b). In 2002, the Swedish government became interested in the topic. Beginning in 2005, a voluntary collaboration was established between the Swedish trade association of the research-based pharmaceutical industry (LIF), Stockholm County Council, Apoteket AB, the Swedish Medicines Agency and the Swedish Association of Local Authorities and Regions. This collaboration resulted in the release of **Fass.se**, a voluntary environmental information and classification system hosted by the pharmaceutical industry (Ågerstrand et al., 2009; Ramström et al., 2020; Linder et al., 2023b). However, the fact that the system is product-based was criticized by users (SE02) and conflicts arose due to only risk but not hazard being included into the classification (SE01). As a consequence, in 2016 a second database “Läkemedel och miljö” (Pharmaceuticals and the environment) was released on **Janusinfo.se** by the Stockholm region (Ramström et al., 2020).

Parallel to developments regarding environmental effects of pharmaceuticals, in 1996 a new law came into force which called for the establishment of Drug and Therapeutic Committees (DTCs) at the regional level with the aim of standardizing and rationalizing therapies within Sweden (Eriksen et al., 2017). Based on this legal framework and with the help of multiple stakeholders, the **Wise List** was implemented which includes evidence-based recommendations for the rational prescription of medicines in key therapeutic areas, developed by local Drug and Therapeutics Committees (Godman et al., 2009; Gustafsson et al., 2011; Linder et al., 2023b; SE03).

3.1.1.2. Fass.se. As a concise platform for APIs, Fass.se provides product-based environmental data for pharmaceuticals, including summarizing concise statements on environmental risk based on PEC/PNEC (predicted (no) effect concentration) values,

biodegradation and bioaccumulation classifications (partly based on the then valid ERA technical guidelines; (Guideline on the environmental risk assessment of medicinal products for human use of 9/1/2024; SE06). The data are submitted by Marketing Authorisation Holders and independently reviewed by the Swedish Environmental Institute (IVL). In contrast to the ERA approach to evaluating risk, Fass.se uses a five-level classification where about 90 % of the APIs are classified in the lowest risk category.

Key strengths of Fass.se include easy accessibility, a wide collection of environmental information on pharmaceuticals, and an institutional review process through IVL. A further strength is a tiered data presentation on two levels, with the first layer showing an overview of summarized data and a second section with more detailed insights. However, limitations of Fass.se include sometimes incomplete and unharmonized data, product-based visualization, and poor data transparency. In addition, the system relies on voluntary data provision by the pharmaceutical industry, which means that industry also can, and sometimes does, actually remove the data from the system (Ågerstrand et al., 2009).

Regarding its effectiveness, Fass.se has become a reference point in Sweden's environmental health policy, even though it is only moderately effective in influencing prescribing behaviour due to its separation from clinical guidance systems (Gustafsson et al., 2011). Ågerstrand et al. (2010) criticized that data from open scientific literature were not optimally used, and that the contributing companies pursued very different data collection strategies. The environmental impact of Fass.se was assessed in a survey of DTCs in 2023 as relatively low (approximately 40% "very/somewhat useful"; 54% "less/not useful") (Linder et al., 2023b).

3.1.1.3. Janusinfo.se. Janusinfo.se is a non-commercial and freely accessible website, which provides substance-based environmental assessments combining data from European Public Assessment Reports (EPARs which include ERA results assessed by EU authorities in marketing authorisation procedures (Linder et al., 2023a). In cases where EPAR data are unavailable, it commissions expert reviews, uses open scientific literature or relies on Fass.se entries. Furthermore, for specific compound groups comparative environmental risk assessments from external experts are commissioned which take into account Measured Environmental Concentration (MEC) as well as predictions. The substance information summarizes environmental profiles in terms of persistence, bioaccumulation, toxicity, and risk. Similar to Fass.se, the information is presented in two levels, the first providing short summaries, the second providing more detailed information, conclusions from studies and specific values. If necessary, academic experts will be consulted to interpret scientific studies and analyses, and the Swedish Medicines Agency, as well as the EMA or LIF, will be contacted to clarify available assessments (SE02).

As of 29.03.2019, where the last study on the Janusinfo-database was conducted, it contains 851 APIs, of which 154 APIs are exempt from the environmental assessment and 143 are fully classified (Ramström et al., 2020). According to current random samples, more classified active substances are now available. Even though its effectiveness is quite low regarding a direct usage in everyday work, it remains relatively high through its implementation by the DTCs to integrate environmental information into therapeutic decision making (e.g. dissemination systems) like the Wise List.

Advantages of Janusinfo.se include transparency, the substance-based approach, and the ease of accessibility. Disadvantages include complex environmental information not suitable for healthcare praxis. For example, comparing between two drugs in terms of

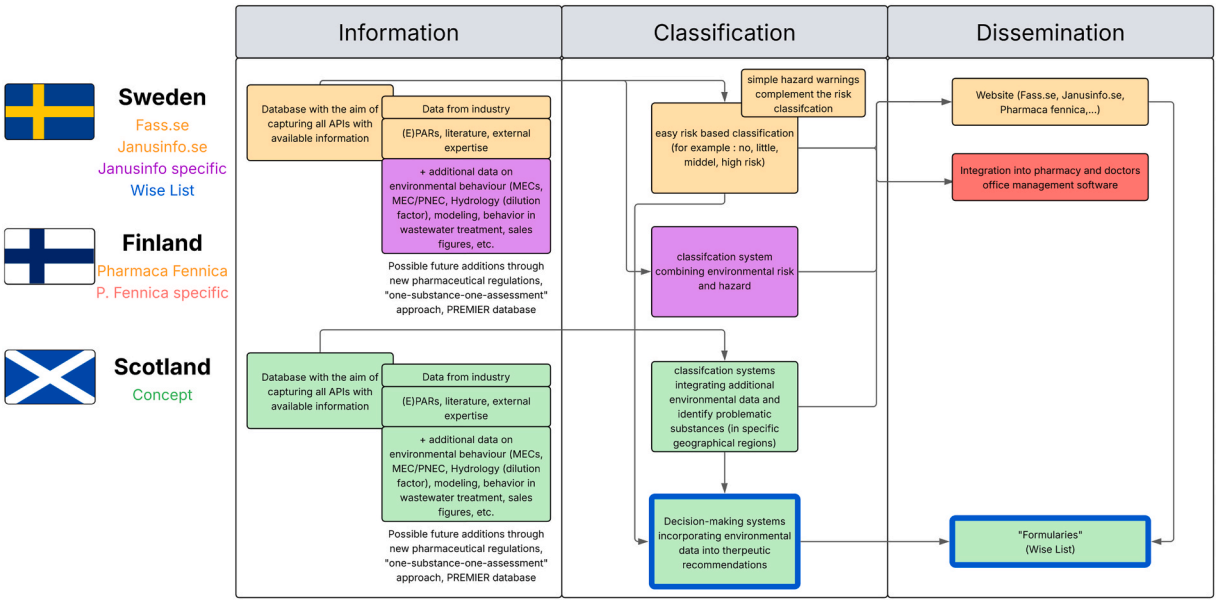

Fig. 3. Information, classification and dissemination systems identified in case studies from Sweden, Finland and Scotland. Orange color of boxes and letters symbolize the respective affiliation to Fass.se, Janusinfo.se and Pharmace Fennica system. Purple color of box and letters symbolize specific additional affiliation to Janusinfo.se, blue framed boxes symbolize affiliation to Wise List while green-colored boxes symbolize affiliation to the Scottish concept. White boxes do not have an affiliation to the systems from the case studies but will be important for German dissemination systems.

environmental profile is not possible on the website, and it does not suggest alternatives if a drug is actually environmentally harmful (Ramström et al., 2020; Linder et al., 2023a). However, the system is widely used both in Sweden and also internationally (Ramström et al., 2020).

3.1.1.4. The Wise List. The Wise List is a dissemination system for APIs and compiles annually revised prescribing recommendations for about 200 drugs treating about 80 % of the most common diseases in Sweden. Alongside therapeutic efficacy, safety, and cost of a given API, its possible environmental impact is also considered when developing these recommendations (SE04; SE05). The Wise List is created by the local DTC for the Stockholm region, but other regions have similar lists created by their local DTCs (SE04). Although compliance with the Wise List is voluntary, adherence to its recommendations among physicians is very strong (Gustafsson et al., 2011). In the Stockholm region the adherence rates among prescribers exceed 80 %, and studies show rapid shifts in prescription practices following recommendations called "Wise Advices" (e.g. naproxen instead of diclofenac, cf. Supplemental material chapter 9). High acceptance and adherence rates can be explained by the involvement of respected medical spokespeople in the guidance development. The high adherence rates have also been linked to an accompanying comprehensive communication strategy, ranging from academic and scientifically verifiable content to rapid electronic access to specific practical recommendations (Gustafsson et al., 2011; Eriksen et al., 2017; SE05). The Wise List demonstrates that the implementation of environmental recommendations in everyday healthcare work is feasible. Used approaches for information, classification and dissemination for each country and its different systems are summed up in Fig. 3.

3.1.2. Case study Finland

3.1.2.1. Projects and aspirations towards eco-directed systems for APIs. The EPIC project (Efficient Treatment of Pharmaceutical Residue at Source, 2016-19), led by the Finnish Environment Institute (SYKE), developed different potential implementation options for an environmental information and classification system for Finland (Karlsson, 2019; FI03). In 2019, before the project had concluded, the private company Pharmaca Health Intelligence introduced a system for an environmental information and classification system, called Pharmaca Fennica Pro, based on data from Fass.se and Felleskatalogen.no (the Norwegian equivalent of Fass.se, (NO01)). The system displayed a joint basic solution regarding the demands from physicians and pharmacists. In 2021, the results were integrated into the Pharmaca Fennica compendium, an information system for healthcare workers (Minkkinen et al., 2020; Leppä, 2023; FI01).

3.1.2.2. Pharmaca Fennica compendium. The Pharmaca Fennica compendium is a medical information system used by the majority of public pharmacies and hospitals across Finland (FI02). The environmental information and classification system was integrated into the compendium in 2021. It is substance-based and classifies environmental risk according to five tiers, but features no hazard parameters. Environmentally critical substances from the EU water framework directive are marked with an asterisk. Data from Fass.se are primarily sourced by Felleskatalogen.no and then tailored to Finnish national conditions (using Finnish sales and delivery statistics for PEC determination) (FI02; NO01; SE06). Unlike Fass.se which is open access, admission to parts of the Pharmaca Fennica compendium, including those providing information on environmental risk, require a professional subscription. The system has been criticised due to environmental information not being available for all substances. Recent reports demonstrate this is only the case for approximately 200 – 300 APIs (Alajärvi et al., 2022; Leppä, 2023; FI02).

Due to a lack of data, a broad evaluation of the effectiveness of the Pharmaca Fennica environmental classification system is currently not possible. A specific monitoring of the use of the environmental information is technically not feasible, as the environmental information is presented on the same page globally with other pharmaceutically relevant information. In 2022, Pharmaca Health Intelligence launched a six-month user feedback survey, which received limited feedback (a few dozen responses, primarily from physicians). However, based on this feedback and general discussions, the subjective reception of the service by various health stakeholders is seen as positive. As far as we are aware, the topic has not received significant attention from customers or patients in Finland so far (FI02).

Advantages of the Finnish approach include the simple and clear presentation, data review by an independent research institute (again Swedish IVL), and the possibility of comparing the environmental data for several drugs. Disadvantages include limited access in Finland, dependence on Fass.se, lack of transparency, and limited comparability of APIs based only on the five-stage risk statements.

3.1.3. Case study scotland

3.1.3.1. Projects and aspirations towards environmentally directed medication systems. The Scottish model is driven by the concept of "eco-directed pharmaceutical prescribing" originally developed by Daughton (2014). In 2017, NHS Highland (the healthcare system for one of Scotland's 14 regions) conducted a baseline assessment of drug residues in the wastewater at Caithness Hospital in Wick, detecting seven of the eight commonly used APIs monitored in both the hospital's wastewater and the treated wastewater effluent. A wider evaluation showed that in particular ibuprofen, clarithromycin, erythromycin, diclofenac, ethinylestradiol, metformin, ranitidine, and propranolol may pose ecotoxicological risks in Scottish surface waters. Results were taken up in a Geographical Information System (GIS) whose database is updated on a monthly basis and hosted as open access by SEPA (Scottish Environment Agency). The system helps to understand the relationship between prescribing patterns, such as the seasonal use of antibiotics, and measured environmental drug residue concentrations. However, data gaps exist regarding spatial monitoring coverage and the actual number of pharmaceutical residues studied (SCT01; SCT03).

Simultaneously, following the baseline assessment, NHS Highland began raising awareness of the environmental impact of medicines at hospitals. Among other effects, this approach led to specific requests for more sustainable prescribing. However, prescribers lacked easily accessible information for making environmentally friendly decisions (SCT03).

3.1.3.2. The one-health breakthrough Partnership and project towards a "green formulary". The One Health Breakthrough Partnership (OHBP), a regional initiative based in the Highland region of Scotland, implemented a project with the aim of introducing a "green formulary" to guide environmentally-oriented prescribing in primary care and hospitals (SCT01; SCT03). The project's aim was to develop a scientifically sound framework for considering environmental impacts of APIs, which would serve as a decision-making aid for physicians and pharmacists. This was done following the concept of Niemi et al., (2024). For four APIs a contamination risk was calculated based on a risk and hazard assessment, respectively. An online mapping tool presents the risk factors, monitoring results and other data referring to different regions of Scotland.

Niemi et al. (2025) conducted a qualitative interview study with representatives of prescribers and the general public, with the aim of providing an overview of current attitudes and the potential for eco-directed sustainable prescribing (EDSP) (Niemi et al., 2025). The study demonstrated a growing awareness in both groups of environmental pollution caused by APIs. It also showed that more training, awareness-raising campaigns, patient-centred work, drug take-back schemes, and clear labelling of environmentally problematic APIs are needed to further raise awareness of the issue and promote reduction measures. Prescribers positively noted that EDSP fits well with existing sustainability initiatives in the healthcare system (e.g. preferential prescribing of powder-based inhalers over metered-dose inhalers containing propellants). However, at the time of data collection for this paper, the Scottish system was not yet an integral part of local prescribing guidelines, therefore an analysis of its actual effectiveness is not viable. Nevertheless, the Scottish approach system represents a significantly different and more geographically targeted approach compared to the systems in place in Sweden and Finland, which develop recommendations at the national level.

3.2. Three pillars of a proposed environmental pharmaceutical index: effectiveness and analysis

In the literature review and stakeholder interviews, we identified key features of a proposed effective environmental information and classification systems for Germany. To roll out environmental data for pharmaceuticals to the stakeholders within the German

Table 1
Collection of needs to achieve high effectiveness and adherence from case studies as well as needs and claims from stakeholder from German healthcare system.

System	Requirements for effectiveness – conclusions from case studies	Stakeholder needs and wishes German healthcare system	References
Information	• Substance-based presentation • Data from EPARs (if available), otherwise janusinfo.se, open scientific literature or external reports • External data review • Free access • Hosting through a public institution • Technical expertise for the interpretation of ecotoxicological endpoints • Data gaps specified through worst-case scenario	• Automated data collection • Data transparency, assessment of evidence • External data review • Substance-based presentation • Hosting though public institution independent of producers' interests • Multi-stakeholder free access • Data from ERAs (if available), otherwise EPARs and PARs • Integration of dosage form and non-pharmacological therapies • Rapid development even without complete coverage of medicines • Data gaps specified through transparent label • Later expansion by CO_2/water footprint	(1st expert panel meeting, 2024; DE01; DE03; DE04; DE06; DE07; DE08)
Classification	• Risk and hazard-based classification • Comparison within indication group • Symbolization needed • Alternatives should be displayed on same site	• Risk and hazard-based classification • Traffic light visualization (wish for classification similar to www.embryotox.de with red, green and grey) • Special symbol against over-alerting • Comparison within indication group possible • European network with experts for conscious improvement	(DE04; 1st expert panel meeting 10.04.2024; 2nd expert panel meeting 26.06.2024)
Dissemination	• Required for effectiveness in reducing the use of environmentally harmful medicines • adherence can be fostered through stakeholder participation, long-term strategic leadership and comprehensive communication strategy • integration of system at point-of-care • marketing campaign for system launch	• System should not restrict therapeutic freedom • Eco-directed decision making prior to point of prescription/dispensing • Practice-oriented and user-friendly approaches • Stakeholder participation • Accompanying educational and information measures	(DE03; DE04; DE06; Stakeholder Workshop, 2024)

healthcare system, three pillars are needed: 1) environmental information system 2) environmental classification system 3) dissemination system. These three pillars have to be connected and work together to increase effectiveness. Different levels of detail and types of information are required depending on the addressee.

An effective **information system** is therefore defined as a database containing relevant data on the environmental impact of various API. These data can cover various levels of detail. A functional **classification system** is defined as a system for classifying pharmaceuticals that allows for a certain degree of comparability or prioritization from an environmental perspective. A clear visual classification, including risk and hazard, enables users to quickly and easily compare APIs within the same indication group in terms of their environmental impact. This will help when fast and rational decisions including environmental information need to be made in daily work in pharmacies and doctors' practice. A practical **dissemination system** is defined as a system that communicates and leverages information and classification of APIs, for example, by using it to develop recommendations or integrating it into existing systems like therapeutic guidelines. Naturally, the dissemination system is crucial for high effectiveness as could be seen in chapter 2.1.1.4 for the Wise List in Sweden. Accordingly, German stakeholder in our project repeatedly confirmed that tedious detailed research on environmental information for a given drug is not possible in everyday work, which is why this information have to be included into early decision making on drug prescribing, dispensing and usage. In total, the complete system needs to achieve high effectiveness in reducing environmental harmful drugs by balancing therapeutic needs and transferring information to healthcare stakeholders. All collected expectations, claims and needs are summarized in Table 1 to provide a comprehensive overview what parameters have to be taken into concern for developing a suitable concept towards an effective environmental information, classification and dissemination system in Germany.

3.3. *Views of German stakeholders*

The following figure gives an overview of relevant stakeholders. On the basis of their respective position within the healthcare sector, stakeholders were classified according to their potential to either contribute to the proposed system, or to be directly affected by it. Accordingly, they are clustered in the figure regarding their prospective main role as data user or as data contributor (Fig. 4). Stakeholder and institutions with influence on multiple steps of this decision-making process are shown by wider boxes covering their respective roles.

Previous to concept development, stakeholders' perspectives regarding the implementation of such a system in Germany were collected. Scientific and grey literature was analysed to identify previous stakeholder statements on the topic. Based on the stakeholder

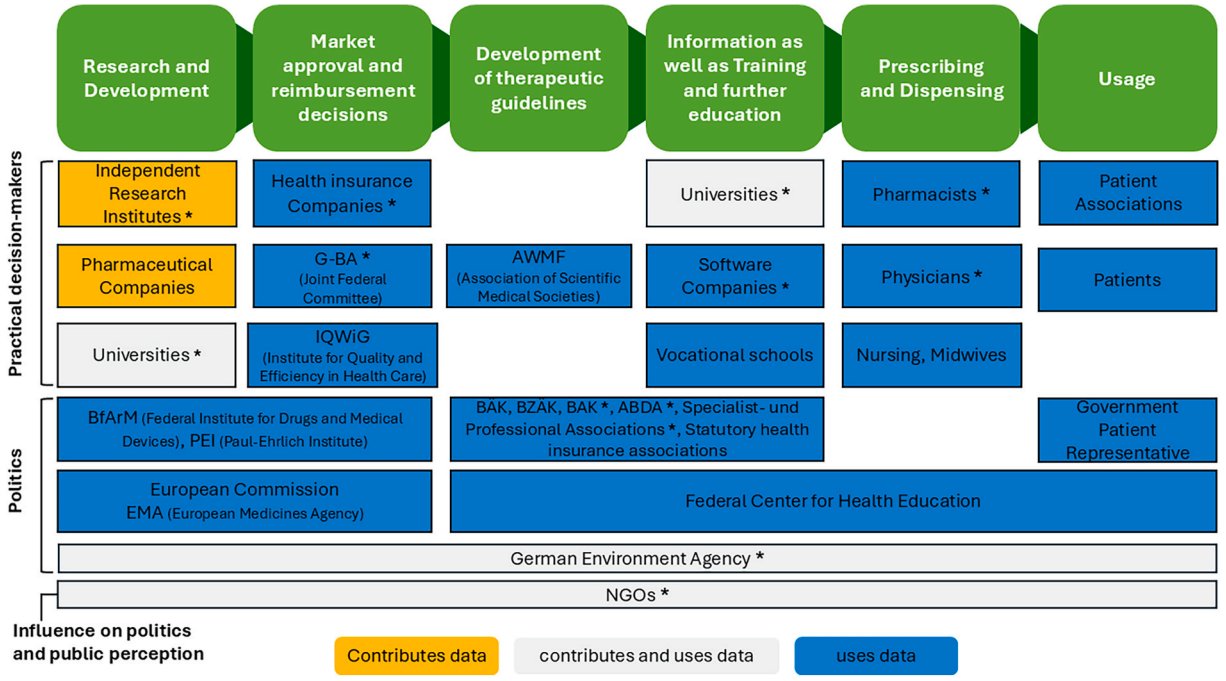

Fig. 4. Overview of German stakeholders using clustering on data contribution or usage, position within decision making along the pharmaceutical life cycle and within the German healthcare system. Blue colour stands for stakeholders using data from an environmental information and classification system, yellow for stakeholders potentially contributing data to it and grey for stakeholders able to do both. Stakeholders marked with asterisk * were involved in expert panels and workshops. Abbreviations not explained within the figure are BÄK = Bundesärztekammer (Federal Medical Association), BZÄK = Bundeszahnärztekammer (German Dental Association), BAK = Bundesapothekerkammer (Federal Chamber of Pharmacists), ABDA = Bundesvereinigung Deutscher Apothekerverbände (Federal Union of German Associations of Pharmacists) and NGOs = Non-Governmental Organisations.

overview (see Fig. 4), relevant stakeholders were identified. To collect further insights into their positions, we performed in-depth interviews with a selected number of stakeholders; opinions were elicited from a larger group of stakeholders in expert panel meetings.

3.3.1. General perspectives for the German system

All interviewed German stakeholders (n = 8) rate the introduction of an environmental information and classification system as a useful and effective toll for mitigating the entry of environmentally problematic APIs into the environment. No significant differences emerge between stakeholders: physicians and pharmacists, as well as public institutions and health insurance companies see potential applications within their respective fields and a strong need for implementing an environmental pharmaceutical index. Pharmacists, in particular, see broad scope for action in the OTC (over the counter) sector, as patients' initial contact for health advice is often a pharmacy (DE02). Health insurance companies, in turn, see potential applications primarily related to environmental relevant criteria for prescription medicines, as such a system would allow for prioritization of APIs in, or their exclusion from, tenders for discount contracts between health insurers and pharmaceutical companies (DE07).

Half of the interviewees would use an information system in everyday work. In addition, four out of the eight interviewees emphasised that an environmental information and classification system should be designed so that information is easily accessible, without the need for users to perform additional research. Five out of eight are in favour of a two-stage structure of information involving more simple initial information and a second, detailed level behind it. Only one out of eight is not in favour of this approach and would not use the further system with reference to limited time resources (DE03).

> "The ABDAta [ed. note: a database containing therapeutic information of API], let's say, it doesn't include ten papers per entry, but provides a summary. Still, it's nice to be able to click on the papers. […] So, I get the summary first and, if I have time and interest later, I can go into the detailed sources. If I had to restrict myself, I'd skip the detailed sources." (DE02)

The interviewees are in favour of immediately pushing ahead with the implementation of an environmental information and classification system, even if the necessary data is not complete from the very start. Accordingly, information gaps should be closed in due course, or new criteria should be added over time after the system's launch (DE04). Some stakeholders do see potential for changes in the evaluation of APIs over time (e.g. due to new criteria and data). Continuous updating of therapies and information is anyway a common feature in the work of the relevant professional groups (*DE01*, 2024; DE*02*, 2024; DE*03*, 2024; DE*04*, 2024; DE*05*, 2024; DE*06*, 2024; DE*07*, 2024). Furthermore, continuous change and optimisation can be viewed positively, as they ensure the ongoing integration of the latest evidence (*DE02*, 2024; DE*04*, 2024). Health insurance companies also prefer updates, e.g. every two to four years, as discount contracts are advertised for two years. This would ensure that information and classifications are up-to-date in time for the announcement of new discount contracts (*DE05*, 2024; DE*07*, 2024).

3.3.2. Need for a practical information, classification and dissemination system in Germany

The following representative statement of an interviewed German stakeholder (1 of 8) illustrates stakeholders views on the need for such a system.

> "I searched for data on how to make my prescribing behaviour a bit more environmentally friendly. And that was very disappointing. I worked with pharmacists from TK and AOK [ed. note: two of the biggest German health insurance companies], and we found maybe a list of ten medications where something could be done. And that's all the data available. "(DE01)

This and other statements clearly show that physicians are willing to include environmental information in their prescribing behaviour, but face problems related to information availability and time constraints in their everyday work. Following the need for an environmental information, classification and dissemination system, we collected perspectives for each of the three pillars needed.

3.3.3. Perspectives towards the information system

A study by Cannata et al. shows that different stakeholder groups involved in the topic "pharmaceuticals in the environment" typically have varying perspectives on data that appear linked to their respective field of interest/work (Cannata et al., 2024). The study shows that stakeholders related to the health sector, pharmaceutical industry or competent authorities involved in the authorisation of pharmaceuticals (Cluster 1) had a stronger interest in pharmacological parameters such as pharmaceutical mode of action, and a lower interest in parameters relevant for stakeholders related to the environmental sector (Cluster 2), who showed higher interest in data related to compounds' behaviour in water treatment plants and on transformation products/metabolites. Experts at the panel meetings emphasised that system users must be able to see where the basic data in the information and classification system comes from by referencing the sources of the data and who entered it into the system (1st expert panel meeting 10.04.2024).

> "[…] It must be clear why something is labelled yellow or red, and what led to that." (DE04)

An assessment of the evidence base would also be desirable. Information such as the number of studies indicating a given residue's effect in the environment, as well as assessments of the quality of these studies, would promote trust in the system (1st expert panel meeting 10.04.2024). The issue of data control, e.g. as in the voluntary approaches in Sweden and Finland where control of the data in the system lies with industry, was considered critical. Expert group participants emphasised that the system to be developed must ensure that the pharmaceutical industry "cannot simply delete data" (1st expert panel meeting 10.04.2024). Stakeholders also expressed a preference for data that is subject to external review rather than using data obtained directly from industry. EPARs and Public Assessment Reports (PARs) were identified as relevant and suitable data sources. Additional data provided by industry could be integrated into the system, constrained to quality standards or if certain overlaps with already reviewed data exist (1st expert panel

meeting 10.04.2024). In line with this notion, participants in the expert panel meetings repeatedly emphasised that any system to be established in Germany must be independent of manufacturer interests during implementation and maintenance (1st expert panel meeting 10.04.2024).

> "[…] But it has to be something simple. And whatever is listed there needs to be based on solid evidence. […] It needs to be clear what's behind it: why is drug X listed as it is, what are the criteria, how are they weighted? The whole matrix must be transparent, so people understand the classification." (DE05)

Stakeholders who are in favour of manufacturers being obliged to publish environmental data of their products made similar arguments (DE06). German stakeholders, particularly from the medical profession (practice and research), requested free availability of data, especially from ERAs (DE01). Access should not be limited to healthcare professionals: data should also be available for e.g. statistical analyses (1st expert panel meeting 10.04.2024). Most importantly, information and classification require a valid database. In principle this already exists in terms of the ERA data from marketing authorisation procedures. ERA data are publicly available as summary tables in EPARs but only for marketed APIs since 2006. The process of collecting data from EPARs is additionally difficult to automate, as these are only available individually as PDFs on the EMA website (DE08, 2024). Therefore, obtaining active ingredient-specific data from the EPARs is challenging, time-consuming, and without guarantee of success (Gildemeister et al., 2023). However, a collection of available ERA data so far at German Environment Agency (UBA) is currently underway (DE09, 2024).

Overall, stakeholders clearly prefer an API-based (i.e. substance based) presentation of data, for instance sorted by medical indication (*DE01*, 2024; DE*07*, 2024; *1st expert panel meeting*, 2024). Embryotox (ed. Note: an information system for APIs relevant to pregnancy and breast feeding, hosted by the Charité university hospital Berlin) is mentioned as a template.

> "There I just enter the drug. I might be pointed to alternatives, but I would prefer a system that is based on indications." (DE01)

Stakeholders also argued for users being able to access the corresponding API directly from a specific pharmaceutical formulation (1st expert panel meeting 10.04.2024). Specific drug formulations should be considered, as these can influence environmental impacts (DE04). For example, orally administered diclofenac shows a significantly higher bioavailability compared to topical diclofenac formulations, of which only approx. 6 % penetrates the skin barrier, with the rest being washed off into wastewater (Haleon, 2024). If possible, non-pharmacological therapies supported by evidence could be included. Physiotherapy instead of diclofenac treatment was given as an example (DE06).

Stakeholders' views on which and how many APIs should be included in such a system were collected. A recent study by Gunnarson et al. has indicated that approximately 20% of APIs currently available on the market have the potential to pose a significant environmental concern. However, the study also emphasises that for the majority of APIs (>80%), even under a worst-case scenario, the risk quotient remains below one (Gunnarsson et al., 2019).

These are only a relatively small share of the environmentally relevant total number of 1350 APIs, of which approximately 300 are sold in quantities greater than one ton per year (1st expert panel meeting 10.04.2024). Prioritizing these highly relevant substances based on both their specific toxicity and sales volume is necessary and would be quite effective towards environmental protection (DE03; 2nd expert panel meeting 26.06.2024).

Participants in interviews and expert panel meetings strongly advocated for a rapid development and timely roll-out of the Environmental Pharmaceutical Index in Germany. They suggest a launch of a system which evolves and is being updated with data that becomes available. In line with this notion, continuous expansion after the launch is expected (DE01; DE04). In general, the starting point could be the integration/use of already available ERA data, even if this approach is considered not to be sufficient (1st expert panel meeting 10.04.2024). The future integration of additional environmental impacts, such as the CO_2 and water footprint, would be a useful extension for numerous stakeholders (1st expert panel meeting 10.04.2024). An information system could also be supplemented, for example, with monitoring data on environmental concentrations of pharmaceuticals to document the actual environmental impacts and demonstrate potential improvements in reducing pharmaceutical exposure due to the information system's use (1st expert panel meeting 10.04.2024).

3.3.4. Perspectives towards the classification system

A traffic light system for classifying APIs was viewed by stakeholders as appropriate, as it would provide simple and clear information about environmental impacts (DE04; 1st expert panel meeting 10.04.2024; 2nd expert panel meeting 26.06.2024). The approach used by the German "Embryotox" website (traffic light system and database to flag drugs for pregnant and breastfeeding women) was mentioned repeatedly as a possible template for classifying APIs. Embryotox uses red, green and grey flags (1st expert panel meeting 10.04.2024) to classify compounds. However, an API's environmental classification should not appear concealed alongside various other symbols, as this could easily lead to loss of information due to complexity (DE04).

> "Personally, I think the traffic light system is very good - because it's very simple. Kind of like a short and long version of a guideline: for those who just want to know quickly, the traffic light is enough, and for those who are curious, there's more detailed information elsewhere." (DE06)

3.3.5. Perspectives towards the dissemination system

Due to the differences between healthcare systems, successful concepts such as the Swedish Wise List are only transferable to a limited extent to the German context. For instance, and in contrast to Sweden, in Germany pharmaceutical representatives act as a central source of information for many doctors' practices or clinics and influence prescribing behaviour. On the other hand, German

pharmacists have limited options regarding the selection of APIs beyond OTC drugs, and physicians also have little leeway in this regard: discount contracts between health insurers and pharmaceutical companies, mostly concluded based on price, in practice bind patients to use those pharmaceutical products for which their insurer has closed a contract.

These regulations instruct pharmacies to dispense certain discounted products, even if a physician has prescribed differently. As long as the discounted medicine has the same API and is therapeutically equivalent, the pharmacy must dispense the drug listed under the patient's health insurers' discount contract (1st expert panel meeting 10.04.2024).

An aspect strongly and repeatedly emphasised by stakeholders is the limited capacities and time resources of physicians and pharmacists.

> "How could it be implemented […] It would need to happen more or less automatically. You know the concept of duty to retrieve versus the duty to provide. You cannot expect doctors to go and get this information as well. There simply isn't enough time at the moment." (DE03, 2024)

Where possible, decisions should be formally integrated into decision-making processes beforehand, for example during the development of therapeutic guidelines (DE04; DE06).

> "The individual decision-maker is naturally […] possibly overwhelmed with this knowledge. But if we approach the guideline societies […] and say: when there are equally effective therapeutic alternatives, please also consider the environmental impact of the medication you recommend, then it takes on an official character and can gradually become integrated into the decision-making process about which substances or therapies appear in guidelines and become implemented in the long term." (DE04)

In this project, 6 out of 8 interview partners named therapeutic guidelines as an effective dissemination system, 3 out of 8 mentioned the integration of environmental information into pharmacy and physician's management software, and 2 out of 8 recommend the creation of OTC-lists. One interviewed person would prefer approaches regarding integration into medication management, drug commissions in hospitals, and into discount agreements. Integration into this dissemination systems usually eliminates the need for a decision under time pressure at the point of prescription and dispensing; instead, a decision is made beforehand by an expert committee in a plausible and evidence-based manner. This also relieves the burden on those at the end of the decision-making chain (DE02; DE03; DE04; DE06; DE07). The G-BA guidelines (German Federal Joint Committee, the highest decision-making institution in the German healthcare system, responsible for defining which medical services are covered by statutory health insurance) are considered even more effective because, compared to guidelines with a recommendation character, they are legally binding (2nd expert panel meeting 26.06.2024). A change to these guidelines would immediately affect practice, even though the therapeutic guideline adherence is considered to be lower in Germany e.g. compared to the adherence to the Wise List in Sweden (Stakeholder Workshop 12.11.2024).

> "I'm actually currently conducting a study on guideline adherence, and with chronic diseases, about 60% of patients are treated according to the guidelines. So I'd say if it's in the guideline, you only have a certain success rate." (DE06)

Many stakeholders within the expert panel and 7 out of 8 interviewed stakeholders rate a dual system with 1) classification at the point of prescription and 2) integration into therapeutic guidelines as effective. From the perspective of pharmacists, systematic integration of eco-relevant data into therapeutic guidelines is rated as more effective compared to such integration in pharmacy software, although the latter is also considered as useful. Arguments include that data within pharmacy software workspace is often too complex for rapid decision-making. Some stakeholders were of the opinion that a traffic light classification would have only minor benefits due to "alert fatigue", as such a visual classification is used frequently in other contexts (DE04).

Health insurance companies consider specific lists of APIs with prioritization based on environmental harmfulness within an indication group to be particularly useful, provided these are communicated transparently and neutrally by a government agency so they can be used legally (DE05 of 6/24/2024). Health insurance stakeholders considered it challenging to roll out a system for all APIs; they would rather focus on APIs that have been identified as harmful. Furthermore, health insurance companies see themselves as a key stakeholder in dissemination as they can contribute to various aspects of an index with information. Raising awareness, adapting treatment guidelines in specialist contracts, giving recommendations, reviewing guideline compliance and their remuneration in disease management systems, and the aforementioned targeted (non-)awarding of discount contracts which would include environmental behaviour of APIs among its criteria could generate significant impact (DE07; Stakeholder Workshop 12.11.2024). All collected expectations, claims and needs are summarized in Table 1.

3.4. Concept for an environmental pharmaceutical index for Germany

3.4.1. Information system

We developed a proposal for an environmental information and classification system for pharmaceuticals that relies on scientific and publicly available information. Regarding the information system, learnings from existing case studies and feedback from German stakeholders were considered to be key. The major data source are results from ERAs (see Fig. 5).

An additional data source are the environmental quality standard (EQS) dossiers developed as part of the "Water Package". These data dossiers, developed for so-called priority substances, have been developed for 11 pharmaceutical active substances. ERA data are only publicly available through European Public Assessment Reports (EPARs) or Public Assessment Reports (PARs) on a product basis and are not collected substance based in a public database so far. Hence, a laborious manual inspection on a case-to-case basis is needed to mine this data. However, as the competent authority for the environmental risk assessment in Germany, UBA has access to the

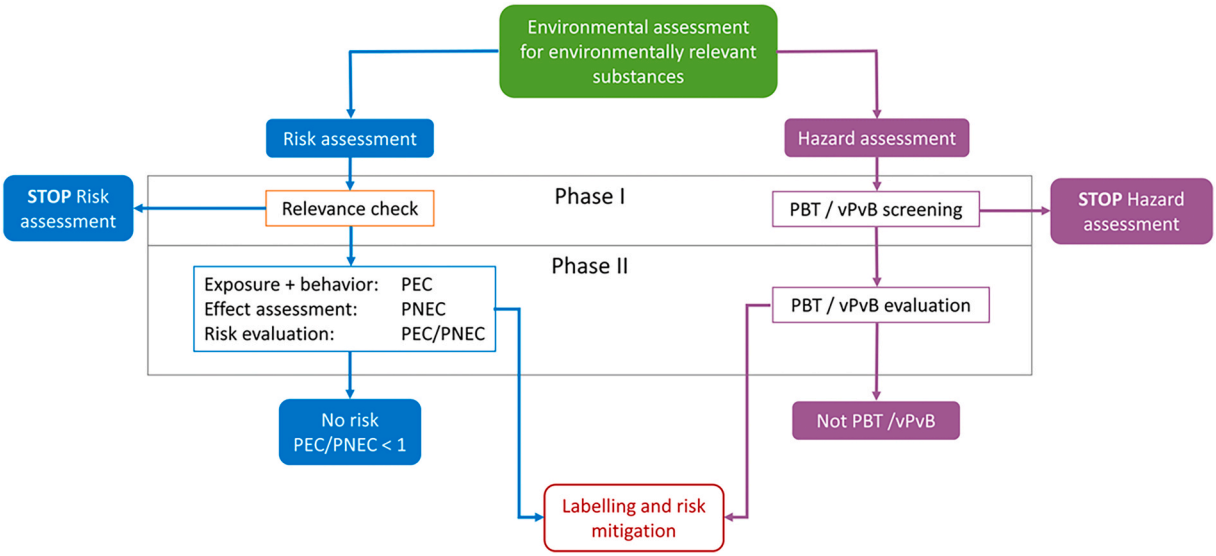

Fig. 5. Overview of the ERA with risk assessment including endpoints and hazard (PBT/vPvB) assessment based on EMA (2024). The risk and hazard assessments are carried out in two phases. In Phase I of the risk assessment (relevance check), the expected environmental concentration in surface water (PEC_{SW}) is determined. If the PEC_{SW} is below 0.01 μg/L, the risk assessment ends in Phase I, as it is assumed that the medicinal product is unlikely to represent a risk to the environment. However, if a PEC_{SW} of 0.01 μg/L or more is calculated, or if the substance is endocrine active, a more detailed risk assessment (Phase II) is required. In Phase II the potential toxicity to sewage treatment plant microorganisms and aquatic surrogate organisms through ascending trophic levels (algae, daphnia and fish toxicity tests) is assessed and the predicted no-effect concentration (PNEC) of the most sensitive organism is determined. The PNEC is then combined with the PEC value to calculate a PEC/PNEC quotient, which provides an indication of the risk. In the hazard assessment, regardless of the risk assessment, each substance is examined to determine whether it could be potentially persistent (P), very persistent (vP), (very) bioaccumulative (B or vB) and toxic (T). If the substance meets the PBT/vPvB criteria, it is assumed to be highly hazardous. Naturally occurring substances such as vitamins, peptides, proteins, carbohydrates, amino acids, lipids and herbal medicinal products are exempt from the ERA, as the environmental risk posed by these substances is considered as unlikely.

comprehensive ERA dossiers. This can help filling gaps in the ERA results tables for the more detailed information level that would be made available for the interested reader, alongside a traffic light classification system (see below) based on results from the underlying tests. Using ERA data in this proposed environmental classification system has the advantage that it can be easily adopted in other countries (at least within the European Union) as a basis for classifying the environmental relevance of APIs in the environment.

A new data platform would not be required for the proposed information system. In Germany, the data and classification can be included in the existing ChemInfo database and website (ChI), an information system for chemicals organized by the German federal and state governments and hosted by UBA. Advantages of employing the established ChemInfo system include the ability of data exchange especially regarding other dissemination systems, provision of different levels of access in the software and easy adaptability to desired requirements (e.g. simple and detailed information levels). This approach would also fulfil German stakeholders' wishes for an information system being independently hosted and run by public authorities, and matches the outcome of the literature review from Sweden.

> "Yes, I think we need to move toward having a central authority that classifies these substances. Because this will never be done by a professional society, they're too vulnerable to influence. It must be done by a neutral body based on a transparent criteria catalogue." (DE05)

3.4.2. ERA-based classification colour code and legal aspects

Regarding the user interface for the proposed classification system, we suggest implementing simple traffic light icons (see below and Fig. 6), including the colours red, yellow and green as well as grey. The colour classification combines the outcomes of both risk and hazard assessments performed as part of the ERA. This system of flagging was assessed as intuitive for physicians and pharmacists in their day-to-day work (2nd expert panel meeting 26.06.2024; Stakeholder Workshop 12.11.2024).

An API is flagged as red in three cases: 1) if according to its ERA it may pose a risk to the aquatic or terrestrial environment (ERA risk quotient (RQ) ≥ 1), or to predators consuming contaminated prey (secondary poisoning); 2) if it is a priority substance according to the Water Framework Directive (as established in the latest amended version of Annex I to Directive, 2008/105/EC); 3) if it is identified as a PBT or vPvB substance (hazardous chemicals classified for their **P**ersistence, **B**ioaccumulation, and **T**oxicity, or for being **v**ery Persistent and **v**ery Bioaccumulative (vPvB) (Directive of the European, 2025; ECHA 11.2024).

An API is flagged as yellow if in its ERA the calculated RQ is close to one ($1 \geq RQ \geq 0.1$), meaning there is a low risk. This classification is considered an early warning that a risk might be possible in the future if there is a change in indication, dosage or treatment regimen.

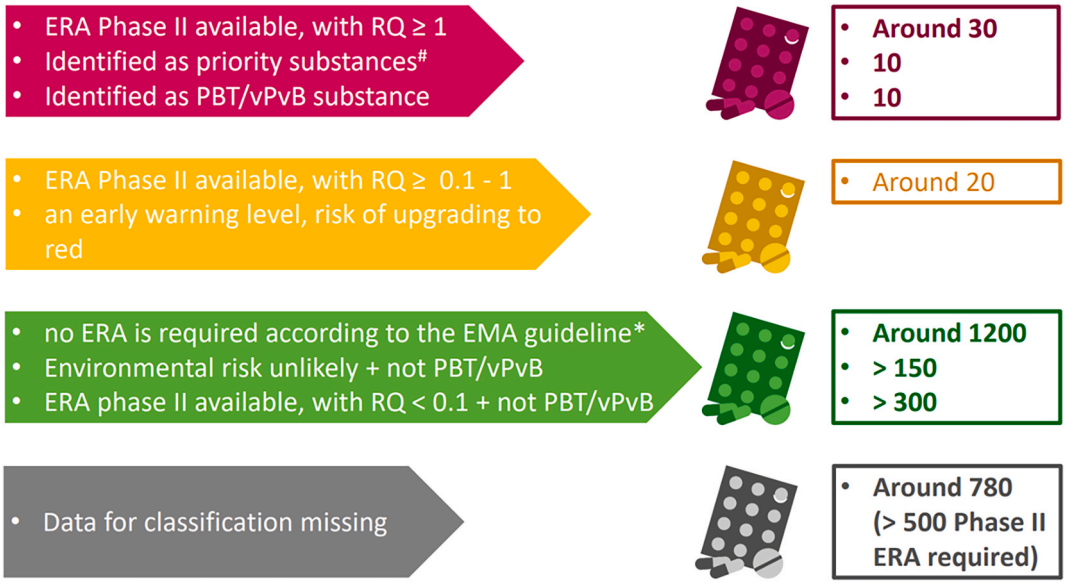

Fig. 6. Concept for the environmental classification of pharmaceuticals and preliminary impact analysis of the approx. 2500 active substances on the market in Germany (status 05/2025); according to the amended annex I to Directive 2008/105/EC, * EMEA/CHMP/SWP/4447/00 Rev. 1-Corr.

APIs are flagged as green if they are not expected to pose a risk to the environment. This applies for 1) naturally occurring substances, the use of which will not alter the concentration or distribution of the substance in the environment (includes the majority of marketed APIs, namely vitamins, electrolytes, amino acids, peptides, proteins, nucleotides, carbohydrates, lipids as well as herbal medicinal products), 2) APIs for which an environmental risk is unlikely and bioaccumulation potential is not indicated, and 3) APIs with a calculated risk quotient <0.1 and if it is not is not a PBT or vPvB substance.

APIs are flagged as grey if data on environmental risk or hazard is lacking, meaning that a risk cannot be excluded.

A preliminary analysis of this classification system for all APIs on the German market in 2024 (n ~ 2500) concluded that approximately 2 % would be classified as red, 1 % as yellow, 66 % as green and 31 % as grey (Fig. 6). Following the latest draft for the EU 'pharma package' from 2023 (European Commission, 2023), one declared aim is to fill data gaps on environmental information for pharmaceuticals authorized before 2006. Therefore, it is likely that the current number of APIs flagged as grey will decrease.

In future the hazard criterion M referring to the Mobility criterion, where 'M' signifies a substance's high potential to move through water systems, might be added to the existing PBT/vPvB, for instance as PMT/vPvM to the classification scheme (EU 2024/2865 (CLP) of 10/23/2024 (EC, 2024)). This would improve the assessment process by identifying those substances that may cause long-term environmental damage across multiple compartments. The M criterion is particularly relevant for water suppliers or wastewater treatment systems.

It is important to highlight that a comparison and the advice to consider an alternative medicine can only be realized if there are multiple equivalent therapeutic options within the same indication class present. An example classification, performed for nasal antiallergics marketed in Germany as OTC products, is described in the supplemental material chapter 10. For groups containing several red flagged active substances, such as steroid hormones, a more in-depth analysis may help to identify less harmful alternatives. A more data-intensive approach, taking into account additional data (e.g. metabolism, formulation, selling numbers and concentrations measured in the environment) as in the concept from Faber et al. (2023), similar to the Swedish Goodpoint reviews on specific substances may help too. Goodpoint reviews are available for example for antidepressants, AT2-antagonists, painkillers and antiepileptics (Goodpoint, 2018, 2019a, 2019b, 2020). In contrast to the classification system proposed by us, the approach proposed by Faber et al. is considerably more complex and results in a somewhat complex matrix regarding potentially environmentally more friendly alternatives. This approach is difficult to implement for APIs in general, but it could serve as an orientation in practice for particular cases.

3.4.3. Dissemination systems and strategy for Germany

We evaluated different approaches for an effective dissemination system that ensures environmental information and classification is accessible and incorporable into decision-making processes at relevant points in the healthcare system. Based on our project findings we identified in total eight different possible dissemination systems which can be structured according to their implementation in the short, middle and long term (see Table 2). Short-term effects can be obtained by presenting information and classification for APIs on a public website. In the middle-term, effects can be achieved through integrating the system into software applications for pharmacies, doctors' practices and medicine commissions in hospitals. Lastly, long-term effects can be obtained by implementing information and classification into medicine formularies of health authorities, therapeutic guidelines, by labelling medicines as well as into drug market authorisation, drug discount agreements, and reimbursement decision processes.

Table 2
Identified dissemination systems within the German healthcare system.

Short term		Website
Middle term		Pharmacy- and Doctors office management software
		OTC-lists/general recommendations lists (formularies)
		Drug Commission in the hospital
Long term		Implementation into health policy and therapeutic guidelines
		Market authorisation and reimbursement decisions
		Discount agreements of health insurance companies
		Labelling

As discussed above, the already existing German Chemical Information System (ChemInfo, www.chemikalieninfo.de, also available in English) can serve as the initial dissemination approach and as basis for the additional specifical ones. Hereby, scientifically sound data will be published by UBA that will ensure independence in processing data. Connection to further existing systems or platforms (e.g. ABDATA Pharma data service) by export from ChemInfo and the integration of environmental information into other systems such as pharmacy and doctors' office management software is necessary for achieving additional impact (DE07). Recommendation lists, primarily for the top OTC indications, could help emphasizing the environmental compatibility of a given API in medical and pharmaceutical practice. Such OTC lists would provide an easily accessible overview for APIs in specific indications, directly involving medical- and pharmacy staff to promote their awareness for environmental aspects of drugs. A further step would be hospitals' medicine committees creating in-house product lists based on common (inter-)national guidelines and frequently occurring clinical cases. By integrating environmental aspects at this point, less environmentally problematic APIs could be specifically promoted (see Fig. 7).

Beyond these measures, the integration of ecological aspects into health policy and medical guidelines and directives offers both opportunities and challenges. These guidelines and directives are well established as trustworthy instruments that enable the efficient communication and consolidation of therapeutic knowledge. A key advantage of this procedure would be the reduction of individual responsibility and prompt decisions regarding environmental aspects of APIs from stakeholders with less knowledge on this topic.

As part of a long-term approach, integration of environmental aspects into market approval and reimbursement would lead to the systematic integration of environmental interests. Processed for example by the superordinated IQWiG (German Institute for Quality and Efficiency in Health Care, an independent scientific institute that evaluates the benefits and cost-effectiveness of medical interventions to support health care decision-making) or the G-BA (see chapter 3) would make it significantly easier for users to incorporate environmental aspects into their daily work. The integration of environmental aspects into the system of discount agreements of health insurance companies has strong potential for impact. In principle, it would be possible for health insurance companies to refrain from entering into discount agreements for certain particularly environmentally critical APIs or formulations, provided that therapeutic alternatives are available.

Voluntary labelling on pharmaceutical packaging is another way to directly communicate environmental aspects also to patients. The goal would be to label pharmaceutical products as "environmentally friendly" in order to address patients' legitimate interest in environmental issues. At the same time, this target group typically brings low levels of knowledge regarding the environmental impacts of pharmaceuticals, which is why education and information would initially be necessary. Other, not environmentally focused systems such as the French and German "Nutri-Score" for food products have shown to impact consumers' purchasing decisions (Skretkowicz and Perret, 2023). In any case, such labelling must be thought through well to achieve the desired effect. Various aspects must be considered including the design and message conveyed by a label, as well as the prior knowledge, existing attitudes, and consumption patterns of the target group. In this respect, for pharmaceutical products such a label could certainly only play a useful role in combination with further communication approaches.

Furthermore, modifications to the design and integration of labels on medicinal packaging cannot be unilaterally implemented by the German legislator, as the information presented on such packaging is fully harmonised at the European Union level under Directive 2001/83/EC. Consequently, any substantive changes would necessitate amendments to the relevant European legislation.

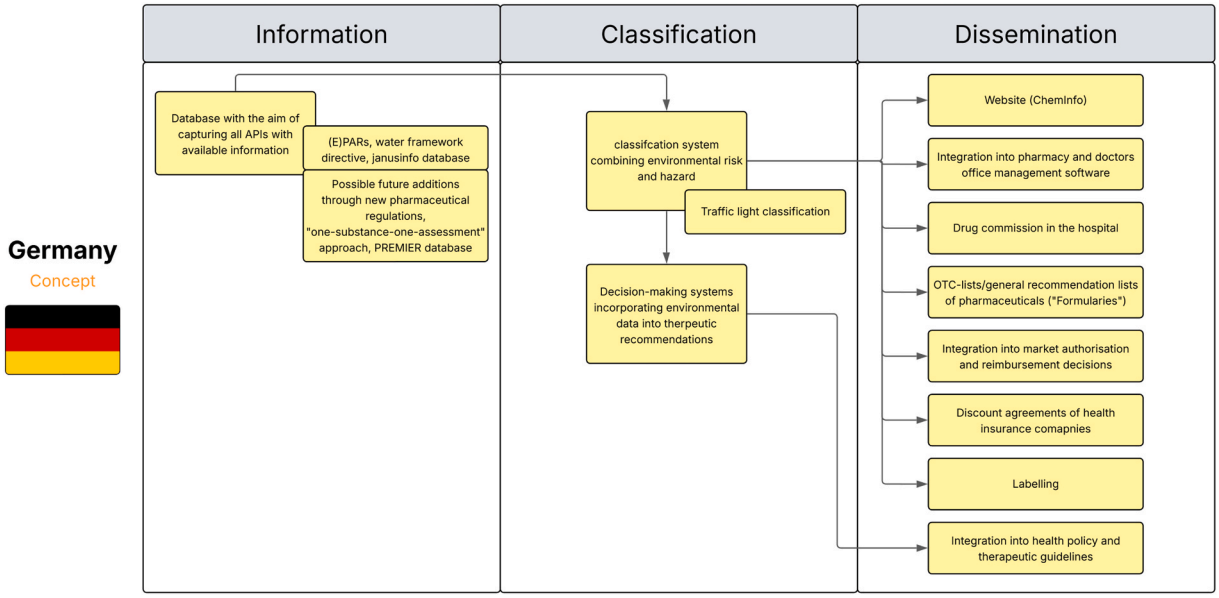

Fig. 7. Summed concept developed for Germany including approaches for information, classification and dissemination. Connecting arrows display information flow from collected information in ChemInfo that are used for ERA-based traffic light classification and finally can be used in dissemination by associations hosting and updating these systems.

Voluntary systems could be used as an alternative for the time being. E.g. the Swedish "Välvald" initiative, integrates multiple pharmaceutical manufacturers and presenting a green label on the shelf in the pharmacy and not directly on the packaging. However, a voluntary system does not necessarily integrate all manufactures and their respective medicines on the market and often lack transparency.

Besides the approaches addressing professionals within the healthcare system, campaigns directly addressing patients and the public should be implemented. Seven out of eight interviewees consider it useful to implement such measures to increase the effectiveness and monitor the effects of such a system alongside the introduction of a Pharmaceutical Environmental Index. Firstly, it is considered useful to publicise the existence of such an index in specialist media with a wide reach, in order to increase effectiveness through broader awareness (DE01). Furthermore, a pharmaceutical evaluation or a scientific study simultaneously initiated with the introduction of the Pharmaceutical Environmental Index to record its effects is proposed (DE03; DE06). For example, this could be done by analysis of sales data as well as measured environmental concentrations in relation to environmental limits (compare 2.2.3). Such evaluations are important to maintain high levels of adherence in the healthcare system – especially when it becomes apparent that the measures taken are having an impact (Stakeholder Workshop 12.11.2024). Collaboration with other EU countries is necessary, particularly to address the challenge of data gaps. By sharing data, knowledge and approaches, national authorities can work together to improve the management of environmentally harmful medicines. The accompanying implementation of environmental aspects into university teaching in the fields of pharmacy and medicine was considered necessary by almost all respondents. This measure is already addressed by other projects and initiatives, especially in the provided material the freely available and editable teaching materials via the "Pharmaceuticals and Environment" portal, available in German and English (www.uba.de/ham, www.uba.de/hmp) (Peifer et al., 2023; Kemper et al., 2025).

3.4.4. Barriers for the implementation

Despite broad stakeholder support from the German healthcare system, several barriers towards an implementation could be identified. First, time constraints among healthcare professionals represent a structural barrier. Physicians and pharmacists emphasised that additional research steps are not feasible in clinical day to day practice, requiring environmental information to be seamlessly embedded into existing workflows rather than accessed separately.

This concludes to the next barrier: Unlike the Wise List in Sweden, there is no central therapeutic dissemination and recommendation system in Germany. Therefore, it remains a time-consuming process to integrate environmental information into all existing systems with different leading stakeholder groups.

Furthermore, the implementation has no legal basis in Germany. The integration of environmental information into the identified dissemination systems depends on the motivation of the relevant institutions and stakeholders, as it is not yet legally mandatory. This will remain complicated due to Germany's highly fragmented federal landscape. We could not identify any regulations in Germany making use of the developed database and integrating environmental information into therapeutic decision-making, which was indirectly reflected by the difficult communication with software providers.

Operators of these databases are responsible for verifying the validity of the results presented, leading to partly non-transparent

systems and emphasizing the need for legally mandatory implementation.

Fourth, discount agreements between health insurance companies and pharmaceutical companies currently override individual prescribing decisions. As decisions are based on providing the most effective therapy with the lowest costs, the practical room for environmentally informed substitution at the point of dispensing is limited. Last, education of patients and practitioners is an important aspect as knowledge and awareness rising can reduce the barrier for the implementation of environmental aspects into prescribing and dispensing. Information and classification systems can only be as good as the decision makers have to know about its existence and how to use it and patients have to be aware of the environmental consequences and, for example, agree to a possible environmental directed substitution of a medicine. To foster this, initiatives were initiated by the authors but continuous education is needed (Kemper et al., 2025).

4. Outlook on legal aspects and possibilities of integration

An additional, again long-term improvement could be the integration of such a system into existing laws to make the use of environmental information mandatory.

> "Ultimately, the law must change. The framework must be defined. We can only do what's within our means, but we are trying to influence politics in many areas." (DE07)

During the project, several starting points could be identified for the integration of the proposed environmental classification system into existing laws in Germany regulating for example therapeutic guidelines, discount agreements or pharmacy/doctors' office management software. Due to the extremely fragmented legal and regulatory landscape in Germany's health law, there is a large array of possibilities for such an integration. The central starting point of respective legal reforms is where prescribing behaviour (and also dispensing behaviour by pharmacists) is already regulated by law.

In that respect, a basic distinction can be made between amendments to Part V of the German Social Code related to (statutory health insurance), which is used by approximately 90% of the population, and other amendments that are generally applicable. With regard to feasible modifications of the Social Code, a primary consideration is ensuring that Medical Practice Management Software incorporates the relevant environmental information. It is first important to ensure that Medical Practice Management Software contains the relevant environmental information. Potential legal reforms extending beyond the Social Code could include, for example, the introduction of a duty for pharmacists to inform clients about the environmental classification system. Another potential amendment pertains to the requirement that, in the future, product information provided by pharmaceutical manufacturers to physicians, as well as package leaflets, should include information on the aforementioned system.

In addition, the German Federal Joint Committee (G-BA) should be authorized to inform contract doctors about the environmental impacts of the APIs under consideration and to oblige them to adjust their prescribing behaviour accordingly under certain conditions. Further, the legal framework conditions of the tendering of discount agreements from the statutory health insurance organisations may be amended to make consideration of environmental impacts of medication mandatory. Similar amendments appear reasonable for regulations concerning the benefit assessment of medicinal products and their prescription by contract physicians.

As support and as example how the developed environmental classification system can be included into therapeutic decision-making, a flow chart can be found in the supplemental material chapter 11. The developed classification system is a key step for choosing APIs with less harm to the environment, while the other steps are mainly based on bioavailability or prevention of drug use. Finally, it must be emphasised that the primary responsibility of healthcare professionals is to cure patients as effectively as possible, for example by using the most effective API and application route with the fewest side effects. Following that, exchange due to environmental reasons is only applicable if multiple therapeutic possibilities or APIs are suitable with the same therapeutic effectiveness. Based on this, medical and pharmaceutical knowledge is needed in every step and environmental information is added to it with the help of the developed system and flow chart.

CRediT authorship contribution statement

Clemens Woitaske-Proske: Writing – original draft, Visualization, Methodology, Investigation, Data curation. **Arne Hein:** Writing – review & editing, Visualization, Supervision, Methodology, Data curation, Conceptualization. **Rodrigo Vidaurre:** Writing – review & editing, Methodology, Investigation, Data curation. **Yannick Heni:** Methodology, Investigation, Data curation. **Christian Peifer:** Writing – review & editing. **Ulrich Gassner:** Investigation. **Gerd Maack:** Writing – review & editing, Supervision, Conceptualization.

Data statement

All data generated or analysed during this study are included in this published article and its Supplementary Material files.

Interview transcripts cannot be shared as the number and nature of the statements made would allow conclusions to be drawn about the persons involved. Protocols from expert panel meetings and stakeholder workshop are available on request in German language.

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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.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.scp.2026.102439.

Data availability

The data that has been used is confidential.

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