



An Integrated Management Strategy for Pharmaceuticals in the Water Cycle

Florian Keil (keil@isoe.de)

Institute for Social-Ecological Research, Frankfurt/Main, Germany

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The Uncertainty Issue

- **Real hazardous potential difficult to assess:**
 - Effects through life-long intake of active agents a trace levels: **unexplored**
 - Effects of metabolites and substance mixtures: **open questions**
 - Pharmaceuticals with specific properties: **e.g. antibiotics, cytostatics**
- **Fundamental and practical limits of knowledge**
due to systemic complexity and multitude of substances on the market
- **Which level of protection and when is it breached?**
...dependant on interpretation and evaluation of problem specific knowledge

A New Type of Risk

- **Pharmaceuticals in the water cycle as systemic risk:**

Risks produced as side effects in the regular operation of a system

- **Externalisation of hazards by the health care system:**

Risks of drug use are related to adverse reactions in organisms during medication therapy but not to possible adverse effects after excretion

- **Systemic risk analysis:**

Identification of structures and processes that systematically produce hazards;
e.g. health care system: over prescription, improper disposal of unused drugs

Precautionary Principle in *start*

■ *start*-Project assumption:

Pharmaceuticals in the water cycle: "Reasonable ground for concern"

■ *start*-Project objective:

Development of precautionary, integrated risk management strategy

■ *start*-Project rationale:

- Precautionary measures can trigger social and technical innovation
- ...can be complementary to single substance risk assessment
- ...can foster dialogue on risk/problem perception among stakeholders

start. Project Framework



■ **Transdisciplinary research approach:**

- Research partners from sociology, chemical sciences, eco-toxicology, water research, risk research, economics
- Expert panel with representatives from pharmaceutical industry, water management, physicians' and pharmacists' associations, consumer councils, health funds and public authorities
- Regular workshop meetings with research partners and expert panel
- Focus on human pharmaceuticals, veterinary drugs not considered

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Towards an Integrated Strategy

Innovations in water infrastructure

Conventional procedures for sewage treatment and drinking water processing are largely replaced by only scarcely applied or innovative procedures.

Innovations by behaviour modification

Change of current prescription practices, use and disposal patterns of pharmaceuticals towards a higher environmental sensibility.

Innovations in drug development

Design of sustainable pharmaceuticals which are optimised for both efficacy in humans and degradability in the environment.

Precautionary, integrated risk management strategy

Water Infrastructure: Which Part of the Pipe?



■ Pharmaceuticals in the water cycle can be reduced at

- Start of pipe: reduction/avoidance of emissions into sewage
- Middle of pipe: sewage treatment in sewage plants
- End of pipe: drinking water purification in water works

■ End-of-pipe example: water works using surface water

- Area-wide installation of activated carbon filtration units
- Advantage: widely used, established technique, efficient elimination
- Germany: approx. 100 plants without AC; estimated costs: 130.000 €/a
- Disadvantage: loads of pharmaceuticals in the environment not reduced

Water Infrastructure: Assessment

	Elimi- nation effec- tiveness	Produc- tion of metabo- lites	Additi- onal waste	Additi- onal energy needed	Hygienic problems	Coupling with sus- tainable techniques	Opera- tion by qualified staff
Increase of sludge age	low	no	no	no	n.a.	no	yes
Adsorption	high	no	yes	no	yes (water works)	possible	yes
MBR	medium	no	no	yes	yes (water works)	no	yes
Ozonation	high	yes	no	yes	no	no	yes
Photo oxidation	unknown	yes	no	yes	unknown	no	yes
Sewage separation	n. a.	no	no	no	n.a.	possible	(yes)

n.a.: not applicable

Püttmann et al. 2008

Water Infrastructure: Conclusions

- **Core principle of a sustainable strategy:**
Reduction of emissions into municipal sewage
- **Transformation of centralised water infrastructure:**
Decentralised or semi-centralised system solutions & hot-spot solutions
- **Advanced sewage treatment:**
Most likely activated carbon, more data from pilot plants needed, costs unclear
- **Upgrading of water works with activated carbon:**
Probably necessary until sustainable strategies become effective

Behaviour Modification: Strategy Elements



Environmental classification	Ready for use environmental classification list for pharmaceuticals
Problem awareness of physicians and pharmacists	
Initiate discourse	Communication via professional journals, conferences, online fora etc. about precautionary risk management strategies
Retraining	Topic as regular part of physicians' and pharmacists' retraining
Avoidance and reduction of drug consumption	
Regulation of demand by cost and amount transparency	Reduction of unnecessary drug consumption by feedback mechanisms
Regulation of demand by co-payments	Reduction of unnecessary drug consumption by increased co-payments
Promotion of drug-free therapies	Facilitation of prescription of drug-free therapies by health funds
Proper disposal of unused medication	
Disposal standards	Consistent and binding disposal standard via return in pharmacies
Take back systems	Simplification of current take back systems for pharmacies
Communication campaigns	Promote proper disposal of unused pharmaceuticals
Disposal advice on package	Clearly visible advice for proper disposal on package and package insert
Dispensary of amounts adjusted to need	Varying package sizes, starter packs, labelling of blisters packs per unit

Behaviour Modifications: Conclusions

- **Prerequisite for problem relevant behaviour modifications:**

Alliances with other desirable transformation or reform processes in HCS

- **Make action alternatives available to practitioners**

Environmental classification, prescription of drug-free therapies,...

- **Proper disposal of unused medication:**

Establishment of binding disposal standard via return in pharmacies

Drug Development: Strategy Elements



Research & Development	
Funding programmes	Independent research institutes and pharmaceutical industry are supported in developing sustainable pharmaceuticals
Evaluation of programmes	Funding programmes and incorporated innovation strategies are evaluated with respect to their utility for pharmaceutical industry
Summary of Best Practices	Examples of successful developments of sustainable pharmaceuticals are published to promote the innovation strategy in pharmaceutical industry
Changes in education	
University programmes	Establishment of thematic programmes at universities in order to support Benign-by-Design principle in research and education
Awards and competitions	Awards and competitions shall support the innovation strategy and the topic „Sustainable Pharmacy“ in research, education and in the broader public
Changes in regulatory framework	
Patent terms	Patent terms are extended for sustainable pharmaceutical in order to increase economic safety for pharmaceutical industry when pursuing corresponding R&D
Market authorisation procedure	Authorisation and environmental risk assessment are more strongly coupled in order to support the innovation strategy

Drug Development: Conclusions

■ Long-term strategy, dependent on multitude of factors:

- Number and early availability of successful examples
- Time to establish Benign-by-design approach in R&D
- Development of QSAR methods
- Substitution of reliable drugs with sustainable products
- Economic market potentials, development of QSAR methods
- ...

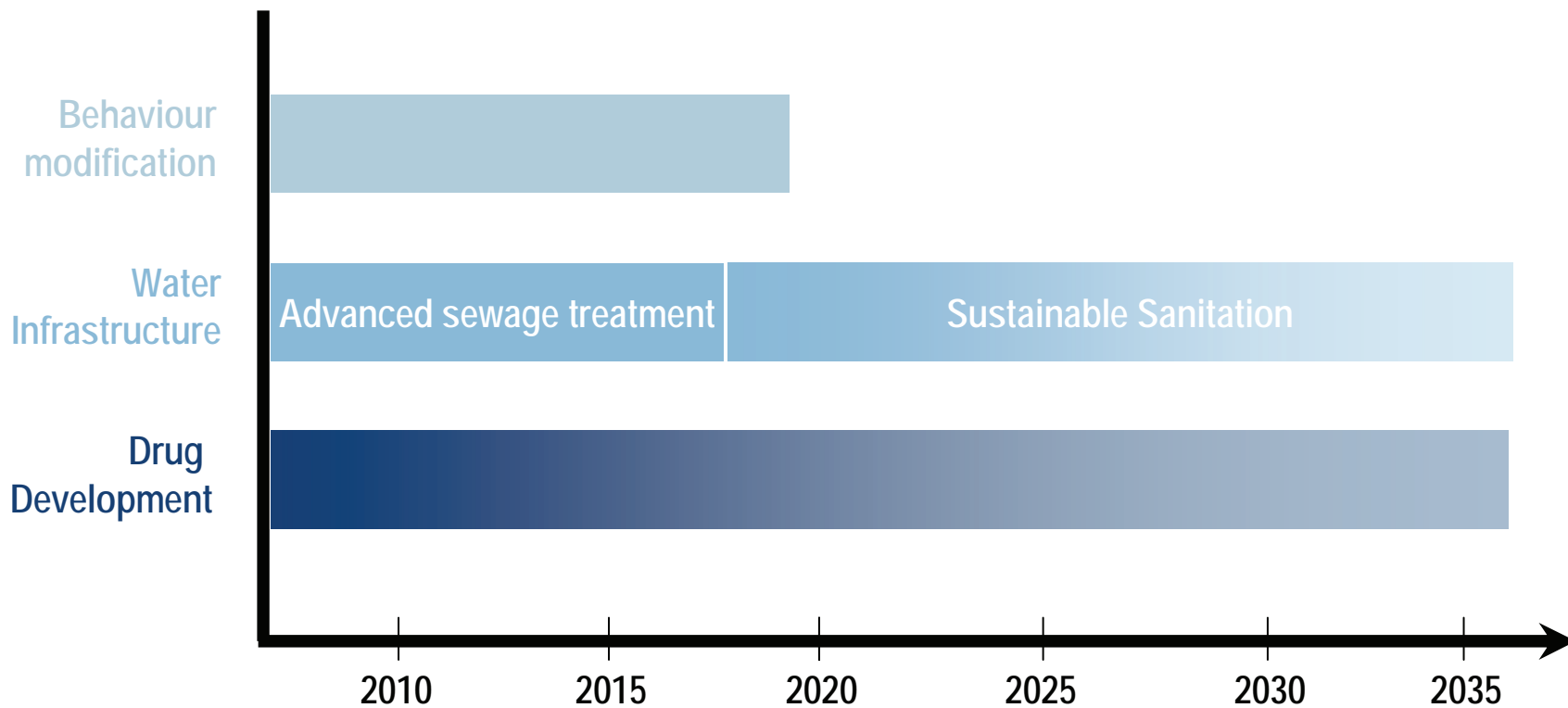


Time Scale for Strategy Implementation

	Efficacy [%]	Time [years]	Costs [M EUR]	Depth of Intervention	Innovation
Water Infrastructure	25 (+3, -8)	24 (± 10)	1.600 (+320, -970)	6	13
Behaviour Modification	24 (+2, -7)	11 (± 4)	23 ($\pm 7,0$)	4	23
Drug Development	40 (± 20)	30 (± 12)	170 (+34, -102)	4	14
Weight of Criterion	25%	10%	13%	11%	13%

Plus 'acceptance' and 'substance reach' criterion!

Time Scale for Strategy Implementation



The Integration Issue

- **Efficient and sustainable problem solutions:**

Require collective effort of various actors across all three strategy areas

- **Core principle of an integrated risk management:**

Shared stewardships along with individual goals among actors

- **Prerequisites for motivating collective problem coping:**

- Transparency as regards options and willingness for action of others
- Orientation as regards the individual problem solving options
- Innovation: precautionary action must support individual goals

- **Integrated risk management framed as innovation strategy**

Research Partners



Strategy Development	Dr. Florian Keil Alexandra Lux Dr. Engelbert Schramm	
Social-Empirical Research	Dr. Konrad Götz Jutta Deffner Dr. Irmgard Schultz	
Benign by Design	Prof. Dr. Klaus Kümmerer	
Risk Communication	Gotthard Bechmann Christian Büscher	
Actor Analysis and Scenarios	Prof. Dr. Petra Döll Dr. Alexandra Titz	
Environmental Fate of Pharmaceuticals	Prof. Dr. Wilhelm Püttmann	
Environmental Risk Assessment of Pharmaceuticals	Prof. Dr. Jörg Oehlmann Dr. Ulrike Schulte-Oehlmann	

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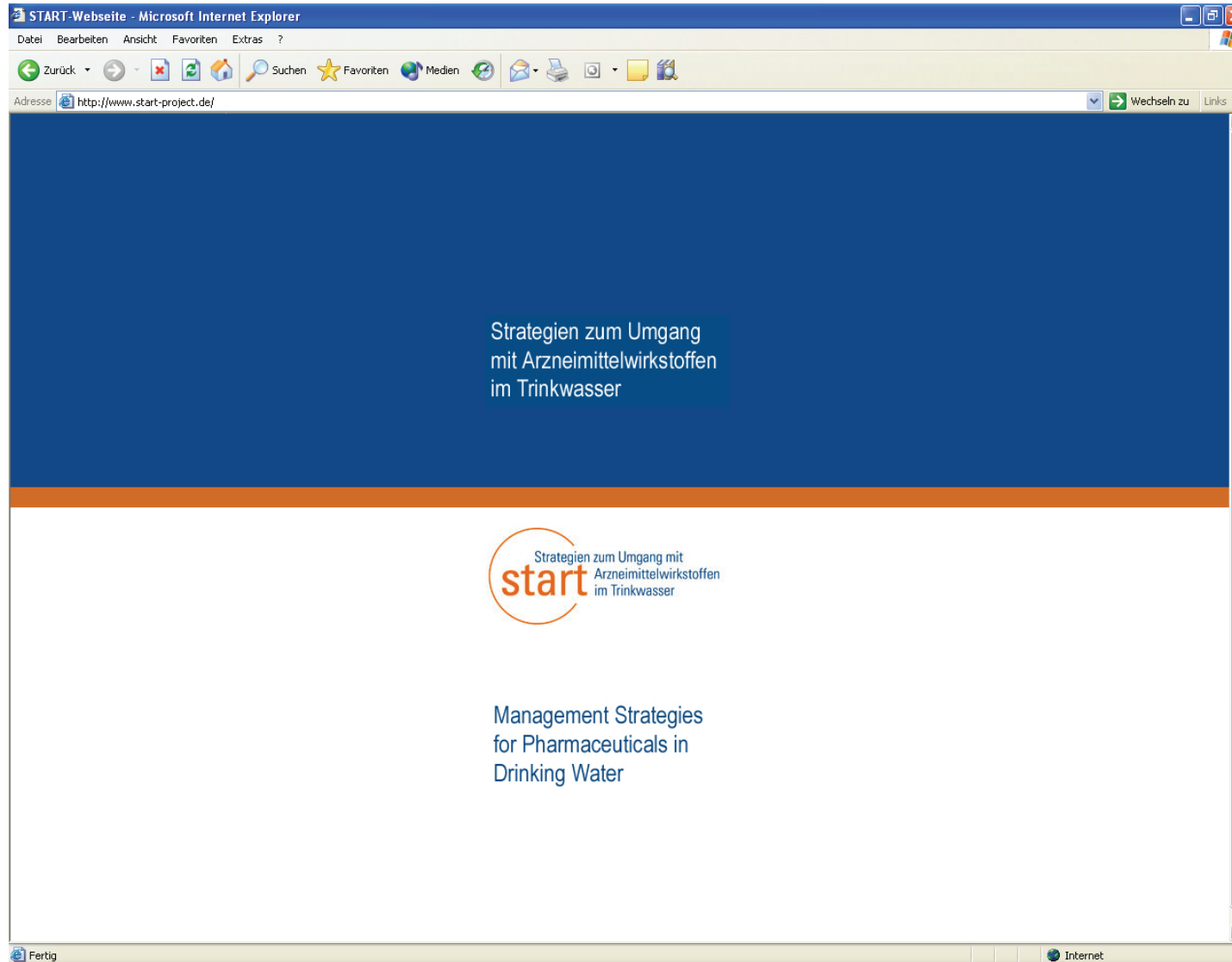
Project Expert Panel:

Prof. Dr. Thomas Beck (Arzneimittelkommission der Deutschen Apotheker, Eschborn), **Dirk Betting** (badenova AG & Co. KG, Freiburg), **Dr. Peter Diehl** (Rheingütestation Worms), **Dr. Paul Eckert** (Stadtwerke Düsseldorf AG), **Dr. Karin Gerhardy** (Deutscher Vereinigung des Gas- und Wasserfachs, DVGW, Bonn), **Dr. Klaus Heuck** (Bayer HealthCare AG, Wuppertal), **Peter Jagemann** (Emschergenossenschaft, Essen), **Ute Kerschensteiner** (Barmer Ersatzkasse, Landesgeschäftsstelle Hessen, Frankfurt am Main), **Prof. Dr. Gottfried Kreutz** (Arzneimittelkommission der Deutschen Ärzteschaft, Berlin), **Dr. med. Peter Ohnsorge** (Deutscher Berufsverband der Umweltmediziner, Würzburg), **Dr. Silke Hickmann** (Umweltbundesamt, Dessau), **Dr. Jürg Oliver Straub** (F. Hoffmann-La Roche Ltd, Basel, Schweiz), **Prof. Dr. Åke Wennmalm** (Stockholm City Council, Stockholm, Sweden)

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Forthcoming



Pharmaceuticals:
Options for Action
to Reduce
Environmental Loads
Assistance for Practitioners



Pharmaceuticals: Options for Action to Reduce Environmental Loads. Assistance for Practitioners

Brochure appearing soon,
can be ordered via info@isoe.de