



# Requirements and impacts of an environmental information/classification system for pharmaceuticals

*Results from the Pharmas Project (WP 6)*

[www.pharmas-eu.org](http://www.pharmas-eu.org)

## Part I: Stakeholder requirements re. information and system characteristics

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# Methodology

- ▶ *Qualitative, in-depth interviews (~ 60 minutes)*
- ▶ *Topics:*
  - ▶ *attitude towards system,*
  - ▶ *evaluation of use and impacts,*
  - ▶ *information requirements,*
  - ▶ *own use (e.g. decision-making),*
  - ▶ *characteristics and design,*
  - ▶ *risk perceptions.*
- ▶ *Characteristics and functions of system left open*

**Questionnaire for PHARMAS interviews**

Date	
Name of Interviewee	
Name of Interviewer	
Title of Interviewee	
Department / Organization	
Characteristics of Interviewee	

**Questions:**

(Only ask one question at a time - wait for spontaneous answer, then proceed to next question. Give after question number a guideline for amount of time to be used for question, based on total of 45 min.)

1. (5 min) What is your opinion on the need for an EU-wide environmental risk and hazard classification system for pharmaceuticals? (Total for spontaneous answer)
  - a. Would you approve of the existence of such a system?
  - b. Would you be involved in using it yourself?
  - c. For which purposes would you use the system?
2. (2 min) What would be the most of such a web-based classification system be?
  - a. Environmental?
  - b. Economic?
  - c. Medical?
  - d. Regarding behavior of citizens? (e.g. consumer choice of unused pharmaceuticals, behavior of doctors prescribing)
3. (2 min) What are your (or your organization's) needs for information on PPs in the environment? (Total for spontaneous answer)
  - **QUESTION:** Which information (which data) would you require?
    - **ORAL QUESTION:** Can cover parts from following list or additional ones:
      - a. characteristics of compound, e.g.
        - QUANTITATIVE: amount
        - QUALITATIVE: name
        - ADDRESS AND ADMINISTRATION: address
        - PRODUCTION: origin
        - MANUFACTURE: name
        - ADDRESS ON PLACE OF ADMINISTRATION
        - ADDRESS ON MANUFACTURE: name
        - ADDRESS ON MANUFACTURE: address
        - ADDRESS ON MANUFACTURE: address
      - b. uses (uses, e.g.
        - QUANTITATIVE: uses data from interviewees country / European countries
4. (10 min) Going into more detail...
  - **QUESTION:** Which information (which data) would you require?
    - **ORAL QUESTION:** Can cover parts from following list or additional ones:
      - a. characteristics of compound, e.g.
        - QUANTITATIVE: amount
        - QUALITATIVE: name
        - ADDRESS AND ADMINISTRATION: address
        - PRODUCTION: origin
        - MANUFACTURE: name
        - ADDRESS ON PLACE OF ADMINISTRATION
        - ADDRESS ON MANUFACTURE: name
        - ADDRESS ON MANUFACTURE: address
        - ADDRESS ON MANUFACTURE: address
      - b. uses (uses, e.g.
        - QUANTITATIVE: uses data from interviewees country / European countries

on detail in (spontaneous) interview parts  
 (Total for spontaneous answer)  
 on needs to meet them (inter-views) in European inter-views  
 on needs to management of pharmaceutical: needs  
 on needs on (spontaneous) advice for the management of pharmaceutical (needs) (Total e.g. for QUANTITATIVE because of their multiple properties)  
 detail (level of application)  
 information be prepared and presented (figures, graphs, level of  
 do you use the classification system in your work? (Total for spontaneous  
 question) influence your decision-making processes?  
 • Would your organization (use) such a classification system? (Why / why not?)  
 • Which organizations in your country would be pro / against such a system? (Why / why not?)

5. (3 min) What should the main characteristics of a classification system be to ensure the system works appropriately? (Total for spontaneous answer)
  - a. Type of information (the system) used: determining absolute quality of information, neutrality, external relation, language
  - b. Which categories of PPs should it cover? (Total for spontaneous answer)
  - c. Any other things to focus on in the system (e.g. inter-views)?
  - d. Should both theoretical and DTIC cover the current stage be covered?
7. (3 min) What would your requirements of a web-based classification system be, e.g. in terms of usability?
  - **QUESTION:** Are they familiar with (Total)
    - a. Do you see the use of the system is built? (e.g. regarding your own needs, regarding the different levels of information between broad public and specialized users)
    - b. What changes would you like to see in the system?
    - c. What are the shortcomings of the system? (Total for spontaneous answer)
      - i. Lack information
      - ii. Lack functioning
      - iii. How could these be overcome?
  - **QUESTION:** Are they not familiar with (Total)
    - a. In your opinion, what should the main characteristics of the system be? (e.g. what kind of structure, inter-views), should the system meet? Should there be different levels of information and if yes, for which kind of users and which kind of knowledge?
8. (2 min) What is your perception of the risk posed by PPs in the environment?
  - a. Is the media attention justified?
  - b. Are the efforts for addressing the problem justified?
9. (2 min) Do you have any other comments? (If you think of additional comments after the end of the interview (e.g. later on today or tomorrow), please send them to us via email)



# Methodology

## ▶ 12 stakeholder groups:

1. <i>Env. authorities (including RBOs) / Chemical authorities</i>	<b>6</b>	<b>interviewees</b>
2. <i>Pharmaceutical Industry</i>	<b>3</b>	<b>"</b>
3. <i>Water industry</i>	<b>2</b>	<b>"</b>
4. <i>Drinking Water authorities</i>	<b>2</b>	<b>"</b>
5. <i>Research organizations (different disciplines)</i>	<b>5</b>	<b>"</b>
6. <i>Medicines Authorities</i>	<b>3</b>	<b>"</b>
7. <i>Medical associations</i>	<b>2</b>	<b>"</b>
8. <i>Pharmacies / Pharmacy Associations</i>	<b>1</b>	<b>"</b>
9. <i>Consumer NGOs</i>	<b>1</b>	<b>"</b>
10. <i>Environmental NGOs</i>	<b>2</b>	<b>"</b>
11. <i>Public Health authorities</i>	<b>1</b>	<b>"</b>
12. <i>Pharmaceutical Waste/Recycling Companies</i>	<b>+</b>	<b>1</b>

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**Total : 29 interviewees**



## Main findings

### a) Attitudes and exp. impacts

- ▶ ***Approval all through:*** 100% approve system
- ▶ ***Widespread potential uptake:*** 62% would use
- ▶ ***Environ. impacts:*** most opinions +
- ▶ ***Economic impacts:*** + predominant (few opinions)
- ▶ ***Behavioural impacts (doctors/public):*** diverging opinions



## Main findings

### *b) Information requirements*

- ▶ ***Strong and widespread requirements through most groups for:***
  - ▶ *physico-chemical data*
  - ▶ *toxicity and ecotoxicity*
  - ▶ *behaviour in environment*
  - ▶ *behaviour in water TPs*
  - ▶ *sales and volumes data*
  - ▶ *environmental levels*



## Main findings

► ***Strongest requirements:***

### ***b) Information requirements***

**water actors, research actors, env NGOs.**



Staholder group	Environmental authorities						Pharmaceutical industry			Water actors			Research inst.				Medicinal products authorities		Medical associations		Pharma. Assoc.	Env. NGOs		Public Health Systems	Pharma Waste Companies					
	SH number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18 <sup>1</sup>	19	20	21	22	23	24	25	26	27	28	29
Physico-chemical	X		X	X				X	X	X	X	X	X	X	X	X	X	X	X	X	X				X	X	X			
Ecotoxicological	X		X	X	X <sup>2</sup>					X <sup>3</sup>	X	X	X	X	X	X	X	X <sup>4</sup>	X	X				X	X	X	X	X	X	
Stability and biodegradation -feature	X		X	X				X		X	X	X	X	X	X	X	X	X	X	X	X				X	X	X			
Pharmacokinetic			(X)								X	X	X	X	X	(X)	X			X							X			
Excretion data	X		X							X	X	X	X	X	X	X	X	X	X	X	X						X	X		
Routes of administration			X							X		X	X	X	X	X	X	X	X		X					X	X			
Pharmacodynamic			(X)								X	X	X	X	X	X	X			X							X			
Side effects			(X)										X	X	X		X	X		X						X	X			
Mammalian toxicology data	(X)		X								X		X	X	X		X	X		X					X	X	X			
Sales data	X <sup>5</sup>		X	X	X		6	X		X	X	X	X <sup>7</sup>	X	X	X <sup>8</sup>		X	9	X <sup>10</sup>						X	X <sup>11</sup>	(X)		
Behavior in drinking water and wastewater treatment	X		X	X			X	X		X	X	X	X <sup>12</sup>	X	X	X	X	X		(X)	X				X <sup>13</sup>	X	X	X	X	
Behavior in drinking TP				X	X					X	X	X	X	X	X	X	X	X		(X)	X				X	X	X	X	X	
Water flows / quality in EU river basins	X		X	X			X				X <sup>15</sup>	X	X	X	X	X <sup>16</sup>	X	X		X					X	X <sup>16</sup>	X	(X)		
Management of PP wastes	(X) <sup>18</sup>		X	19	X					X	X	(X)	X	X	X	X		X		(X)					X		X			



## Main findings

- ▶ ***Strongest requirements:***
- ▶ ***Less strong requirements:***

## ***b) Information requirements***

water actors, research actors, env NGOs.

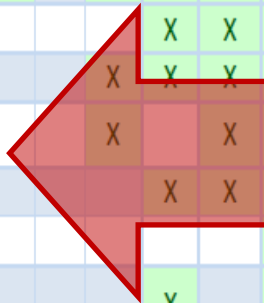
**environmental authorities**





Staholder group	Env. authorities						Pharmaceutical industry			Water Utilities and Associations		Drinking Water Authorities		Research institutions					Medicinal products authorities		Medical associations		Pharma. Assoc.	Consumer NGOs	Environmental NGO		Public Health Systems	Pharma Waste Companies	
	SH number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18 <sup>1</sup>	19	20	21	22	23	24	25	26	27	28
Physico-chemical	X		X	X				X	X	X	X	X	X	X	X	X	X	X	X	X					X	X	X		
Ecotoxicological	X		X	X	X <sup>2</sup>					X <sup>3</sup>	X	X	X	X	X	X	X	X <sup>4</sup>	X	X				X	X	X	X	X	
Stability and biodegradation -feature	X		X	X				X		X	X	X	X	X	X	X	X	X	X	X					X	X	X		
Pharmacokinetic			(X)							X	X	X	X	X	X	(X)	X			X						X			
Excretion data	X		X							X	X	X	X	X	X	X	X	X	X	X						X	X		
Routes of administration			X							X	X	X	X	X	X	X	X	X	X	X						X	X		
Pharmacodynamic			(X)							X	X	X	X	X	X	X	X	X	X	X						X	X		
Side effects			(X)										X	X	X		X	X		X						X	X		
Mammalian toxicology data	(X)		X							X		X	X	X			X	X		X					X	X	X		
Sales data	X <sup>5</sup>		X	X	X		6	X		X	X	X	X <sup>7</sup>	X	X	X <sup>8</sup>		X	9	X <sup>10</sup>						X	X <sup>11</sup>	(X)	
Behavior in drinking water and wastewater treatment	X		X	X			X	X		X	X	X	X <sup>12</sup>	X	X	X	X	X	(X)	X					X <sup>13</sup>	X	X	X	
Behavior in drinking TP				X	X					X	X	X	X	X	X	X	X	X	(X)	X					X	X	X	X	
Water flows / quality in EU river basins	X		X	X			X			X <sup>15</sup>	X	X	X	X	X	X <sup>16</sup>	X	X		X					X	X <sup>16</sup>	X	(X)	
Management of PP wastes	(X) <sup>18</sup>		X	19	X					X	X	(X)	X	X	X	X		X	(X)						X		X		

Gaps related to human effects / human toxicology





## Main findings

▶ ***Strongest requirements:***

▶ ***Less strong requirements:***

▶ ***Some requirements:***

## ***b) Information requirements***

water actors, research actors, env NGOs.

environmental authorities

**pharmaceutical industry**



# Pharma industry

Staholder group	Environmental authorities						Pharma industry				Water Utilities and Associations		Drinking Water Authorities		Research institutions				Medicinal products authorities		Medical associations		Pharma. Assoc.	Consumer NGOs	Environmental NGO		Public Health Systems	Pharma Waste Companies		
	SH number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18 <sup>1</sup>	19	20	21	22	23	24	25	26	27	28	29
Physico-chemical	X		X	X				X	X	X	X	X	X	X	X	X	X	X	X	X					X	X	X			
Ecotoxicological	X		X	X	X <sup>2</sup>					X <sup>3</sup>	X	X	X	X	X	X	X	X <sup>4</sup>	X	X				X	X	X	X	X		
Stability and biodegradation -feature	X		X	X				X		X	X	X	X	X	X	X	X	X	X	X					X	X	X			
Pharmacokinetic			(X)								X	X	X	X	X	(X)	X			X							X			
Excretion data	X		X							X	X	X	X	X	X	X	X	X	X	X	X						X	X		
Routes of administration			X							X		X	X	X	X	X	X	X	X		X					X	X			
Pharmacodynamic			(X)								X	X	X	X	X	X	X			X							X			
Side effects			(X)										X	X	X		X	X		X						X	X			
Mammalian toxicology data	(X)		X								X		X	X	X		X	X		X					X	X	X			
Sales data	X <sup>5</sup>		X	X	X		6	X		X	X	X	X <sup>7</sup>	X	X	X <sup>8</sup>		X	9	X <sup>10</sup>						X	X <sup>11</sup>	(X)		
Behavior in drinking water and wastewater treatment	X		X	X			X	X		X	X	X	X <sup>12</sup>	X	X	X	X	X	X	(X)	X					X <sup>13</sup>	X	X	X	
Behavior in drinking TP				X	X					X	X	X	X	X	X	X	X	X	(X)	X					X	X	X	X		
Water flows / quality in EU river basins	X		X	X			X				X <sup>15</sup>	X	X	X	X	X	X <sup>16</sup>	X	X		X				X	X <sup>16</sup>	X	(X)		
Management of PP wastes	(X) <sup>18</sup>		X	19	X					X	X	(X)	X	X	X	X		X	(X)						X		X			



## Main findings

▶ **Strongest requirements:**

▶ **Less strong requirements:**

▶ **Some requirements:**

▶ **Minimal requirements:**

## b) Information requirements

water actors, research actors, env NGOs.

environmental authorities

pharmaceutical industry

**doctors / pharmacists**



## Doctors / pharmacists

Staholder group	Environmental authorities						Pharmaceutical industry			Water Utilities and Associations		Drinking Water Authorities		Research institutions						Medicine products authorities		Associations		NGOs		Environmental NGOs		Public Health Systems	Pharma Waste Companies	
	SH number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18 <sup>1</sup>	19	20	21	22	23	24	25	26	27	28	29
Physico-chemical	X		X	X				X	X	X	X	X	X	X	X	X	X	X	X	X	X					X	X	X		
Ecotoxicological	X		X	X	X <sup>2</sup>					X <sup>3</sup>	X	X	X	X	X	X	X	X <sup>4</sup>	X	X				X	X	X	X	X		
Stability and biodegradation -feature	X		X	X				X		X	X	X	X	X	X	X	X	X	X	X					X	X	X			
Pharmacokinetic			(X)								X	X	X	X	X	(X)	X			X							X			
Excretion data	X		X							X	X	X	X	X	X	X	X	X	X	X	X						X	X		
Routes of administration			X							X		X	X	X	X	X	X	X	X		X					X	X			
Pharmacodynamic			(X)								X	X	X	X	X	X	X			X							X			
Side effects			(X)										X	X	X		X	X		X						X	X			
Mammalian toxicology data	(X)		X								X		X	X	X		X	X		X					X	X	X			
Sales data	X <sup>5</sup>		X	X	X		6	X		X	X	X	X <sup>7</sup>	X	X	X <sup>8</sup>		X	9	X <sup>10</sup>						X	X <sup>11</sup>	(X)		
Behavior in drinking water and wastewater treatment	X		X	X			X	X		X	X	X	X <sup>12</sup>	X	X	X	X	X	(X)	X						X <sup>13</sup>	X	X	X	
Behavior in drinking TP				X	X					X	X	X	X	X	X	X	X	X	(X)	X					X	X	X	X		
Water flows / quality in EU river basins	X		X	X			X				X <sup>15</sup>	X	X	X	X	X <sup>16</sup>	X	X		X					X	X <sup>16</sup>	X	(X)		
Management of PP wastes	(X) <sup>18</sup>		X	19	X					X	X	(X)	X	X	X	X		X	(X)						X		X			



## Main findings

### c) *Two approaches for IS on PIE*

Two (**non-exclusive!!!**) concepts:

#### 1) *Knowledge-base approach*

- ▶ Collects **wide array of information**, e.g.
  - *intrinsic properties, environmental behaviour*
  - *data on environmental occurrence,*
  - *further information (e.g. behaviour in WWTPs)*
- ▶ **Strong stakeholder support** (many affected by data gaps)
- ▶ **Basis for development of specific DSS** (e.g. WWTP processes).
- ▶ Used for **science and transparency** in emerging env. issues.



## Main findings

### c) *Two approaches for IS on PIE*

## 2) *DSS for doctors / pharmacists / patients*

- ▶ Information on **environmental performance** of substances, i.e. limited to:
  - a) *intrinsic properties,*
  - b) *substance's environmental risk / hazard.*
- ▶ Aims to **influence behaviour routines** and **increase awareness**:
  - ▶ ***Possible criteria*** when choosing ***otherwise equivalent pharmaceuticals***
  - ▶ ***Improved disposal*** of medicines.
- ▶ Could **incentive companies** to develop products with **lower impact**.

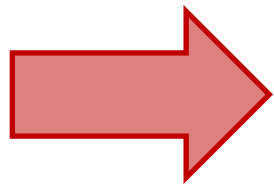


## Main findings

### c) *Two approaches for IS on PIE*

*Classification system for doctors / patients has widespread support, but....*

*Strong “pull” for more data, stakeholders affected by gaps*



To **increase impact**, system should **go beyond needs of doctors / pharmacists**, and **include elements of Knowledge-base approach**



**Multiplier effects** (e.g. wastewater treatment)



**More chances of uptake** and use / impact



**Fass.se** already provides (some) additional data





## Main findings

### *d) Other findings*

#### *Data quality / Sources of information:*

- ▶ Requirement for **simple, “raw” data** (rather than interpreted / aggregated).
- ▶ Some **issues with industry data** : vested interests
- ▶ **Independent body** favoured: **Data quality** crucial for **trust**.

#### *Risk perception:*

- ▶ **Focussed** on: Steroidal estrogens, diclofenac, antibiotics (incl. resistance)

#### *Action:*

- ▶ Most interviewees: **efforts** to address problem **are justified**
- ▶ Many interviewees: actions **now rather than later**
- ▶ **Priority: Ranking** of issue's importance varies.



**Thank you for your attention.**

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