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Title:

‘Homemade’ – the vicious circle of household pharmaceutical waste

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‘Homemade’ – the vicious circle of household pharmaceutical waste

Katerina Mitkidis and Panagiotis Mitkidis

Abstract:

Pharmaceutical science has provided humans with increasingly better and cheaper treatments. However, with improved access to medicines, the amount of pharmaceutical waste also grows. Pharmaceutical waste is regularly mismanaged by households, which is considerably and unnecessarily adding to the ‘pharmaceuticals in the environment’ problem. Redesigning existing pharmaceutical take-back schemes and their regulation is a potential step towards improvement of the problem. Interdisciplinary research between the fields of psychology, law, public health and medical science is necessary to tackle the issue and to design effective regulation steering responsible patients’ behaviour.

I. Introduction

Securing global public health is listed as goal number three of the UN Sustainability Goals. During the last few decades, innovation in the pharmaceutical sector has been astounding,¹ successfully fighting illnesses so far considered fatal and improving living conditions of people facing short- and long-term medical conditions. Now, in the midst of the COVID-19 pandemic, we turn our eyes towards the pharmaceutical sector in hope of quick treatment development. Access to treatment has also been improving, although still facing multiple barriers, especially in developing countries. While celebrating these advances, we have been shutting our eyes to a threat: What happens when pharmaceuticals enter the environment as waste through their production, use, and disposal? This concern has been lingering above our heads since the 1960s,² but has not sparked enough interest to initiate substantial action. Regulators have mostly reacted by imposing mandatory environmental impact assessments during pharmaceutical marketing authorization procedures. However, in many jurisdictions (including the European Union), in the case of pharmaceuticals for human use, even a negative assessment does not prevent marketing authorization. In other words, ensuring access to treatment for human population remains the major concern and society may be willing to take larger risks in respect to medicinal products than other chemicals, making pharmaceutical waste a challenging issue to tackle.

With growing scientific evidence on the detrimental effects of pharmaceutical residues in the environment on other species and ecosystems, such as feminization of fish or near extinction of certain species,³ the possible effects on humans have come to the centre of attention of scientists

¹ Klaus Kümmerer, ‘Pharmaceuticals in the Environment’ (2010) 35 *Annu Rev Environ Resour* 57.

² Rachel Carson, *Silent Spring* (Houghton Mifflin 1962).

³ D. G. Joakim Larsson et al., ‘Ethinyloestradiol—an undesired fish contraceptive?’ (1999) 45(2) *Aquat Toxicol* 91; Rhys E. Green, ‘Diclofenac poisoning as a cause of vulture population declines across the Indian subcontinent’ (2004) 41(5) *J Appl Ecol* 793.

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and regulators alike.⁴ The rise of anti-microbial resistance is of special concern.⁵ However, regulatory action lags behind intentions.

Pharmaceuticals enter the environment through production processes, patient use, and disposal of unused and expired medicines. We focus on the last route regarding pharmaceuticals for human use and their disposal in households. While acknowledging that industrial and veterinary processes as well as pharmaceutical waste disposal by health professionals pose similar threats, they pose different social and regulatory challenges. We thus refer to household pharmaceutical waste as consumer medications leftovers, i.e. unused and/or expired pharmaceuticals accumulated in households.⁶ Household pharmaceutical waste is often disposed of through municipal waste or sewage systems. Such improper disposal leads to pharmaceuticals entering the environment, especially water and soil.

The aim of this report is to redirect the discourse on the ‘pharmaceuticals in the environment’ problem from natural science area to patients’ behaviour in respect to household pharmaceutical waste. We propose redesigning current inefficient regulations on take-back schemes connected with possible introduction of pharmaceuticals’ redispensing. We base our suggestions on the results of research into patients’ behavioural patterns regarding pharmaceutical waste management.

II. Context

The problem of household pharmaceutical waste is most urgent in developed countries, with the USA and Europe leading the pack, being responsible for about two thirds of global pharmaceutical sales. Regulators in this part of the world address some of the sub-optimal decisions when dispensing medicines on the individual and institutional level that lead to unnecessary discard⁷ through regulating the dispensed amounts (especially after hospitalization) or the pharmaceutical packaging size. Yet and surprisingly, there has only been limited inquiry into patients’ and consumers’ attitudes to proper disposal of household pharmaceutical waste, i.e. after they acquired and used the medication. The available evidence shows that a legal framework, lack of information, and perceived inconvenience of take-back schemes are the primary influences of patients’ behaviour.⁸ However, other factors such as individuals’ demographics and mind-set (values, attitudes, motivations, and emotions) have not been systematically investigated, despite the fact that studies on other types of waste suggest these factors to be potentially important.⁹ Patients’ or consumers’ decisions on the disposal route for pharmaceuticals thus often represent a trade-off between environmental protection and convenience.

⁴ E. Spencer Williams et al., ‘Human health risk assessment for pharmaceuticals in the environment’ in Bryan W. Brooks and Duane Huggett (eds), *Human Pharmaceuticals in the Environment* (Springer 2012); European Commission, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, European Union Strategic Approach to Pharmaceuticals in the Environment, COM/2019/128 final, 11 March 2019.

⁵ Naomi Lubick, ‘Dumped drugs lead to resistant microbes (2011) *Nature News*, published online 16 February 2011.

⁶ Christian G. Daughton, *Drugs and the Environment: Stewardship & Sustainability* (U.S. Environmental Protection Agency, EPA/600/R-10/106, 2010).

⁷ OECD, *Tackling Wasteful Spending on Health* (OECD Publishing 2017) 163.

⁸ Alfred Y. C. Tong, Barrie M. Peake and Rhiannon Braund, ‘Disposal practices for unused medications around the world’ (2011) 37(1) *Environ Int* 292.

⁹ Jessica Aschemann-Witzel, ‘Waste not, want not, emit less’ (2016) 352(6284) *Science* 408.

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It seems unrealistic to expect that the production and use of medicines and consequently the production of household pharmaceutical waste would decrease considering both positive and negative features of the globalized society. On the positive side, while the global population is growing and aging, new treatments are constantly being developed and access to (cheaper) medicines improved. On the negative side, we face current and future pandemics and even without them fight with medicines' overuse and over-prescription.¹⁰ Considering remaining gaps in scientific evidence on the harmful effects of pharmaceuticals in the environment on human health, especially in respect to mixture toxicity and long-term low levels exposure,¹¹ as well as the strength of the pharmaceutical lobby, taking more precautionary action by regulators does not seem feasible.

III. Suggestion

What seems feasible is to better manage household pharmaceutical waste. For example, it is a legal requirement that EU's member states implement appropriate collection systems (take-back schemes) for pharmaceutical products that are unused or have expired.¹² However, the EU does not provide any guidelines on the implementation of these schemes. The vagueness of the legal text and the lack of proper guidelines have contributed to the absence of the introduction of such collection systems in some Member States, significant differences among the current collection systems in the Member States where they exist, and overall a lack of their effectiveness. It is reported that 50% of unused medicines in the EU are disposed of improperly, representing between 5% (Sweden) and 50% (France, UK) of all sold medicines on national markets.¹³ To put these amounts in a financial context, the unused and discarded medicines in the UK amount yearly to about 375 million €. ¹⁴ This amount is literally frittered away.

Given the complex problem of household pharmaceutical waste and finding a balance between health and environmental issues, reducing household pharmaceutical waste is something we can and should strive for. Improving the malfunctioning take-back schemes or introducing new ones is one path to achieve this objective. This is in consonance with the new Strategic Approach to Pharmaceuticals in the Environment of the EU (2019), which recommends to: "assess the implementation of collection schemes for unused pharmaceuticals and consider how their availability and functioning could be improved, how to increase public awareness of the importance of using them, and how extended producer responsibility could play a role in reducing inappropriate disposal."¹⁵

We propose that when (re-)designing the take-back schemes, attention should be paid to reframing the household pharmaceutical waste problem: for example, from framing it as an environmental

¹⁰ Kümmerer, *supra*, note 1.

¹¹ Alistair B. A. Boxall et al., 'Pharmaceuticals and personal care products in the environment: what are the big questions?' (2012) 120(9) *Environ Health Perspect* 1221.

¹² Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] OJ L311/67, art 127b.

¹³ BIO Intelligence Service (BIOIS), Study on the environmental risks of medicinal products (Final Report prepared for Executive Agency for Health and Consumers 2013)

<https://ec.europa.eu/health/sites/health/files/files/environment/study_environment.pdf> accessed 26 March 2020.

¹⁴ Paul Trueman et al., *Evaluation of the Scale, Causes and Costs of Waste Medicines* (YHEC/School of Pharmacy 2010) <http://discovery.ucl.ac.uk/1350234/1/Evaluation_of_NHS_Medicines_Waste_web_publication_version.pdf> accessed 26 March 2020.

¹⁵ European Commission, *supra*, note 4.

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issue (bigger problem, further away from an individual, harder to be perceived and to be dealt with) to a personal health issue (smaller, but personally-felt problem)¹⁶ or as an in-group intervention.¹⁷ Furthermore, when we consult psychology and behavioural science, we identify other possible improvements that should inform the regulatory process. For example, governments can provide a supportive context, by adopting legislation on more user-friendly labels and packaging of medicines and regulating direct-to-consumer marketing practices. Producers can help with innovative product and packaging solutions to allow for easy withdrawal of small amounts while the rest remains usable. Retailers can be proactive, by reminding patients and consumers, and making them commit to return pharmaceuticals to be disposed.¹⁸ Similarly, campaigners and NGOs can trigger consumers' interest and action.¹⁹

Household pharmaceutical waste reduction has not been in the centre of attention. Awareness raising campaigns are rare. We believe that we should encourage patients and consumers to become aware of the extent and consequences of pharmaceutical waste and how small changes in habits may help tackle the problem. However, information alone does not necessarily change behaviour.²⁰ Therefore, steering behavioural changes, for example through choice architecture, could prove helpful. We do have evidence from other strategies on waste (for example, e-waste or food waste) that consumers may be responsive to perceived behavioural control,²¹ recycling convenience,²² and the possibility of surplus' redistribution.²³ Such strategies should be (experimentally) tested for usability and effectiveness also in respect to household pharmaceutical waste.

Besides focusing on take-back schemes, waste creation could be avoided by reusing of pharmaceuticals. So far, redispensing of returned medicines is not allowed due to concerns regarding biochemical integrity. For example, improper storage by a patient may degrade the active ingredient. This concern can be tackled by increasing safe-keeping of household medications and the on-time return of the pharmaceuticals to be reused. Still, we must be careful not to trade the increased societal focus on household pharmaceutical waste avoidance for dismissing legitimate pharmaceutical safety concerns by patients. There is a fragile balance between health, moral, legal, economic, and public acceptance issues, and thus all pharmaceutical policy goals should be aligned.

¹⁶ Leila Scannell and Robert Gifford, 'Personally relevant climate change: The role of place attachment and local versus global message framing in engagement' (2013) 45(1) *Environ Behav* 60.

¹⁷ Ezra M. Markowitz and Azim F. Shariff, 'Climate change and moral judgement' (2012) 2(4) *Nat Clim Chang* 243.

¹⁸ Anne Marike Lokhorst et al., 'Commitment and behavior change: A meta-analysis and critical review of commitment-making strategies in environmental research' (2013) 45(1) *Environ Behav* 3.

¹⁹ Christine Vatovec, Emily Van Wagoner and Corey Evans, 'Investigating sources of pharmaceutical pollution: Survey of over-the-counter and prescription medication purchasing, use, and disposal practices among university students' (2017) 198 *J Environ Manage* 348.

²⁰ Elke Weber, 'Experience-Based and Description-Based Perceptions of Long-Term Risk: Why Global Warming does not Scare us (Yet)' (2006) 77(1) *Clim Change* 103.

²¹ Sebastien Lizin, Miet Van Dael and Steven Van Passelab, 'Battery pack recycling: Behavior change interventions derived from an integrative theory of planned behavior study' (2017) 122 *Resour Conserv Recycl* 66.

²² Jean-Daniel M. Saphores, Oladele A. Ogunseitan and Andrew A. Shapiro, 'Willingness to engage in a pro environmental behavior: An analysis of e-waste recycling based on a national survey of U.S. households' (2012) 60 *Resour Conserv Recycl* 49.

²³ Aschemann-Witzel, *supra*, note 9.

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IV. Conclusion

Better management of household pharmaceutical waste is a step that can be taken immediately without waiting for conclusive scientific evidence on the detrimental effects of pharmaceuticals in the environment on human health. Moreover, it is a step that most stakeholders – including the pharmaceutical industry and citizens – will likely agree upon. The challenge is to overcome biases, decades of bad habits, and inflexible regulations, and to align individual incentives with societal ones and support them with adequate policy and regulation. In doing that, we must bear in mind that household pharmaceutical waste cannot be treated only as a side-effect of (over-)consumption, but also (and mainly) as a side-effect of the privilege of broad access to patients' treatment. We call for more interdisciplinary research, from the fields of public health, psychology, law, and medical science, to successfully face the problem and inform the policy-makers.