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Veterinary pharmaceutical residues seen from a Swedish environmental and regulatory perspective

The case of intense livestock farming in close location to drinking water supplies

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Abstract

Veterinary pharmaceuticals used in areas with intense agriculture and livestock/horse yard facilities may leach into the soil and be further transported as runoff into surface waters used as drinking water supplies. The focus of this thesis is to clarify how the existing legal framework on monitoring and regulating these residues, help Sweden to comply with two of the national environmental quality objectives related to drinking water. While scientists point to potential unknown risks of the behaviour of pharmaceutical metabolites in the aquatic environment and to the largely unexplored long-term effects, the legislation addressing this matter seems rather poor. A review of a wide range of literature on legislation on water and pharmaceuticals in the EU and Sweden was conducted. Actors from several areas of expertise were identified through a case study of Lake Vomb in southern Sweden, which is a typical location for the described scenario. Interviews with some of the experts were conducted, and the results were analysed through the focus of actors and regulations. The research confirms that veterinary pharmaceuticals are perceived to likely end up as part of the runoff in the specified locations and that there is a lack of pressure from the authorities, both from the EU and Sweden, to monitor the residues. However, in comparison to other contaminants from these agribusiness intense areas, like nutrients and pesticides ending up in the nearby water bodies, veterinary pharmaceuticals are regarded to be less of a problem to the environment. Instead, the majority of the actors assent to focus more on upstream, preventative efforts to reduce the pharmaceuticals ending up in the water bodies in the first place. In the course of the collaborating work at a local level to reduce runoff from pesticides and nutrients, veterinary pharmaceuticals should also have a natural place.

Keywords: veterinary pharmaceutical residues, aquatic environment, monitoring drinking water supplies, livestock areas.

Executive Summary

Veterinary pharmaceuticals (VPs) are used in husbandry and livestock farming for the purpose of preventing and combating parasites, insects, and treatment of injuries and diseases. The substances are administered to animals through feed, injections or by topical application. The residues may then reach the environment through excretion, as manure, when applied on soils, or it simply washes off grazing/outdoor animals in rain. Highly mobile pharmaceuticals pose a potential risk to leach into the soil and be further transported via drainage runoff into surface waters. The fact that pharmaceuticals are designed to affect biological systems and thereby have different times of metabolism and degradation, enable some of them to leave the treated animal rather unaffected, and pose a risk to soil-dwelling and aquatic organisms as well as ecosystems when these are exposed to the residues. Even if these substances do not have a direct toxic effect on aquatic life, and EU waters are not as a whole suffering from large on-going pharmaceutical emissions, some of them may have accumulative long-term effects that need to be considered.

According to the precautionary principle, preventative care should be applied in risk management, also in cases of insufficient scientific proofs. Therefore, from this perspective, should the long-term risks of VPs in natural environment be regarded a risk and taken seriously. This is particularly relevant in the areas with intense farming and clustered livestock production, especially those that are in the immediate vicinity of sensitive ecosystems and drinking water supplies.

To create and develop a sustainable future in line with international agreements, conventions and EU legislation, the Swedish parliament has decided on several environmental quality objectives, two of which are addressed in this thesis, namely *Good Quality Groundwater* and *Flourishing Lakes and Streams*. However, many water bodies are affected by microbiological contaminants and lack a long-term protection, making the quality objectives hard to reach.

The objective of this study is to highlight the current situation and identify potential policy gaps in the monitoring and control of VPs ending up as runoff in drinking water supplies in close location to intense farming and livestock production. In this way, the author intends to provide information to raise awareness amongst stakeholders, such as public authorities, regulators, and policy makers about the need for improved legislation in this area. Based on this objective the following research question and sub-questions were posed:

"How does the current legislation on monitoring and regulation of veterinary pharmaceutical residues in Swedish drinking surface waters, help complying with the two national environmental quality objectives?"

"What are the policy gaps?"

"How can they be addressed from the precautionary principle point of view?"

Primary data was collected by conducting interviews with several actors, which were relevant through their different fields of expertise related to pharmaceutical contamination of water bodies. The actors were identified through a case study, which also provided a specific context in which the observations could be made more clearly. Lake Vomb in Scania, southern Sweden, represents a typical southern Swedish location with the described scenario of intense agribusiness and livestock/animal facilities. Secondary data was collected through a review of a wide range of literature in the fields of pharmaceuticals (the substances in VPs are basically the

same as in human medicines), and legal frameworks on drinking water and pharmaceuticals in the EU and Sweden.

The results from these parts were systematically analysed by focusing on *actors* and *regulations*, and how they collaborate.

The main findings from this study were that the EU legislation does not require any regular monitoring of pharmaceuticals, let alone pharmaceuticals for veterinary purposes. However, in 2013, three human medicines were added on a watch list, for surveillance as potentially harmful substances, and for which the EU Member States are obliged to carry out recipient controls. Contrary to pharmaceuticals intended for humans, environmental impact risks will be taken into account when the mandatory environmental risk assessment is being performed in the registration process of a VP, disqualifying it for the market. Since many human pharmaceuticals are also used for veterinary purposes, this distinction does not give a complete coverage. On a national level, the Swedish River Basin District Authorities (Vattenmyndigheterna) are commissioned to implement the WFD. The county administrative boards and municipalities carry out the largest part of the operative work to monitor and collect ecological and chemical data from all water bodies at regional and local levels. Veterinary pharmaceuticals are not included in that work, since there is no legislation demanding it.

Part of the summary of the interviews revealed that since the restrictions concerning the use of pharmaceuticals in Sweden are more stringent (in particular antibiotics) in comparison to other countries, VPs are not perceived to be a major problem to the aquatic environment. In comparison to human pharmaceuticals reaching the watercourses through the application of sludge from waste water treatment plants as fertiliser, the large volumes of pesticides, and the overload of nutrients in the areas in question, the concern for VP residues leaching into the environment is rather low. Yet, the majority of the contacted actors did acknowledge the lack of information about the fate of veterinary pharmaceuticals in the environment. Some of them expressed concern about the absence of a discussion regarding this matter and appreciated that the issue is raised.

Being part of EU law and valid in all Member States, the precautionary principle should be used as a guiding approach to protect the environment even when sufficient scientific proof does not exist. To find out the behaviour, synergistic effects, and interactions of metabolites is a highly complex business and decades may pass before scientific proofs of causation are available. Since the knowledge about the consequences of neglecting the risks is poor, the precautionary principle should be considered to a greater extent in regards to a pharmaceutical's entire lifecycle.

One recommendation to policy makers would be to include veterinary pharmaceuticals in the preventative upstream work performed by local water councils in collaboration with local stakeholders. Successful outcomes have been reported on the efforts made to reduce the amount of agricultural runoff, such as pesticides and nutrients.

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Abbreviations

DWTP	Drinking Water Treatment Plant
EC	European Commission
EEA	European Environmental Agency
EMA	European Medical Agency
EPA	Swedish Environmental Protection Agency
ERA	Environmental Risk Assessment
LIF	Swedish Association for the Pharmaceutical Industry
MPA	Swedish Medical Product Agency
MRL	Maximum Residue Level
NFA	Swedish National Food Agency
POP	Persistent Organic Pollutant
PP	Precautionary Principle
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Minimisation Measures
SBA	Swedish Board of Agriculture
SECIS	Swedish Environmental Classification and Information Systems for Pharmaceuticals
SwAM	Swedish Agency for Marine and Water Management
SWWA	Swedish Water and Wastewater Association
VP	Veterinary Pharmaceutical
WFD	Water Frame Directive
WISS	Water Information Systems Sweden
WWTP	Waste Water Treatment Plant

1 Introduction

This chapter provides general background information to create a context for the thesis. Further, it provides definitions on the research topic and the research question as well as scope, limitations, and targeted audience.

1.1 Background

Chemical substances of various kinds are found in many watercourses and lakes around the world. Examples of such are nitrogen and phosphorous in fertilisers, pesticides, and pharmaceutical residues from the manure deriving from medically treated livestock, and from the use of wastewater treatment plant sludge on soils. Seen from a production perspective, some of the substances are regarded as necessary tools to reach, maintain, or increase the set yield targets of animal feedstock and cereals. Seen, however, from an environmental perspective, many of these substances are regarded as harmful, in either a short or a long-term perspective, or both. Pharmaceuticals play an important role in prevention and treatment of diseases in humans and animals. They are designed to affect biological systems in different ways and for different durations of time (de Knecht et al., 2009).

Non-metabolised pharmaceuticals generally leave the body by excretion, which usually ends up in a wastewater treatment plant [WWTP]. This is the normal scenario for the human use of pharmaceuticals in Sweden connected to a WWTP. Fifty percent is the mean value of WWTP purification of the 1 000 tonnes of pharmaceuticals used in Sweden yearly (Barkeman, 2015) or put differently; the purification level is close to 100 percent of some pharmaceuticals, while some are not degraded at all (Carstensson & Gunnarsson, 2006; Swedish Medical Products Agency [MPA], 2014). The degree of toxic components, their persistency, and bioaccumulative natures will determine how well these compounds will degrade or become purified in the WWTPs. The cleaning capacity and techniques of the treatment plants also vary, meaning that pharmaceutical substances may be found downstream of WWTPs and close by aquatic systems (Andersson et al., 2006). Non-metabolised veterinary pharmaceuticals (VPs) and pesticides will to a large extent end up in the environment untreated, bypassing WWTPs. In addition, pharmaceuticals from the 20 percent of the Swedish households with onsite wastewater treatment facilities, many with substandard purification, will also contribute to the pharmaceutical residue load (Ejhed et al., 2012).

1.1.1 Veterinary medicines in the aquatic environment

Veterinary pharmaceuticals [VPs] are used in husbandry and livestock farming for the purpose of preventing and combating parasites, insects, and treatment of injuries and diseases. The substances are administered to animals through feed, injections or by topical application (Boxall et al. 2009). The drugs and chemicals may then reach the environment through excretion, as manure, when applied on soils, or it simply washes off grazing/outdoor animals in rain. Highly mobile VPs constitute a potential risk to leach into the soil and be further transported via drainage runoff into surface waters (figure 1) (Metcalfe et al., 2009; Tolls, 2001). Behavioural and reproductive changes in fish and antimicrobial resistance are a couple of examples of what may be the result of pharmaceutical residues released into the environment. According to several authors cited in this thesis, there is a need for different and more sensitive parameters for measuring long-term effects of pharmaceutical residues as these are largely unexplored. The standardised tests may underestimate the subtle effects that pharmaceutical metabolites may have on the aquatic and terrestrial organisms (Brandt et al., 2012; Breitholtz & Bengtsson, 2014; Brooks et al., 2009; Kümmerer, 2008; World Health Organization [WHO], 2012).

Veterinary pharmaceuticals are often considered as a single group of chemicals. In reality they contain a wide range of different classes of chemicals and substances for different purposes and targets in the animal body. Antibiotics, antiparasitic drugs and endectocides are examples of the very diverse group of VPs. With the exception of ectoparasitic drugs and aquaculture products, most VPs are metabolised by the animal before entering the environment. This is an important issue to consider when performing an environmental impact assessment (EIA), that not only should the parent medicine be addressed for its environmental impacts, but also how its metabolites may contribute to the overall environmental impact risk (de Knecht et al., 2009).

Traces of pharmaceuticals, both from human and veterinary use, have been found in watercourses worldwide (Andersson et al., 2006; Brandt et al., 2012; Breitholtz & Bengtsson, 2014; Janusinfo, 2014; Swedish Water and Wastewater Association [SWWA], 2015). It is, however, important to underline that EU waters and ecosystems are not as a whole suffering from large on-going pharmaceutical emissions, rather the concern regards possible effects from low concentrations (nanograms to micrograms per litre) during a long time of exposure (Jelić, Petrović, & Barceló, 2012; MPA, 2014). Crucial issues like bioaccumulation, different pharmacological pathways, toxicity and pharmaceutical transformation processes influence the risk assessment and management of pharmaceuticals for both human and veterinary use (Brandt et al., 2012; Breitholtz & Bengtsson, 2006; de Knecht et al., 2009; Tolls, 2001; WHO, 2012).

Pharmaceuticals are often designed to remain stable during the transport through the body before reaching its target organs/receptors in a sufficiently high concentration without getting degraded by the acidic stomach or by storage elsewhere in the body. Pharmaceuticals bind to different proteins, for instance enzymes or receptors in order to affect certain processes. Many of these proteins are also found in other species, especially other vertebrates, such as fish or reptiles. For instance may fish and some other aquatic organisms be more susceptible to pharmaceutical residues because they breathe through their gills. These are adapted to facilitate the flow of certain molecules, such as oxygen, between the surrounding water and the blood. This feature may also enable other less suitable molecules, such as pharmaceutical residues, to pass through the gills and into the fish (Breitholtz & Bengtsson, 2006; MPA, 2014). This is the reason why pharmaceuticals, which are not entirely metabolised in the body entering the terrestrial and aquatic environment, may pose a risk of affecting other species.

Pharmaceuticals that are resistant to a fast degradation process are thus attractive from a therapeutic perspective. From an environmental perspective however, a slow degradation is negative as such pharmaceuticals tend to persist in the environment, and may spread and concentrate at such levels that harm may occur to other organism and ecosystems surrounding the lakes (MPA, 2014).

In *Pharmaceuticals in the Environment,* Kümmerer (2008) writes about the risk of toxicological effects from drinking water contaminated with pharmaceutical residues being minimal for humans. Highlighting this statement, the author presents the example of how a maximum lifespan intake of 2 litres of water per day for 70 years would not come close to the therapeutic doses. Additional information, however, illustrates the complexity of such a statement as it assumes (Kümmerer, 2008, p. 17):

> ***(i)*** *that effects and side effects during therapeutic use (short term, high dosage) are the same in quality and quantity as during a life-long ingestion (long-term ingestion, low dosage),*
>
> ***(ii)*** *that the effects are the same for fetuses, babies, children, healthy adults and elderly people,*

(iii) *that the risk imposed by a single compound is comparable to the one imposed by a mixture.*

The author further illustrates how results may be incomplete and misleading through "…extrapolating data from high dose short-term ingestion during therapy to low dose long-term ingestion." (Kümmerer, 2008, p.17).

1.1.2 Legislation

In the article *Environmental Framework to Evaluate Environmental Policy Instruments* (2003), Mickwitz emphasises the importance of proper evaluations as basis for policy instruments, as environmental concerns often entail very complex features related to them. For instance, the long timeframes often involved when evaluating potential harmful impacts, the uncertainties of science, and the unequal distribution of cause and effect. If these characteristics are neglected or not appropriately considered, there is a great risk of creating and implementing policy instruments of "… low effectiveness. Since the time between action and ultimate effects of an environmental policy is often very long due to the nature of environmental processes, not all effects can be evaluated at any point in time. Often it will be necessary to focus the evaluation on outputs and administration." (Mickwitz, 2003, p. 423).

Currently there are no legal demands from the EU to remove pharmaceutical residues from treatment plants. Within the EU Water Framework Directive, pharmaceuticals are not generally addressed, although in 2013, three human medicines were added on a watch list, for surveillance as potentially harmful substances, and for which the EU Member States are obliged to carry out recipient controls. According to present methods of assessment and monitoring, both human and veterinary pharmaceuticals are regarded to pose a low risk of environmental toxicity. However, for the same levels of concentrations as found in the environment, negative effects have been found in laboratory and field studies, both from specific substances and from combinations of substances (MPA, 2014). In a screening on pharmaceuticals for human use carried out in 2010, 66 out of 101 tested pharmaceuticals were detected in surface waters. Five of those were found in concentrations high enough to cause a pharmaceutical response in fish if they were exposed to those waters. In drinking water, 26 of the tested pharmaceuticals were detected in lower levels (nanograms per litre) (Fick, Lindberg, Kaj, & Brorström-Lundén, 2011). In the national screening by Andersson et al., (2006), antibiotics, anti-inflammatory drugs, and hormones were detected in point sources around pigs, cattle, and nearby a racing track for horses.

As with food additives and cosmetics, human and veterinary pharmaceuticals are not covered by the EU chemical regulation REACH. Instead, The Environmental Code (SFS 1998:808) and the precautionary principle may be applied for the purpose of regulating pharmaceuticals (Swedish Environmental Protection Agency [EPA], 2008). Veterinary pharmaceutical products constitute around 600 of the 8 000 pharmaceuticals products on the Swedish market. The substances in VPs are largely the same as in human medicines and they are qualified, registered, and promoted in the same way. Several human pharmaceuticals are also used in veterinary medicine (MPA, 2014a; Swedish Board of Agriculture [SBA], 2015).

One key difference is that contrary to pharmaceuticals intended for humans, impact risks will be taken into account when the mandatory environmental risk assessment [ERA] is being performed in the registration process. The risk/benefit assessment might disqualify a VP for the Swedish market if shown to have negative environmental impacts (FASS, 2015b; MPA, 2015).

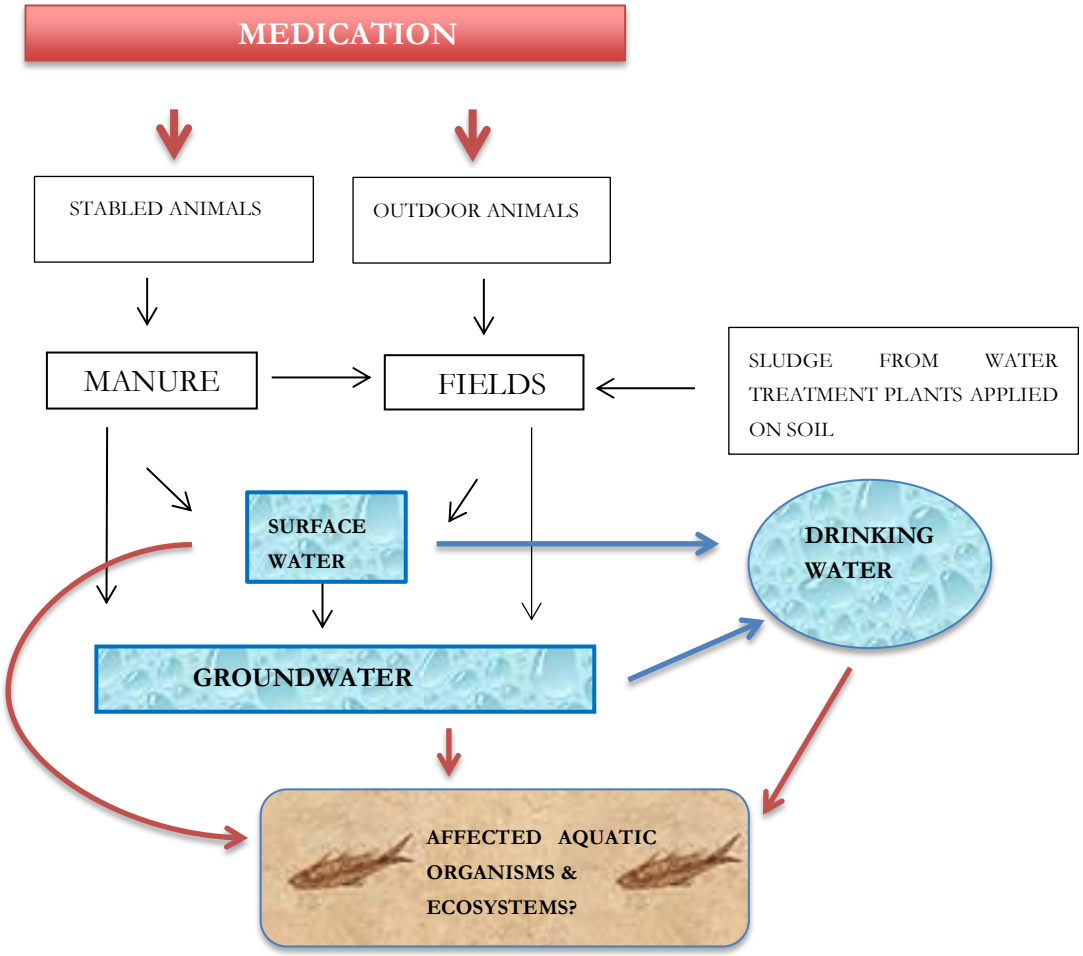

Figure 1. Feasible pathways for veterinary pharmaceuticals used in livestock and horses to enter the aquatic environment. (Modified after Halling-Sørensen, Nors Nielsen, & Jensen (2002), cited in Swedish Environmental Protection Agency (2007).

1.2 Problem definition

1.2.1 Environmental quality objectives

Human and veterinary application of pharmaceuticals is the main source of pharmaceutical active compounds in the environment. These substances are designed to achieve certain physiological and biological effects, thus also with a potential of affecting aquatic life and environment when discharged. Even if these substances do not have a direct toxic effect on aquatic life, some of them may have accumulative effects that need to be considered. According to the precautionary principle, preventative care should be applied in risk management, also in cases of insufficient scientific proofs. Therefore, from the precautionary principle perspective; the long-term risks of VPs in natural environment must be regarded and taken seriously. This is particularly relevant in the areas with intense agricultural activities, especially those that are in the immediate vicinity of sensitive ecosystems and sources of drinking water.

To create and develop a sustainable future in line with international agreements, conventions and EU legislation, the Swedish parliament has decided on sixteen environmental quality objectives. They provide a generic picture of the Swedish policy objectives in the environmental field. They also describe in what condition the Swedish environment should be at by the year of 2020 (EPA, 2013). Two of the objectives involve the quality of lakes and watercourses where pharmaceutical presence could be negative, namely:

- Good Quality Groundwater
- Flourishing Lakes and Streams

Good Quality Groundwater

The Swedish government has decided upon six specifications addressing this objective. Among these are "…that, aside from a few exceptions, good groundwater quality are of good enough levels not to prevent it from being used as a source for drinking water…" (Author's translation). Just as for the following objective, groundwater is included in the Regulation SFS 2004:660 on administration on quality of the aquatic environment. The status of the groundwater will naturally affect the environment in surface drinking water sources through the constantly on-going water cycle. Particularly in areas where intense agribusiness is taking place, for instance in southern Sweden, the groundwater will contain higher levels of runoff from nutrients, pesticides, and possibly veterinary pharmaceuticals.

Flourishing Lakes and Streams

The Swedish government has decided upon eleven specifications for this quality objective, out of which a few are especially addressing the issue of drinking water supplies. Among these are: *Good ecological and chemical status* according to Regulation SFS 2004:660, on administration on quality of the aquatic environment, *water courses aimed to supply drinking water should have a good quality* (EPA, 2013). In areas with intense husbandry and livestock farming, the levels of nutrients, pesticides, and other chemicals, like veterinary pharmaceuticals, are likely to be higher.

According to the EPA (n.d.), only one of Sweden's 21 counties will manage to reach the Good Quality Groundwater objective until 2020, with the current policy instruments and implemented measures (Värmland). An additional seven counties may reach this objective with the implementation of newly planned policy instruments. None of the counties will reach the targets for Flourishing Lakes and Streams for 2020. The major reasons are that many drinking water supplies are affected by microbiological contaminants and lack a long-term protection. In addition, the restoration work on affected waters is a slow process.

Depending on region, different pharmaceuticals at different levels will be presented in the surrounding river basins, lakes, and groundwater. Lakes and rivers in intense agricultural and livestock production areas are likely to contain more residues from veterinary medicines. EU legislation does not require any monitoring of VPs on a local level, but if the risks from VP leaches are to be addressed, not only are different approaches to tackle the treatment of them needed, but the monitoring of these needs to be improved and effective regulations need to be in place too (de Knecht et al., 2009). The purpose of this study is therefore to improve the understanding of the existing legal framework that regards this issue, and if or how Swedish

authorities monitor the veterinary pharmaceutical residues in lakes located in intense agribusiness areas.

1.3 Objective and research question

The objective of this study is to highlight the current situation and identify potential policy gaps in the monitoring and control of the veterinary pharmaceuticals ending up as runoff in drinking water supplies, in close locations to intense farming and livestock production. In this way, the author intends to provide information to raise awareness amongst stakeholders, such as public authorities, regulators, and policy makers about the need for improved legislation in this area. So far, the level of scientific evidence about the behaviour of pharmaceutical metabolites seems to be rather low. The way the residues act in conjunction with other substances, and the long-term effects on other organisms and ecosystems, are poorly explored. For this reason, public authorities and decision-makers ought to take a more precautionary role on the legislation that regards monitoring medicines and chemicals intended for veterinary purposes in the described locations. For Sweden to meet the requirements of the Water Frame Directive (WFD) as well as the environmental objective target for lakes and rivers, the author believes that the precautionary principle should be taken into account to a greater extent.

According to Turabian (2013), an applied research question is the kind of question that will provide understanding about a problem in order to know what to do about it. The research problem described in this thesis concerns a problem of that kind. The guiding research questions have been framed as follows:

- How does the current legislation on monitoring and regulation of veterinary pharmaceutical residues in Swedish drinking surface waters, help complying with the two national environmental quality objectives?

Sub-questions:

  - What are the policy gaps?
  - How can they be addressed from the precautionary principle point of view?

1.4 Limitations and scope

The focus of this study is on monitoring veterinary pharmaceutical residues in the aquatic environment under the specific circumstances of intense farming and livestock production/animal facilities. Since Swedish municipalities are responsible for providing their inhabitants with drinking water of good quality, the initial idea was to find out how Swedish municipalities monitor the quality of their drinking water in regards to pharmaceutical residues. However, circumstantial constraints soon became apparent when discovering the lack of national policies and regulations addressing this issue at a municipal level. Instead, collection of primary data was retrieved by interviewing other actors, and by analysing EU and national legislation and policies relevant to the thesis topic.

The scope included interviews with actors from a wide range of knowledge on water quality issues, inter alia, environmental inspection, ecotoxicology, biologists, engineering, and advisory bodies on water quality issues. While not all relevant stakeholders were contacted, the obtained information was deemed sufficient enough to draw conclusions in combination with parts of the reviewed literature. A rather general focus is put on the topic of pharmaceuticals in the environment, while a particular focus is placed on veterinary pharmaceuticals. Within this context, the author seeks to investigate existing/absence of legislation and policies

addressing the issue of monitoring the leach of VPs into surface waters. The literature review focus in this study includes how the EU legal framework, which addresses monitoring and control of drinking water quality standards, and pharmaceutical residues in the aquatic environment, has been implemented into Swedish legislation. Additionally, it includes how Sweden has divided the responsibilities, the coverage, gaps, monitoring efficiency, and legislation enforcement.

This thesis aims at highlighting the problem of veterinary pharmaceutical residues. As pharmaceutical for human use are more frequently discussed and written about, some information has been deemed necessary to include for clarity and comparative reasons or when no information on VPs exist. Companion animals have been excluded as they are seldom found in large groups like livestock or horses, hence tracing pharmaceutical residues from them would be more difficult. Nor are residues from pharmaceutical production, removal of pharmaceutical substances from treatment plants, or handling of pharmaceutical leftovers included in the study.

1.5 Audience

The outcome of the study should serve the purpose of raising awareness among the Swedish public authorities and decision-makers about the potential harm of veterinary residues in Swedish lakes, in particular natural lakes providing drinking water located in areas with intense husbandry and livestock farming activities. The research also intends to guide policy makers in their work towards an improved and targeted monitor performance of pharmaceuticals such as in the area around the Lake Vomb in Scania.

1.6 Disposition

Chapter 1 provides general background information to create a context for the thesis. Further, it provides definitions on the research topic and the research question as well as scope, limitations, and targeted audience.

Chapter 2 introduces data collection and research methods used in this thesis. Apart from literature on the issue of veterinary pharmaceutical residues in the aquatic environment and policy framework addressing this subject, the theoretical framework and analytical approaches are presented.

Chapter 3 provides an overview of the legal framework for drinking water and pharmaceuticals in the EU and in Sweden. General gaps and shortcomings are highlighted, and a brief review of some recent efforts made within Sweden and the EU to improve pharmaceutical-related impacts in the aquatic environment is presented.

Chapter 4 focuses on the case of Lake Vomb to illustrate the current state with VP monitoring in Sweden under the existing European and national policy regimes and regulations. This section will also provide the main research findings stemming from the interviews with municipal environmental inspectors and experts within different fields of work and scientific areas of research.

Chapter 5 includes reflections and analysis of the findings from the interviews and literature review in connection to the posed research questions in chapter 1.3. Further and finally, the used research method is reviewed and reflected upon.

Chapter 6 reviews how the research question stated in section 1.3 relates to the performed research. It also presents the conclusions from the literature review and stakeholder interviews. Finally, it provides some suggestions for further research.

2 Methodology

This chapter introduces data collection and research methods used in this thesis. Apart from literature on the issue of veterinary pharmaceutical residues in the aquatic environment and policy framework addressing this subject, the theoretical framework and analytical approaches are presented.

2.1 Research design

The thesis relied on an inductive research approach by means of observing a phenomenon, analysing it, and drawing theoretical conclusions.

In their book *Methods of collecting and analyzing empirical materials*, Denzin and Lincoln (1998) write about the use of the multi-method approach to attain a more thorough outcome of the research. Triangulation is such an approach. For instance in this paper, a literature review has been made in combination with interviews in order to provide a more nuanced picture of the thesis outcome. While the primary data (Kumar, 2005) is collected from the interviews with municipality inspectors and specialists from various relevant fields of expertise, secondary data is collected through the literature review of veterinary pharmaceuticals and the legal frameworks addressing drinking water and (veterinary) pharmaceuticals in the EU and in Sweden. A study was added as a method to identify the stakeholders and to analyse the current issue. Further, the results of the literature review and the stakeholder interviews are discussed and analysed. Finally, conclusions based on the findings are drawn.

To illustrate the research structure, the author has organised the approach of gathering information and data collection through a conceptual model (figure 2).

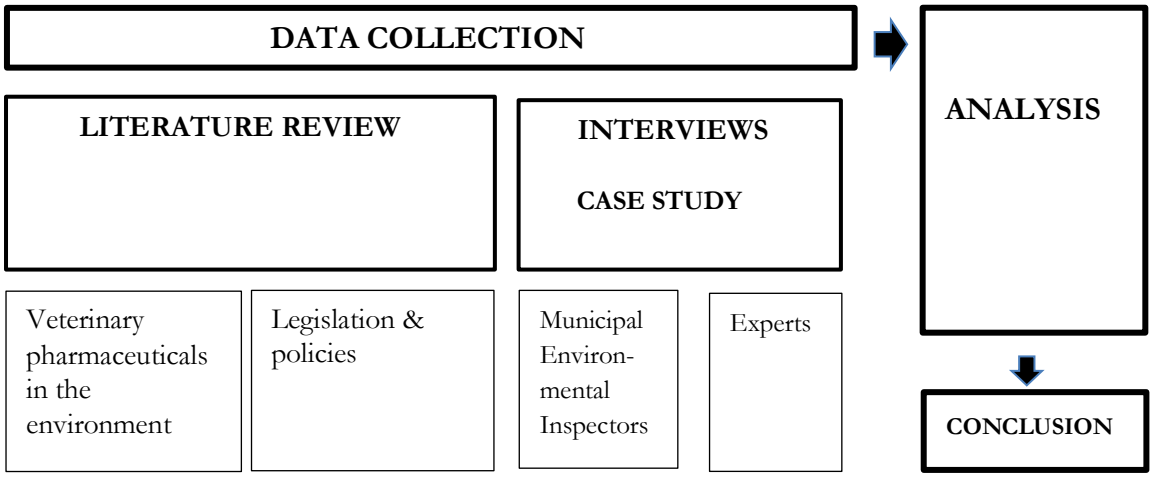

Figure 2. Conceptual research model

2.2 Data collection

2.2.1 Literature review

A preliminary literature review was carried out to achieve a decent level of understanding of the topic in order for relevant stakeholder communication to take place, as this was due shortly after beginning with the thesis writing. For a more thorough understanding of the thesis topic complexity, secondary data collection was achieved through a literature analysis,

which went from a general perspective of pharmaceutical residues in the aquatic environment to a more specific veterinary ditto. The author took note of a range of peer reviewed papers addressing relevant topics, inter alia: pharmaceutical removal from WWTPs, biochemical processes of degrading and mobility of pharmaceuticals, potential impacts on non-target organisms and ecosystems from long-term, low-level exposure from VP metabolites, and environmental classifications systems for ex ante environmental risk assessments. Published reports and website information from a wide range of public authorities and organisations were reviewed on matters like screenings for detection of veterinary pharmaceuticals in the environment, pharmaceuticals in drinking water, and improved upstream management of river basins.

The literature search also included European and Swedish legislation on pharmaceuticals, drinking water, and surface water monitoring under the Water Frame Directive (2000/60/EC). The statistical databases from the Swedish Board of Agriculture and the Federation of Swedish Farmers have been consulted for the purpose of finding animal density in the municipalities surrounding the Lake Vomb. Non-European legislation was avoided for scoping reasons, since the thesis concerns Swedish surface waters in close location to intense farming, where the EU and Swedish legislation applies.

Several other databases served the purpose of finding relevant publications and peer-reviewed articles, for instance the academic database LUBsearch through Lund University, the Swedish Agricultural University (SLU), and Chalmer University databases. Google Scholar was also a valuable source in the search for literature and official reports as well as the many EU and Swedish public authorities' databases. Key words for searching were, inter alia; "veterinary pharmaceuticals in the aquatic/environment"; "pharmacovigilance of veterinary pharmaceuticals in aquatic environment"; "screening veterinary medicines in Sweden"; "pharmaceuticals and livestock and manure/runoff"; and "environmental policy evaluation".

From the literature review, insight was gained about, inter alia: the research field of pharmaceuticals in the environment and how they are/are not dealt with, potential environmental impacts from pharmaceutical residues, and European and Swedish legislation and policies addressing monitoring of drinking water.

To increase the opportunities to get hold of more specific research papers and relevant competence within the field of the thesis topic, the contacted interviewees were asked for suggestions about appropriate literature and other contacts for further research.

The literature review, however, still did not provide answers to some questions. For instance, whether the relevant experts at all consider veterinary pharmaceutical residues as a potential problem. To fill these gaps and also to get a better explanation of the existing theoretical understandings how things work, municipal environmental inspectors and several experts, identified through a case study were contacted (described below in 2.3).

2.2.2 Interviews

This study aims at a deeper understanding of a real life phenomenon. For this purpose, interviews with practitioners are often used as a valuable method for data collection (Kumar, 2005). Interview techniques range from *unstructured* to *structured* interviews. Where the unstructured kind, allows for the contents and questions to be of a flexible structure, the structured alternative has a more rigid form. The unstructured interview technique is a particularly useful method for data collection when in-depth information is aimed for and where little is known of the area (Kumar, 2005).

For the purpose of this research, the author has chosen a personal qualitative semi-structured interview version with open-ended questions. The interviewees were asked the same questions to start with, as a guide for data collection, but the open-end left room for the interviewees to add more information and to discuss reasons behind their answers.

To begin with, the primary data collection relies largely on personal qualitative semi-structured open-ended interviews that were held with the municipalities contributing with livestock farming and husbandry runoff to the Lake Vomb. Originally, the interviewees were selected based on their knowledge about water quality issues and experience of monitoring, researching, or consulting, in this area. Overall, the interviewees questioned in this study had a high relevancy to the scope of research. All interviewees but one were environmental inspectors, with either agriculture, chemicals, separate sewage related issues, and/or drinking water control within their areas of responsibility for inspection[1]. One county veterinarian was also contacted in this group of interviewees in order to find out about how animal welfare relates to pharmaceuticals in the aquatic environment. The next group of interviewees included experts within the fields of biochemistry, microbiology, veterinary public health, biomedical science, marine ecology, consultants in environmental and water related issues, and a water treatment plant engineer.

These experts, who by Denzin and Lincoln (1998) are defined as a focus group interviewees, were contacted specifically in order to gain primary data on their expertise and opinions about the potential toxicity risk of veterinary pharmaceutical residues if present in drinking water supplies. Other stakeholders, such as livestock/large animal veterinarian practitioners and keepers of horses and livestock, were initially to be included for interviews, but their participation was considered to be of less relevance for the scope of this thesis.

The issue is complex and very context specific, and in order to get a more thorough picture a case study approach was decided upon. The case study provides a smaller sample of a specific context, in which observations can be made more easily. Nevertheless, the case study was selected in such a way that it could be representative example of the problem at stake and be able to draw conclusions on the issue in a national perspective. All the interviewees described above were identified through the case study.

2.3 Case study

The methodology approach was partly carried out by conducting a background material analysis, and partly by performing a single case study of the Lake Vomb in Scania, southern Sweden. This lake is an appropriate example of a valuable basin whose water, used as drinking water supply for 400 000 people, is heavily polluted by runoff from surrounding agricultural and livestock farms (The County Administrative Board of Skåne [CAB], 2011). It also represents rather typical conditions and location, so that to a large extent a generalisation of findings is possible for the southern Swedish context. The case study also served as guidance to locating relevant actors, because the lake's catchment area is shared between several municipalities, and different areas of responsibility are under the jurisdiction of different authorities, including at regional and national level

An additional reason for choosing this particular lake is that a study on collaboration between authorities and stakeholder has been made. With focused upstream work, where knowledge and experience from the participation of local actors has come forward and been applied in

[1] All municipalities do not have a person strictly dedicated to inspection of drinking water.

the Lake Vomb context, efforts have been made to reach a higher level of management (Parkefelt et al., 2015; River Kävlinge Water Council, n.d.).

2.3.1 Stakeholders

Through the case study, several stakeholders and actors were considered relevant to contact. Identified national and regional boards and agencies with an overall responsibility and part of the problem ownership were the Swedish Environmental Protections Agency, the Swedish Board of Agriculture, the National Food Agency, the Swedish Medical Products Agency, and the Swedish Chemical Agency. Authorities with local responsibility of control and monitoring included the municipalities of which the Lake Vomb is part, as well as the local Water Councils. Other local stakeholders, like the drinking water suppliers do also have a responsibility in controlling and monitoring the drinking water quality. Associations and organisations were included for their positions as lobbyists and stakeholder representatives. Veterinarians were included due to their work with animal health and responsibility regarding prescribing and administering medicine. Inhabitants around the Lake Vomb, farmers, and animal keepers were also included, both as contaminators and as potentially becoming affected by pharmaceutical residues in a long-term perspective. Finally, researchers within the fields of ecotoxicology, and biochemistry were included to get a more specific understanding about the complexity of pharmaceutical residues in the aquatic environment. Table 2 provides further explications on stakeholders' areas of expertise and main tasks.

While all of the identified stakeholder were not available, or were decided not to be contacted, the author got sufficient information from the ones finally interviewed. One of them was excluded though, as the information fell outside the scope of this thesis. Initially veterinarian practitioners and animal keepers were also to be interviewed, but the author decided to exclude them for reasons of delimitation, since the primary focus of the thesis is on monitoring policies and regulation. One veterinarian was however included due to her work at the County Administration Board, which has an overall responsibility of the animal welfare inspection.

Table 2. Stakeholder table. Stakeholder written in bold letters were contacted for the interviews.

ORGANISATION	MAIN TASK
Environmental Protection Agency (EPA)	The Swedish authority overviewing the environmental state. Coordinating, monitoring and evaluating the work of the environmental quality objectives.
Swedish Board of Agriculture (SBA)	The government's expert authority in matters of agro-food policy, responsible for the agricultural sector.
National Food Agency (NFA)	**National control body for food and drinking water**
Medical Products Agency (MPA)	Responsible for regulation and surveillance of the development, manufacturing, and marketing of drugs and other medicinal products.
Swedish Chemicals Agency	Biocides used in insect repellents
Swedish River Basin Water District Authorities	The overall responsibility for implementing the Water Framework Directive in Sweden.

Municipalities	**Authority responsible to control operators/producers of drinking water. Environmental/drinking water inspectors**
County Administrative Board of Skåne (CAB)	**Overall responsibility of animal welfare inspections.**
Local water councils – River Kävlinge Water Council	**To inform, assist and give advice regarding the control, care, and use of the local aquatic environment.**
Southern Sweden Water Supply (Sydvatten)	**Producer of drinking water for 900 000 inhabitants in Scania (around 400 000 from Lake Vomb)**
Farmers and horse yards	Livestock producers, horse breeders, racing stables
The Federation of Swedish Farmers (LRF)	**Farmer and stakeholder organisation**
Inhabitants around Vombsjön & consumers of drinking water produced from the Lake Vomb	Interest in good quality drinking water, recreation, healthy aquatic environment.
Veterinarians	**Animal health prevention and medical treatment providers.**
Researchers	**Expertise within the fields of eco-toxicology, biochemistry, engineering, veterinary public health, and biology.**

2.4 Analytical approach

In order to guide and structure the analysis of the collected primary and secondary data, a framework was chosen. As for this thesis, a literature review was performed, and interviews were carried out with stakeholders, which were chosen through the set-up of a case study. The collected data from these parts were then systematically analysed by focusing on *actors* and *regulations*.

Analysing the actors mainly emanated from their area of work, research field, area of knowledge, responsibilities, and from their previous experience of addressing veterinary pharmaceutical residues in drinking water supplies/aquatic environment. When analysing the legal framework, delimitation has been made to EU rules and regulations addressing the question at stake and how these have been implemented into Swedish legislation. The main captured aspects were the regulation coverage and gaps, nature in terms of strictness and enforcement, burden sharing (between different agencies, authorities and councils), and monitoring efficiency. The analysis then focused on how actors and regulations collaborate, that is to say, how the actor liability matches the regulations, and finally the gaps between intentions and actual outcomes.

3 Legal frameworks for drinking water and veterinary pharmaceuticals in the EU and Sweden

The Swedish environmental goals addressing drinking water quality (*Good Quality Groundwater* and *Flourishing Lakes and Streams)* are rather generic, abstract and lack further explanations. To make it more tangible, information regarding relevant legislation designed to address water quality issues and risks from pharmaceuticals has been gathered. The following sections will cover the EU and Swedish legislation and policy instruments on water quality and monitoring of pharmaceuticals in drinking water.

The first section, 3.1, presents an overview of the EU Water Framework Directive, the EU Drinking Water Directive and the implementations of these directives and legislations into the Swedish context.

The following section, 3.2, outlines the pharmaceutical legislation in the EU and Sweden. Moreover, the precautionary principle and the WHO standpoint on pharmaceuticals in drinking water are outlined.

Section 3.3 highlights general gaps and shortcomings related to monitoring and environmental risk assessments (ERAs) of veterinary pharmaceuticals.

Further, section 3.4 provides information about recent efforts made within Sweden and the EU to improve pharmaceutical-related impacts in the aquatic environment.

There are important differences between VPs and pharmaceuticals aimed for human use, such as how the environmental concerns are applied in the mandatory ERAs. Still, throughout this chapter, veterinary and human pharmaceuticals are largely equated where the same regulations apply to them.

3.1 Water Legislation and Policy Instruments in the EU

3.1.1 The EU Water Framework Directive

The water management legislation in Europe, with the purpose of improving the aquatic ecosystems and preventing deterioration of them, is mainly addressed under the Water Framework Directive [WFD] (Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy). The WFD covers all European waters, such as surface water, groundwater, coastal and transitional waters, and aims to achieve good ecological and chemical status for all water bodies in Europe by this year (2015). According to the European Commission [EC] (2012), the good status objective is a necessity "… to ensure long term availability of sufficient water of good quality. Achieving good status for all waters will allow aquatic ecosystems to recover and to deliver the ecosystem services that are necessary to support life and economic activity that depend on water." (p.5).

Good status will however not be reached for a substantial number of European waters by 2015, and renewed objective are set for 2021. The information reported to the Commission by the Member States in 2012 revealed that only 53 percent of the European surface waters either were or would be in a good ecological status by this year (2015)[2]. Estimations for the chemical

[2] "Ecological status: countries that have not reported River Water Basin Management Plans, or not reported exemptions or have high unknown status, are not included." (EC, 2012, p. 6).

status in surface waters were unclear as over 40 percent were reported to be unknown in 2009 (the equivalence for the ecological status was 15 percent). Part of the difficulties in assessing the chemical status in the EU surface waters is explained by the different degrees of implementations of the WFD throughout the Member States. Additionally, how well the WFD has been further integrated into policy decisions also varies, making comparisons between the EU countries difficult. A lack of coherent monitoring is however a reality; for over 50 percent of the water bodies in some EU countries, the ecological and chemical status is not known (EC, 2012).

Agricultural activity put a substantial strain on water basins through diffuse and point-source contamination from organic matter, nutrient overload, and pesticides, among other hydromorphological impacts. According to the EC, there is a lack of specific targets within the River Basin Management Programmes to deal with these issues, and the farmers need to be better associated to implement the requirements within the WFD (EC, 2012).

Monitoring surface waters according to the EU WFD

All waters in the EU should be covered by the WFD, although the protection approach is somewhat different in surface water and groundwater. Because the ecology in water basins differs in different locations and in biological communities, no absolute standard for good ecological status can be valid for all. Instead, good ecological status in surface waters is defined according to its own biological community, chemical and hydrological characteristics. The specified controls allow "…only a slight departure from the biological community which would be expected in conditions of minimal anthropogenic impact." (EC, 2015, webpage). The microbiological and chemical status for surface waters is defined according to how it complies with the established European quality standards for the included parameters. To ensure a minimum level of quality, renewed standards can be established, as substances may be prioritised as harmful. The EU has a priority list, which consists of several harmful substances, for which environmental quality standards have been set, and which all Member States need to monitor and keep track of. In 2013, three human pharmaceuticals were added for the first time, although not to the priority list, but to EU's so-called watch-list over emerging pollutants that one day might be added to the priority list (two types of hormones and one anti-inflammatory drug) (European Parliament News, 2013).

3.1.2 The EU Drinking Water Directive

The objective of the Drinking Water Directive (Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption) is "…to protect human health from adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean." (EC, 2015a, webpage). The directive applies for distribution systems supplying water to over 50 people or 10 cubic meters per day[3]. It also applies to drinking water from tankers, bottles, containers, and water used in the food-processing industry (EC, 2015a)[4]. Consumers are to be regularly informed about the water quality, and information about the water quality is to be reported to the EC every third year. Additional requirements for regulation are allowed to be adopted when Member State translates the directive to national legislation. Higher standards can be set, for instance may

[3] This also applies if the distribution systems supplies less than 50 people or less than 10 cubic meters per day if the water is supplied as part of a business.

[4] The Drinking Water Directive does neither apply to natural mineral waters (identified as such by the competent national authorities), nor to products defined as medicinal products within the meaning of Council Directive 65/65/EEC.

harmful substances, considered relevant for specific locations, be included in the monitoring regulations (EC, 2105a).

3.1.3 Sweden and the Water Framework Directive

In Sweden the WFD was incorporated into Swedish legislation through the *Water Quality Management Ordinance* (SFS nr: 2004:660) in 2004. The Swedish Agency for Marine and Water Management [SwAM] (HaV), the Environmental Protection Agency, the Geological Survey of Sweden, and the Swedish Board of Agriculture are all subjects to the Ministry of the Environment and are among the government agencies with the overall responsibility for water issues in Sweden. They provide guidelines and regulations addressing surveillance and monitoring the status of Swedish lakes, groundwater and water bodies. In turn, Sweden's 21 County Administrative Boards (CABs) have been designated the responsibility of managing the aquatic environment quality throughout Sweden (figure 3).

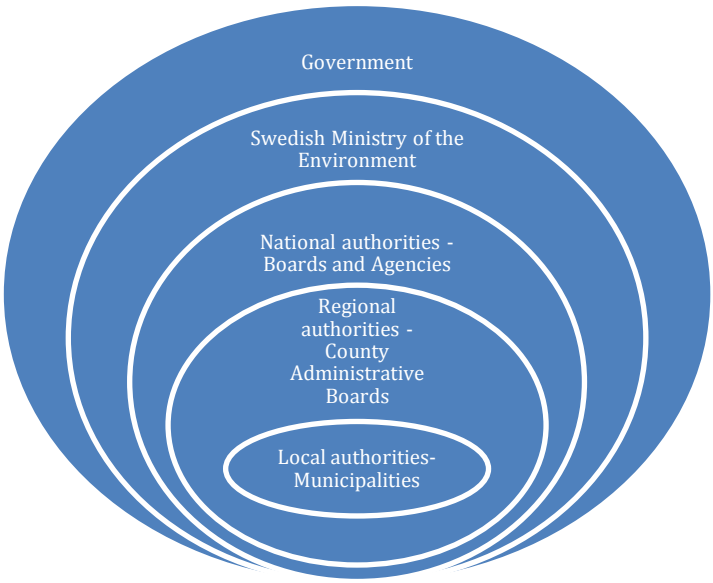

Figure 3. The implementation of the EU Water Framework Directive in Sweden is addressed at all legislative levels.

Through the introduction and implementation of the WFD in 2004, a new holistic approach of the Swedish water issues was deemed necessary in order to coordinate and organise the efforts to improve the water quality throughout the country. Five of the CABs were therefore appointed to form a new agency; the Swedish River Basin District Authorities (Vattenmyndigheterna), which are commissioned to implement the WFD in Sweden. The five river basins are divided by natural water boundaries, which establish the basis for the work of the district authorities.

The CABs and the municipalities play important roles in the water management, since they carry out the largest part of the operative work to collect the data at regional and local levels. The data is used by the River Basin District Authorities to charcterise all the water bodies within the districts and to suggest environmental quality standards, and to develop strategies to fulfil and reach the standards. After a management cycle period of six years, the data and results are reported to the European Environmental Agency [EEA] (figure 4) (National Food Agency [NFA], n.d.; SwAM, 2014b; Swedish River Basin District Authorities, n.d.).

Local participation in the management of the Swedish river basins is highly encouraged for collaboration during the entire process. Example of such are the regionally and locally operating water councils, which consist of a mix of representatives of landowners, farmers,

industry, and municipalities, and act as referral organisations and partners to the River Basin District Authorities. The overall work includes initiating, coordinating and carrying out remedies to reduce the contamination load in the river basin, lakes, and groundwater (Swedish River Basin District Authorities, 2009).

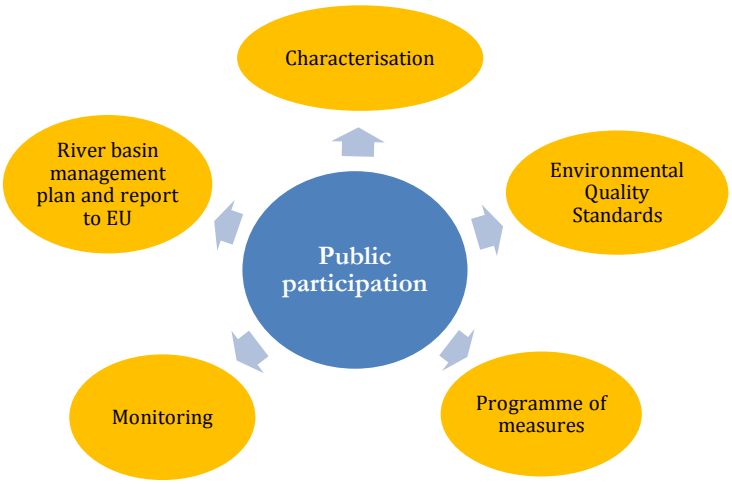

Figure 4. A managing cycle period of six years carried out by the Swedish River Basin District Authorities. (Modified after the Swedish River Basin District Authorities, 2009).

Half of the drinking water in Sweden comes from surface water and half from groundwater. It is the most important food stuff, and should be protected if it supplies more than 50 people or delivers more than 10 cubic metres of water per day. This is specified in both the WFD and the two national quality objectives stated in this thesis *Good Quality Groundwater* and *Flourishing Lakes and Streams*. While the Drinking Water Directive demands protected drinking water areas by law, the environmental quality objectives are merely objectives and not legally binding (CAB, n.d.).

According to the Swedish Food Act (SFS 2006:804), drinking water is defined as foodstuff from the point where it enters the water treatment plant until it reaches its end users. Hence, at a national level it is subject for quality controls by the National Food Agency (NFA, 2014). At a regional level, the CABs carry out some of the control and at a local level, the municipal Environment and Health Protection Committees perform monitoring, with involvement of the previously described local water councils. Swedish municipalities have a great deal of autonomy in the sense that they plan and carry out their missions rather independently. Part of the NFA's and the CAB's task is therefore to provide guidance for the national food control, and to make sure the controls within the different counties are coordinated. The producer of the drinking water is responsible for the water quality (NFA, 2014; Swedish River Basin District Authorities, n.d.).

Monitoring of water quality in Sweden

Through several national programmes under the WFD, as described in the previous section, Sweden is committed to report the results from monitoring at a river basin district scale to the European Environmental Agency. One example of a monitoring systems used for this purpose is the Water Information System Sweden [WISS]. It is a classifying and mapping database tool to facilitate information retrieval and to get easy access to the overall status of all

major Swedish lakes, rivers, groundwater, and coastal waters. The reported monitoring results may also serve as basis for future water environmental load assessment and as indicators on how well Sweden manages to meet the national environmental objectives *Good Quality Groundwater* and *Flourishing Lakes and Streams*. According to the Swedish EPA (2013, webpage), the two targets are described as follows:

> **Good Quality Groundwater:**
>
> *Groundwater must provide a safe and sustainable supply of drinking water and contribute to viable habitats for flora and fauna in lakes and watercourses. This objective is intended to be achieved within one generation.*
>
> **Flourishing Lakes and Streams:**
>
> *Lakes and watercourses must be ecologically sustainable and their variety of habitats must be preserved. Natural productive capacity, biological diversity, cultural heritage assets and the ecological and water-conserving function of the landscape must be preserved, at the same time as recreational assets are safeguarded. This objective is intended to be achieved within one generation.*

3.2 Legal Frameworks and Policy Instruments for Pharmaceuticals

3.2.1 The Precautionary principle

The precautionary principle is part of EU law and applicable to all Member States. The principle says that pre-emptive measures should be taken to protect the environment or human health, if there are reasons to believe that a product, method or likewise may involve unacceptable risks, even though sufficient scientific proof do not exist.

Regarding monitoring of veterinary pharmaceutical residues leaching into surface waters, the precautionary principle should be used as a guiding approach. To learn from previous mistakes in the past, where early warnings existed but nothing was done to prevent it from happening, the so-called *false negatives,* is one important reason to regard potential risks with caution and to improve environmental monitoring. Foss Hansen and Tickner (2013) write that contrary to the *false negatives*, its opposite *false positives* often pop up when the precautionary principle is brought up to discussion: regulation on non-existent or minor risks may become exaggeratedly regulated, due to unjustified public fears. Precautionary action may sometimes be crucial though, as environmental damage may take decades to discover and for scientific proofs of causation to appear. It simply takes too long. Some pharmaceutical residues in soil and water may have long-term, low-level exposure effects on aquatic organisms, on ecosystem and possible on human health as well. To reach a mitigating management strategy, the poorly understood active compounds and metabolites need further research in combination with a precautionary approach (Gee, 2006; Kümmerer, 2008).

3.2.2 The WHO Guidelines on Pharmaceuticals in Drinking Water

The WHO guidelines and the opinion of the Commission's Scientific Advisory Committee serve as the scientific basis for the set quality standards in the EU drinking water regulation (EC, 2015b). According to the EU Drinking Water Directive, there are several chemical, microbiological, and indicator parameters, that EU members are obliged to monitor in drinking water on a regular basis (WHO, 2012). In the report *Pharmaceuticals in drinking water*, the WHO (2012) refers to international tests carried out on drinking water, the results of which show a substantial margin of safety and minimal risk of adverse impacts on human health from pharmaceutical residues. Thus, the WHO's conclusions and recommendations

are, that since the levels of exposures are judged to be so low, specialised reduction methods for residue treatment are not warranted. The limited public health benefits would not justify the costs. The WHO do however in the same report, point out the necessity for relevant stakeholders to take action in local watercourses judged to be suffering from elevated levels of pharmaceutical contamination. The knowledge gaps about the long-term, low-concentration exposure effects on other organisms, and the possible synergistic effects of mixed pharmaceutical compounds, are also expressed to be of concern for the future.

Apart from a preventative approach, including consumer education through take-back programmes, regulations and policy guidance, the WHO advocates future research to address the issue of pharmaceutical mixtures for a more accurate assessment to take place. Data is generally lacking on the diverse group of human and veterinary pharmaceuticals in drinking water. The data that do exist are usually from ad hoc studies or research that has addressed specific human or veterinary pharmaceuticals in special locations, and standard sampling protocols for analyses do not exist. This adds to the challenge of assessing the pharmaceuticals in drinking water. Since pharmaceuticals residues in drinking water is of rising concern, the WHO advocates further research support for the development of cost-effective methods to address this issue (WHO, 2012).

3.2.3 Legislation on Pharmaceuticals in the EU and Sweden

Like other EU Member States, most of the Swedish pharmaceutical legislation is regulated at the EU-level for both human and veterinary pharmaceuticals. The EU legal requirements concerning veterinary pharmaceuticals are based on Directive 2004/28/EC *of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products* (European Parliament 2004a, and on Regulation EC/726/2004 *of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency* (European Parliament 2004b).

As part of the efforts to protect human and animal health, only pharmaceuticals authorised in accordance with objective scientific criteria are allowed on the European market. While the EC has the overall responsibility to continuously follow the development and enforcement of the legislation, the European Medicines Agency (EMA) has the administrative responsibility for the evaluation of new pharmaceuticals. The scientific trials are however under the responsibility of the national authorities. The EC directives are transposed into acts and ordinances by the Swedish government and into provisions by the Medical Products Agency, the authority in charge of the approval of pharmaceuticals entering the Swedish market (EPA, 2008).

The MPA also has a sectorial responsibility for environmental issues connected to its activities, such as issuing permission of pharmaceutical manufacturing. It should be noted though, that permission of pharmaceutical manufacturing is separate from permission granted according to the environmental legislation. In Sweden, the incorporated EU directives regarding environmental protection are mainly carried out with the support of the Environmental Code (SFS 1998:808) (EPA, 2008; MPA, 2015b; MPA, 2015c).

3.2.4 Monitoring and Environmental Risk Assessment in the EU and Sweden

Pharmaceutical emissions into the aquatic environment are mainly regulated through the formerly described Water Framework Directive. As part of the EU regulatory approval since

2006, pharmaceutical companies are required to perform an ERA on any new pharmaceutical entering the market of an EU country. Potential environmental risks and impacts on aquatic and terrestrial organisms and plants should be included in the assessment and risk minimisation measures (RMM) should also be suggested. Apart from the potential environmental risks, the drug application should state the precautionary and safety measures for storage, administration to patients, and disposal of leftovers. National MPAs will then inspect the performed ERAs, but according to EU legislation, environmental impacts cannot be decisive for whether the pharmaceutical is approved or not. For pharmaceuticals aimed for human use, the priority is put on human health and safety, not on potential environmental risks and impacts. Hence, no considerations are taken to the environment and potential harm caused by the pharmaceuticals within the risk-benefit valuation of them. This is however the case when the MPA assesses pharmaceuticals for veterinary purposes (excluding environmental effects that can be attributed to the manufacturing process) (MPA, 2007).

Seen from an environmental point of view, veterinary pharmaceuticals environmental precautions are given a stronger consideration than are pharmaceuticals aimed for people. This goes for both the legislation and the general notion on guiding the risk assessment (de Knecht et al., 2012).

It is the company producing the pharmaceuticals that performs the ERA described above. By estimating the concentration of a substance which the environment is likely to be confronted with, assessment of the potential harmful effects are predicted effects prior to authorising the pharmaceutical (MPA, 2007).

Among the questions addressed during the approval process, an environmental risk assessment should aim at answering the following (MPA, 2007).

- How is the pharmaceutical metabolised in the body?
- Where in the environment do the residues end up?
- How are the pharmaceutical residues downgraded in the environment?
- How do the pharmaceutical residues affect animal and plant life?

According to the MPA (2014a), the mandatory environmental risk assessment results and the identified risk minimisation measures are currently not stored for the purpose of public benefit, or made available to the public neither in the EU nor in Sweden. Moreover, no data analyses are made to get an overall picture of the environmental impacts. The present level of knowledge that do exist on the environmental impacts risks of pharmaceutical residues is owed to the research-initiated studies performed by university researchers and industries, and is not the results from the pharmaceutical risk assessments (MPA, 2014).

One example of such initiatives is the Swedish Environmental Classification and Information System for Pharmaceuticals (SECIS). It was initiated by the Swedish Association for the Pharmaceutical Industry (LIF), and is a voluntary system for classification of pharmaceuticals regarding environmental information. Based on pharmaceuticals' effects in non-target environmental species, the system aims at providing environmental information to public and health care sectors about all active pharmaceutical ingredients on the Swedish market. Thus, contrary to what is argued by the MPA (2014a) above, the environmental information from the ERAs is being published, although after having been reviewed by an external consultant. The environmental information and classifications are then published on the LIF webpage *fass.se*, which is frequently used as a source of information by several end-users, such as patients, medical staff, and veterinarians (Ågerstrand & Rudén, 2010).

Nonetheless, the information used in SECIS is partly based on the ERAs performed by the medical companies themselves. It has been shown that different products containing the same substances are classified differently by different pharmaceutical companies, and according to the MPA (2014), the tests that form the basis for risk classification are often inadequate regarding the identification of potential long-term environmental effects on non-target organisms. Results from SECIS have confirmed that 59 percent of the products assessed within the SECIS system did not have enough ecotoxicity data to enable a classification according to their criteria (Ågerstrand & Rudén, 2010).

Comprehensive information about environmental concerns in regards to pharmaceuticals is also provided by the Stockholm County Council website for medical staff at *janusinfo.se*. That information is independent from pharmaceutical producers (MPA, 2014).

3.2.5 Approval Procedures for VPs in the EU

The potential toxicity of veterinary pharmaceuticals is predominantly monitored with a prospective risk assessment focus. Several recommendations and guidelines on how to approach the risk assessments are available, the most internationally used model are the two-phase process ERA-guidelines developed by International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products (VICH). The VICH-model was developed to harmonise registration data required for veterinary medicines between Europe, the Unites States, Japan, Canada, Australia, and New Zealand.

A very general overview of the approval process is provided as follows: A first assessment decides whether the pharmaceutical should be further investigated in phase II-assessment or if Phase I is enough. Phase II divides the pharmaceuticals into aquatic and terrestrial branches. Veterinary pharmaceuticals intended for open systems, such as in an aquaculture, are directly referred to the phase II if the concentration in effluent water is estimated to be exceeding 1 microgram per litre. Parasitic drugs used in pasturing animals are also directed straight to phase II, as this group of VPs are active against organisms related biologically to vertebrates found in pastures. For all other VPs, the phase II assessment will only be required if the estimated VP concentration are over 100 microgram per kilo in soil. The phase II guidance is further divided into three different sectors, each with criteria specifically adapted to them: 1) aquaculture, 2) intensively reared terrestrial animals, and 3) pasture animals. Two tiers (A and B) guide the assessment further in phase II. These are based on physical, chemical data parameters requirements from OECD or ISO, testing environmental effects and fate (de Knecht et al., 2009). Steps however not included in pharmaceutical ERAs, are the risks from pollution and emissions during the production process, and guidelines on the risks associated with the development of resistance (MPA, 2014). For further and more illustrative information on the approval process of VPs according to the VICH-system, the reader is referred to Appendix II.

3.2.6 Monitoring and Screening Programme in Sweden

In Sweden, the screening programme is a supplement to the National Environmental Monitoring Scheme and serves the purpose of obtaining information about persistent organic pollutants (POPs) that either are newly discovered, are used in large volumes, or for some other reason has caught the attention of national or international authorities. The selected substances for the screening are measured in different media on one or more occasions during one year (EPA, 2007).

For VPs, three screenings have been carried out in Sweden in the last ten years: *Results from Swedish national screening programme 2005. Subreport. 1. Antibiotics, Anti-inflammatory substances, and Hormones* by Andersson et al. (2006), *What concentrations of hazardous substances do we find in the environment? Results from the Swedish Screening Programme 2005-2007*, by the EPA, (2007), and *Screening of veterinary medicines in agricultural areas* by Sternbeck, Österås, Josefsson, Andreasson and Kreuger (2007). Some of the substances in the screening were regarded as hazardous to the environment. However, none of the screened pharmaceuticals could be detected in the two latter screenings, only the former screening (Andersson et al., 2006), traced veterinary pharmaceuticals in surroundings close to animal facilities. The method of analysis did not address the degraded metabolites though, thus the potential long-term effects on the aquatic environment could not be concluded from these screenings.

In their paper *Occurrence and fate of pharmaceutically active compounds in the environment, a case study: Höje River in Sweden*, Bendz et al. (2005), evaluated the impacts of low and constant influent of pharmaceutical compounds on downstream concentrations. They also studied whether there was a connection between highly physically metabolised pharmaceuticals and a low persistency in the environment. No such connection could be concluded, but part of their pharmaceutical findings were two different kinds of persistent antibiotics (trimethoprim and sulfamethoxazole) used both for humans and animals (mainly in horses) (Fass, 2015a; Fass, 2015b; SBA, 2015). It was also showed that some pharmaceuticals were present in fluctuating concentrations along the reservoirs and within the river.

3.3 General shortcomings in veterinary pharmaceutical monitoring

Several authors (Brandt et al., 2012; Brooks et. al., 2009; de Knecht et al., 2009; Kümmer et al., 2008; Metcalfe et al. 2009), write about the limitations and shortcomings with the currently used measuring methods for veterinary pharmaceuticals in aquatic systems. Part of the reason being that they are released episodically, and because the detection and sampling methods may not be accurate for these groups of medicines.

3.3.1 Environmental Risk Assessments limitations

According to Brandt et al. (2012), the standardised toxicological tests performed on aquatic organisms are suitable for detecting substances in levels that may have a direct toxic effect. For pharmaceutical residues, however, with possibly more subtle effects on the environment and organisms, these tests are of less value. The authors give examples of questions that may still be unanswered when standardised tests have been performed (p. 24):

- *What are the effects of long-term exposure at low concentration, including on fertility and offspring?*
- *What particular effects might be expected on wildlife given what we know about the mechanism of action of a substance in humans?*
- *What effects might a substance have when mixed with a real-world cocktail of other chemicals and pharmaceuticals?*

The authors further emphasise the importance of ex-post monitoring of pharmaceutical residues in surface waters as an important part of the overall risk assessment. More exquisite and thorough identified endpoints should be used for monitoring the effects caused pharmaceutical residues, for instance behavioural and reproductive changes in organisms (Brandt et al., 2012).

In their paper, *Assessing the Aquatic Hazards of Veterinary Medicine*, Brooks et al. (2009), write about how the conventional standardised ecotoxicity tests may elicit indirect causes from VPs.

Endpoints such as mortality, growth, and reproduction may not be the most suitable parameters through which to determine the risks associated with certain VP compounds since there is a risk they may elicit indirect effects. Instead, they advocate methods where combined information on toxicology and substances' efficacy in targeted organisms and mammals are included.

Moreover, different laboratory-based approaches to assess the aquatic environment effects of VPs and methods for analysing the data from these measures are complex. The laboratory represents a distinct setting to the real environment, where veterinary pharmaceutical residues exist together with other contaminants in the aquatic environment, such as pesticides, nitrogen, and phosphorous. The aquatic ecosystems are also complex, consisting of interlinked communities of different organisms, multispecies response, synergistic effects of residual mixtures, and other scenarios undetectable in a laboratory setting. Other complicating factors are that the exposure of VPs is not always constant. Episodic releases are common and this fact makes the assessing harder as the metabolites may become degraded in the environment and harm may already been caused when the analysis is taking place (Brooks et al., 2009).

3.3.2 Ex-post monitoring

Monitoring of VPs can be performed in several ways, just like the many pathways of exposure enabled by medicines. Not always is the interpretation of these data straightforward, since chemical standards and criteria have not been set for all VPs. Testing for VP residues is both costly and technically challenging as metabolites and degrades often are less stable than the parent compounds. Obtaining large enough quantities of the test substances, good laboratory practises, and lack of appropriate analytical standards and methods for metabolites or degrades, are also contributing to the challenge of interpretations of data (de Knecht et al., 2009). Brooks et al. (2009), argue that for improved retrospective ecological risk assessment (ex-post monitoring) to take place, increased knowledge about the target mode of action of a VP could facilitate the most appropriate methods for testing, and develop more adapted endpoints to measure the aquatic effects. They do, however, point out that from a resource perspective, performing separate toxicity studies on all pharmaceutical residue compounds is not viable.

The enforcement of VP label requirements is also often lacking in many countries and this fact weakens the reliance on risk mitigation measures. Even though the approval and authorisation of VPs are regulated at a national or EU level, the actual enforcement of the mitigations take place at lower (local) level. The authors thus believe that risk assessors should be well aware of the enforcement law limitations regarding the control of the mitigation measure implementations. On a local level, no surveillance or monitoring of veterinary pharmaceuticals is required from the EU[5]. The only exception is the maximum residue level [MRL], (described in the following section 3.3.3.), of some veterinary pharmaceuticals in foodstuff from animal origin, with the overall purpose of protecting human health. In Sweden, for instance, manure from pharmaceutically treated animals can be spread without restrictions (Sternbeck et al., 2007).

[5] Although, as previously mentioned in paragraph 3.1.2, all EU Member States are allowed to include higher levels of monitoring than the minimum standards set by the EU.

3.3.3 Pharmacovigilance of veterinary medicines

The European Veterinary pharmacovigilance is collaboration between with the EC, European Medical Agency [EMA], and the national authorities. It involves prevention of medicine-related side effects in both animals and humans. By law, the marketing authorisation holders are obliged to report any adverse effects of the VP to relevant national competent authority (EC, 2011). Adverse effects are for instance potential environmental impacts, clinical safety, off-label use, or violations to the withdrawal period[6], or the so-called Maximum Residue Level. According to the *Council Regulation 470/2009/EC on procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin*, the MRL-values exists for food safety reasons, to protect humans from harmful VPs in foodstuffs of animal origins. The values are decided for muscles, liver, kidney, fat, milk, egg, and honey, and are the basis of residue level control and withdrawal periods. For some pharmaceuticals, the MRL-value has not been possible to establish, hence the prohibition of treating food-producing animals with some medicines (SBA, n.d.). For marketing authorisation renewals, the use of pharmacovigilance is therefore important information for revaluation of the balance of risks and benefits of a VP (de Knecht et al., 2009).

Pharmacovigilance data are submitted on a regular basis to the EU Periodic Safety Update Reports, where it is used for assessing whether the risk-benefit balanced has changed or if any new risks have been identified (EMA, n.d.a). This is done by comparing sales volume of a VP to the reported individual side effect cases. In practise, though, the environmental aspects will not be included, which is partly explained by the passive process of reporting side effects: reporting depends to high degree on the goodwill of veterinarians, animal keepers, and pharmacists to actually report them. Besides, to prove a direct link between a pharmaceutical product and an environmental problem is a complex task. The risk assessment would need to consider a large scope of possible pathways, species, and involved ecosystems to be able to achieve such evidence. De Knecht et al. (2009), argue that because of this "…a regulatory scheme that does not involve credible post authorization monitoring is likely to suffer from an unknown number of false negatives, in which the environmental risks of chemicals are underestimated." (p. 49).

3.4 Improved environmental considerations for pharmaceuticals

Both in Sweden and within the EU, agencies and several stakeholder groups work to improve the impacts related to the manufacturing, the use-phase, and end-of-use of pharmaceuticals. Although veterinary pharmaceuticals in specific are rarely mentioned in these fora, the environmental concerns are generic and involve veterinary pharmaceuticals indirectly. Besides, many human pharmaceuticals are also used for veterinary purposes. The following paragraphs highlight some of the efforts for improvement both on a Swedish and on an EU-level.

In 2013, the Swedish government decided on new milestone targets regarding increased environmental concerns in the EU and international legislation on pharmaceuticals. More specifically, latest by the year of 2020 decisions will be taken on increased environmental concerns into the manufacturing process and the use-phase of pharmaceuticals. In 2014, the Swedish government launched a lobbying within the EC to start developing a strategic approach to the pollution of water bodies with pharmaceutical residues. Particular emphasis is put on the EC to identify and investigate the consequences of different courses of action in terms of environmental considerations in the risk-benefit assessments on pharmaceuticals. The Swedish government has designated the MPA to such further analysis, which should include societal costs of pharmaceuticals and the development of new ones, and the costs of

[6] Withdrawal period is the time that must elapse between medical treatment and slaughter or consumption.

environmental damage. The results will be used to push the matter further within the EU and internationally (Government Offices of Sweden, 2014). Within this mission to identify and analyse suitable undertakings for increased environmental concern in pharmaceutical legislation, the MPA have decided on four main actions, parts of which include increased accessibility to the ERA data, previously described in 3.2.4 (MPA, 2014a).

The Swedish research programme MistraPharma, which is a collaboration between one British and five Swedish universities, started its work in 2008. The overall aim with MistraPharma is to identify human pharmaceuticals that pose a risk to the aquatic environment, to suggest mitigation risk management strategies, and to strengthen the stakeholder network. In order to increase the access to data on human pharmaceuticals on the Swedish market, MistraPharma provides the publicly available ecotoxicity data for free through the database WikiPharma (MistraPharma, n.d.).

On the European level, the EurEau, who represents the members from national associations for water services, exerts pressure on the European Commission to act for a more holistic problem solving approach on pharmaceuticals in the aquatic environment. In a position paper from 2014, *Contribution to the European Commission Strategic Approach on Pharmaceuticals in the Environment*, several mitigation actions at different levels are proposed to reduce pharmaceutical load entering water bodies. For instance, on a design level, green pharmacy is brought up, where the entire life cycle of a substance is regarded. On the level of market authorisation, the ERA is suggested to include a broader risk-benefit analysis, which should also address the protection of water sources. The ERAs are suggested to become publicly available on the EMA's website, as opposed to today when they are not published in the registration dossier. This fact makes it harder for users or other actors to foresee the environmental impacts of the approved pharmaceutical product. Even though the primary focus is on human pharmaceuticals in this paper, the veterinary ditto are acknowledged to contribute to the total load (EurEau, 2014).

4 The case of Lake Vomb, Scania

This section focuses on the case of Lake Vomb to illustrate the current state of monitoring VPs in Sweden under the existing European and national policy regimes and regulations. This section will also provide the main research findings stemming from the interviews with municipal environmental inspectors and experts within different fields of work and scientific areas of research.

4.1 Case study – the Lake Vomb

The lake Vomb is located 20 km east of Lund in the region of Scania in Southern Sweden. It is a natural lake, with a total area of 12 km^2, a mean depth of 6.6 m and a maximum depth of 16 m. Since 1948 Lake Vomb has provided the inhabitants of Malmö and other surrounding villages and towns with drinking water. Today around 400 000 people depend on it for drinking water. The lake is the main catchment area for water transported by River Kävlinge. Three municipalities border the lake: Eslöv, Lund, and Sjöbo. The surrounding area is an extensive agriculture and husbandry region, up to 70 percent of the Lake Vomb river basin area consists of arable land. Nutrients, mainly nitrogen and phosphorous, pesticides, and other residues from the activity in the surrounding region contributes heavily to the runoff entering the lake (WISS, 2013). Because the soil in this area easily drains, it allows only for a brief retention time for the water upstream Lake Vomb. The contaminants may therefore to a large extent end up the river basin quite unaffected (Parkefelt et al., 2015, April).

According to the Swedish Board of Agriculture database for the year of 2013, in the three municipalities around Lake Vomb, there were around 10 000 horses[7], 36 000 livestock (cattle, dairy, and calves), 7 500 sheep, 79 000 pigs and 450 000 chicken (Swedish Board of Agriculture (SBA), n.d.). The lake is designated as nationally valuable water; apart from being a drinking water supply, it is an attractive recreational area for fishing and leisure, and an important location for shorebirds. However, major cyano-bacterial blooms occur yearly because of the high load of nutrients entering the lake (CAB, 2011).

The classification standards of the Lake Vomb can be used to exemplify the national quality objectives relevant to this thesis, namely *Good Quality Groundwater* and *Flourishing Lakes and Streams*. While the latter quality objective is directly linked to the ecological and chemical status, the former is indirectly affected through the water cycle.

For instance, the ecological status of the lake is classified as poor due to the following environmental issues: nutrient and organic enrichment, environmental pollutants, and altered habitats (WISS, 2013). The environmental quality objective will not be reached neither by 2015, nor by 2020. Instead, it has been deemed appropriate to define the environmental quality standard for good ecological status with a new deadline for 2027, which will be achieved if all possible and reasonable measures are taken (WISS, 2013). In 2009, the chemical status of the Lake Vomb was classified as good, but in 2013, it was *failing to achieve good*, due to the presence of mercury in fish, which exceed the EU limit values (WISS, 2013).

[7] 10 000 horses is a rough estimation of the amount of horses in the municipalities of Eslöv, Lund, and Sjöbo. Only horses from registered farm businesses are available in the Swedish Board of Agriculture databases. On a national scale, the amount of horses from registered farm businesses corresponds to a third of the total amount of horses in Sweden, according to Jimmie Enhäll, statistician at the Swedish Board of Agriculture (personal communication, August 12, 2015). Hence, 10 000 horses are the amount of farm company horses registered in 2013, multiplied by three.

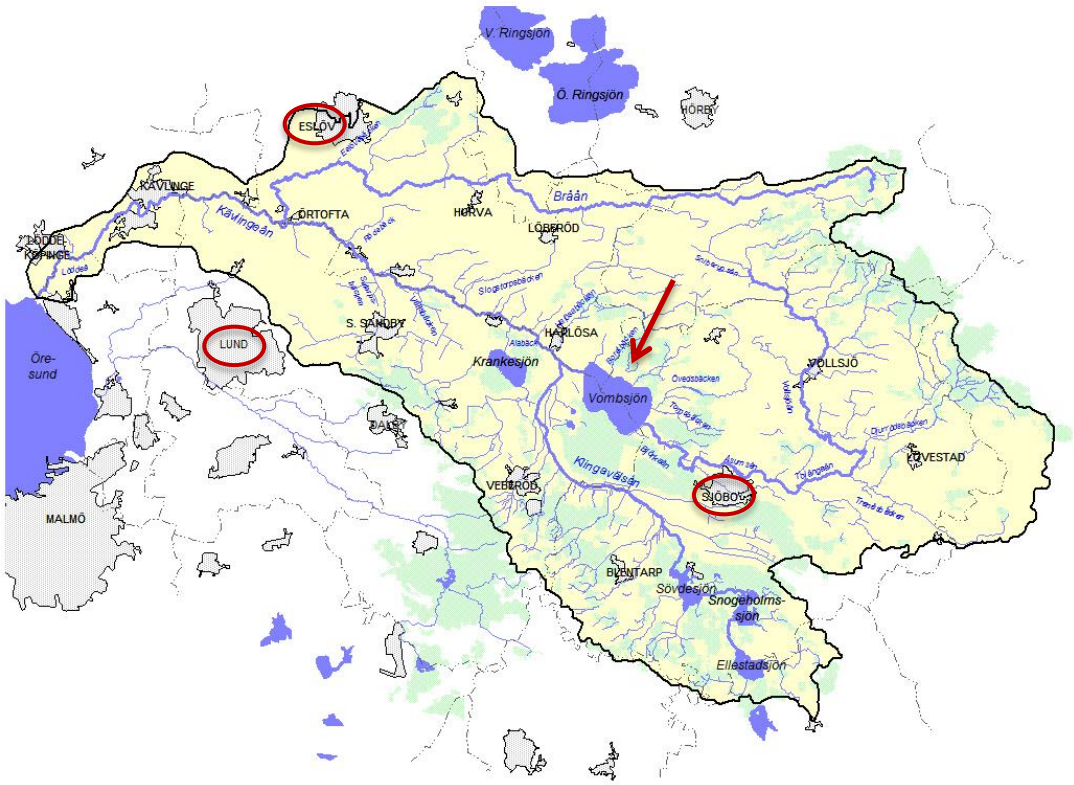

Figure 5. The catchment area of Lake Vomb in Scania surrounded by the three municipalities Eslöv, Lund and Sjöbo. Source: River Kävlinge Water Council.

4.1.1 Upstream - preventative work

To improve the local river basin management, several water councils operate both regionally and locally. They consist of a mix of representatives of landowners, farmers, industry, municipalities, and act as referral organisations and partners to the River Basin District Authorities. The overall work includes initiating, coordinating and carrying out remedies to reduce the contamination load in the river basin, lakes and groundwater. To encourage local participation and taking part of local knowledge and experience is fundamental to the water councils (Swedish River Basin District Authorities, n.d.a).

For the area in question, around the Lake Vomb, the River Kävlinge Water Council is one of several water councils managing water-related issues. Construction of wetlands is one example of preventative action and measure to reduce the loss of nutrients and leachate of pesticides into surface and groundwater. In a recent study, a new form of local collaboration within the water management was investigated: Through dialogue, raise farmers' awareness and knowledge about the water impact of their activities to achieve a long-term improvement of nutrient and pesticide leachate into the river basin. The study was carried out in one part of the river basin to the Lake Vomb, and included local farmers, turned out to be a successful way to increase the communication amongst different stakeholders. The aim is for long-term improvements of the water quality in the intensively farmed area around the Lake Vomb to be established (Swedish Water and Wastewater Association, 2015). The study did not include pharmaceutical residues, only nutrients and pesticides. More on this in section 4.3 further down.

4.2 Environmental inspectors and veterinarian responsibility

A total of eight environmental inspectors from the municipalities of Eslöv, Lund, Sjöbo, and the Ystad-Österlen region Environmental Association were contacted. The latter represents the three municipalities of Ystad, Tomelilla, and Simrishamn, and which were contacted to find out whether the topic question was treated similarly in other Scanian municipalities. In addition, one veterinarian from the County Administration Board of Skåne was contacted to find out more about the veterinarians' role of pharmaceuticals in relation to the aquatic environment.

Most of these calls were very brief, and ended more or less after the author posed the question "Do you carry out any form of monitoring of veterinary pharmaceutical residues in the Lake Vomb?" It soon became clear that monitoring VPs in the lake Vomb was not taking place in any of the contacted municipalities and the author was repeatedly referred to someone else more likely to provide an answer. Since these brief calls did not add much information, they were not included in the interview material. Additional valuable information was however gained from the rest of the interviewees, as follows.

Helena Wellershaus, Environmental inspector of drinking water, Lund municipality

Helena Wellershaus was one of the environmental inspectors contacted to find out more about the monitoring of veterinary pharmaceuticals in the Lake Vomb. She said she had so far never encountered requirements of having to monitor veterinary medicines in specific. Within the *Environmental Monitoring Programme* for water, there are four monitoring points, in which pharmaceutical residues are sampled yearly, but only some pharmaceuticals frequently used by humans. Helena Wellershaus mentions the increased frequency of pharmaceutical debates, both internationally and in Sweden. A special concern regards the pharmaceutical residues that originate from sludge, which is applied as fertiliser on fields, and which may further leach into surrounding water bodies. If fertilising is taking place close to a water body, and the buffer zones are not respected, the leachate will definitely end up in the water. She believes this is a problem on the rise, and that more research will focus on this in a near future. Helena Wellershaus thinks it is important to discuss and raise awareness about the subject of veterinary pharmaceuticals.

Ida Grimlund. Agronomist and Environmental Inspector of agriculture and husbandry, Lund Municipality

Ida Grimlund was contacted on suggestion from Helena Wellershaus, due to the agricultural/husbandry connection to veterinary pharmaceuticals in the area round Lake Vomb. According to her, the discussions regarding veterinary pharmaceuticals concerns more practical issues, such as returning old or unused medicines, and used material. Usually the veterinarians take it back with them, or it is handed back to the pharmacies.

Pharmaceutical residues in sludge, applied on fields for fertilising is discussed from time to time, but what originates from animal excretion and manure is not addressed at all. Ida Grimlund says she does not quite know what they could do differently in their inspections to prevent the leaches, because the animals move around on pastureland next to water bodies, like at the Lake Vomb. How manure should be spread and the mandatory creation of buffer zones have already been addressed through legislation, but that does mainly concern nutrients. Ida Grimlund thinks that the veterinarians are rather restrictive when it comes to medication in Sweden, although, for instance pigs were perceived by her to be the group of animals most frequently medicated. Pig farms usually keep to the same vet, and horse yards seem to keep in touch frequently with their veterinarians. These were expressed to be important remarks, as

good and trustworthy collaboration also means that the patients are followed up more thoroughly and higher restrictions on medical use are applied.

Maria Lantz, Environmental Inspector of onsite wastewater treatment, husbandry and agriculture, pesticides, and water protection areas. Municipality of Eslöv

Maria Lantz was contacted due to her role as an environmental inspector, with a range of special areas for inspection. Just like other contacted environmental inspectors, she does not monitor any veterinary pharmaceuticals in the Lake Vomb. She says that if pharmaceuticals are discussed it mostly concerns what pharmaceutical residues are found in the sludge, which is used as field fertiliser. Media brings up the topic from time to time.

(Maria Lantz, 2015): ”We do not discuss large farms contributing with pharmaceutical emissions to water bodies, but we talk about pharmaceutical ending up in waste and how to prevent it. As inspectors, we are entitled to look through the medical journals to check exactly which pharmaceuticals are being used, when, and on which animal, if we believe there is a reason to do so. It is, however, important to make sure that the right regulatory chain applies all the way.” In the municipality of Eslöv, there are many large estates with large seed crops; hence, large volumes of pesticides are being used. Animal-wise, there are mostly chicken farms, but also pig and cattle/dairy farms, and plenty of horse yards with up to 10-25 horses. In general, Maria Lantz does not think that the veterinarians consider the risk of leaching pharmaceuticals into water surfaces when they treat the animals. Except for the sludge, and the ongoing discussion about whether the sludge should be certified or not, most efforts are put on the heavy load of pesticides entering water bodies and private wells.

Charlotta Kamaterou, County Veterinarian at the Animal Welfare and Veterinarian Department, the County Administrative Board of Skåne

The County Administrative Board (CAB) of Skåne has the overall responsibility for control in several areas in the food chain in the region. Charlotta Kamaterou was contacted in order to find out more about the veterinarian role in the area of responsibility addressing veterinary pharmaceuticals in the aquatic environment.

(Charlotta Kamaterou, 2015): “Primarily, the veterinarian should make sure that the prescribed medicine is suitable for treating the condition of the patient, but other aspects, such as informing the animal keeper on how to recycle the medical leftovers, are also included. This is how far the individual veterinarian responsibility goes. For the animal keeper, the responsibility includes the returning of medicine leftovers to the relevant place [to a pharmacy, recycling station, or through a collecting service if the animal keeper has a registered business]. The pharmaceutical residues that leave the animal body are not regulated though.”

She further mentions that currently there are not restrictions on having animals grazing next to drinking water supplies, such as around the Lake Vomb, or having farming facilities in close location to water bodies, so there may be a risk of pharmaceuticals ending up as runoff in the nearby waters. Some of it may however be prevented by the buffer zones, [which are part of the legislation regulating manure spreading], but she underlines that her knowledge on this matter is limited.

(Charlotta Kamaterou, 2015): “As part of our monitoring work at the CAB, we control the use of medicines. Among other things, we control that medicines are used only when necessary and that the risk of developing resistance is taken into account by the veterinarian as

antibiotics are prescribed. In comparison to several other EU countries Sweden is doing really well in this area, particularly concerning the use of antibiotics as it is associated with major risks of resistance. The preventative animal health care in Sweden is unique. For many years, we have worked hard to fight and control several animal diseases, and as a result of this work it has also been possible to reduce the use of antibiotics. This means that when we really do need to use them, we can opt for the ones with a narrower spectrum of treatment, simply because we are not yet suffering as badly from resistance as many other countries are. There is of course always room for improvements, but in general and in comparison to most other countries, Sweden is doing well in the restricting the use of medication."

Charlotta Kamaterou further argues, with regards to my question on monitoring of veterinary pharmaceuticals in drinking water supplies, that the question should be addressed already at the start with the animal health care and safety. She underlines the pre-emptive upstream work on how to reduce the use of pharmaceuticals in the first place. In several places in Europe it is still possible to buy antibiotics over-the-counter, without prescription. The Swedish approach is that the assessment of whether the medication should be given or not should be made by a veterinarian. Along with efficient work on animal health care, these are very important parts of the preventative work to avoid pharmaceutical residues in water in the first place.

4.3 Expertise

Eight water quality experts were contacted to gather more specific information about veterinary medicines in the aquatic environment from their different perspectives. The experts work within the field of engineering, policy work and innovation, advisory on drinking water, sewage and private wells, chemistry and ecotoxicology, biomedicine and veterinary public health, and advisory on veterinary medicine within the farming association. They were all deemed as relevant stakeholders for the thesis topic to start with. Nevertheless, one of the contacts was focusing mostly on EU and antibiotics, which the author judged to be outside the scope and therefore discarded that interview. The remaining seven interviews are summarised below.

Britt-Marie Pott, Process Engineer at the Vomb Drinking Water Treatment Plant, Southern Sweden Water Supply (Sydvatten)

The complexity of monitoring medical residues was reflected in the conversation with a process engineer at the Vomb water treatment plant: (Britt-Marie Pott, 2015): "When you want to analyse these compounds, where should you start? There are numerous original compounds and even more metabolites, probably both known and unknown." To identify metabolites, which may also have interacted with other substances, is a complex process. The spectrum of chemical properties is enormous and this fact places great demands on the purification methods. It is particularly complex to get to know how different residues interact, hence the purification difficulties. In the Vomb water treatment plant, biological degradation of material and substances takes place in the infiltration basins. This process is an efficient purification step for plenty of the organic substances present in the lake. When dealing with pharmaceuticals though, the effect of purification is limited, because what is not metabolised and degraded within the body, in faeces, in soil or in the lake; where high biological activity is already taking place, might not to any larger extend be further degraded or adsorbed in the basins. Highly persistent pharmaceuticals may therefore still be present in the outgoing water.

Additional cleaning methods exist, such as ozone and active carbon. These methods also give rise to new substances needing attention. More focus should perhaps be placed on upstream, preventative work, as it is the most feasible solution for reduction of unwanted substances. The fewer substances entering the lake from the catchment area, the lesser the need for

purification, naturally. This approach would put a heavy financial load on the farmers if they were obliged to deal with the waste already at the farm level, unlike the situation today where the municipalities bear the costs. A discussion concerning the most cost efficient and environmentally beneficial treatment methods, and where they should take place, is necessary.

Additional issues to consider when addressing upstream work is how well the preventative measures that do exist are monitored. For instance, buffer zones [the interface between arable land and a watercourse] are mandatory by law to prevent nutrients and pesticides from draining straight out into the lake from the soil, but unless these measures are controlled, they may not do any good. Besides, the fact that Scanian soils are well drained might make protective measures like buffer zones in this particular region a less efficient mitigation method.

Ann-Marie Camper, Marine Biologist, former Assistant Project Manager of InnoVatten, Project Manager for the Marine Center, Simrishamn Municipality

Ann-Marie Camper was contacted due to her prior role as the chairperson of the InnoVatten project. This project served as a regional network project for Scanian actors working with water related issues, and in which pharmaceuticals in the environment was highlighted as one of the areas in need of particular attention. Ann-Marie Camper focused on pharmaceuticals in both the marine and freshwater bodies, which included areas like treatment techniques, how the aquatic environment is affected, and international and national policies addressing this issue.

During her work, it soon became clear that Sweden did not have any policies at all addressing the problem with pharmaceuticals in the aquatic environment. (Ann-Marie Camper, 2015): "Legislative improvements have happened during the last few years though, which is expected to have positive effects on pharmaceutical surveillance in general. Different policy documents regarding pharmaceuticals are increasing. Regarding veterinary medicines, we didn´t specifically look at them, because a lot of the focus on medicines and animals is included in the handling of antibiotics in food producing animals, for instance, the withdrawal period for slaughtering medicated animals [MRL-values, mentioned in chapter 3]. In the InnoVatten network, the Swedish Farmer Association collaborated with us, and we talked about how the farmers in the old days had to stall the animals when they were being treated with antibiotics, and you could separate the excretions from those animals. That was a regulation at the time, but maybe it disappeared in connection to the EU entry."

(Ann-Marie Camper, 2015): "Anyway, that is only a very small part of the problem, because most of the pharmaceutical emissions will take place out in the fields. I did discuss this with several stakeholders within the veterinary field of medicine, but pharmaceuticals do not seem to be regarded as a problem. Besides there are no legal demands exerting any pressure to deal with the problem. It is actually the same with the human pharmaceuticals and purification; when the government does not demand the municipalities through legislation to increase the levels of treatment/purification of pharmaceutical residues at the wastewater treatment plants, because it is too costly. I think this will change in the future. The more scientific evidence we get on how pharmaceutical residues and other chemicals may affect the environment. We are not talking lethal or no lethal effects, but rather more subtle effects, like changes of behaviour or other vital functions. If we alter an entire ecosystem, then what can we do? ".

Peter Sörngård, Specialist/Advisor in sewage and environmental issues related to agriculture and water at the Swedish Water and Wastewater Association (SWWA)

(Peter Sörngård 2015): "The SWWA is involved in the pharmaceutical residue problems in different ways, although veterinary pharmaceuticals are not specifically addressed. As other pharmaceuticals, they may end up in drains/sewage to a certain extent and find their way to drinking water sources. The issue with pharmaceutical contamination has lately been raised at the EU-level through the Water Framework Directive. Presently, three antibiotics and three hormonal pharmaceuticals, VPs included, are on the EU watch-list. They are to be monitored for a certain period of time, for further review of the preconditions and needs for mitigation measures for EU Member States to adopt and carry out." Peter Sörngård underlines the importance of preventative upstream work, highlighting the efforts by MistraPharma[8] in collaboration with the Medical Products Agency on solving pharmaceutical related to environmental problems. Peter Sörngård mentions two reasons hampering improved environmental concerns regarding pharmaceuticals: Environmental aspects are not regarded at all in pharmaceuticals for humans, long-term environmental affects has no priority what so ever. The other aspect regards the economy: If a cheaper option [generics] is available to a prescribed medicine, it should by law be offered to the customer, regardless other aspects. According to Peter Sörngård, in this way the subsidy only covers the economy, excluding the environment.

Dr. Jenny Kreuger, Research leader in organic chemistry och ecotoxicology, Swedish University of Agriculture (SLU)

Dr. Jenny Kreuger was contacted due to her participation in two studies on several veterinary pharmaceuticals: the first one was a screening study conducted in 2005 on behalf of the Swedish Environmental Protection Agency, and the second study was conducted in 2007 This study was conducted in southern Sweden (Kalmar, Skåne, Västergötland and Halland).

The spots for measuring were chosen with particular concern for the location and time of the year: watercourses close to intense farming in early spring, being time of the year when the most intense fertilising of fields with manure will take place and therefore the highest likelihood of finding veterinary pharmaceutical residues. Only one veterinary pharmaceutical was traced during this screening, but it was not clear whether it originated from veterinary use or from human use. Based on the results of these two screening occasions, Dr. Kreuger is of the opinion that VPs do not represent a hazardous risk to the environment. A further comment was the comparatively low volumes of veterinary pharmaceuticals that are used in Sweden, which in itself indicates it is less of a problem for the aquatic environment, than the use of pesticides. As opposed to pesticides, VPs are usually administered to the animals [given by injection or orally], hence the pathways are limited to the spread of manure in early spring, or when the animals are free ranging and excretions enable the runoff to close by rivers and lakes. Some of the antibiotics that are used on animals are pretty short-lived, although the antiparasitic drugs are more persistent. Still, in Sweden antiparasitic drugs are not applied to entire herds unless strongly indicated as necessary. It is not as some places in the US, where thousands of free-ranging cattle are outdoor all year round, which is a completely different dimension compared to the Swedish context.

Dr. Kreuger's experience is based on the two occasions of screening investigation she participated in and according to them; there are no real indications of us having greater problems with veterinary pharmaceuticals in Swedish waters. On the other hand, what she

[8] Since 2008 the Swedish research programme MistraPharma, work with the aim to pin down and reduce the risks of human pharmaceuticals in the environmental (Brandt et al., 2009).

does think indicates a larger problem is the findings of human pharmaceuticals from the WWTPs, to which large populations are connected and where higher concentrations of some pharmaceuticals are detected. Nevertheless, what toxicological effects this may or may not have on humans and on the environment, are hypothetical questions to which she cannot provide an answer.

Dr. Gunnar Carlsson, Researcher at the department of Biomedical Sciences and Veterinary Public Health, Swedish Agriculture University (SLU)

Dr. Gunnar Carlsson was contacted due to his previous research on potential toxicological effects from veterinary pharmaceutical on fish embryo development: *Toxicity of 15 veterinary pharmaceuticals in zebrafish (Danio rerio) embryos* (Carlsson, Patring, Kreuger, Norrgren, & Oskarsson, 2013). More specifically, the research focused on potential effects, which could occur in water bodies with a close location to pasture land or where manure had been applied.

According to Dr. Carlsson, pharmaceutical residues in the environment is currently being debated quite frequently and in line with the majority of other interviewees, he mentions the focus on human pharmaceutical residues from WWTPs. The difference to veterinary pharmaceuticals, according to him, is that it is usually released locally and in smaller volumes. In general, pharmaceutical metabolites are difficult to study, as other than additive effects from the pharmaceuticals, combinations of the metabolites, are believed to also have impacts. Several studies describe that the antiparasitic drug Ivermectin [used on horses, sheep, and cattle] as extremely toxic to crustaceans, even at very low concentrations. It does, however, not cause immediate toxic effects; rather it alters reproduction in crustacean populations. Ivermectin is supposed to have detrimental effect on ectoparasites [inter alia], which are closely related to crustaceans. Thus, its toxic effect does not come as a surprise[9].

Pär Aleljung, Microbiologist and Advisor for drinking water matters related to private wells at the Swedish Food Agency

Pär Aleljung was contacted due to his expertise in contamination of drinking water in private wells and was asked to share his thoughts and opinions on the thesis topic [veterinary pharmaceuticals ending up in surface waters, to some extent may also end up in ground water and private wells, whose water also is used for the same purpose]. He is of the opinion, that regardless the user of the pharmaceutical, it is equally bad when the residues end up in drinking water sources, and that this question is clearly not prioritised from policy makers on authority level. Veterinary pharmaceutical residues are just as likely to end up in private wells, but in comparison to other substances, pesticides for instance, residues from VPs are likely to be considered a minor problem to the environment. When residues end up in private wells, it is particularly problematic. The water from private wells does not have the same legal and safety protection in comparison to municipal water treatment plants, due to the fact that property owner bear the full responsibility and costs for testing the water quality. Seen from this perspective, the quality and safety levels for drinking water from private wells are inferior to those for municipal drinking water.

In general, awareness about contamination from their own proper activities is rather low amongst farmers, but Pär Aleljung mentions the good results from the upstream work

[9] Ivermectin is very harmful to the environment and to aquatic crustaceans in doses around 0.01 ng/L. Ivermectin passes through the gastro-intestinal without any major metabolism taking place, and may have intoxicating effects on the terrestrial organisms decomposing the faeces (MPA, 2014).

performed around the Lake Vomb as a fine example of the opposite. Southern Sweden Water Supply (Sydvatten) and River Kävlinge Water Council worked in collaboration with local farmers for increased reciprocal awareness through dialogue, lectures, and discussions [previously described in section 4.1.1]. That occasion regarded nutrients and pesticides, yet the use of veterinary medicines in livestock and horses could be addressed similarly, at least partly. It would not be a change of legislation requiring monitoring of the emission though, rather the work of individual actors. Pär Aleljung was asked what he thought would be necessary for a more stringent legislation on monitoring of veterinary pharmaceuticals in drinking water to come true. Because medical residues and chemicals may be hormonally disruptive, mutagenic, or even carcinogenic, and because they are present at low levels, it may take a very long time to prove the side effects from them. This calls for more radical changes to take place.

Anna Olsson, Biologist and Coordinator at the River Kävlinge Water Council, Lund municipality

Anna Olsson was contacted to find out more about the upstream work conducted by the Kävlinge River Water Council, in collaboration with local farmers in a river basin close to the Lake Vomb, previously described in section 4.1.1.

Focus was to create awareness amongst the farmers on how to reduce the leachate of phosphorous and pesticides from the agricultural activity. (Anna Olsson, 2015): "There is a heavy nutrient load on the environment in this area, but we still need to maintain a viable agriculture and sustainable food production. Some trade-offs must be made, but it is still important to reduce the runoff to the river basins. The dialogue project got started a few years ago. The idea was to involve farmers and create an understanding for each other's needs and requirements in order to avoid shortcomings and to reach a deeper understanding for our different standpoints. We aimed for a restricted part of a river basin, involving only around ten to fifteen local farmers to join lectures and further discussions. One of the key issues is to keep the groups relatively small in order for people to become active in the discussions, as larger groups are more likely to end up just listening to the lecturer. We also invited them to join us for water sampling occasions, for them to see what we looked for."

(Anna Olsson, 2015): "This project has ended now, and focus will further be on the actual preventative measures taking place. The participants are said to have been satisfied with the project setup and increased discussions and collaboration amongst the farmers have also occurred, which is positive". Anna Olsson underlines the importance of getting reciprocal understanding for each other's perspective to solve the upcoming problems. Often farmers just receive directives on what they have to comply with and what is required from them by the authorities, which may result in less understanding and motivation for mitigation methods.

"Regarding veterinary pharmaceuticals, or any pharmaceutical for that matter, we do not sample for those in our recipient controls. "Anna Olsson believes that the biggest reason for the lack of control is that the general knowledge about pharmaceutical residues is very low, even though the subject is frequently debated nowadays, at least pharmaceutical residues for human use, but a lot is unknown. The analyses are costly, which is another reason for not performing them on these substances. She believes the farmer dialogue could be one way of approaching the issue, to involve them from the start, but we are still far from addressing the issue thoroughly.

4.4 Conclusion of interviews

All of the environmental inspectors claimed that more focus is put on the control of pesticides and nutrients that occur extensively in the area around the Lake Vomb. Additional cause for

concern was the reported pharmaceutical residues deriving from applied sewage sludge on soils, contaminating the aquatic environment. Discussions regarding this matter pop up from time to time due to media attention.When asking the interviewees about their opinion on the prevailing monitoring policies addressing the issue veterinary pharmaceuticals within water bodies, all the inspectors and three of the experts regarded them as inadequate or non-existent. The issue is clearly given a lower priority by the authorities, meaning there is a lack of pressure from the authorities to monitor these substances (Ann-Marie, Camper, personal communication, June 24, 2015; Pär Aleljung, personal communication, July 17, 2015). On the other hand, it was pointed out that the pharmaceuticals, both for human and veterinarian use, that have been found in watercourses, generally occur in such low doses that water in Sweden is not considered dangerous to drink (Britt-Marie Pott, personal communication, July 14, 2015).

Additional topics were also brought up during the interviews. For instance, that the level of knowledge among the users of pharmaceuticals and chemicals is regarded by two of the experts to be rather low, and there is a risk of self-inflicted contamination due to this fact. Part of the important upstream work need to address this issue, and to increase public awareness of indirect and direct pathways for these substances (Pär Aleljung, personal communication, July 17, 2015; Anna Olsson, personal communication, August 17, 2015).

Another source of aquatic contamination mentioned in the context of veterinary products, is the group of biocides used as insect repellents on horses. These products are perceived to be rather widely used and poorly controlled regarding analysis and marketing. In the event of rain, the topically sprayed repellents may easily wash off the animals' coats and enter the soil and water as part of the drainage (Britt-Marie Pott, personal communication, July 14, 2015).

As previously mentioned, Swedish drinking water is not regarded to suffer from toxic levels of pharmaceutical or other toxic residues by any of the environmental inspectors or experts contacted for this research. However, there are concerns about why there are so few discussions at authority level regarding the fact that pharmaceutical residues are being found in water from both DWTPs and WWTPs. It is not as if the pharmaceuticals will disappear by themselves, and there are not many scientific studies showing *how* the metabolites may interact with other substances, the potential synergistic effects of mixed substances detected in the same water body (Britt-Marie Pott, personal communication July 14, 2015).

Another comment was that the use of antibiotics is more restricted in Sweden in comparison to other countries, as it is neither allowed for preventative health reasons nor as growth promoters [which is the case for all EU Member States since 2006] and that infected animals are treated individually and not as an entire group [except in aquacultures and chicken farms] (Ida Grimlund, personal communication, June 16, 2015; Jenny Kreuger, personal communication, June 26, 2015). The preventative animal health care was also mentioned as one very important upstream work in this direction. Sweden's stringent approach to the use of antibiotics is mentioned as one important measure, which has paid off well judged by the comparatively low use (Charlotta Kamaterou, personal communication, September 1, 2015).

The overall conclusion from the interviews, the majority of which were carried out with experts on water quality from various scientific fields, is the large focus on whether veterinary pharmaceutical residues are to be considered as a problem or not. There was a general consensus that, yes, there will be VPs present in lakes and other water bodies, especially in those with a close location to intensive animal husbandry and horse yards, but in comparison to other contaminants, such as pesticides and nutrients, there is a general belief that they are

of less importance in terms of environmental impacts. The topic of research for this thesis was generally perceived as important amongst the contacted stakeholders. The importance of upstream work was however emphasised, with increased collaboration with farmers/animal keepers and their veterinarians to address and prevent the risks of VP runoff in drinking water sources.

5 Discussion

This chapter reflects upon the findings from the interviews and literature review in connection to the posed research questions in chapter 1.3. Further and finally, the used research method will be reviewed and reflected upon.

5.1 Knowledge gaps

5.1.1 Uncertainties in assessments

Pharmaceutical residues exist in the aquatic environment: in groundwater, in surface water, and in outgoing water from DWTPs, WWTPs, and onsite wastewater treatment from separate households (Ejhed et al., 2012). In general, the concentrations of pharmaceuticals are higher in treated water from the municipal WWTPs than in surface waters. The EU mandatory environmental risk assessments, since 2006 for both veterinary and human pharmaceuticals, do not consider risks connected to emissions from the pharmaceutical production, merely the consequences from the actual use of the pharmaceuticals are addressed. Nor does the ERA include guidelines on how to address the environmental impacts concerning the development of resistance to certain antimicrobials (MPA, 2014; de Knecht et al., 2009).

According to the MPA (2014a), the results from the ERAs and the mandatory risk minimisation measures provided by the pharmaceutical companies are not kept for public access. Ågerstrand and Rudén (2010), showed in their study of evaluation of environmental classification performed by the Swedish Environmental Classification and Information System for Pharmaceuticals (SECIS) that the greater part of the assessed pharmaceuticals lacked enough ecotoxicity data to carry out a thorough classification. Still parts of the SECIS are based on the results from ERAs conducted by medical companies.

Pharmaceuticals intended for human use do not need to conform to proven environmental impacts, whereas it is the case for veterinary pharmaceuticals. Plenty of pharmaceuticals for humans are used for veterinary purposes though (MPA, 2014a), which means that the environmental considerations during the risk assessments do not give the full picture of the used medicines.

Exactly what environmental impacts pharmaceuticals may have is to a large degree unknown, since the scientific information on ecotoxicological consequences on ecosystems and non-target organisms is still sparse. Little is known about the long-term effects on non-target organisms, as degraded pharmaceuticals are manifold and their fate in ecosystems and interactions with organisms are highly complex. This fact was encountered repeatedly both in the literature review (Brandt et al., 2012; de Knecht et al., 2009; Tolls, 2001; WHO, 2012) and in the stakeholder interviews (Gunnar Carlsson, personal communication, June 25, 2015; Britt-Marie Pott, personal communication, July 14, 2015). What is not metabolised within the body may not necessary degrade much further in the aquatic systems, nor in the biological basins in the WWTPs/DWTPs (Britt-Marie Pott, personal communication, July 14, 2015; Carstensson & Gunnarsson, 2006). Instead, the degradation process may transform the metabolites into new substances with preserved or altered features which may not only be additive but also with the possible capacity of causing synergistic effects (Gunnar Carlsson, personal communication, June 25, 2015; Kümmerer, 2008). These may further be of different chemical properties, some of which may be potentially harmful to other aquatic organisms and ecosystems.

Environmental risk assessments need to cover a wide range of processes, such as bioaccumulation, persistency, pathways, toxicity, and transformation processes (de Knecht et al., 2009) for an even wider range of compounds to be on the safe side. Yet, the used standardised test may not be the appropriate ones for mixtures of pharmaceutical compounds, as it may result in underestimated environmental effects. The literature review provided several authors advocating the use of different and more sensitive parameters to cover for the more subtle effects on other organisms and ecosystems (Brandt et al., 2012; Brooks et al., 2009; WHO, 2012; Kümmerer, 2008).

5.1.2 Monitoring gaps

Measuring and monitoring VPs in Swedish watercourses is performed sparsely. As mentioned in section 3.2.6, the Swedish Environmental Protection Agency performs screening programmes in addition to the National Environmental Monitoring Scheme. The author of this thesis has looked closer at three screening studies where veterinary pharmaceuticals have been included. In the first one *Results from Swedish national screening programme 2005. Subreport. 1. Antibiotics, Anti-inflammatory substances and Hormones* by Andersson et al. (2006), veterinary pharmaceuticals were found in the adjacent environment of horses, cattle, and pigs. The second study, *Screening of veterinary medicines in agricultural areas* (Sternbeck et al., 2007), is the same screening study referred to by Dr. Jenny Kreuger in chapter 4. In this study, 50 substances were screened for; only one veterinary pharmaceutical was traced during this screening, but it was not clear whether it originated from veterinary use or from human use (Jenny Kreuger, personal communication, June 26, 2015). This was despite the thorough preparations prior to the screening: agribusiness intense areas in southern Sweden, with topography enabling easy runoff, located close to water, and in early spring when manure is spread most intensely on the fields. The third screening study *What concentrations of hazardous substances do we find in the environment. Results from the Swedish Screening Programme 2005-2007*, by the Swedish EPA (2007), did not detect any veterinary pharmaceuticals in their screening of antibiotics and antiparasitic drugs for cattle and pigs.

As previously mentioned, the sampling methods may however also contribute to the results. The majority of the samples taken in the report from Sternbeck et al. (2007) were only carried out once. This can be of significant importance when trying to detect certain pharmaceuticals as they may be released episodically and some pharmaceutical concentrations may fluctuate in different places along the watercourse (Bendz et al., 2005; Brooks et al., 2009; EPA, 2007). As mentioned by Dr. Gunnar Carlsson, in comparison to human pharmaceuticals, VPs tend to be released locally and in smaller volumes (personal communication, June 25, 2015). In the screening study from EPA (2007), manure used as fertiliser is suggested to be causing veterinary pharmaceuticals to end up in the groundwater, although it was not analysed in that study.

Neither the study by Sternbeck et al. (2007) nor the EPA-study (2007), applied methods allowing the analysis of pharmaceutical metabolites. Hence, no conclusions could be drawn about the potential environmental effects from these modified substances. These observations illustrate the need for repeated sampling occasions and other sampling methods in order to detect certain substances, also mentioned in the screening report from the Swedish EPA (2007). The study by Sternbeck et al. (2007), states that horses and pigs are the groups of animals using most antibiotics. Yet, horse yards were not included in neither of the two screenings (EPA, 2007; Sternbeck et al., 2007). In their case study of the River Höje, Bendz et al., (2005) found two groups of persistent antibiotics frequently used in horses. This case study and the mentioned screening reports above had different reasons for analysing though, which disqualifies any closer comparisons between them.

The screening study by Andersson et al., (2006), included horses, pigs, and cattle. Antibiotics, hormones, and anti-inflammatory drugs were detected in horse and cattle surroundings, and hormones and anti-inflammatory drugs were detected around pig farms. An additional form of analysing method (bioassay[10]) was also used for closer analysis of certain groups of hormones, but no effects of these were detected in the outlets from the tested farms. One interesting part of this study was the use of risk assessment quotients (measured concentrations (MEC)/predicted no effect concentration (PNEC)). Quotients of ≤ 1 meant that no negative effects of the substance could be expected, while quotients ≥1 meant the substance could pose an environmental risk and required further investigations. For some of the samples taken on surface waters in close location to animal facilities, the quotients were >1, which implied an indication for further investigation in these types of areas. Anderson et al., 2006, summarise (p.69):

> *Livestock facilities may constitute point sources of pharmaceuticals to the environment as increased concentrations were found in some of the samples. However these results should be seen as an indication and more measurements are needed to evaluate the importance of animal breeding.*

5.1.3 Data shortage

Prior to the screening performed by Sternbeck et al., (2007), a compilation of data was done on the included pharmaceuticals, to serve as a basis for the screening *Litteraturstudie av veterinärmedicinska produkter inför screeningen 2006,* by Hellström and Kreuger (2005). For the data collection, it turned out to be hard to get hold of relevant information on the medicinal properties of substances, behaviour and effects in the environment. This problem was also encountered in the literature review (MPA, 2014a; WHO, 2012; Ågerstrand & Rudén, 2010). As pointed out in the preceding section, data results from conducted ERAs are not collected for a public benefit purpose, which complicates the access to environmental data for other parties. Some of that environmental information is used by The Swedish Environmental Classification and Information System for Pharmaceuticals (SECIS). This data is published on their webpage *fass.se*, and is frequently used by the health sector, veterinarians, and patients, after it has been reviewed by an outside consultant. Lack of consistency has been shown though, different medical companies have classified products of the same substances differently, and as pointed out in the literature, there is a lack of information on potential long-term effects from pharmaceutical residues.

Runoff from VPs

In what volumes different compounds are present in the aquatic environment also depends on where the surface water is located and what kinds of activities are taking place in the surrounding area. In agricultural areas with intense livestock farming and/or horse yards and where veterinary pharmaceuticals are being used, these may reach the environment through excretion, as manure when applied on soils, or it simply washes off from grazing/outdoor animals in rain. Injected and orally administrated medicines are metabolised to different degrees within the body. For outdoor animals, the non-metabolised residues end up as excretions on fields, and for stabled animals, it will end up in the manure, later used as fertiliser on the fields. Both ways enable pathways for runoff to end up in soil for further transport in the river basins (Metcalfe et al., 2009; Tolls, 2001).

[10] To detect the occurrence of hormone activity at very low concentrations as part of environmental impact assessment (Andersson et al., 2006).

The problem with runoff was also mentioned repeatedly in the stakeholder conversations, although then concerning nutrients and pesticides (Helena Wellershaus, personal communication, June 15, 2015; Ida Grimlund, personal communication, June 16, 2015; Maria Lantz, personal communication, June 25, 2015). The buffer zones, which are part of the legislation regulating manure spreading, may not be sufficient to prevent unwanted runoff into the surrounding water bodies in the Scanian well-drained soils (Britt-Marie Pott, personal communication, July 14, 2015). Good agricultural practice guidelines recommend the buffer zones as barriers for leachate, but all animal-related problems may not be attended, as highlighted by de Knecht et al. (2009 p. 43): "…should not be assumed that requirements imposed in order to control nutrients are sufficient to control all other environmental risks arising from the use of veterinary medicines."

All of this points to several gaps in current analytical and risk assessment practices when it comes to monitoring the risks from the runoff of VPs.

5.1.4 Risks for drinking water

As reviewed in the literature and mentioned by several of the interviewees there are couple of major differences between pharmaceutical intended for humans and animals. Medicines for humans are used in much larger volumes and most of it (with the exception for the 20 percent of the population with onsite wastewater treatment facilities), will be connected to a WWTP, and this is where the highest rates of detection of most pharmaceuticals are found. As opposed to that, veterinary pharmaceuticals will bypass the purification systems and so will most of the wastewater from households with onsite treatment facilities; septic tanks in combination with infiltration or sand bed system represent rather poor levels of purification[11].

Surface water used as a source for drinking water, such as the Lake Vomb, will be passing several treatment steps in the DWTP steps before reaching its recipients. The biological basins, efficiently reducing organic material, may however not be suitable to downgrade metabolites for the many different pharmaceuticals entering the water systems (Britt-Marie Pott, personal communication, July 14, 2015). The drinking water quality of water for use in private wells is even more problematic as it has not the same legal and safety protection as drinking water provided by the municipalities. The fact that the well-owners bear the full responsibility and costs for testing the water, may indirectly cause the water quality to be inferior to that of municipal DWTPs (Pär Aleljung, personal communication, July 17, 2015). Inhabitants getting water from municipal water suppliers certainly also pay for testing the water quality, but the sum is embedded in the regular billing and is by far not affecting the households as much as the costs of individual testing of private wells.

5.1.5 Lack of legal requirements for testing and treatment

The municipality inspectors from the area round Lake Vomb do not monitor any aquatic parameters linked to the use of veterinary medicines, simply because there is no legislation obliging them to do so. Rather, the control that is carried out, concern information to the animal keepers/farmers on the importance of returning used material, the control of medical storages, and journals of animal treatments. The lake of Vomb is used as a drinking water supply for nearly 400 000 people, it is designated as nationally valuable water with surrounding ecosystems important to other species. Further, it is located in an area with intense agribusiness taking place on well-drained soils. Thousands of livestock and thousands of

[11] Over 500 000 of the Swedish households' onsite wastewater treatment facilities consist of a septic tank in combination with an infiltration system or a sand bed. After this treatment step, the wastewater goes straight out to the surrounding waters (Ejhed et al., 2012).

horses live in the area, but as far as the author of this thesis has been able to conclude, no regular monitoring or samplings procedures of residues from veterinary pharmaceuticals are taking place in neither this lake or in any other lakes in Sweden.

As pointed out, there are no legal demands to remove all pharmaceuticals from neither human nor veterinary use. Within the Water Framework Directive, pharmaceuticals are not addressed specifically, with the exception of the three human pharmaceuticals, which in 2013 were added to an EU watch-list for a closer observation, and possible future transfer to the priority list of harmful substances. In Sweden, drinking water is classified as foodstuff from the point where it enters the DWTP until it reaches its user. The regulations and general guidelines that apply for foodstuff, also apply for drinking water, but there seem to be a discrepancy on what this includes in terms of pharmaceutical contamination. The previously described MRL-values in products from animal origin are decided for several medicines in order to protect human health from certain pharmaceutical residues. For drinking water no MRL-value or equivalence exists although veterinary pharmaceuticals may be present in some of the drinking water supplies, especially those adjacent to intense livestock facilities. Besides, human health is not necessarily isolated from environmental impacts in a long-term perspective. This fact has been elucidated from both the literature review and from the stakeholder interviews: there is a clear lack of evidence on what happens to pharmaceutical metabolites in the aquatic environment, regardless the pharmaceutical user.

5.1.6 Concluding remarks

Residues from veterinary pharmaceuticals in the aquatic environment may be viewed as a marginal phenomenon in comparison to the amount of pesticides and human pharmaceuticals that are found in much larger volumes in the aquatic environments specified in this thesis. It is, of course, important to reflect on the relative amounts of contributing runoff from different sources. Nevertheless, to rely entirely on the ecosystems ability of self-purification of veterinary pharmaceuticals may be risky, as too little is known about the behaviour of mixed compounds and what the long-term effects from exposure of low concentrations of them may be. Besides, even though some substances are used less widely, environmental concerns for reasons such as persistency or bioaccumulation may still exist.

During the stakeholder conversations it was repeatedly expressed that increased discussions related to pharmaceutical residues in the aquatic environment are needed. Both in the stakeholder interviews, and in the literature review (Breitholtz & Bengtsson, 2006), the importance and opportunities in upstream, preventative work by various means was emphasised. To engage with local knowledge, such as with farmers and animal keepers on a local level, on how to prevent pharmaceuticals and other residues to end up in the soil and water in the first place, may be the most environmentally and cost-effective way to deal with unwanted substances in the aquatic environment. In regards to veterinary pharmaceuticals, maintaining a high level of animal health care is of major importance, since fewer medicines will then be needed, and they will thus not end up in the environment to begin with.

5.2 Discussion of methodology

To start with, and as a basis for analysis, qualitative unstructured interviews where made with several environmental inspectors at municipalities around the Lake Vomb. The information gained from some of these interviews was rather limited, partly because of the way the questions were framed, and partly because little information was to gain. On the other hand, being the first contacts, their answers, and reflections on the thesis topic served to probe the area for where next to turn with the queries.

When using open-ended interviews there is always a risk that the interviewee switches to talk about the areas s/he knows best or finds most interesting. There is balance between letting the interviewee talk freely and for the interviewer to interrupt and turn the talk back to the main point again. After all, the reason why these people were contacted in the first place was for the author to find out more about an issue from people with specific knowledge about a subject, and which there is only little material about in the Swedish context. Besides, the open-ended interviews are suitable for this particular reason, as the conversations does not get stuck on framed questions, but may develop in a non-expected direction, where other information may be gained. Kumar (2005) confirms that the unstructured form of interviewing gives most freedom to develop the content of the interview.

Triangulating the information from the interviews and analysing it along with the reviewed literature proved a useful practical approach to identify limitations in the current monitor procedures and knowledge gaps, and to some degree find explanations to existing observations.

Looking back, a wider sample of interviewees would probably have given the thesis a deeper insight into the Swedish ongoing work with pharmaceutical issues related to the environment. To involve other groups, like farmers, veterinary practitioners, and medical companies would also have added more depth to the study, which would have been possible if the delimitations had been set differently from start.

6 Conclusions

This chapter reviews how the research question stated in section 1.3 relates to the performed research. It also presents the conclusions from the literature review and stakeholder interviews. Finally, it provides some suggestions for further research.

In this thesis, the author has outlined the area of the possible problems related to veterinary pharmaceuticals as part of the leachate runoff into the drinking surface waters in areas with intense livestock facilities. The author has carried out a general literature review on veterinary pharmaceutical residues in the aquatic environment, and the policy framework addressing the subject in the EU and in Sweden. Through a case study of Lake Vomb, stakeholders have been identified and interviewed in order to find out about their expertise in the thesis topic.

6.1 Review of the research question

To highlight how the use of veterinary pharmaceuticals relates to the aquatic environment, two Swedish environmental quality objectives *Good Quality Groundwater* and *Flourishing Lakes and Streams* were used. They are, however, very generally described, and leave plenty of room for interpretations of what good quality and flourishing water should entail. Besides, it is not known to what extent the ecotoxicological and ecological effects from veterinary pharmaceutical residues may represent a risk to the environment in a long-term perspective, which also adds to the sense of incertitude. Swedish drinking water is regarded to be of high quality and of no risks to drink, yet there is a general recent and rising concern about these compounds in Swedish watercourses, not specifically by the ones around intense livestock facilities, but in general.

The research question and sub-questions stated in this thesis are:

> *How does the current legislation on monitoring and regulation of veterinary pharmaceutical residues in the Swedish drinking surface waters, help complying with the two national environmental quality objectives?*
>
> - *What are the policy gaps?*
> - *How can they be addressed from the precautionary principle point of view?*

To the first environmental quality objective *Good Quality Groundwater,* the thesis topic relates indirectly. Through the water cycle the surface water will both affect and be affected by the quality of the groundwater. In Sweden, contaminated groundwater primarily occurs in densely populated and agricultural areas, and according to the EPA (2013), the water supplied by one fourth of the all the private wells in Sweden are unfit for human consumptions.

To the second quality objective *Flourishing Lakes and Streams*, the topic relates more directly through the specification *Good ecological and chemical status,* according to Regulation SFS 2004:660, on administration on quality of the aquatic environment, *watercourses aimed to supply drinking water should have a good quality* (EPA, 2013). Nevertheless, as previously mentioned in section 1.2, none of the Swedish counties will reach the targets for Flourishing Lakes and Streams. Reasons being that a majority of the drinking water supplies are microbiologically contaminated, they lack a long-term protection, and because mitigation measures take a long time to carry out.

On a European level, the Water Framework Directive obliges the Member States to comply with a range of regulations to improve the aquatic ecosystems and prevent deterioration of

them. This will however be the reality for only around half of European surface waters by the end of this year (2015). Moreover, the chemical status in large number of the surface waters is even less known of, partly due to the Member States being at different stages in the implementation of the WFD and further integrated into national policy decisions. There is a lack of coherent monitoring of ecological and chemical status throughout Europe's surface waters. By law, the WFD demands protection of watercourses if they supply more than 50 people/10 cubic metres of drinking water per day, where the environmental quality objectives, on the other hand, are merely objectives and not legally binding.

Despite its vagueness, the research question is legitimate and part of the intention with this thesis is to highlight this uncertainty or ambiguity in the environmental quality objectives and the legislation addressing a matter that may be of a greater concern in the future.

One of the main findings was that since the restrictions concerning the use of pharmaceuticals in Sweden are more stringent (in particular antibiotics) in comparison to other countries, the VPs do not appear to be a major problem to the aquatic environment. A general perception amongst the contacted water quality experts and actors was that, in comparison to human pharmaceuticals reaching the watercourses through the application of WWTP sludge as a fertiliser, the large volumes of pesticides, and the overload of nutrients in the areas in question, the concern for VP residues leaching into the environment is rather low. Yet, the majority of the contacted actors did acknowledge the lack of information about the fate of veterinary pharmaceuticals in the environment. Some of them expressed concern about the absence of a discussion regarding this matter and appreciated that the issue is raised.

An additional finding was the upstream, preventative work in collaboration with local knowledge, was stressed to be one the most important measures in order to tackle contaminants to enter the aquatic environment in areas with intense agriculture and livestock farming. This is partly done through the Swedish River Basins District Authorities, where local water councils work in collaboration with a mix of local representatives such as farmers, industry, and landowners. Amongst the interviewees, it was perceived to be a useful method for the prevention of veterinary pharmaceuticals as well. To avoid medicating animals in the first place, by strategic pre-emptive work to achieve a high standard of animal welfare, was underlined as one very important part of this work.

The two environmental quality objectives relating to drinking water quality have been used to illustrate where monitoring of veterinary pharmaceuticals should be legitimate: in areas with close location to livestock/horse yard facilities. Veterinary pharmaceuticals are not explicitly linked to the contaminations according to neither the literature review nor the stakeholder interviews undertaken for the purpose of this thesis. Rather it has been implicitly understood through the general literature and stakeholder discussions about pharmaceuticals being regarded as an emerging group of aquatic polluters, whose long-term effects on aquatic ecosystems are very little explored. This fact is also reflected in the lack of policies addressing this issue.

6.1.1 Policy gaps

The existing policies within the EU governing how water bodies are monitored are mainly carried out under the EU Water Framework Directive. European legislation does not demand the Members States to remove pharmaceutical residues from treatment plants nor to monitor them on a regular basis. Several harmful chemicals are on the EU list of priority substances, which has been established as one strategy to combat pollution of the aquatic environment. Pharmaceuticals in general are not included on this list, let alone pharmaceuticals for veterinary use. Nevertheless, in 2013 three human pharmaceutical compounds, believed to

pose a risk to surface waters, were added to a so-called watch-list. These compounds are monitored for their potential harmful effects on other organisms, and may later be added to the priority list of substances. On a national level, the Swedish River Basin District Authorities (Vattenmyndigheterna) are commissioned to implement the WFD. The county administrative boards and municipalities carry out the largest part of the operative work to monitor and collect ecological and chemical data from all water bodies at regional and local levels. Veterinary pharmaceuticals are not addressed in this work, since there is no legislation demanding it.

Since 2006, pharmaceutical companies are obliged to perform ERAs on new drugs entering a Member State's market. The ERAs do not include risks connected to the production of pharmaceuticals; it is the use-phase that is primarily addressed. Nor does it include guidelines on how to address the potential risk of developing antimicrobial resistance. Moreover, the results from the ERAs and suggested risk minimisation measures are not kept for public benefit, or made publicly available, making it complicating for other stakeholders to take part of the information. In Sweden this information is however used as part of the basis of the environment information and classification initiated by the Swedish Environmental Classification and Information System for Pharmaceuticals (SECIS), accessible on *fass.se,* which is a frequently used source of pharmaceutical information for end-users. Different products containing the same substances have received different environmental classifications though, likely because the ERAs have been conducted by different medical companies. Ecotoxicological data was missing for a majority of the products assessed by SECIS.

Pharmaceuticals intended for human use do not need to conform to proven environmental impacts, whereas it is the case for veterinary pharmaceuticals. Plenty of pharmaceuticals for humans are used for veterinary purposes though, which means that the environmental considerations during the risk assessments do not give the full picture of the used medicines.

The Drinking Water Directive objective is to protect human health from adverse effects from contamination in drinking water by ensuring it is wholesome and clean. In Sweden drinking water is defined as food stuff, yet it does not seem to be controlled with the same level of accuracy as food of animal origin in regards to pharmaceutical residues and human health. Swedish municipalities are responsible for providing its inhabitants with drinking water of good quality, yet they do not carry out any monitoring of veterinary pharmaceutical residues in the drinking water sources, since there is no legislation explicitly demanding them to do so.

The pathways of VPs are different to those of human pharmaceuticals. Apart from leaching from grazing/outdoor animals, manure and sludge from treatment plants enable the residue runoff to enter the watercourses (figure 1, p.4). When screening these locations for veterinary pharmaceuticals, different approaches may be necessary as VPs tend to be released episodically and in smaller volumes.

According to several cited research papers in this thesis, the standardised test used in ERAs for pharmaceuticals may not be the appropriate ones for the mixture of residues ending up in the aquatic environment. Swedish drinking water is considered to be of good quality for human consumption, despite the fact that little is known about the effects and impacts of pharmaceutical residues on non-target organisms and ecosystems in the long run. The synergistic effects and interaction of different metabolites and compounds is a highly complex area and is to a large degree unexplored.

6.1.2 The Precautionary principle

The author of this thesis acknowledges that veterinary pharmaceutical residues constitute a smaller proportion of all pharmaceutical residues ending up in the aquatic environment. The same goes for the amounts of pesticides used in the locations in questions. Still, pharmaceuticals used in livestock/horse yard facilities have different and diffuse pathways, making them more complex to locate and sample. Moreover, not knowing the long-term effects of pharmaceutical runoff or the possible harm of synergistic effects of metabolites, bear resemblance to typical scenarios were making use of the precautionary principle is justified.

Being part of EU law and valid in all Member States, the precautionary principle should be used as a guiding approach to protect the environment even when sufficient scientific proof does not exist. As has been pointed out repeatedly, little is known about the long-term effects of a low-concentration exposure of pharmaceutical residues in the environment. To find out the behaviour, synergistic effects, and interactions of metabolites is a highly complex business and decades may pass before scientific proofs of causation are available. Meanwhile, damage might be happening to organisms and ecosystems with subsequent problems, which could also include human health. Behavioural and reproductive changes and antimicrobial resistance is a couple of examples of some of the aftermath of pharmaceuticals in the environment. Since the knowledge about the consequences of neglecting the risks is poor, the precautionary principle should be considered to a greater extent in regards to a pharmaceutical's entire lifecycle.

Not only should it be regarded in the manufacturing process, but also to guide the environmental risk assessments carried out by the pharmaceutical companies prior to marketing the products, and finally in the end-of use phase. Apart from medical leftovers, the residues should also be attended since what is not degraded within the body will end up elsewhere in the environment.

6.2 Suggestions for future research

This thesis is far from providing a full picture of all aspects included in the use of VPs in areas with intense livestock farming and its potential impacts in the aquatic environment. Nor does it claim to give a completely fair reflection on all efforts made on different authority levels, by associations, organisations, and other stakeholders out there, aiming for legislative changes to happen through the work to improve the situation regarding environmental risk assessments of pharmaceuticals in general. Partly through their work, a greater considerations for medicines used for veterinary purposes shall also be achieved.

Many more aspects within this topic area could do with a more thorough review though. A couple of suggestions are given to anyone who wishes to proceed with further questioning:

- Look further into how much of the manure and sludge from treatment plants add to the presence of pharmaceuticals in surface waters, such as in the Lake Vomb.
- Find out more about pharmaceutical leaches from onsite treatment plant facilities into surface water drinking supplies, like Lake Vomb. How they are addressed by legislation.
- Scrutinize legislation on private wells, receiving drinking water from intense agribusiness areas.

- Investigate the use of biocides frequently used as insect repellents on horses. How these are regulated by REACH and how the control of them is enforced by law and in reality.

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Appendix I

List of interviewees

Pär Aleljung	Pär Aleljung, Microbiologist and Advisor for drinking water matters related to private wells at the Swedish Food Agency
Ann-Marie Camper	Marine Biologist, former Assistant Project Manager of InnoVatten, Project Manager for the Marine Center, Simrishamn Municipality
Gunnar Carlsson	Researcher at the department of Biomedical Sciences and Veterinary Public Health, Swedish Agriculture University (SLU)
Ida Grimlund	Agronomist and Environmental Inspector of agriculture and husbandry, Lund Municipality
Charlotta Kamaterou	County Veterinarian at the Animal Welfare and Veterinarian Department, the County Administrative Board of Skåne
Jenny Kreuger	Research leader in organic chemistry och ecotoxicology, Swedish University of Agriculture (SLU)
Maria Lantz	Maria Lantz, Environmental Inspector of onsite wastewater treatment, husbandry and agriculture, pesticides, and water protection areas. Municipality of Eslöv
Anna Olsson	Biologist and Coordinator at the River Kävlinge Water Council, Lund municipality
Britt-Marie Pott	Process Engineer at the Vomb Drinking Water Treatment Plant, Southern Sweden Water Supply (Sydvatten)
Peter Sörngård	Peter Sörngård, Specialist/Advisor in sewage and environmental issues related to agriculture and water at the Swedish Water and Wastewater Association (SWWA)
Helena Wellershaus	Environmental inspector of drinking water, Lund municipality

Appendix II

Table 2. VICH Phase I dion tree. Source: de Knecht et al, 2009, p.28.

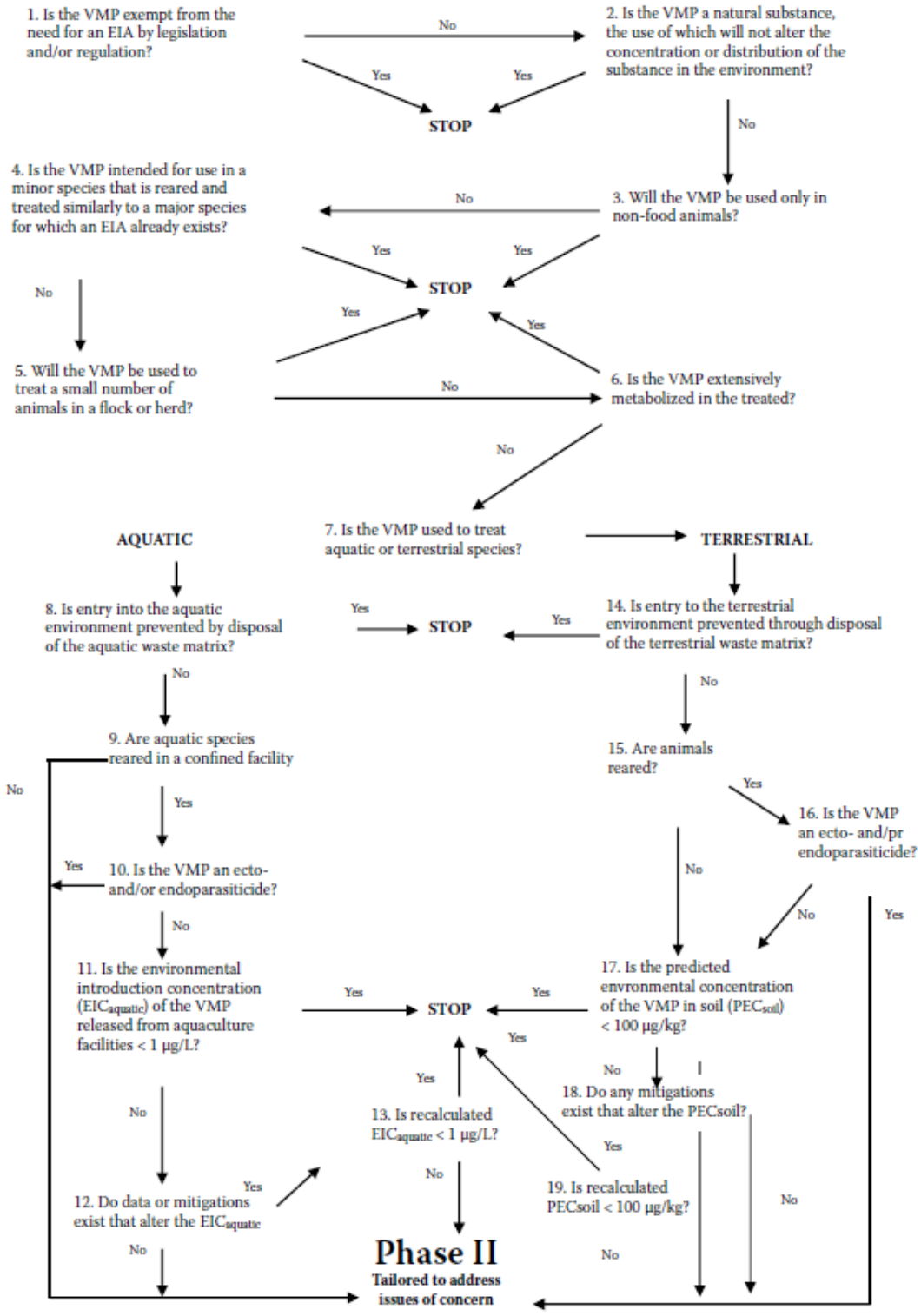

Table 3. VICH Phase II decision tree. Source: de Knecht et al., 2009, p.29.