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THE CLASH OF THE TITANS: THE RELATION BETWEEN THE EUROPEAN WATER AND MEDICINES LEGISLATION

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1. Introduction

There are thousands of European directives and regulations, but general rules on precedence are lacking. It should therefore not come as a surprise that clashes occur. It is difficult to prevent clashes, because each of the objectives of the EU, whether it concerns a high level of protection of the environment or the free movement of goods or capital, has an equal ranking.[1] The question therefore is how clashes can be resolved. The focus of this article is on the clash between internal market and environmental legislation: specifically, the clash between medicines and water regulation. The regulatory challenge that lies at the basis of this clash is the integration of environmental concerns into internal market legislation.[2] In the case at hand, the challenge is to limit water pollution caused by the use of medicines which benefit from free movement on the internal market.[3] This detailed case study offers valuable insights into the role of regulation and governance techniques in reconciling regulatory challenges under EU law, in particular in the context of environmental law and internal market law. First, the European legal regime concerning water quality and the European legal regime of medicines, including their environmental impact assessment, will be analysed. Then a closer look at this and other clashes will be taken. Finally, in so far as it appears that the current legal framework

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1. Dhondt, *Integration of Environmental Protection into other EC Policies. Theory and Practice*, (Europa Law Publishing, 2003).

2. See on the integration of environmental concerns into other policies, such as the CAP, Dhondt, op. cit. previous footnote and, more recently, concerning fisheries, Wakefield, "Fisheries: A failure of values", (2009) CML Rev., 431–470.

3. Medicines include both medicines for human use and veterinary medicines. Veterinary medicines may also be used and authorized as feed additives, but the risks posed by these feed additives will not be extensively addressed in this article, because many medicines that were administered as feed additives are being phased out. The deadline for the last antibiotics thus administered is set in 2012.

does not sufficiently address water pollution caused by medicines, the question will be addressed whether governance instruments or amendments of European water and product legislation may improve the protection of the environment and public health without hindering the free movement of authorized medicines. The solutions that will be proposed combine a governance approach with regulation.

Before delving into the legal details of this case study, the environmental problem that lies at its basis deserves some scrutiny. What is all the fuss about? Traces of commonly used medicines, such as birth control pills, tranquillizers, antibiotics, pain relievers and anti-depressants can be found in the European aquatic environment and in drinking water.[4] Concentrations in surface water depend on consumption in the area, the metabolism of the medicine in the body of the patient, excretion, removal of the medicine through waste water treatment, volume of the waterbody and the degradation and adsorption in the environment.[5] Measurements between 2002 and 2008 in the Rhine at Lobith revealed that tons of carbamazepine, diclofenac, and pentoxifylline pass there each year.[6] At a single moment, the concentrations of these medicines are tiny, as they are measured in parts per million, far below the levels of a therapeutic dose, even when consumed for years.[7] Nevertheless, the risks of this involuntary consumption of medicines for aquatic life and human health are unknown.[8]

Since medicines are developed to have effect at very low concentrations, the low concentrations that are frequently found in surface water may already pose a threat to the ecology.[9] They may be toxic for fish, frogs and other aquatic species or affect their reproductive systems. Potential human risks identified are the development of allergies, genotoxicity and the transfer of resistance

4. Fent, Weston and Caminada, "Ecotoxicology of human pharmaceuticals", (2006) *Aquatic Toxicology*, 122–159.

5. Halling-Sorensen, Nielsen, Lanzky, Ingerslev, Lutzhoft and Jorgensen, "Occurrence, fate and effects of pharmaceutical substances in the environment – A review", 36 *Chemosphere* (1998), 357–394.

6. Houtman, Van der Aa and ter Laak, "Relatie tussen gebruik geneesmiddelen in Rijnstroomgebied en concentraties in de Rijn", (2010) *H2O*, 33.

7. Versteegh, Van der Aa, Dijkman, *Geneesmiddelen in drinkwater en drinkwaterbronnen*, (2007) RIVM report 703719016/2007. (RIVM is the Dutch National Institute for Public Health and the Environment) Available at <www.rivm.nl>

8. Fent, Weston and Caminada, op. cit. *supra* note 4. See on knowledge gaps and future research needs, Daughton, "PPCPs in the Environment: Future Research – Beginning with the end always in mind", in Kummerer (Ed.), *Pharmaceuticals in the Environment*, 2nd ed (Springer, 2004), pp. 463–495.

9. Halling-Sorensen et al. op. cit. *supra* note 5; Johnson, Jurgens, Williams, Kummerer, Kortenkamp and Sumpter, "Do cyotoxic chemotherapy drugs discharged into rivers pose a risk to the environment and human health? An overview and UK case study", (2008) *Journal of Hydrology,*167–175.

genes, for instance antibiotic resistance genes.[10] In the midst of uncertainty about the risks posed by medicines, it is likely that their presence will increase due to the ageing European society if no action is taken. Despite the absence of certainty about the environmental risks of the use of medicines, European action is warranted because European law regulates the presence of medicines on the internal market and sets the agenda for water management. The precautionary principle, the principle that pollution needs to be rectified at the source and the integration principle encourage finding a regulatory approach that minimizes the presence of medicines in water, especially in drinking water.[11]

2. European water legislation

The European water legislation is one of the oldest areas of European environmental law. It used to consist of many different water directives for each type of water, from fishing water to bathing water. Their main function was to impose environmental quality standards and regulation of discharges through prohibitions and emission limit values. The fragmentary outlook of water law changed when the Water Framework Directive (WFD) entered into effect.[12] Its ultimate objective is to achieve a good status of all European waters, preferably by 2015. This includes good ecological and good chemical status of all surface waters.[13] This objective is further elaborated in several environmental quality standards. These environmental quality standards are either set at the European level, in the Annexes to the Priority Substances Directive and the Groundwater Directive (daughter Directives of the WFD), or at the national level.[14]

10. Van Vlaardingen and Montforts, *Geneesmiddelen in het milieu. Twee verkennende studies samengevat*, (1999) RIVM report 734301017/1999.

11. Cf. Dhondt, op. cit. *supra* note 1..

12. Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy (WFD), OJ 2000 L 327/1. See e.g. Van Rijswick, "EC Water Law in Transition: The challenge of integration", in Somsen et al. (Eds), (2003) *Yearbook of European Environmental Law*, pp. 249–304; Lee, "Law and Governance of Water Protection Policy", in Scott (Ed.), *Environmental Protection: European Law and Governance* (OUP, 2009) pp. 27–55.

13. See Howarth, "The progression towards ecological quality standards", (2006) *Journal of Environmental Law*, 3–35.

14. Directive 2008/105/EC of the European Parliament and of the Council of 16 Dec. 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/167/EEC, 83/153/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, OJ 2006 L 64/52 and Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration, O.J. 2008, L 348/84.

2.1. *Environmental quality standards*

The criteria that determine the placing of a substance on the Annexes to European Water Directives are related to the hazardous characteristics of these substances. The WFD prescribes that a European environmental quality standard for a substance should be formulated if a risk assessment reveals that it poses significant risk to the aquatic environment or to human health via aquatic exposure. This risk assessment is based on (1) evidence regarding the intrinsic hazard of the substance concerned, and, in particular, its aquatic ecotoxicity and human toxicity via aquatic exposure, (2) evidence from monitoring of widespread environmental contamination, and (3) other proven factors which may indicate the possibility of widespread environmental contamination, such as production, use volume and use pattern of the substance concerned.[15] European environmental quality standards do not necessarily include all substances which are used in medicines or their metabolites. Substances that are used in pesticides or biocides as well may be covered on that ground, but other substances may escape attention.

The absence of medicine-related environmental quality standards can be explained by two factors. First of all, it is left to the Member States to set environmental quality standards for less dangerous substances which only affect the ecological status. Secondly, monitoring data are lacking for many substances. It is not easy to obtain monitoring data because the Member States are not obliged to monitor substances which are not listed in the Annex to the Water Framework Directive and its daughter directives, in particular the Priority Substance Directive and Groundwater Directive.[16] Yet without alarming monitoring data, it is not likely that a European environmental quality standard would be set for substances which meet the criteria for placement on the Annex to the Priority Substances Directive or the Groundwater Directive. This could result in the absence of environmental quality standards, but the Water Directives oblige the Member States to carry out regular monitoring of water bodies and set national quality standards and threshold values for substances whose local presence threatens the achievement of the good ecological status of a water body. Therefore national quality standards should be set for medicinal substances which pose a threat to the ecology.[17] In the absence of adequate national standards, the presence of medicinal substances in water may not be

15. Art. 16 (2) WFD.

16. Cf. Montforts, Van Rijswick, Freriks, Keessen and Wuijts, *The relationship between product registration and water quality legislation, medicines, veterinary medicines and feed additives*, (in Dutch, English summary) (2006) RIVM Report 601500003/2006.

17. Art. 3 Directive 2006/118 and Art. 3 Directive 2006/11.

monitored and/or the waste water treatment may not be adequate to remove these substances.

2.2. *Instruments to tackle water pollution*

The WFD prescribes taking a combined approach to handle point source and diffuse source pollution in order to attain environmental quality standards.[18] This combined approach consists of (a) emission control measures, (b) environmental quality standards or (c) in case of diffuse effects, control measures, including best environmental practices, if applicable.[19] This combined approach is further elaborated in Article 11 WFD. Depending on the substance, the Member States should regulate point source pollution either by a prohibition to discharge or by emission standards imposed by general rules or a permit. They should regulate diffuse source pollution through measures aiming at the prevention or control of the introduction of polluting substances. These measures may take the form of a prohibition to discharge a certain substance, a consent or a registration on the basis of general rules, if European law does not already provide for this.

Permits are generally considered to be an apt instrument for combating point source pollution.[20] Permits can be used to oblige hospitals, airports and municipal waste water treatment facilities to use a waste water treatment method which eliminates traces of medicines from their waste water. A similar approach is difficult to envisage concerning veterinary medicines, as they mainly disappear into the environment via manure and urine. This constitutes non point source pollution, or diffuse pollution, and is notoriously more difficult to control. It is difficult to enforce permit conditions in the absence of data pinpointing the source and quantity of the pollution. Instead, it seems more appropriate to regulate diffuse pollution through plans and programmes of measures. According to Article 11(3)(h) WFD, one of the measures that could be taken is the prevention or restriction of the introduction of dangerous substances. This provision might be used as the missing link between water legislation and product legislation, as it hints towards taking environmental quality standards into account in the authorization and evaluation procedure of products.[21]

18. The difference between point source pollution and diffuse pollution is whether the discharge comes from a single source, e.g. a factory, or from many different sources, e.g. runoff from agricultural areas.

19. Art. 10 WFD.

20. E.g. Case C-231/97, *Van Rooij,* [1999] ECR I-6355; Case C-232/97 *Nederhoff en Zn,* [1999] ECR I-6385.

21. As occurs in the regulation of plant protection products and biocides. See Van Rijswick and Vogelezang-Stoute, 'The Water Framework Directive and pesticides legislation. The influ-

However, that is unlikely, since medicines are authorized through a completely harmonized European system (see below) and therefore a Member State cannot use this provision to prevent placing certain medicines on its market.[22] Instead, this provision can be used to justify the imposition of additional waste water treatment obligations concerning medicines on waste water treatment facilities or to justify the establishment of safeguard zones around bodies of water, where spreading manure which may contain medicines is prohibited.[23]

2.3. *Failure to achieve the environmental quality standards*

It is not certain what the legal consequences are if water pollution with medicines were to cause a failure to achieve the good chemical or good ecological status objective of the WFD. Since the WFD is a new Directive, the legal meaning of most of its provisions is not yet underpinned by a firm body of ECJ case law. It follows from the Court ruling in *Commission* v. *Luxembourg* that the Member States have to transpose the environmental goals of Article 4 WFD into binding statutory provisions.[24] That points in the direction that these goals are obligations of result rather than obligations of best efforts. Most Member States take the approach that the limits imposed by the specific quality standards may not be exceeded.[25] This is in line with the definition of environmental quality standards – a concentration which should not be exceeded – in the WFD[26] and with the status given to environmental quality standards under older European water Directives in the case law of the ECJ.[27] The ECJ has held that compliance with environmental quality standards must be regarded as an obligation of result and that if compliance is not attainable by means of legal measures such as permits, then additional measures have to be taken.[28] It is likely that this case law is still valid today, as the level of

ence of environmental quality standards and the river basin approach taken in the Water Framework Directive on the authorization of plant protection products', (2008) *European Energy and Environmental Law Review*, 78–89.

22. Cf Joined cases C-211/03, C-299/03 and C-316-319/03, *HLH Warenvertriebs Orthica* v. *Deutschland,* [2005] ECR I-5141 and Case T-70/99, *Alpharma* v. *Council* [2002] ECR II-3945.

23. As stated in several cases, e.g. Case C-142/05 *Mickelson and Roos*, [2009] ECR I-4293 (and see Horsley op. cit. *infra* note 91, for comments on these cases), national rules on use fall within the ambit of Art 34 TFEU (ex 28 EC), but can be justified under Art. 36 TFEU (ex 30 EC).

24. Case C-32/05 *Commission* v. *Luxembourg* [2006] ECR I-11323.

25. See Keessen et al. "European River Basin Districts: Are They Swimming in the Same Implementation Pool?", *Journal of Environmental Law*, forthcoming, and Uitenboogaart et al, *Dealing with Complexity and Policy Discretion. A Comparison of the Implementation Process of the European Water Framework Directive in Five Member States*, (SDU, 2009).

26. Art. 2 (35) WFD.

27. See Van Rijswick, op. cit. *supra* note 12.

28. E.g. Case C-121/03 *Commission v. Spain* [2005] ECR I-7569, Case C-268/00 *Commission* v. *the Netherlands* [2002] ECR I-2995, Case C-316/00 *Commission* v. *Ireland* [2002] ECR

protection of the quality of water should not deteriorate as a consequence of the replacement of the old water directives with the WFD.[29]

If it becomes apparent from data of the regular and representative monitoring of the water quality (as reported to the Commission) that environmental quality standards are being exceeded, the WFD prescribes the desired course of action. First an investigation into the causes of the pollution should take place, and then the Member States should take appropriate measures so that the objectives and standards are met.[30] If the monitoring data reveal that the standards are exceeded due to illegal use of medicines which are not authorized, then it goes without saying that the Member States should intensify enforcement. It is more problematic if the monitoring data reveal that the standards are exceeded due to use of authorized medicines, because the water authorities do not have the instruments to act upon these threats. The authorization of these products and their conditions of use are not within their competence and in the absence of regulation on the use of medicines, they cannot impose measures to reduce emissions.

2.4. *Exemptions*

Instead of trying to achieve compliance with environmental quality standards, a Member State can also invoke the exemptions offered by Article 4 WFD. A Member State may first of all invoke delay in case of water pollution caused by medicines, if problems can be solved by taking measures that will take effect later on. For instance, building a specific waste water treatment plant or using another waste water treatment method that significantly reduces pollution caused by medicines at airports or hospitals requires investments, the construction will take time and therefore results may not be expected before 2015, when the WFD deadline for achieving good status expires. Second, a Member State might invoke *force majeure* as an exemption for not achieving good chemical status: both because the authorization of medicines took place in accordance with European law without considering their effect on water quality, and because the water pollution by medicines may originate from other Member States or third countries. A Member State should then also notify the Commission that Community action – e.g. adaptation of the European medicines legislation – is required in order to enable it to meet the objectives of the WFD.[31]

I-10527, Case C-266/99 *Commission* v. *France,* [2001] ECR I-1981, Case C-198/97, *Commission* v. *Germany* [1999] ECR I-3257.. See Van Rijswick, "De betekenis en vormgeving van waterkwaliteitseisen", (2007) *Milieu & Recht*, 395–407.

29. Rec. 51 Preamble to Directive 2000/60.
30. Art 11 (5) WFD.
31. Art. 12 WFD.

A third exemption that can be invoked is setting lower objectives for water bodies, provided that the conditions for invocation of this exemption are met. First, it should be impossible or unreasonably expensive to curb pollution caused by medicines. Second, there should be no environmentally friendly alternative to the medicines in use and an increase in the pollution should be prevented. Perhaps setting lower goals may not be possible in case the environmental quality standards are exceeded in a water body used for the abstraction of drinking water, if the WFD indeed determines that its standards must be met in these water bodies.[32] A different course of action will be taken if pollution is caused by medicines containing substances that are not regulated under European water legislation. In that case, their presence in water, including drinking water, cannot result in not meeting European standards.[33] Action is then only required if national standards are exceeded or if pollution threatens the achievement of the good ecological status.

3. European medicines legislation

The European medicines legislation completely harmonizes the regulation of the placing of medicines on the internal market. It provides for authorization procedures, to establish the quality, effectiveness and safety of a medicine, and for a pharmacovigilance system to evaluate these aspects once medicines are on the market and being used.[34] A marketing authorization is required before a medicine can enter the market of an EU Member State. Either a national competent authority issues an authorization decision for its territory (the so-called decentralized procedure) or the Commission issues an authorization decision for the entire European territory on the basis of the advice of the European Medicines Agency (EMA, formerly called EMEA) (the so-called centralized procedure) without any further implementing acts by the Member

32. Art. 4, 6 and 7 WFD. See Keessen and Van Rijswick, "Drinkwaterwinning in een Natura 2000 gebied: het juridische regime voor beschermde gebieden", (2008) *Milieu & Recht*, 557–566 and Veltman, "Reactie op drinkwaterwinning in een Natura 2000 gebied: het juridische regime voor beschermde gebieden", (2009) *Milieu & Recht*, 151–153.

33. The European standards for the product drinking water (after treatment) are set in Council Directive 98/83 on the quality of water intended for human consumption, O.J. 1998, L 330/32.

34. Regulation 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, O.J. 2004, L 136/1; Directive 2001/83 of the European Parliament and of the Council on the Community code relating to medicinal products for human use, O.J. 2001, L 311/67; and Directive 2001/82 of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, O.J. 2001 L 82/1.

States required.[35] When a Member State issues a marketing authorization, other Member States can use the mutual recognition procedure. The mutual recognition procedure is streamlined to the extent that when a medicine is authorized by one Member State, another Member State can authorize the medicine without any further scrutiny.[36] However, under strict conditions and for a limited number of reasons, recognition can also be refused. Non-recognition is followed by a dispute settlement procedure, in which EMA is involved as well. This procedure results in a binding Commission or Council decision, which is then implemented by the Member States involved.[37]

New applications for marketing authorizations have to include an environmental assessment.[38] This assessment has the potential of preventing or limiting the impact of medicines on water quality. It always includes the estimated concentration of excreted substances in surface water and groundwater and biodegradability. These results may warrant further investigation into issues such as fish toxicity, acute and reproductive toxicity in *Daphnia* (a test species) and tests with mysterious names, like "activated sludge respiration inhibition".[39] The question is whether the potential of the environmental assessment is realized. In other words, what is the function of the environmental assessment? Can it be used to justify non-recognition or refusal to issue a marketing authorization? If not, what purpose does the environmental assessment have if it cannot lead to refusal of an authorization? The applicable rules differ insofar as a medicine is used for humans or for animals. Therefore, the applicable rules on the environmental assessment and its value in the decision-making procedure will be analysed separately, while the effect of environmental

35. Art. 6 Directive 2001/83/EC. The decentralized or mutual recognition procedure, established by Directive 2001/83 and Directive 2001/82, applies to most medicines. The centralized procedure, established by Regulation 726/2004, applies to biotechnology medicines and other high tech, innovative medicines. See for an overview of the functioning of these and the other two regulatory procedures (single licence and national decisions), Keessen, *European Administrative Decisions. How the EU regulates products on the internal market*, (Europa Law Publishing, 2009).

36. Directive 2001/83; Notice to the Applicants Vol. 2A Chapter 1, p.2.

37. See Keessen, op. cit. *supra* note 35.

38. Art. 8(3) and 10 Directive 2001/83, Art. 12 (3) and 13 Directive 2001/82, Art. 6 and 31Regulation 726/2004.

39. See for an example <www.ema.europa.eu/humandocs/PDFs/EPAR/votrient/H-1141-en6.pdf> It is argued that the environmental assessment could be improved. These improvements include chronic effect testing as a general approach, the use of invertebrate tests including sexual reproduction, the application of endpoints reflecting the mode of action of the medicine or known side effects and the simulation of more realistic exposure conditions in terrestrial laboratory tests. See Schmitt, Boucard, Garric, Jensen, Parrot, Péry, Römbke, Straub, Hutchinson, Sánchez-Argüello, Wennmalm and Duis, 'Recommendations on the Environmental Risk Assessment of Pharmaceuticals: Effect Characterization', (2009) *Integrated Environmental Assessment and Management*, 588–602.

risk management measures and the access to this information are discussed together.

3.1. *Environmental assessment of medicines for human use*

The original versions of Directive 2001/83 and Regulation 726/2004 aimed to protect public health and the free movement of authorized medicines for human use. They were amended by Directive 2004/27/EC, which introduced environmental rules, without however including protection of the environment as an aim of the medicines legislation or establishing a link with other European environmental legislation.[40] From then on, it has been recognized that a medicine can have undesirable effects on the environment.[41] However, it is not clear when effects on the environment are considered undesirable. Yet the simple acknowledgment of a risk has led to the imposition of duties on the applicant. Applications for medicines have to include an evaluation of the risks which the medicine potentially poses to the environment due to use, storage or disposal.[42] Irrespective of the outcome of this assessment, the risk is not weighed in the risk-benefit balance that determines whether the medicine is authorized or not. This is because the risk for the environment may not constitute a criterion for refusal of a marketing authorization.[43] Apparently, the environmental assessment was only introduced in order to know the environmental risks and to propose measures to mitigate the consequences for the environment of the use, storage or disposal of the medicine.[44]

Directive 2004/27 does not contain any provisions concerning the transitional period during which medicines are on the market without an environmental assessment or environmental information on the label or the leaflet. It had to be transposed by 30 October 2005. This means that from that day onward, all applications for medicines have had to include an environmental assessment.[45] It also means that an environmental assessment does not have to be undertaken for medicines that were already on the market on 30 October

40. This omission runs counter to the trend to include environmental protection as an objective of product regulation, e.g. Regulation 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation) O.J. 2006, L396/1.

41. Art. 1(28) Directive 2001/83.

42. Art. 8(ca) and Annex I Directive 2001/83. This is further elaborated in Guidance Document at <www.ema.europa.eu/pdfs/human/swp/444700en.pdf> and for genetically modified medicines in Guidance document <www.ema.eu.int/pdfs/human/bwp/13514804en.pdf> According to the Guidance documents, this obligation may also apply to variations or extensions.

43. As follows from Directive 2001/83 and the Guidance documents (see footnotes above).

44. Art. 8(ca) and 8(3) (g) Directive 2001/83.

45. This may also apply to applications for variations (e.g. a new indication) or extensions.

2005. Such an obligation can only be introduced by a provision with retroactive effect. However, the question is: what should be done with applications filed for generic medicines, i.e. medicines which are comparable with already authorized medicines concerning their quality, effectiveness and safety? In general, these medicines are authorized in accordance with a simplified procedure under which it is sufficient to refer to the research already done for a comparable medicine, which prevents a repetition of all these tests.[46] However, if an environmental assessment is lacking, there is no research to which can be referred. This may mean that environmental assessments have to be done in the course of the simplified procedure. To further complicate matters, even when an environmental assessment has been made, it may have to be repeated for the application of a generic, because it is not explicitly included in the list of information to which others may refer under the simplified authorization procedure.

3.2. *Environmental assessment of veterinary medicines*

While the authorization procedure for veterinary medicines under Directive 2001/82 and Regulation 726/2004 is similar to the authorization procedure for medicines for human use, the environmental assessment has a different place in the decision-making process. Similar to what has been stated above in the context of regulation of medicines for human use, applications should contain an environmental assessment and indicate the risks for the environment from the use, storage and disposal of the medicine. Annex I to Directive 2001/82, which also applies to authorization procedures under Regulation 726/2004, and Guidance documents further elaborate the environmental assessment, which was introduced by Directive 2004/28.[47] The main purpose of the environmental assessment of veterinary medicines is to evaluate the potential risks for the environment and to recommend preventive measures.

The environmental assessment is important for the decision on authorization of the medicine, as the environmental risks are included as a factor in the risk-benefit balance. The dispute settlement procedure can therefore be used if a Member State raises concerns on the impact of use of the medicine on the environment in the course of the mutual recognition procedure.[48] The environmental risks do not explicitly constitute a ground for refusal, but they may nevertheless be the reason for refusal when the environmental risks are such

46. Arts. 10 and 8 Directive 2001/83.

47. Directive 2004/28 of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, O.J. 2004, L 311/1.

48. E.g. *Fenflor* case, see <www.emea.europa.eu/pdfs/vet/press/pr/26832009en.pdf>.

that the risk-benefit balance is considered to be unfavourable.[49] According to the Guidance Documents, a risk to the environment is potentially serious if it follows from the risk assessment itself or from the proposed risk management measures that the risk for the environment posed by the use, storage or disposal of the medicine cannot be sufficiently addressed.[50] Risk management measures are not limited to giving information on the label or the leaflet. They may also include restriction or prohibition of the use of the product concerned in a specific area. A Guidance document acknowledges that risk management measures concerning the use of the product can be contemplated during the authorization stage, but require action at the local level to be executed.[51]

3.3. *The environmental risk mitigation measures*

If the environmental assessment reveals that a medicine for human use posed serious environmental risks, the authorization is not refused because the environmental risk does not constitute a ground for refusal. A veterinary medicine may not obtain authorization in this situation. In general, it will be decided that the environmental risks of the use or disposal of medicines, be they for human or veterinary use, can be addressed by taking risk mitigation measures. The main risk mitigation measure is that information for users be placed on the label or the accompanying leaflet of medicines. It is assumed that this information will lead the user to act accordingly. However, the only binding obligation that can be imposed in the marketing authorization decision is that the authorization holder informs the user on the label or in the leaflet. In the absence of a provision to this effect in the medicines legislation, the user is not obliged to take measures in order to mitigate the impact on the environment of the use, storage or disposal of the medicine.[52] Therefore, it is not certain what the effect will be of such proposed environmental risk mitigation measures.[53] Other protective measures, for instance the obligation for hospitals to

49. Art. 30 Directive 2001/82.

50. Environmental Impact Assessment (EIAs) for veterinary medicinal products (VMPs) Phase 1 VICH GL6 (Ecotoxicity – Phase 1) and Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II, VICH GL38 (Ecotoxicity Phase II). VICH is a trilateral (EU-Japan-USA) programme aimed at harmonizing technical requirements for veterinary products.

51. CVMP, Guideline Environmental Impact Assessment for Veterinary Medicinal Products Phase II, 2004. CVMP is the Committee for Medicinal Products for Veterinary Use. It is part of the European Medicines Agency (EMA, formerly called EMEA).

52. Montforts, Van Rijswick and Udo de Haes, "Legal constraints in EU product labeling to mitigate the environmental risks of veterinary medicines at use", (2004) *Regulatory Toxicology and Pharmacology*, 327–335.

53. See previous footnote.

use a specific waste water treatment method, that a medicine may only be used during a hospital stay or a that a waiting time applies before spreading contaminated manure, are not foreseen by the European medicines legislation.

3.4. *Access to environmental information*

The medicines legislation provides for a general regime on access to information. When a medicine has been authorized for placing on the market, the competent authority has to make its assessment report and the grounds for authorization publicly available.[54] Since the environmental assessment is part of the tests that should be done before a medicine may be placed on the market, and the proposed risk mitigation measures are based on it, it seems logical that a summary of the environmental assessment has to be included in the assessment report. However, the environmental assessment results are not mentioned at all in the list of information that the authorities will make publicly available through publication of their assessment report.[55] This has created uncertainty as to whether environmental information needs to be made publicly available or not.[56] Consequently, this information is generally not placed in the assessment report that is made public.[57]

Access to the environmental data of a medicine falls within the scope of the general rules on access to environmental information. It follows from the Aarhus Convention, as implemented into EU law, that environmental information should in principle be publicly available, unless an exception is justified.[58] A relevant exception is that the environmental information about the medicine

54. Art. 25 Directive 2001/82; Art. 21 Directive 2001/83; Art 10(6) and 35(6) Regulation726/2004.

55. The absence of a transparency clause concerning environmental information of medicines renders it different from the transparency regimes concerning environmental information present in genetically modified organisms, plant protection products and biocides legislation. Consequently, case law such as Case C-552/07, *Commune de Sausheim* v. *Pierre Azelvandre* [2009]ECR I-0000, where the transparency regime of Directive 2001/18 supersedes the general environmental information transparency regime, does not apply to this situation.

56. Montforts and Keessen, *The public nature of environmental information acquired at the registration of (veterinary) medicines* (in Dutch, with English summary), (2007) RIVM report 601500006/2007.

57. See previous footnote.

58. The UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, done at Aarhus on 25 June 1998 (Aarhus Convention), available at: <www.unece.org/env/pp/welcome.html>; Directive 2003/4 of the European Parliament and of the Council on the access of the public to environmental information O.J. 2003, L 41/26 and Regulation 1367/2006 of the European Parliament and of the Council on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies, O.J. 2006, L 264/13.

is commercially sensitive.[59] The environmental assessment constitutes confidential information because it is carried out after the medicine has been patented, with the sole purpose of obtaining a marketing authorization. This research is not protected by intellectual property rights. In order to prevent competitors from using it for their applications, the medicines legislation states that applicants that want to refer to the data of an already authorized, essentially similar medicine can only do so eight years after authorization has been granted, unless the authorization holder has given his consent before expiry of this period.[60]

When the authorities consider that information might be commercially sensitive, an individual examination is required to appropriately balance the private right to commercial sensitivity against the public interest in access to the information.[61] Here it becomes relevant that similar results of other research done in order to get a marketing authorization are included in the assessment report. In view of the general rule that environmental information should be public and that exceptions should be interpreted narrowly,[62] it becomes obvious that the environmental assessment is comparable to the other tests that should be done before a medicine may be placed on the market and whose results are made public, and that therefore the results of the environmental assessment should be included in the assessment report that is made publicly available. The only difference is that there is not a provision on publication of the environmental assessment results.[63] That makes all the difference, because this is the reason that the results of the environmental assessment may not be published in the report, but only made available on request.[64] Consequently, while the European Medicine Authority publishes the results of the environmental assessment on its website, national medicines regulators may fail to do so as well.

59. Art. 4 Aarhus Convention, Art. 6 Reg.1367/2006 and Art. 4 Directive 2003/4.

60. Eight years is the average period. Under circumstances it can be longer. See: Art. 10 Directive 2001/83, Art. 13 Directive 2001/82 and Arts. 14(11) and 39(10) Regulation 726/2004.

61. See Adamski, "How wide is 'the widest possible'? Judicial interpretation of the exceptions to the right of access to official documents revisited", (2009) CML Rev., 521–549. Note that this article is on the general regime on access to information.

62. See de Abreu Ferreira, "The Fundamental Right of Access to Environmental Information in the EC: A Critical Analysis of WWF-EPO v. Council", (2007) *Journal of Environmental Law,* 1–10.

63. Montforts and Keessen, RIVM report cited *supra* note 56.

64. Ibid.

4. The clash between European legislative acts

European law does not provide for a ready-made solution to settle conflicts between European legislative acts. And despite all the rhetoric about integration of environmental concerns into other policies (Art. 11 TFEU, ex Art. 6 EC), the clash between the water and medicines legislation provides another example of how difficult this integration is.[65] There is no ranking between regulations and directives, with the exception of framework and daughter directives such as the Water Framework Directive and the Groundwater Directive.[66] Just like the objectives they pursue, they are in principle equal.[67] General references such as "This Directive applies without prejudice to ..." do not offer much guidance in cases like these. They are only useful to explain the relation between similar pieces of legislation,[68] unless of course both pieces of legislation contain this phrase.[69] More specific references are not necessarily present. If, as in our case, European legislative acts do not refer to each other, from the outset none prevails over the other. However, that does not absolve the Member States from being responsible for compliance with regulations and for achieving the results prescribed by directives (Art. 288 TFEU, ex Art. 249 EC and Art. 4(3) TEU, ex Art. 10 EC). Thus, a Member State where water pollution caused by medicines occurs, should find a solution to limit the pollution caused by the authorized medicines at a level in accordance with the environmental quality standards prescribed by the Priority Substances or Ground Water Directives for the achievement of good chemical status or prescribed by national law for the achievement of good ecological status.[70] The problem is that it has to do so while respecting the place of environmental concerns in the medicines regulation in view of the full harmonization brought about concerning the authorization of medicines in the EU.

The risk of medicines causing water pollution was recognized when in 2003 an environmental assessment was introduced in the European medicines legislation to understand and mitigate the environmental risks of medicines. At first sight, this environmental assessment seems perfectly in line with the

65. See on integration of environmental concerns into other policy fields, such as the CAP and the common transport policy Dhondt, op. cit. *supra* note 1.

66. Even in that case there is not a formal ranking, as daughter directives remain separate directives.

67. Dhondt, op. cit. *supra* note 1.

68. For instance Art. 2(2) of Directive 2002/96/EC of the European Parliament and the Council of 27 Jan. 2003 on waste electrical and electronic equipment (WEEE), O.J. 2003, L 37, states that it applies without prejudice to specific Community waste management legislation.

69. Beijen, *De kwaliteit van milieurichtlijnen. Europese wetgeving als oorzaak van implementatieproblemen* (Boom Juridische Uitgevers, 2010).

70. See above.

requirements of the integration principle. Yet it could be seen above that the environmental assessment has its limitations. First, environmental assessments are only mandatory for medicines that entered the market after 30 October 2005, when the environmental assessment was introduced. Second, the environmental information may remain with the medicines regulator, as the medicines legislation does not impose an obligation to make this information to be made public and consequently uncertainty persists about its commercial sensitivity. Third, the environmental information hardly plays a role in the authorization of medicines. The environmental risks are excluded from playing a role in the risk-benefit balance of medicines for human use, and in case of medicines for veterinary use they carry only a limited weight. The lack of coordination between the water and medicines regulation diminishes the usefulness of the environmental risk assessment of medicines and may place the achievement of good chemical or ecological water status at risk.[71]

4.1. *Obligation to take into account*

Inspiration on how to settle such conflicts can be drawn from various cases in which the Court of Justice had to find a solution. In the *Nederhoff* case, the Court settled a conflict between Directive 76/464 (the old Priority Substances Directive) and Directive 76/769 (the Biocides Directive).[72] The conflict arose when the Netherlands limited the placing of wooden posts treated with creosote in surface water, because intensive use would result in water pollution above the environmental quality standard limits of the Priority Substances Directive. Consequently, despite the status of creosote as an authorized biocide for use on wood, authorizations for use were only granted in the Netherlands if no alternatives were available. The ECJ declared that the Water Directive takes precedence over the Biocides Directive because the former protects water quality in particular, while the latter concerns the free movement of goods and the marketing of substances and products. Moreover, Article 1 of the Biocides Directive states that other Community law should be taken into account. Therefore, the Biocides Directive allowed for the imposition of stricter conditions in the Dutch authorization for use.

Such an obligation to take other EU legislation into account is lacking in the European medicines legislation. In the absence of specific provisions in the medicines legislation, it may not be possible to oblige the authorities to

71. Vos and Janssen, *Options for emission control in European legislation in response to the requirements of the Water Framework Directive*, (2005) RIVM report 601300003.

72. Case C-232/97, *Nederhoff en Zn* [1999] ECR I-6385. See Van Rijswick, op. cit. *supra* note 12 and Van Rijswick, *De kwaliteit van water* (Kluwer, 2001).

take action when the good status obligation or specific environmental quality standards are not met, as occurred in the *Nederhoff* case. Nor is it possible to oblige the medicines authorities to impose stricter environmental standards on the basis of an alternative legal framework. A quick fix in the form of application of the strict environmental requirements of the REACH Regulation is not available.[73] Even though medicines often contain chemicals as well, to which the requirements of REACH could be applied, the REACH Regulation explicitly excludes the substances used in medicines from its scope of application.[74]

4.2. *The Article 114 TFEU (ex 95 EC) exception*

Nevertheless, a recent case, the *Dutch diesel vehicle* case, suggests that environmental law can take precedence over internal market law.[75] It could well follow from this case that a Member State where the environmental quality limits are exceeded is allowed to invoke the Article 114 TFEU (ex 95 EC) derogation to enable it to impose more stringent environmental measures. While the CFI ruled this option out, the ECJ left this option open. It ruled that the Commission had not done its homework well when it simply refused approval for a national derogating provision under Article 95 EC (now Art. 114 TFEU). The Commission had not explained sufficiently well why it decided that the Netherlands had not demonstrated that there was a specific problem. The ECJ left in the middle whether it agreed with Advocate General Kokott that exceeding an environmental quality limit value is in itself a specific problem, instead of it being a general problem, as the Commission had suggested, when neighbouring Member States are confronted with the same problem.

In view of the uncertainty whether the water or the product legislation prevails, a Member State wishing to tackle water pollution caused by medicines may be tempted to simply impose stricter environmental rules through the national body of rules that implement the European regulation of medicines for human or veterinary use. Whether this is permissible depends on the content and the purpose of the European medicines legislation and of the various Treaty provisions that might be invoked as a justification for measures to protect the environment, in particular Article 36 TFEU (ex 30 EC) and Article 114 TFEU (ex 95 EC). In any event, Article 36 TFEU cannot be used as a justification, because the medicines legislation (based on Art. 114 TFEU)

73. REACH Regulation (1907/2006) cited *supra* note 40.

74. Art. 2 Reg. 1907/2006.

75. Case C-405/07 P, *Netherlands* v. *Commission (Dutch Diesel Vehicles)* [2008] ECR I-8301.

completely harmonizes the authorization procedure for medicines and does not leave room for setting stricter environmental standards in the authorization procedure.[76] It does not make sense for a Member State to take unilateral action, because it has to accept Commission authorizations, and the mutual recognition regime established by the medicines legislation ensures that medicines authorizations issued by other Member States have to be recognized and cannot be refused on environmental grounds, unless the Commission and other Member States also become convinced of the seriousness of the issue.

Despite the *Dutch diesel vehicle* case, it remains uncertain whether the safeguard clause of Article 114 TFEU (ex 95 EC) can be successfully relied on, e.g. to prohibit the sales of a medicine that poses a risk to the environment or to add additional information on the label.[77] This safeguard clause allows the Member States to impose stricter environmental measures provided that the Commission has stated that the provision's conditions are met.[78] Three conditions determine whether the Commission will approve a new measure. First, the new national measure has to be based on new scientific evidence. "New" refers to scientific evidence obtained after the entry into force of the European legislation. Since the environmental requirements were introduced in 2003, that could be difficult, but this condition could be met by submitting recent monitoring results. The second condition concerns the reason for the introduction of the measure. This condition is met, because the national measure concerns the protection of the environment. The third condition is that the national measure is necessary to tackle a problem specific for that Member State. This condition seems not to be met, since medicines may cause water pollution in all Member States. However, in view of the *Dutch diesel vehicles* case, some Member States might be able to successfully argue that this condition is met if conformity with the good status objectives or specific environmental quality standards cannot be achieved in their waters due to medicine pollution. In that case, the water legislation will prevail over the medicines legislation and result in the imposition of stricter environmental standards, provided that they are proportionate to the aim of preventing or limiting water pollution caused by medicines.

76. Cf. Weatherill, "Pre-emption, harmonisation and the distribution of competence to regulate the internal market" in Barnard and Scott (Eds), *The Law of the Single European Market, Unpacking the Premises*, (Hart Publishing, 2002) pp. 41–76.

77. See Wenneras, "Towards an Ever Greener Union? Competence in the Field of Environment and Beyond", (2008) CML Rev., 1645–1685.

78. Case C-512/99 *Germany* v. *Commission* [2003] ECR I-845 and Joined Cases C-439/05 P & C-454/05 P *Land Oberösterreich and Austria* v. *Commission* [2007] ECR I-7141.

5. A way out: a combination of governance and regulation

There are at least four ways to reduce the occurrence of clashes between Directives and Regulations.[79] First of all, it is useful to group European legislation into framework legislation and daughter legislation. That facilitates gaining a good overview of the relevant legislation and it contributes to achieving consistency within policy fields of European legislation. Secondly, the Commission could use thematic strategies to ensure consistency not only within policy fields but also between policy fields. Thirdly, environmental framework directives, such as the Water Framework Directive, should contain provisions referring to flanking policies that are necessary to achieve its objectives. To be more precise, it should contain provisions such as the obligation to take the objectives of the framework directive into account and a derogation clause that can be invoked if flanking policies render it impossible to achieve the objectives of the framework directive.[80] Finally, more attention to transparency and public participation may facilitate solving regulatory challenges that arise as a consequence of clashes between directives and regulations.

The regulatory challenge of limiting water pollution caused by the use of medicines which benefit from free movement on the internal market cannot be solved in a simple way. The health benefits of medicines may continue to override environmental concerns, just as their free movement may continue to override any perceived needs for setting stricter national standards. Thus, the question is how the environmental impact of medicines can be minimized remaining as much as possible within the present, European regulatory framework. It is therefore imperative to consider introducing governance techniques. This is an attractive option because governance techniques can help solving this regulatory challenge without resorting to major changes of the applicable European legislation.

It should not be concluded that the environmental assessment of medicines in its present form is completely devoid of meaning. After all, it encourages preventive action by users on the basis of information on the label or in the information leaflet. Therefore, it does not do justice to the potential value of the environmental assessment to simply propose amendments to the current legal framework. It should also be considered how optimal use can be made of the environmental assessment and risk mitigation measures under the current

79. The first three options are derived from Beijen, op. cit. *supra* note 69.

80. It is important to note that the Water Framework Directive already contains several provisions which link it to other policy fields. However, inclusion of the suggested provisions could strengthen their effect.

legal regime.[81] Much could be achieved if the authorities were to involve the stakeholders, e.g. drinking water companies and veterinarians. Their involvement could be achieved by employing governance instruments: making information publicly available and creating opportunities for public participation.[82] These governance instruments can also be used to involve various administrative authorities in decision-making when their involvement is beyond their competences but of interest to them. It remains to be seen to what extent governance instruments and regulation can contribute to solving the conflict or at least to reducing the tension between European water and medicines legislation.

5.1. *Access to information and regulation*

Due to uncertainty about the confidentiality of the environmental assessment, the environmental information is not necessarily made public by medicine regulators. Making publicly known what the environmental risks are of certain medicines is beneficial because it will raise awareness among a range of stakeholders.[83] For instance the water authorities could use this information to establish an environmental quality standard, to monitor the presence of medicines and to oblige the operators of waste water treatment facilities to use adequate waste water treatment.[84] That would have the positive effect of reducing the efforts of the drinking water companies to deliver clean and safe drinking water. The potential or actual use of this information by the authorities and by other stakeholders, in particular environmental associations and pharmacists, might encourage pharmaceutical companies to go green and develop medicines which are better absorbed by the bodies of their users and better degradable in the environment.[85] Of course the advantages of making the results of the environmental assessment reports public are only present insofar as environmental assessments have been carried out.

The advantages of access to information would accrue if the European water and medicines regulation were amended.[86] First of all, a provision should be introduced in the medicines legislation to carry out environmental assessments

81. It could become an example of the use of not so new governance instruments in European law. See Scott, "Governing without law or governing without government? New-ish governance and the legitimacy of the EU", (2009) ELJ, 160–173.

82. Governance is here used in the sense of how the government interacts with society. See Kjaer, *Governance* (Polity Press, 2004).

83. This is called community control. See Scott, "The governance of the European Union: The potential for multi-level control", (2002) ELJ, 59–79.

84. Montforts et al., RIVM Report (2006) cited *supra* note 16.

85. See <www.teleosis.org/gpp-actions.php>.

86. Thus creating a hybrid of regulation and governance. See Scott, op. cit. *supra* note 83.

of existing medicines to obtain data about most of the current polluting substances.[87] In addition, provisions should be included on access to the environmental information, which would also enable information exchange between the product regulators, the water authorities and the drinking water companies.[88] Without provisions to that effect in the medicines and water legislation, uncertainty about the balance between openness and the commercial interest in confidentiality can prevent the environmental assessment of the product regulators and the monitoring data of the water authorities and the drinking water companies from being published, thus reducing the required openness of this information to access on request.

5.2. *Participation and regulation on use*

Participation of all stakeholders in the decision-making process on the authorization and the necessary risk mitigation measures may render the risk mitigation measures more effective. These stakeholders include the competent authorities in the field of medicines, water authorities, farmers, doctors, veterinarians, patient associations, drinking water companies, environmental associations and consumers. Stakeholders could participate in the discussion about how the environmental risks (and the other risks) should be balanced against the benefits of the medicine, and which risk mitigation measures are feasible and could easily be implemented. This might improve compliance with the conditions of use by doctors, veterinarians and users. Achieving voluntary compliance of the conditions of use is essential under the current legal framework, because the current risk mitigation measures cannot be enforced. The marketing authorization – including the information on the label or the accompanying leaflet – of medicines only binds the holder of the authorization. In the case of product authorization, the holder is either the producer or the importer. The users of the product are not the holders of the authorization and can therefore not be bound by the authorization.[89]

If monitoring data reveal that a voluntary approach does not reduce the water quality problem, it might be useful to introduce European and/or national legislation to create binding conditions on the use of medicines. In the absence of European legislation, the Member States are competent to regulate the use of medicines. Their discretionary margin is limited however. First, regulation on use should be compatible with the Treaty. This includes compatibility with the free movement clauses. Therefore, regulation on use should not cause an

87. Montforts et al., RIVM Report (2006) cited *supra* note 16.

88. The absence of information exchange duties between officials of different policy fields seems to be a common omission in European legislation. See Keessen, op. cit. *supra* note 35.

89. Montforts, Van Rijswick and Udo de Haes, op. cit. *supra* note 52.

unjustifiable restriction of the free movement of goods. It does not suffice that environmental protection constitutes a legitimate aim, as the regulation should also be proportionate and should not result in a complete prohibition of the product.[90] Recent case law of the ECJ suggests that this is more easily said than done.[91]

Second, regulation on use of veterinary medicines easily coincides with the approach taken to reduce nitrate pollution under the Nitrates Directive – because veterinary medicines often enter the environment and water via manure and urine – and the Water Framework Directive, which offers a general protection regime for waters, including the measures based on the Nitrates Directive. Instead of devising new regulations on the use of veterinary medicines, benefits might be realized from measures taken under these regimes. For instance, the use of the buffer zones is expected to reduce water pollution from nitrates and from veterinary medicines. Another reason for being careful with introducing new regulation is that the advantage of creating binding obligations that can be enforced by the authorities may not be realized. The ability to enforce is relatively low concerning the use of veterinary medicines and human medicines used outside hospital settings, because use then causes non point source pollution, which is hard to pinpoint to a specific user and consequently notoriously hard to control. Therefore, it may be more effective to stimulate voluntary compliance with the conditions of use and resort to regulation on use only in so far as it can be enforced.

5.3. *Discretion in regulation*

It might be useful to amend the current legal framework in order to ensure that the risk to the environment of medicines is taken into account during the authorization procedure. European action seems warranted because water pollution caused by medicines is a common problem and not a problem specific to one Member State. Furthermore, water pollution often has transboundary effects because most river basins cross Member States borders. The WFD proposes that the Member States request the assistance of the Commission when they are confronted with problems they cannot solve themselves.[92] The Commission may also act of its own initiative, if monitoring data reveal serious

90. E.g. Dougan, "Minimum harmonization and the Internal Market", (2000) CML Rev., 853–885 and Weatherill, op. cit. *supra* note 76.

91. Horsley, annotation of Case C-110/05, *Commission* v. *Italy*, Case C-142/05, *Aklagaren* v. *Percy Mickelson and Joakim Roos*, and Case C-265/06, *Commission* v. *Portugal*, (2009) CML Rev., 2001-2019. See also Case C-473/98 *Kemikalieninspektionen* v. *Toolex Alpha,* [2000] ECR I-5681.

92. Art. 12 WFD.

or widespread water pollution with a substance originating from a medicine for human or veterinary use. It may then prioritize the inclusion of an environmental quality standard for this substance in the Annex of the Priority Substances Directive or the Groundwater Directive.[93] The Commission may also devise a strategy to combat pollution from medicines even in the absence of alarming monitoring data, as it is entitled to devise a strategy for a certain group of substances.[94] The Commission could also decide to amend the medicines legislation to improve the effect of the environmental assessment and the ensuing mitigation measures.[95]

Nevertheless, the request of a Member State to devise regulation to settle the conflict between medicines and water regulation will not necessarily lead to a revision of the European medicines and/or water legislation. The European legislator appears not to be obliged to introduce very strict environmental protection requirements. This can be derived from the case law of the ECJ on the question whether European legislation should be annulled because environmental interests are not sufficiently protected. In its judgments in the *Safety Hi-Tech* cases, the ECJ used Article 191 TFEU (ex 174 EC) for the evaluation of European legislation in this regard.[96] It held that Article 191 TFEU provides for a number of aims, principles and criteria, which the European legislator should respect in the implementation of environmental policies. However, the ECJ only evaluated this respect in a marginal way. It considered that a number of aims and principles of Article 191 TFEU had to be weighed against each other and, because of the complexity of the applicable criteria, it could only review whether the European legislator had made a manifest error. It also considered that Article 191 TFEU allowed the Member States to adopt more stringent protective measures.

A similar reasoning to that developed in the *Safety Hi-Tech* cases could be applied to the obligations flowing from the European integration principle for the regulation of medicines. This principle is formulated as follows in Article 11 TFEU (ex 6 EC): "Environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities …, in particular with a view to promoting sustainable development." Unfortunately, this does not say anything about the extent to which environmental concerns should be taken into account or whether environmental concerns should take precedence when a conflict of interests is foreseeable.[97]

93. Art. 16 WFD.

94. Art. 16 (9) WFD.

95. See the paragraphs on access to information and participation for suggested improvements.

96. Case C-284/95, *Safety Hi-Tech* v. *S&T*, [1998] ECR I-4301.

97. Krämer, *EC Environmental Law* (Sweet & Maxwell, 2000), pp. 14–15 and Dhondt, op. cit. *supra* note 1.

Like Article 191 TFEU, Article 11 TFEU leaves a wide margin of discretion to the European legislator. Thus, the European legislator appears to have a wide margin of discretion concerning the question whether and how it wants to tackle water pollution caused by medicines through amendments of the European authorization procedure for medicines.

6. Conclusions

The example of the clash between European water and medicines legislation offers some valuable general lessons. It shows, for instance, that environmental legislation does not fully take into account the fact that measures taken in other policy fields may also be important for the achievement of environmental aims. In case of fully harmonized policies, action should be taken at the European level to provide for coherence between European legislative acts from different sectors. This is particularly true in case of a clash between internal market and environmental legislation caused by a problem occurring in many Member States. It is not certain that a Member State has the possibility to set stricter environmental standards to tackle a widely occurring problem, although the *Dutch diesel vehicles* case might enable it to invoke the Article 114 TFEU (ex 95 EC) exception when specific environmental quality limit values are exceeded.

Another eye-opener is that governance instruments may be just as important as regulation to achieve an objective, in this case to improve the quality of the environment. This is because the integration of environmental concerns into other European policies may not have the desired impact. The impact of the introduction of environmental aims is not given, but depends on the balance that is struck between the original objective of the policy and the new environmental objective. The combined use of environmental rules and governance instruments, in particular as regards access to (environmental) information and public participation, into another policy may therefore lead to better results than just including environmental protection rules. After all, stakeholders can only take action if the results of an environmental assessment become known and if they can intervene when their interests, or the environmental interest, are not sufficiently taken into account.

Returning to the example of the clash between water and medicines legislation, it is obvious that even though the potential risks to the environment and to public health of the presence of medicines in water bodies seem very low, they nevertheless call for a European approach in order to lower the environmental impact of medicine use. Action must be taken at the European level, because European law regulates the placing of medicines on the internal

market and sets the agenda for water management. The precautionary principle, the principle that pollution needs to be rectified at the source, and the integration principle all encourage finding a regulatory approach that minimizes the environmental impact of medicines in water. The analysis of the water and medicines legislation reveals that steps have been taken in this direction, but that these two bodies of legislation lack the required coherence to effectively tackle the problem. The relatively low impact of the environmental assessment of medicines and other measures concerning water pollution by medicines demonstrate once again that it is not easy to integrate environmental protection into other European policies, as required by the integration principle. The regulatory challenge to limit water pollution caused by the use of medicines which benefit from free movement on the internal market can be tackled in various ways. Some improvements are suggested below, which would fit relatively easily into the current legal framework.

The European Water Framework Directive was established with the aim of attaining a good ecological status and a good chemical status in 2015, which are further elaborated in environmental quality standards. However, measures need to be taken – also by non-water authorities – to ensure protection of water quality. Instead of taking measures, Member States may also invoke exemptions when they are unable to achieve a good status, for instance because of medicines pollution. Moreover, even when the quality of surface water or groundwater is compromised, it remains possible to ensure safe drinking water by taking "end of pipe" measures, provided that pollution is discovered in time and is adequately treated. Unfortunately, medicines pollution may go unnoticed in the absence of European or national environmental quality standards and the vague monitoring obligations for substances for which no European quality standards have been set. Better protection of water quality could be achieved by amending the European water legislation. It should oblige the Member States to publish monitoring results, including both European and nationally regulated substances, in monthly and/ or annual reports.

European medicines legislation aims to provide for safe and effective medicines that do not pose a risk to human health. Environmental protection is not an objective. Nevertheless, the medicines legislation provides for the environmental assessment of medicines. However, environmental concerns are hardly taken into account in the decision-making process concerning the authorization of medicines. Despite the option left open in the *Dutch diesel vehicles* case that Member States may set stricter national environmental standards when specific environmental limit values are exceeded in their State, the European dimension of the problem calls for a European approach. The potential of the environmental assessment of medicines for the protection of the environment could be realized through three improvements in the European

medicines legislation. First, European medicines legislation should provide that the results of the environmental assessment are made publicly available. Public disclosure of environmental information has effects on the involvement and willingness to take action of stakeholders, which vary from consumers to companies and authorities. Second, European medicines legislation should be amended to ensure that risks to the environment are given due weight during the authorization procedure. Third, it might be an option to introduce European regulation on the use of medicines, as that enables enforcement of compliance with the conditions of use of the authorization by users. In view of the expected difficulty in enforcing this type of regulation, particularly in the area of veterinary medicines, it seems worthwhile to take advantage of the regulatory efforts made to reduce other types of agricultural pollution.