A Review of Drug Disposal in Scotland: with an Emphasis on the Aquatic Environment

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1. Introduction and Background

1.1. Environmental Chemicals – use and input

The number of chemicals that are likely to occur in the environment is estimated to be in excess of one hundred thousand. Chemicals are produced, imported, formed unintentionally as a by-product or during transformation processes, or originate from remote sources as a result of environmental fate processes (Van Wezel, 1999a). Around 2000 of these chemicals are produced or imported into European Union (EU) countries in quantities of more than 1000 tonnes per year. These chemicals are classed as High Production Volume Chemicals (HPVCs)

In 1999, less than 600 of these were included for assessment or attention under international or national policies (Van Wezel and Kalf 2000a). The remaining 1,400 HPVCs were not monitored or assessed. When a chemical is selected for assessment its ecotoxicological risks are assessed or monitored, risk reduction measures are identified and other environmental criteria is gathered. Based on these findings, future applications (i.e. quantity and frequency of use) of the chemical are decided, and policy measures are set and taken around these criteria (Van Wezel, 1999b). Consequently, the eco-toxicological effect from exposure to the majority of these chemicals on humans and the environment remains relatively unknown.

1.2. Pharmaceutical Pollution

Major chemical compounds used in human and veterinary medicine (Pharmaceuticals) are increasingly being detected in the aquatic environment, sewage sludge and soils. Some of these chemicals have also been detected in landfill leachate and in groundwater supplies used as drinking water (Holm et al, 1995). Due to human use and metabolic excretion, many medicines enter indirectly into water supplies from Sewage Treatment Plants (STPs). Likewise, drugs used for veterinary purposes, animal husbandry or as growth enhancers are also excreted via manure from animals on to fields. Since sewage sludge and manures are often spread onto land as fertilisers these chemicals can enter into waterways via agricultural runoff. Additionally, pollution can also occur due to the direct entry of pharmaceuticals into water supplies from aquaculture practices such as fish farms.

1.3. Drug Consumption and Disposal

Worldwide consumption of active compounds is now estimated to be in excess of 100,000 tonnes per year (Kümmerer, 2004a). However, usage and consumption rates of drugs vary from country to country. Around 3,000 different pharmaceutical products are discharged into Urban Waste Water (UWW) collecting systems across Europe (ICON 2001a).

At present there are approximately 3000 pharmaceutical drugs licensed for human use in the UK. Data for the period 2003-04 show that an average of 14 prescribed items per capita per year are dispensed throughout the UK. This number of 'prescription only medicines' (POMs) is increasing on an annual basis, as illustrated in Figure 1. These figures do not include UK sales of 'over the counter drugs' (OTCs). Due to a combination of factors (e.g. increased per capita consumption, aging populations, expanding drug markets, increased availability, and higher patient expectations), usage and availability of drugs has steadily increased over the last decade and is expected to continue to increase in the future (Daughton, 2004a).

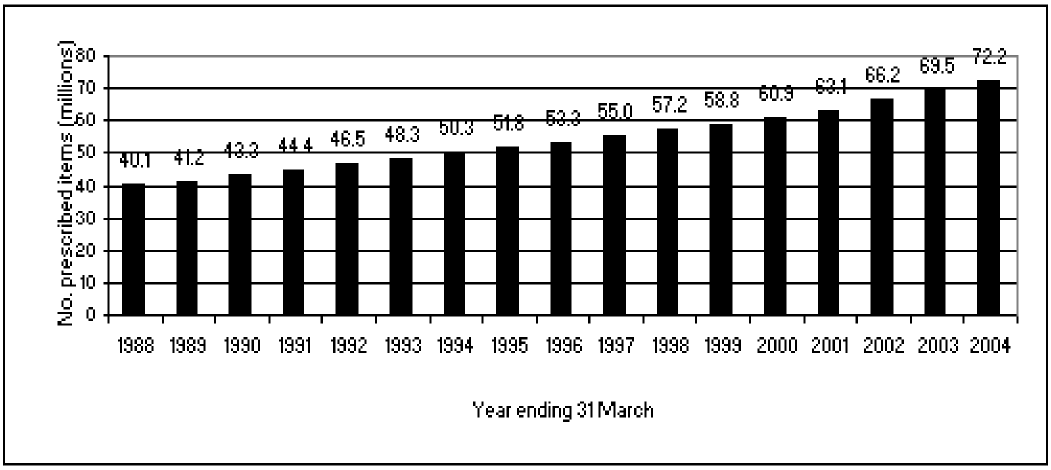

Figure 1: Increases in medicines dispensed in Scotland since 1988 (ISD, 2004a)

In line with current EU Legislation (93/67/EEC), the disposal of unused medicines via household waste streams has been permitted in Member States since 1994. As a consequence, many householders dispose of unwanted drugs via the drain, or along with their general domestic garbage. Research confirms that one-third of the total volume of pharmaceuticals sold in Germany, and about a quarter of that sold in Austria are disposed of via drains or along with general household waste (Kümmerer, 2004b).

Drugs also enter into STPs via trade effluents from industry and clinical waste disposal facilities; drug wastage from healthcare premises has also been detected in STPs and receiving waters (Alder et al, 2003).

Similarly, unwanted or expired drugs from such sources have been detected in landfill sites, and groundwaters (Eckel et al, 1993).

1.4. Increasing Concerns and Scientific Studies

Scientists are becoming increasingly concerned over the potential human and ecological effects of pharmaceuticals that are entering the environment. Over the last decade a variety of pharmaceuticals, ranging from frequently used painkillers to highly toxic compounds, known as Cytotoxics[1] and Cytostatics[2], have typically been identified in treated sewage effluent, surface water, manure and soil (Daughton, 2000). Research now confirms that many of these drugs are difficult to degrade and are only slowly eliminated in the environment – if at all (Kümmerer, 2001).

Until recently, UK authorities assumed that: "since quantities of pharmaceuticals entering into the aquatic environment are relatively low [ng/l], their anticipated impact is probably negligible" (DHI, 2003). However, growing evidence now confirms that even minute amounts [ng/l] of some drugs can cause hormonal and behaviour changes in fish and mammals. Since the early 1990's when German scientists originally found clofibric acid, a cholesterol-lowering drug, in groundwater a whole range of other drugs have been detected (Herberer, 2002). Studies from across the EU (e.g. Sweden, Norway, Italy, Denmark, Germany and UK), USA, Canada and many more countries, report human drugs such as antibiotics, anti-depressants, seizure medication, cancer treatments, and painkillers have all been detected in both untreated and biologically treated surface and ground waters.

While these studies provide invaluable data regarding the occurrence, fate and potential effects of pharmaceuticals at national levels, no such data exists for Scotland. Drug types and dosage rates significantly vary from country to country, or even region to region, depending on local demographics and prescribing customs (Daughton, 2003). Equally, the composition of drug wastage and its effect on the environment will also vary from country to country depending on health statistics, application of drugs, national policies and waste disposal facilities etc. It is, therefore, imperative that data specific to Scotland is collected and analysed in order to determine the potential impacts of pharmaceuticals in Scotland's environment.

1.5. Scottish Research

Glasgow Caledonian University has recently initiated research in this area. The main objectives of this study are summarised as follows:

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[1] Cytotoxics: Chemicals which are directly toxic to cells, preventing their reproduction or growth. (On-line Medical Dictionary: Dept. of Medical Oncology, University of Newcastle upon Tyne)

[2] Cytostatic: Inhibiting or suppressing cellular growth and multiplication (The American Heritage® Stedman's Medical Dictionary, 2004) *NB: Cytostatic, Describes the way an anti-cancer drug works, not what type of drug it is.*

1. Review existing literature on pharmaceuticals (i.e. occurrence, fate and effects);
2. Identify medicinal use and disposal patterns in Scotland;
3. Identify current provision of education and awareness, among the general public and healthcare professional, in relation to the safe disposal of medicines;
4. Analytically test sewage treatment effluents, receiving waters and sewage sludge for the presence of a range of selected pharmaceuticals;
5. Establish benchmarks to determine the level of exposure of pharmaceuticals in Scotland's environment, and where possible suggest mitigation measures;
6. Identify future priority areas of research.

This paper provides an assessment of drug disposal in Scotland and emphasises the need for strategic change. Its contents are limited to the first three objectives listed above, as the final three objectives form part of on-going research, yet to be completed. Results from recent surveys, national demographics, environmental and socio-economic aspects relating to the disposal of pharmaceuticals, are discussed here.

2. Environmental Exposure Routes of Pharmaceuticals

2.1. Entry into the Environment

Pharmaceutical compounds and their metabolites can enter into the environment during production, distribution, use and disposal. However, it is claimed that pharmaceutical pollution does not primarily arise from production processes, but rather from widespread and continual use, excretion, and the improper disposal of both human and veterinary medicines (Jones et al, 2003).

2.1.1. Metabolism and Excretion Rates

Any chemical ingested by humans or animals has the potential to be excreted in urine or faeces. Pharmaceuticals are often biologically transformed within the body, as their active molecules degrade their chemical structure modifies; this can result in changes to their physiochemical and pharmaceutical properties. Metabolism is frequently incomplete and excretion rates of parent compounds and their metabolites can range from 0-100% (Kümmerer, 2004c).

2.1.2. Exposure from Sewage Treatment Plants

Most conventional wastewater treatment plants have been found to be ineffective in eliminating the majority of pharmaceutical compounds. Previous studies report the elimination rates of certain drugs during passage through STP's ranged from 7% for Cabamazapine (an anti-epileptic drug) to greater than 95% for Salicylic acid (an aspirin metabolite) .

Clofibric acid (a breakdown product of lipid-regulating drugs) is highly persistent and resistant to wastewater treatment, since only 15-51% is removed. Lipid regulating drugs are commonly prescribed throughout the EU. It is thought that the daily load of Clofibric acid to UWW collecting systems in Denmark is around a few kilograms. Concentrations of clofibric acid have also been detected in sewage effluent, rivers and lakes. In the UK, clofibric acid has been detected in the 1 mg/l range in the aquatic environment, and in Germany, it has been detected at concentrations up to 165 ng/l (Ternes, 2000). Clofibric acid has been found to survive for 21 years in rivers in Italy (Zuccato, 2000), and although its use is now banned in many EU countries it is still being detected in rivers and lakes. Other pharmaceutical compounds also have the ability to infiltrate aquifers and survive for many years. Pentobarbital, benzafibrate, diclofenac, and carbamezepine, have also been found in aquatic environments, persisting there for up to 20 years (Ternes, 2000b).

It has also been determined that iodinated X-ray contrast media are not degraded during wastewater treatment due to their high polarity. These compounds are designed to be highly stable to give optimum results during X-ray. Ninety percent of X-ray contrast media are excreted un-metabolised (Ternes, 2000c); hence receiving waters will also tend to be contaminated

Although advanced water treatment technologies such as granular activated carbon, reverse osmosis, or ozone treatment can remove drugs from potable water to the extent that they are no longer detectable, these processes are not universally applied. Municipal wastewaters are never treated in this way as these processes are likely to considerably reduce the existing flow rate of discharged treated effluents, as well as substantially increasing operating costs.

This means that many pharmaceutical compounds pass comparatively unchanged through STPs prior to being discharged into the aquatic environment. In addition, some of the excreted metabolites can even be transformed back to the original active drug during aeration processes at STP's (Carballa et al, 2004).

Some endocrine-disrupting compounds such as oestrogens are of major concern. Although they are excreted in an inactive form, previous studies show they can be reactivated in sewage effluent (Ternes, 2000d).

Sewage Treatment Plants are, therefore, the main collection point of many pharmaceutical compounds and their metabolites. As such STPs inadvertently act as a main pathway for the release of drugs into the aquatic environment. Equally, the disposal of drugs to dumps, landfill sites or biological treatment centres pose a further threat to the aquatic environment, as illustrated in Figure 2.

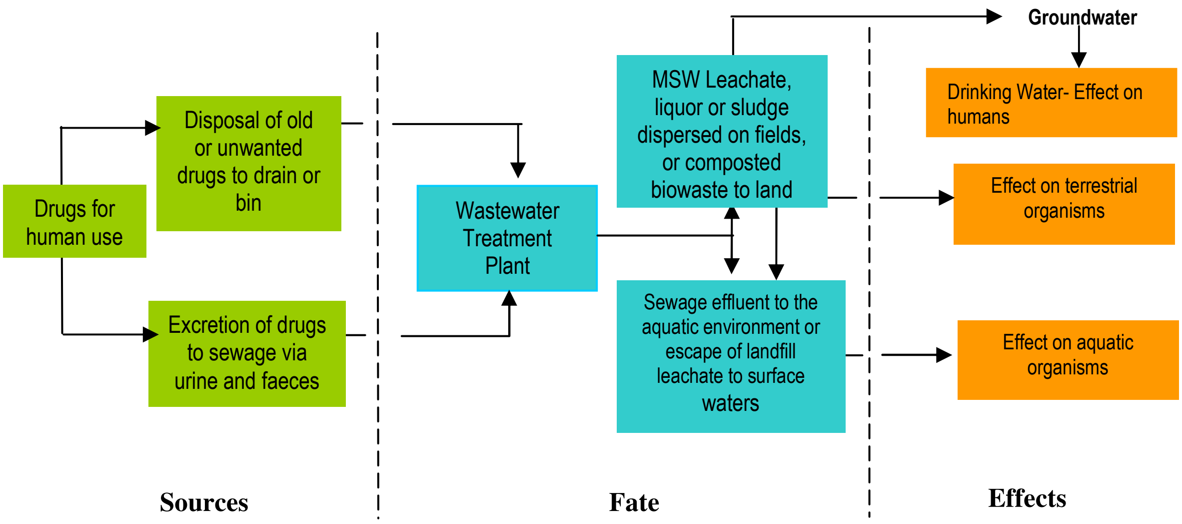

Figure 2: Exposure Route of Human Drugs to the Environment

2.1.3. Exposure via other routes

Agricultural practices also remain a major source of contamination since around 40% of antibiotics manufactured are fed to livestock as growth enhancers (Reynolds, 2003). As a result, manure containing traces of pharmaceuticals and other pollutants can leach into rivers and streams via agricultural runoff or seep through land and contaminate underground drinking water supplies. Similarly, leakage from septic tanks and cracked or damaged sewer pipes also pose a threat to the natural water environment.

2.2. Environmental Resistance and Bioaccumulation

Many pharmaceutical substances have the same characteristics as organic compounds (i.e. they are lipophilic) which allows them to pass through membranes. Some are also designed to be persistent to avoid inactivation prior to achieving their desired healing effect (Halling-Sørensen, 1998).

Due to their resistance to biodegradation and natural physicochemical degradation processes the presence of pharmaceuticals in raw sewage may, therefore, have further implications such as:

a. Adverse effect on the microorganisms' type, number and function, and hence on the performance of sewage treatment plants.
b. Escape through STP effluent into the aquatic environment affecting marine life and resulting in bioaccumulation.
c. Biosolids from sewage treatment plants applied on land may provide a path for pharmaceuticals to contaminate groundwater, terrestrial ecosystems, and food crops [Stamatelatou, 2003a].

Increasing populations of bacteriological pathogens resistant to conventional antibiotic treatments have long since been linked with exposure to sub-lethal levels of antibiotics in the environment. Shortly after the introduction of penicillin, the bacterium *Staphylococcus aureus* developed penicillin-resistant strains. High concentrations of some antibiotics are excreted in urine. For example, up to 40% of the drug Penicillin V (used to treat bacterial heart infections) is excreted unchanged (Christensen, 1998).

Evidence now also confirms an increase in antimicrobial resistant enterococci-bacteria (such as *Campylobacter*, *Escherichia coli*, and *Salmonella*), which can transfer from animals to man via the food chain or by direct contact. Ultimately, this could lead to the establishment of a community reservoir of resistance genes (Barton, 2000). A most prominent medical example of antimicrobial resistance is methicillin resistant *Staphylococcus aureus* (MRSA) commonly found in hospitals (Kümmerer, 2004e).

Studies conducted on the impacts of natural and synthetic oestrogens in sewage works and receiving waters found that the natural oestrogen 17b-oestradiol was oxidised to oestrone, and then linearly removed with time. However, the synthetic contraceptive 17a-ethinyloestradiol was persistent and highly stable under environmental conditions (Ternes, et al 1999).

Because of their Persistence, Toxicity and Bio-accumulative (PTB) properties, pharmaceuticals have been considered as having a PTB-profile that gives reason to be precautionary (Van Wezel and Kalf, 2000b). This Profile provides information on the persistence, toxicity and bio-accumulative properties of a chemical. It should be noted, however, that for most chemicals, no PTB-profile exists.

3. Fate and Effects of Pharmaceuticals in the Environment

3.1. Effects on Human and Ecological Health

Medicines are developed with the intention of producing specific biological effects on target organisms. They will, however, also affect non-targeted organisms susceptible to the pharmaceutical's mode of action [Stamatelatou, 2003b].

The fate of pharmaceutical substances can be is divided into three main groups:

1. Mineralization to CO_2 and water (e.g. aspirin).
2. Retained in sludge, if the compound is lipophilic and not readily biodegradable.
3. Emitted to receiving water due to transformation into a more hydrophilic form but still persistent, (e.g. clofibrate).

An increasing number of human pharmaceuticals have been linked with reproductive and developmental abnormalities in various types of fish (rainbow trout, carp, roach, flounders, bluegill sunfish, zebra fish etc.) and other aquatic species (freshwater green algaes, saltwater diatoms, water fleas, shrimps, muscles, frogs and tadpoles etc.).

Hermaphrodite fish (fish that display both male and female characteristics) have also been observed in rivers below sewage treatment plants in a number of countries including the UK (Jobling et al 1998).

3.1.1. Endocrine-disrupting substances

Endocrine-disrupting compounds such as synthetic oestrogens used in birth control pills, hormone replacement therapy (HRT) and steroids have been detected in streams and rivers. Synthetic oestrogens are of a major concern, as they can be reactivated in sewage effluent (for details see section 2.1.1. above).

Oestrogen receptors are located in the cell nucleus; oestrogen-like molecules can thus enter the cells and potentially interact with DNA, causing damage which may lead to tumour formation. Prolonged exposure to these compounds may induce female characteristics in males, and there is increasing speculation that these compounds may be linked to a reduction in male fertility and reproductive complications (Montagnani et al, 1996).
The UK Environment Agency (EA, 2004) recently demonstrated the effects on the endocrine systems of fish exposed to sewage effluent water, due to synthetic contraceptives present in effluents in the low ng/l range.

In a survey of more than 1,500 fish at 50 river sites in England over a third of male fish exhibited female characteristics. This investigation highlighted that the feminising effects found in fish are directly related to their exposure to treated sewage effluent polluted with natural and synthetic steroid hormones, all of which were excreted naturally from women, or as a result of taking the contraceptive pill. These findings could prove to have serious implication on fish populations, and ultimately the fishing industry.

3.1.2. Anti-depressants

More recent studies have identified that antidepressants can trigger premature spawning in shellfish and some cardiovascular drugs can block natural functions, such as the ability of fish to repair damaged fins. Further research also reveals evidence of the antidepressant drug ‘Prozac’ in the brains, liver and muscles of bluegill fish caught downstream from a water reclamation plant near Dallas.

Until recently most scientific studies concentrated on the impacts of pharmaceuticals on aquatic species collected from their natural environment. While these studies provide important data the accuracy of such studies may be influenced by other external factors, such as contamination from other sources. In order to reduce the possibly of external contamination, controlled laboratory-scale studies are now being undertaken. During controlled laboratory studies conducted by aquatic toxicologists at the University of Georgia certain antidepressants, such as Prozac, Zoloft, Paxil and Celexa, were found to cause problems of sterility, mutations and delayed metamorphosis among fish and frogs (Holmes, 2003). These studies recently demonstrated the effects of the drug Prozac (50 ppm) on tadpole species (*Xenopus laevis*) after 57 days of laboratory development, as illustrated in Picture 1.

Photographer: Emily Rogers

Picture 1: Two tadpoles after 57 days of development in the laboratory.
The one on the right, which has yet to sprout limbs, was exposed to Fluoxetine, also known as Prozac.
(picture reproduced with kind permission of The University of Georgia, Athens, USA).

3.1.3. Antibiotics

Antibiotics are widely used in human and animal treatment and also as growth promoters in veterinary use. In 1997 the EU used around 54,000 tonnes of antibiotics in human medicine alone. The increased use of antibiotics has led to an increase in drug resistant micro-flora. This resistance is actually favoured by low concentrations of antibiotics (Jorgensen, 2000), thus the presence of antibiotics in the environment may be problematic. Antibiotics by their nature are designed to affect microorganisms, so their presence in STP's may have an adverse effect on bacterial cultures in sewage bioreactors and will affect a STP's ability to treat raw sewage. Antibiotics have also been found in groundwaters and terrestrial environments derived from sewage sludge and manures applied to land as fertilisers. However, it remains unknown whether the presence of antibiotics in water systems is contributing to the spread of antibiotic-resistant microorganisms as previously discussed in section 2.2 above (Kümmerer 2004[f]).

3.1.4. Anti-cancer drugs

Anti-cancer drugs are primarily used for chemotherapy and are found, sporadically, in a range of concentrations in the environment. These drugs have the potential to act as mutagens, carcinogens, teratogens, and embryotoxins (Daughton, 1999).

3.1.5. Analgesic drugs

Analgesic drugs used to relieve pain are among the most commonly used medicines in most countries**.** UK figures for 1998, show paracetamol as the most frequently used drug at 2000 tonnes per annum (t/a), with aspirin in second place at 770 t/a. These substances are considered to be relatively biodegradable in sewage treatment works and in activated sludge processes (EA, 2000).

3.2. Pharmacology versus Eco-pharmacology

The terms 'pharmacology' and 'eco-pharmacology' are retrospectively used to differentiate between the effects of pharmaceuticals on humans i.e. target species, and the effects of pharmaceuticals on the environment i.e. non-target species (Kümmerer, 2004g). The occurrence, fate and effect of pharmaceuticals on human health with that of ecological health can vary greatly as illustrated in Table 1.

Table 1: Pharmacology and Eco-pharmacology

Action	Pharmacology (humans)	Eco-pharmacology (environment)
Number of components administered	Only one or a few compounds at the same time	An unknown cocktail of different compounds
Desirable physiochemical properties	Stable	Readily (bio)degradable
Administration	Targeted, on demand, controlled	Diffuse i.e. emissions from medical care units and the community
Wanted effects/side effects	Active wanted effects, side effects	Wanted "effects" in target organisms are often most important "side effects" in the environment
Metabolism/biotransformation/affected organisms	One type of organism	Various type of organisms of different trophic levels

Source: As adapted from "Pharmaceuticals in the Environment", (Kümmerer, 2004)

Although scientific evidence appears to indicate certain drugs pose a threat to aquatic animals. Even among scientists there are different opinions. Some scientists believe individual exposure levels are so low they are insignificant. Whereas others are concerned about the long-term effects on humans and animals from continual exposure to a cocktail of compounds designed to cause specific physiological effects in targeted species.

There is a growing debate over "the burden of proof" and "scientific uncertainty" over the adverse effect of drugs in the environment. However, some claim there is already sufficient evidence to adopt a "precautionary principle" on pharmaceuticals in the environment.

Scientific findings to date would indicate that UK authorities may require to reconsider their previous viewpoint pertaining to low doses of pharmaceuticals in water supplies.

4. Scottish Survey of Pharmaceutical Waste

4.1. Introduction: Current Situation in Scotland

During 2003-04 Scottish community pharmacies dispensed 72.2 million prescriptions, equivalent to over 14 prescribed items for every man, woman and child living in Scotland during that period (ISD, 2004b). This figure did not include the amount of medicines dispensed in hospitals, or drugs which are regularly sold over the counter. Overall, it is estimated that 15% of all dispensed medicines end up as waste at an ingredient cost of around £144 (€210) million, exclusive of disposal costs. In 1999/2000 the Scottish Executive estimated that 47 tonnes of POMs were return to pharmacies for disposal by incineration. It is believed that this figure is just the tip of the iceberg, and a far higher percentage of drug waste is likely to exist.

Community pharmacists have a ‘Duty of Care’ to ensure all medicines returned to them by members of the public are incinerated. Under their contract with community pharmacies, most National Health Service Scotland (NHSS) Boards provide “Patient own Medicine” disposal schemes. Under these schemes medicines are collected ‘free of charge’ from NHSS community pharmacies and sent together with other NHSS special waste for disposal by incineration. However, most Boards limit the amount of waste they collect from pharmacies by restricting the number of waste receptacles they issue and collect. Pharmacies own waste (i.e. expired stock) must be paid for and disposed of privately. Due to a lack of incineration facilities in Scotland, most special waste is transported around 800km to specialist incineration facilities in England. As a result the current costs of disposing of POMs and other special waste is around £1250 (€1800) per tonne.

Scotland’s NHS hospitals, on the other hand, are permitted to dispose of “small amounts of medicines via the drain” under their ‘Trade Effluent Consents’ (TECs) with Scottish Water (national sewer undertaker). However, since neither the amount nor the frequency of such discharges are specified on hospital TECs, the quantity of unwanted medicines disposed to drains from this source is not known.

Against this background there has been little to no research conducted in Scotland regarding pharmaceuticals in the environment. Since demographic conditions vary greatly between Scotland and England there is no guarantee conditions found in England or elsewhere will be applicable in Scotland. In order to provide both qualitative and quantitative data on the disposal scenario of unused medicines in Scotland the following surveys were conducted.

4.2. Materials and Methods

In order to determine the current situation regarding the disposal of medicines in Scotland, two separate and anonymous surveys were conducted. The first survey involved1200 members of the public randomly selected from all the major cities in Scotland. The respondents were asked to fill out a one page questionnaire, the main purpose of which was to determine how they generally disposed of their unused prescription only medicines

(POMs) and drugs bought over the counter (OTCs), and whether they felt they were given adequate information on safe disposal of drugs.

The second survey involved a postal questionnaire which was sent to over 300 community pharmacists randomly chosen from NHSScotland's Health Board, and elicited 93 responses. The rationale behind this survey was to provide a cross-sample of how pharmacists in Scotland collected and disposed of medicines returned by patients, and their own expired stock. It was also hoped to determine the level and provision of education and awareness on waste issues that exists within the drug dispensing industry.

4.3. Survey Results

Results from the public survey indicate 44% consign unwanted POMs to the drain, and 37% bin them along with their general household waste. The situation is similar with OTC drugs with 34% of people flushing them down drains and 56% throwing them into garbage bins, as illustrated in Figure 3 below.

Overall, the survey findings revealed 67% of the public did not consider they received adequate information, or were given proper instructions on how they should dispose of unwanted drugs. 62% expressed concern about the potential environmental effects from the unsafe disposal of medicines. Almost all respondents (92%) said they had never seen the Scottish Executive's information poster on "Safe Disposal of Medicines" which should be displayed in all healthcare premises and public information centres.

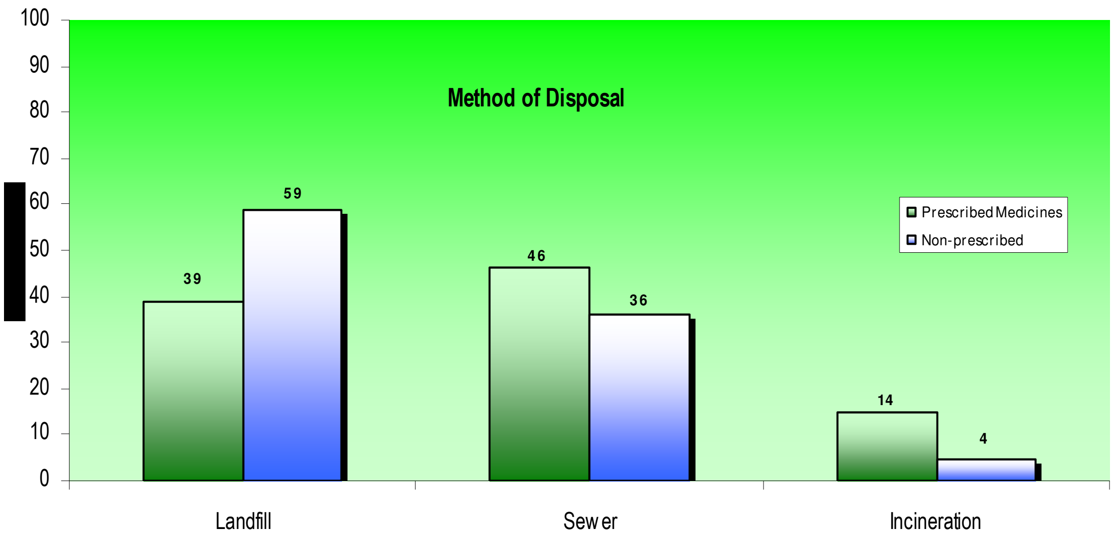

Figure 3: Disposal of Medicines by members of the public in Scotland

The questionnaire on medicine disposal sent out to community pharmacists revealed that 60% were unsure of the correct protocols for disposing of controlled drugs. Only, 33% felt their own training and guidance requirements were adequate. 17% confirmed they flush drugs down the drain, while 4% said they disposed of them along with their general commercial waste (See Figure 4). Only 23% correctly stated that no drugs should be disposed of down the drain.

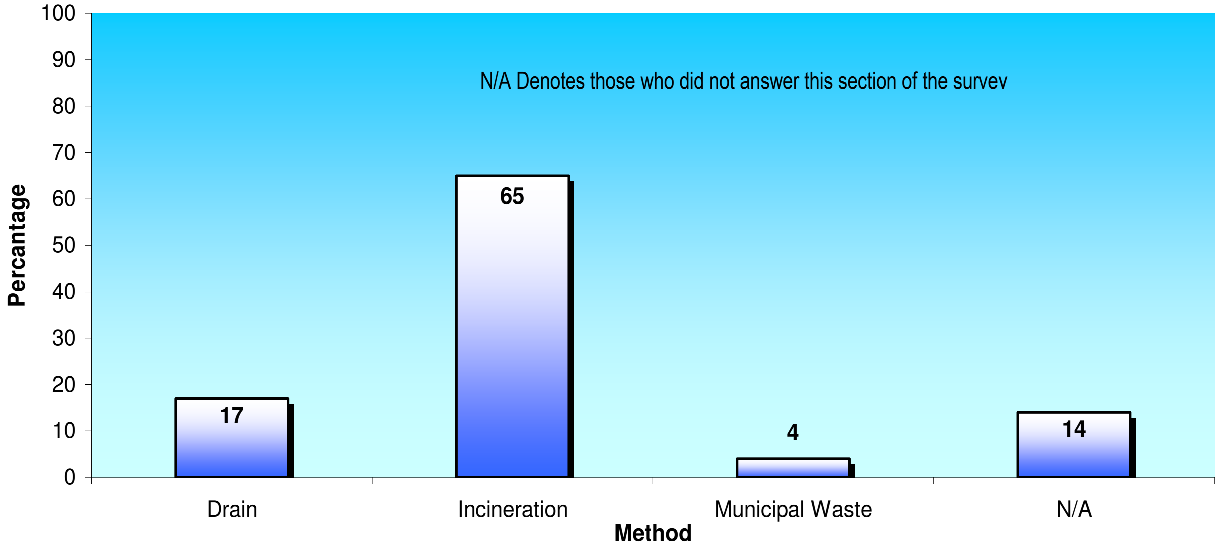

Figure 4: Disposal Methods of Drugs by Community Pharmacists

4.3.1. Analysis of pharmaceuticals in sewerage systems

A joint project between Glasgow Caledonian University (GCU), and the Centre for Environment, Fisheries and Aquaculture Science (CEFAS) was set up in November 2004. The purpose of this study was to analytically test treated sewage effluent and receiving waters for the presence of a range of 12 indicator pharmaceuticals in Scotland. Results confirm not only were many of these chemicals present in significant concentrations of treated effluents; some were also found to accumulate in sewage sludge. A full report detailing this study is currently being prepared.

4.4 Discussion

These results highlight the main disposal routes of unused medicines in Scotland are via the drain or municipal solid waste stream. Although the majority of people expressed their concern over the potential impacts of improper disposal, most of them had never seen the safe disposal of medicines leaflet. Disturbingly, many pharmacists are also unsure how they should dispose of returned drugs, and many feel they are not provided with adequate disposal facilities. Ironically, for the small number of people who do return drugs to pharmacists, there is no guarantee these drugs will be disposed of safely. Hospitals, on the other hand, are allowed to flush drugs down drains. Overall findings highlight the general lack of education and awareness that prevails throughout Scotland regarding the correct procedures for disposing of POMs and OTC's. On the whole results indicate there is an unknown cocktail of medicines entering into the aquatic environment, and this is an area requiring policy attention.

5. Increasing Pressures and Risks to Scotland's Water Environment

5.1. Legal Aspects

Until recently, under Scottish regulations, all POMs were subject to both the Controlled Waste Regulations 1992, and the Special Waste Regulations 1996, and fell under the definitions of both "Clinical" and "Special" waste. Guidance governing the disposal of POMs was included in the 1999 document, "Safe Disposal of Clinical Waste". Under this guidance, POMs were categorised as "Group D" waste, which should be incinerated.

Due to the recent implementation of the Special Waste (Amendments) (Scotland) Regulation 2004, major changes regarding the disposal of medicines have occurred, and previous guidance documents are now obsolete. Instead, and in line with the EC Hazardous Waste Directive (91/689/EEC), the Special Waste (Amendments) (Scotland) Regulations 2004, relates directly only to those waste types listed in the European Waste Catalogue (EWC). A significant difference of the new Regulations is that the term "POM" is no longer included in the new regulations. Only medicines classed as cytotoxic and cytostatic are now considered to be hazardous waste in the EWC; only these will be classified as 'special waste' in Scotland from now on.

Initially, these changes appeared to be more appropriate, as under the old regime all discarded POMs including, for example, sterile water, saline and many other relatively safe substances fell under the definition of special waste. Consequently, this waste was required to be handled, transported and disposed of as such, and it was argued that a large proportion of waste was unnecessarily classified in this way, this creating gratuitous expense.

However, a major problem with the new regulations is the lack of current knowledge and national agreement on what drugs should be classed as cytotoxic and cytostatic, and thus treated as special waste. There is also concern that the deregulation of some drugs, from special waste to municipal waste, could increase the risk of pharmaceutical exposure to humans and the environment. Since a degree of uncertainty remains over which drugs should be included or excluded under the new regulations, it may be necessary for regulators to adopt a precautionary approach, and treat all medicines as special waste.

5.2. Socio-economic and Environmental Aspects

5.2.1. Declining infrastructure

Scotland is a small country, with a population of just over 5 million people, yet has vast reservoirs of fresh water proportionate to its population. In addition to fresh water lochs (lakes), which provide most of Scotland's public drinking water; there are more than 33,000 groundwater aquifers. At present, just over 6% of groundwater is abstracted for drinking water purposes i.e. 3% used for municipal purposes and 3.5% used for private purposes. Accordingly, there is no requirement to reuse or recycle drinking water; wastewaters and drinking water are quite separate processes, which would indicate the improbability of any cross contamination. However, as Scotland's population is widely dispersed, there is a need for a large number of small water and wastewater treatment works. As a result over 46,000 km of water pipes, 39,000 km of sewer pipes, 1,896 waste water treatment plants (including 1,274 public septic tanks) and 371 other water treatment facilities are required to serve over 2.2million households connected to the public water mains.

A major problem with the existing sewerage infrastructure is that some of it dates back 150 years or more, and requires major renovation. In addition most of Scotland is served with combined sewage systems, this means raw sewage, trade effluents and flood waters are conveyed together in the sewers. Subsequently, during periods of extreme rainfall or mechanical failure, many STP's are unable to cope. During 2003, over 400 unauthorised or unsatisfactory Combined Sewer Overflows (CSO's) occurred as a result of these problems.

During such periods the risk of sewage contaminating drinking water supplies is increased. For example, during a recent period of extreme rainfall that seriously challenged Scotland's water treatment processes, several drinking water reservoirs across Scotland were found to be contaminated by the cryptosporidium parasite. This incident highlights the possibility of cross-contamination of drinking water supplies and sewage waste, as well as contamination from agricultural sources.

While it is recognised STP's provide a pathway for the release of many pharmaceuticals into the aquatic environment (i.e. human and veterinary drugs), Scotland's sewerage infrastructure remains in a state of disrepair. At the same time survey results confirm the majority of expired or unwanted medicines are disposed of via drains. It would therefore seem highly probable that pharmaceutical pollution of Scottish waters is inevitable.

5.2.2. Dependence on Landfill

Another significant area of national concern, highlighted in survey results, relates to the disposal of medicines via the domestic waste stream. Historically, landfill has been the predominant method of disposal in Scotland. This dependence on landfill is due to a number of co-incidental factors that occurred in Scotland from around the late 1960's onwards.
These factors included an increase in the types and volume of waste, a decline in mining and quarrying and new environmental legislation which resulted in the closure of Scotland's existing municipal waste incinerators.

The opportunity to use the many redundant coal mines and quarries as landfill sites was adopted by local government. Today there are over 213 licensed landfill sites operating in Scotland. While legislation (e.g. Waste Directive, Landfill Directive) and fiscal measures (phased escalation in landfill tax) are geared towards reducing dependence on landfill, more than 90% of Scotland's household waste still ends up in these sites.

A major concern regarding many of the older landfills is that they are not engineered sites, and they have no liners to prevent groundwater contamination. Due to a previous lack of awareness of the risks coupled with little or no regulation governing the disposal of hazardous waste, much of this waste was dumped in licensed and non-licensed site. As a result many of these sites are now a major source of land and water contamination. Therefore, the practice of disposing of medicines via drains and the household waste stream can only aggravate the current situation.

6. Conclusions and Recommendations

This research indicates there is considerable scope for medicines to enter into waterways, and on-going studies confirm certain pharmaceuticals are present in Scottish rivers. However, due to a lack of national research, the effect of these pharmaceuticals on aquatic species or human health remains unknown. In addition the long-term human and ecological effects of exposure to low doses of pharmaceuticals are also unknown. Currently, neither national nor local authorities in Scotland appear to have strategic plans to monitor the fate or accumulation of pharmaceuticals in the natural water environment. In order to gain a greater understanding of the true extent of this problem, a strategic and co-ordinated approach based on risk assessments of the presence and influence of pharmaceuticals in the environment is needed. Appropriate guidance and training on the correct protocols for disposing of medicines is an essential element for everyone, public and professionals alike, and must be the keystone of any national strategy on pharmaceuticals.

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