



All-Party Parliamentary Drugs Misuse Group

**An Inquiry into Physical Dependence
and Addiction to Prescription and
Over-the-Counter Medication**

**By Gemma Reay, Parliamentary Researcher to
Dr Brian Iddon MP**

2007 - 2008 Parliamentary Session

PHYSICAL DEPENDENCE AND ADDICTION TO PRESCRIPTION AND OVER-THE-COUNTER MEDICATION

REPORT ON AN INQUIRY CARRIED OUT BY THE ALL-PARTY PARLIAMENTARY DRUG MISUSE GROUP IN THE 2007 - 2008 PARLIAMENTARY SESSION

By Gemma Reay (Parliamentary Researcher to Dr Brian Iddon MP)

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FOREWORD

By Dr Brian Iddon MP

The All-Party Parliamentary Drugs Misuse Group (APPDMG) holds regular meetings to inform Members of Parliament in both Houses of Parliament on current issues involving the misuse of controlled drugs. It invites speakers from within and from outside the Houses of Parliament to give their opinions, including Ministers with responsibility for this policy area at the Home Department and at the Department of Health.

From time to time the APPDMG has also carried out inquiries into areas such as dual diagnosis, the misuse of drugs in prisons and the misuse of drugs in the workplace. Our work sometimes prompts either the Home Affairs or Health Select Committee to carry out a more extensive inquiry than our own resources allow.

For more than a decade, I have felt that the misuse of prescription and over-the-counter drugs has been a larger problem than most people admit. I have highlighted this issue before through newspaper articles and TV and radio appearances, when I became aware of the work of a small charity, "Over-Count", run by David Grieves who is from Dumfries.

However, it was the following quotation on page 11 of the Press Kit to the 2006 International Narcotics Control Board Annual Report (published by the United Nations Information Services on 1 March 2007) that persuaded me that the APPG should conduct this inquiry:

"The abuse and trafficking of prescription drugs is set to exceed illicit drug abuse, warned the International Narcotics Control Board (INCB) in its Annual Report released today (1 March 2007). The Board added that medication containing narcotic drugs and/or psychotropic substances is even a drug of first choice in many cases, and not abused as a substitute. Such

prescription drugs have effects similar to illicit drugs when taken in inappropriate quantities and without medical supervision. The “high” they provide is comparable to practically every illicitly manufactured drug.”

I believe that the so-called “War on Drugs” has had unintended consequences. One of them, now acknowledged by a recent United Nations report,¹ is ‘substance displacement’. Perhaps the increased penalties incurred for using illicit drugs is displacing people to using licit drugs instead? Some high profile celebrities have received a lot of publicity for their misuse of prescription drugs in the past decade. Perhaps also the greater ease with which prescription drugs can be obtained through poorly regulated Internet pharmacies has also played a part in the increasing misuse of prescription drugs?

More than half of the evidence that we received in this inquiry was on addiction to benzodiazepines and other classes of tranquillisers. Benzodiazepines are controlled drugs (Class C), but involuntary addiction to them as prescribed drugs is also commonplace. Indeed, this problem was highlighted by Esther Rantzen and her colleagues in the “That’s Life” series of programmes in the early 1980’s, and resulted in the publication of a book in 1984.² After the issue of addiction to benzodiazepines was highlighted, the Committee on the Safety of Medicines (CSM)³ issued guidance to the medical profession on the prescription of this class of drugs.⁴ Sadly, many General Practitioners (GPs) appear still to be ignoring that advice. Unsupervised repeat prescriptions from their surgeries are a part of the problem.

In Parliament the ongoing difficulty that many people have with benzodiazepines and their successor drugs has been highlighted through the work of the All-Party Parliamentary Group for Involuntary Tranquilliser Addiction (APPGITA) (Chairman - Jim Dobbin, Member of Parliament for Heywood and Middleton).

We have divided this report into two main sections, one on addiction to prescription drugs and one on addiction to products containing codeine that are available through over-the-counter sales.

The evidence suggests that the main drugs causing addiction problems in the over-the-counter class are those containing codeine in combination with another drug, such as the product Nurofen Plus.

During our research for this Report we have become aware of two major reports^{5,6} carried out in the State of Victoria in Australia and a further inquiry, looking partly at this area in Scotland.⁷ The findings of these inquiries are very similar to our own. We have not referenced our Report in detail but most of the previous literature in this field can be found through consulting the key references that we give here.

We recognise that millions of people have benefited from the worldwide use of the drugs covered by this Report, which is not intended as an attack on the pharmaceutical industry. Nevertheless, the industry and those who prescribe or sell its products, along with the policy makers and regulators, must recognise their responsibilities and do all they can to prevent addiction to these products. The patient too has some responsibility in that they should always read the Patient Information Leaflet (PIL) that is provided today.

The 2005 Report from the Health Select Committee on the “Influence of the Pharmaceutical Industry”⁸ raised concerns about the activities of the pharmaceutical industry. Subsequently the industry has been working hard on its image. They have recently published a Report on a consultation about the image of the industry. We would like to submit this Report to them as part of the industry’s ongoing consultation process.⁹

Since this Report concentrates on the physical dependence or addiction to licit drugs we make no reference in it to the abuse of prescription and over-the-counter drugs by elite athletes to improve their performance, which has been covered by a House of Commons Science and Technology Select Committee

report recently,¹⁰ or to the use of cognitive enhancers, such as Ritalin (methylphenidate hydrochloride) and the drugs to treat Alzheimer's disease, by students to keep them more alert and to improve their concentration to pass examinations.^{11,12}

At the end of this Report we make several recommendations upon which we hope all concerned will take the appropriate action.

SETTING THE CONTEXT

By Harry Shapiro

Benzodiazepines are widely used in the treatment of anxiety and insomnia. They are 'minor tranquillisers' compared to the 'major tranquillisers' that are used to treat psychosis. The best known of this class of drugs is diazepam (introduced to the market as Valium). Other drugs in this class include chlordiazepoxide (Librium), lorazepam (Ativan) and temazepam (Normison). Antidepressants are not tranquillisers and have very different properties.

The benzodiazepine tranquillisers were introduced in the 1960s and replaced barbiturates as the first drugs of choice to treat anxiety. They were perceived by doctors at the time as effective, with fewer side effects and a low potential for addiction. Compared with the more toxic barbiturates it is considerably more difficult to overdose on a benzodiazepine.

Because of these advantages and because benzodiazepines were very favourably received by most patients, by the mid-1970s they established themselves as the most widely prescribed of all prescription medicines. However, it became clear that people could become physically dependent and even addicted to them. Many of those who tried to stop taking them found that they experienced severe withdrawal symptoms, such as panic, sweating, diarrhoea and agitation.

Benzodiazepines work by impairing the ability of receptors in the brain to receive stress-stimulating messages. Thus, their use is to lessen anxiety. They are effective in treating so-called 'generalised anxiety'. This is anxiety, usually quite severe, which comes without any apparent cause, or the cause of which seems disproportionately small compared to the severity of the symptoms. In such cases temporary symptomatic relief may be necessary and welcomed by the patient to allow for the root cause of the anxiety to be established.

Benzodiazepines can also be used to alleviate 'normal anxiety' – the anxiety felt when under stress, threatened by life's problems, or when nothing seems to go right. In these instances, the stress is understood and the degree of anxiety appears in proportion to the stress.

The borderline between the clinical generalised anxiety disorder and normal stress response is not clear-cut, and the use of benzodiazepines to lessen normal anxiety has been criticised as the 'medicalising' of everyday social problems (a "pill for every ill").

The more recently discovered 'Z-drugs', which are also prescribed for anxiety and insomnia, act in a very similar way to the benzodiazepines. The three main drugs, which belong to the cyclopyrrolone class of drugs, are zopiclone, zolpidem and zaleplon. Like benzodiazepines such as diazepam, they have the potential to cause physical dependence, and GPs are advised that they should be prescribed for a maximum of four weeks, or more infrequently over a longer period of time.

There have long been concerns too that some over-the-counter drugs, mainly those containing the opiate codeine, have been used to mimic (albeit more mildly) the narcotic effects of morphine and heroin.

There is some confusion over terms such as drug use, misuse, abuse, addiction and dependence. Some commentators would say that, where illegal drugs are concerned, the form of use is 'abuse' simply because the drug is illegal. Others suggest that addiction is a more severe form of dependence.

Many years ago the World Health Authority (WHO) dropped the term 'addiction' in favour of dependence because of the stigmatising connotation of the term 'addict'. They admit, however, that there is no internationally agreed definition of dependence nor any scientific way of distinguishing addiction from dependence.

A distinction is often made between physical and psychological dependence. This too, says the WHO, is invalid. The term physical dependence was considered to be confusing because clinicians often interpreted the manifestation of withdrawal syndrome as evidence of both physical dependence and drug dependence. This is not the case. A patient treated with morphine in hospital will experience some physical discomfort when the drug is stopped, but they will not have the cravings, a desire to carry on using the drug, and so cannot therefore be said to be drug dependent.

The simplest explanation of drug dependence is “a state in which the individual has a need for repeated doses of the drug to feel good or to avoid feeling bad”. This is consistent both with the general public understanding and with the more sophisticated definition of drug dependence as used by the ‘WHO Expert Committee on Dependence’, which emphasises the loss of control over one’s drug-seeking behaviour as the core concept of drug dependence, and sets out diagnostic guidelines for dependence syndrome.

There is an added confusion within the context of this inquiry. The term ‘involuntary addiction’ has been coined by some experts and patient groups to describe the type of drug dependence which has occurred through medications taken initially to treat a medical condition (and often under medical supervision) but to which the patient has subsequently become dependent.

INTRODUCTION

For this inquiry the APPDMG has received evidence from across the healthcare, pharmaceutical and drug treatment sectors as well as from support groups and individuals with experience of misuse and addiction.

One of the difficulties in conducting this inquiry has been the lack of statistical analysis and academic research into this problem. Tackling the challenges of addiction to illegal drugs is clearly and rightly a priority for Government policy. However, those who become dependent on, or choose to misuse, prescription or over-the-counter medication must not be overlooked.

This is a field in which terminology is highly value laden. We accept that individuals and specialists may disagree with our definitions of misuse and addiction. For the purposes of this inquiry we have taken misuse to mean the use of a drug outside of its original direction. This does not include involuntary addicts who became addicted as a result of mis-prescribing practices.

The term addiction implies that a drug dependency has developed to such an extent that it has serious detrimental effects on the user. An addict may be chronically intoxicated, have great difficulty stopping the drug use, and be determined to obtain the drug by almost any means.

Current UK legislation to regulate the supply of medicines has been in place for the last 40 years.¹³ This legislation determines which classes of drugs should be available on prescription or more widely available. The legislation in the UK, EU and USA means that newly-licensed products are usually available only on prescription at first, with many not becoming available in pharmacies or over-the-counter until they have been around for a period of years. This allows clinicians to assess the safety levels of the drugs. However, the developing world has less control over their medicines, and many licensed medicines are available without prescription in these countries.

In the UK it is the Medicines and Healthcare products Regulatory Agency's (MHRA) decision as to what category a medicine should be placed in after it is licensed. During this decision-making process the MHRA takes advice from its independent scientific advisory group, the Commission on Human Medicine (CHM).³

The three classifications are as follows; products may be available as prescription only medicines (POM), in the pharmacy but sold under supervision by the pharmacist (P) or on general sale licence (GSL) which means they can be sold by anyone. In the process of assessment the CHM weighs up the potential benefits that easier access could bring to the patient against the potential harms easier access may create. Medicines usually begin as prescription only but may move to pharmacy or even general sale over periods of time during which assessments is made of their usage and any safety concerns.

Allowing patients easier access to medication can be beneficial for the individual and is something the Government is keen to promote. In April 2008 the Department of Health (DH) published a white paper entitled 'Pharmacy in England: building on strengths – delivering the future,' which sets out the Government's policy for giving pharmacies a greater role in treating ill health to relieve some of the burden on doctors.¹⁴

Easier access to medicines means patients can get hold of medication quickly, without having to wait for an appointment with their GP; this allows the patient more autonomy in managing their own health. It also means that the GP can save time as they don't have to write out prescriptions for minor ailments. Easier access allows pharmacists to play more of an active role in advising patients on their treatment. Also, when patients buy their medicines over-the-counter, they pick up the full costs of their medication so reducing the spending on drugs for the National Health Service (NHS).

There are, of course, benefits for the pharmaceutical industry in being able to sell their drugs over-the-counter or even pharmacy only, as it massively

widens their markets and in some cases allows them to advertise and market the drug.

However, there are concerns about the implications of having medication more readily available as it could increase the potential for misuse. It is unlikely in a busy pharmacy that the pharmacist is going to be able to supervise every sale and, in fact, MHRA guidance notes that “you will see the sales assistant show the medicine to the pharmacist when you buy it”.¹⁵ This reduces the opportunity for the pharmacist to warn about the potential risks of a particular medication. There is also some concern over patients who may misdiagnose their condition and self-medicate, and will therefore present later at the doctors with their condition.

As well as decisions about classification of drugs, the MHRA also has responsibility for monitoring the safety of all medicines in the UK. The MHRA keeps a database of drugs and record any adverse reactions people might have to them. By law, pharmaceutical companies must report reactions to their products. Once medicines have been reclassified they do continue to be the subject of safety reviews.

However, questions over the rigor and effectiveness of the MHRA “Yellow Card” reporting system have been raised in Parliament, by academics and in evidence to this inquiry. The “Yellow Card” system allows health professionals and patients to report an adverse drug reaction to the MHRA database.

Simon Maxwell from the University of Edinburgh conducted a study of awareness of good prescribing practice amongst medical students.¹⁶ It concluded that medical students felt ill-equipped by their training to prescribe drugs properly. As the prescribing burden, especially in hospitals, falls disproportionately on junior doctors, it is vital that they feel confident in making prescribing decisions. The Maxwell study found that only 29% of students agreed that the training they received would enable them to achieve the prescribing competences set out by the General Medical Council (GMC)

(Box 1). The study also concluded that graduates had insufficient prescribing practice before graduation.

Box 1: GMC Prescribing Competencies

Graduates must know and understand the principles of treatment including:

- know... how errors can happen ... and principles of managing risks.
- know and understand the principles of treatment ...and... evaluate effectiveness against evidence... the effective and safe use of medicines as a basis for prescribing, including side effects, harmful interactions.
- 'Work out drug dosage ... write safe prescriptions... give intravenous therapy (IV), intramuscular (IM) and subcutaneous (SC) injections Administer oxygen therapy and use a nebuliser correctly.
- Provide enough information ...to allow patients to make informed decisions.

Following this survey by Maxwell *et al.*,¹⁶ which was the largest survey in this field, the GMC set up a working group to respond to the implications of the survey. They made three main recommendations: firstly to ensure that all junior doctors had easy access to the British National Formulary (BNF); secondly to standardise the prescribing forms so that there is one for GPs and another for use on wards; and, thirdly, that testing should be introduced for junior doctors on competency in prescribing in their final year. In addition to this the GMC has commissioned further research on this topic, to be undertaken by the University of Liverpool, that will feed into the GMC document "Tomorrow's Doctors". The final report from this study will be published in January 2009.

The implications for this inquiry are that, if doctors are not following good prescribing guidelines, then they may miss important reactions to drugs, or they may allow repeat prescriptions against the guidance given by the medical

authorities as documented in the cases of benzodiazepine involuntary addiction.

Evidence to this inquiry suggests that there is a high level of co-occurrence of dependency and mental health problems. Mental health problems affect around 300 out of 1,000 people every year. An average GP will see between 60 and 100 people with depression each year¹⁷ and more than 80% of patients with depression are cared for solely in primary care.¹⁸

Mental health problems can be extremely difficult to diagnose due to the range and severity of symptoms and the fact that many of the symptoms can be attributed to various different conditions. Mixed anxiety and depression is the most common problem, experienced by 9% of adults in Britain. This is followed by anxiety, experienced by 5%¹⁹ both these figures and the increasing numbers diagnosed with psychotic illness indicate that experience of mental health problems is widespread within the population and are an important factor in looking at the problems of misuse and addiction to over-the-counter and prescription medication.²⁰

Evidence given to this inquiry from experts in the field, ranging from The Royal College of Psychiatrists (RCP), the British Pain Society and the Royal College of GPs (RCGP), suggests that misuse of and addiction to prescription and over-the-counter medication is anecdotally commonly seen and, whilst no official statistics exist, it is hard to put a precise figure on the scale of the problem. The charity Addiction Recovery Foundation, in their journal *Addiction Today*, published the results of a small survey of doctors in private practice.²¹ The doctors were asked how often they saw patients who were experiencing problems with either prescribed or over-the-counter medication problems. Of those who responded, 4.4% saw patients with these problems on a daily basis, 11.1% on a weekly basis and 36.8% on a monthly basis. The median age of these patients was between 36-45 years old.²¹

However, this was only a very small study of doctors in private practice so, whilst it gives an interesting snapshot of their experiences, it would be

inappropriate to try to extrapolate that data to create a national picture. There is no simple pattern for the abuse and misuse of either prescription or over-the-counter medication; it ranges from mis-prescribing, leading to dependence and addiction to polydrug use, where prescription and over-the-counter drugs are being misused as part of a circle of drug taking, often involving illegal drugs.

The key problem in assessing this area is that there is no definitive report on the scale of the problem. Not enough research has been conducted into this area of abuse and misuse, which makes it very hard to gauge the scale of the problem and the levels of dependency involved. The APPDMG would strongly recommend that greater research must be undertaken to try to determine the scale of this problem.

PREScription MEDICATION

In 2006, more than 750 million prescriptions were dispensed at a cost to the NHS of nearly £8 billion. A 2007 report by the National Audit Office (NAO) “Prescribing Costs in Primary Care”, found that a significant amount of drugs being prescribed were simply being wasted. Estimates put the cost of this wastage at £100 million a year, although this is, of course, difficult to quantify due to the nature of wastage. The majority (98%) of prescriptions are dispensed by GPs; however, the report found that GPs find it hard to assimilate all the information they receive about prescribing. On the back of this report the NAO launched a communication aid to help NHS prescribing advisors communicate more effectively with GPs to improve their prescribing practice.²²

The issue of prescription drugs costs and wastage has long been an area of concern within the NHS. In 2004, the BBC Radio Four programme “Case Notes” looked at prescribing drugs. Their conclusion was that changes to the dispensing procedure, for example only giving a prescription for 28 days at a time, could make a considerable saving in reducing the amount of drugs wasted.²³

The issue of prescription medication wastage is relevant to this inquiry because of the risk of diversion from unused drugs, which may result in them being sold or misused illicitly. Whilst there are no official figures for the amount of prescriptions which may be being diverted for illicit use, anecdotal evidence would suggest that unused medication are one of the sources for illicitly misused drugs such as benzodiazepines.²⁴

Evidence from the 2008 Druglink Street Drug Trends study from the drug charity Drugscope uncovered evidence that there was a growing market for illicit diazepam, which retails at £1 a tablet. In some areas the growth in the market in diazepam can be attributed to the reduction in availability and

quality of heroin. Evidence from the study suggests that, as well as diverted prescriptions, a significant number of diazepam tablets are being smuggled in from abroad, either by individuals or through Internet sites.²⁵

The inquiry received a wide range of evidence on the issue of addiction to and misuse of prescription drugs. The drugs cited can all be loosely categorised into the psychoactive category of drugs. The majority of the evidence came from people who had been prescribed benzodiazepine drugs by their doctors and had been unable to stop taking them. By 'benzodiazepine drugs', we mean drugs including Ativan, Valium, Mogadon and Librium. The remaining evidence detailed people's difficulties with antidepressant drugs.

The APPDMG also received evidence of addiction to codeine containing drugs but this class of drug will be covered in the over-the-counter drug section of this report.

BENZODIAZEPINES – INVOLUNTARY ADDICTION

Defining the Problem

There has already been a great deal of work and campaigning on the issue of addiction to benzodiazepine drugs. Probably the most high profile campaign began in 1985, when Esther Rantzen and the "That's Life" team conducted a survey on benzodiazepine usage and found that, not only were large numbers of people taking the drugs for long periods, but they were also experiencing considerable difficulty in withdrawing from the drugs.²

It would be wrong to classify those who were prescribed benzodiazepines, antidepressants and the 'Z- drugs' by their doctors, and who took them in good faith, as drug addicts in the widely accepted sense of the phrase. Therefore, for those in this category, we will use the phrase "involuntary addicts."

It is, however, important to stress that, for some people, benzodiazepines, if taken as per the guidelines in the BNF, can be helpful in providing short term relief from their symptoms. The APPDMG does not advocate stopping benzodiazepines abruptly and would always recommend consultation with a health professional before attempting withdrawal.

There are an estimated 1.5 million people²⁶ addicted to benzodiazepine drugs in the UK. Many of these people will have been addicted for long periods of time. The inquiry received over 40 submissions from individuals and their families who have suffered from involuntary addiction. In researching the subject we have uncovered references to hundreds more personal accounts of involuntary addiction.

There is a common pattern to their submissions; a visit to their GP, a prescription for a particular benzodiazepine, then years of repeat prescriptions, often without review. For many patients, the drug initially does alleviate their symptoms but, for others, the symptoms continue and their general health deteriorates.

The difficulty with the benzodiazepine class of drugs (and their predecessor drugs, barbiturates) is that their long-term usage can result in dependence. The section in the BNF refers to benzodiazepine drugs as only being appropriate for short periods, as tolerance can develop. "Benzodiazepines are indicated for the short term relief (two to four weeks only) of anxiety that is severe, disabling or subjecting the individual to unacceptable distress." According to the BNF "the use of benzodiazepines for short-term 'mild' anxiety is inappropriate and unsuitable".²⁷

The BNF advocates that withdrawal from benzodiazepines should be gradual as "abrupt withdrawal may produce confusion, toxic psychosis, convulsions, or a condition resembling delirium tremens".²⁶ The BNF even warns that some of the symptoms of withdrawal from benzodiazepines may mirror the original symptoms that resulted in a prescription for a benzodiazepine in the first place, for example anxiety.²⁶

Since 1988, advice from the CSM³ has been that benzodiazepine drugs should not be prescribed for longer than 2-4 weeks. Despite this change to the guidelines and the relevant amends being made in the BNF, the inquiry has received evidence that some doctors are continuing to prescribe outside these guidelines. However, prescription rates of benzodiazepines are beginning to fall gradually. In 2002, there were 12.7 million benzodiazepine prescriptions and, by 2007, this figure had fallen to 11.7 million prescriptions for benzodiazepines in the community. Whilst this figure is dwarfed by the numbers being prescribed antidepressants, it is still a high figure.²⁸

Many of the people making submissions to the inquiry detailed their experiences of withdrawing from benzodiazepines, and two case studies taken from the evidence are replicated below.

Case Study 1

Ms R was prescribed benzodiazepines following treatment for alcohol addiction. For the next 28 years her doctor allowed her repeat prescriptions of the drug despite the fact that she continued to experience feelings of anxiety and ill health. More recently she has attempted withdrawal but failed on a number of occasions.

Her GP told her his medical training did not equip him with the skills to help her withdraw, so she approached her local Drug and Alcohol Action Team (DAAT) who refused to help her as she was “only a prescription drugs addict.” She was told that, as her GP had created the problem, it was up to him to solve it. Her DAAT told her that, if she had become addicted to benzodiazepines through illicit use, they would have been able to help her.

Case Study 2

Mrs B, a former nurse, was prescribed lorazepam and the antidepressant Lustral following a period of stress. She took both drugs for the next 10 years. After withdrawing, over a two month period, from Lustral the frequent panic attacks she had been suffering from ceased.

With help from her GP, two benzodiazepine support groups and alternative therapies, Mrs B devised a programme of withdrawal according to the Ashton Protocol.²⁹

During her withdrawal Mrs B experienced emotional highs and lows, severe joint pain, which resulted in her “taking painkillers like sweets,” dizziness, panic and disorientation.

She has successfully withdrawn from both the benzodiazepine and the antidepressant, and now works for benzodiazepine support groups helping others who want to withdraw.

These cases, which detail the difficulty in accessing support for withdrawal and the ill health suffered during withdrawal, are replicated again and again in submissions to the inquiry.

Some people were not even suffering from anxiety when the drugs were prescribed. The inquiry has received evidence of benzodiazepines being prescribed for anything from a facial tic to irritable bowel syndrome. The longest documented case we have received of a person being prescribed benzodiazepines for is 39 years; this lady is still taking them as she has been unable to access the support she needs to withdraw.

For some of those who do withdraw, the consequences of their involuntary addiction may result in continuing health problems. Little research has been

undertaken into the effects of long-term benzodiazepine usage. Professor Heather Ashton of Newcastle University is the leading expert in this field and author of a withdrawal protocol recommended by many of the self-help group in the field.²⁹ She has tried to undertake research in this area but has been unable to secure funding for it. The APPDMG would recommend that research into the effects of taking these drugs long-term should be carried out.

As can be seen in Case Study 1, it can be very difficult for those wishing to withdraw from benzodiazepines to find the advice and support they need to get through this difficult process. The APPDMG received submissions from various individuals and self-help groups in which a variety of proposals for the provision of services for advice and support were made.

Whilst some evidence suggests that tapering dosage is the most effective way to approach withdrawal, as set out in Ashton's protocol,²⁹ what is clear from the body of evidence on the subject and the submissions received by this inquiry is that each individual will experience withdrawal differently, so it is essential that a wide range of support options are available to them.

In oral evidence to this inquiry, Ashton (who has previously run a NHS benzodiazepine withdrawal clinic) said that two thirds of those addicted to benzodiazepines through long term use are female.²⁴ Many of these patients have co-existing mental health problems, which makes withdrawal and treatment of their original symptoms (which withdrawal can mirror) all the more difficult.

The APPDMG is also concerned about usage of benzodiazepines in old people's care and residential homes to treat a variety of ailments. The nature of benzodiazepines means that, if taken over long periods of time, tolerance to the drugs will develop, and the dosage will need to be increased for effects to be felt. However, if the dosage is not increased and patients (who may be suffering from other health problems and less able to express themselves) are left on the same dosage, they will in effect be experiencing a permanent state of withdrawal without the dosage actually being reduced. This is likely to be an

unpleasant experience for the patient. There is also some concern over the way these drugs could interact with the other drugs an older person might be taking, for example for dementia.

Paul Burstow MP (Sutton and Cheam) has undertaken some research into inappropriate prescribing for older people in care homes. His most recent report suggests that 100,000 older people in care are receiving antipsychotic drugs inappropriately, usually to sedate them due to staff shortages.³⁰ Burstow's work has been backed up by a report from the All-Party Parliamentary Group on Dementia which also found that over-prescribing of antipsychotic drugs to older people in care was widespread.³¹ However, both Burstow's Report and the APPG on Dementia have focused on the mis-prescribing of antipsychotic drugs rather than on tranquillisers. This means that, whilst the APPDMG cannot put a figure on the misuse and mis-prescribing of tranquillisers amongst older people, anecdotal evidence would suggest that benzodiazepine mis-prescribing amongst older people is fairly widespread. Ashton estimates that 40% of those in care homes are prescribed benzodiazepines.²⁶

There is also the issue of benzodiazepine drug use in pregnancy. In 1997, the CSM³ issued a reminder to all doctors to avoid prescribing benzodiazepines in pregnancy and during breastfeeding. In the USA benzodiazepines are classified as either "should not take in pregnancy" or "never take in pregnancy", depending on the particular make-up of the drug. In the USA the manufacturers' information leaflets warn women not to take benzodiazepines during pregnancy.

There is some evidence that prenatal exposure to benzodiazepines can cause toxicity or withdrawal effects in the baby, which may require longer term treatment than babies born to opioid dependent mothers. However, there is not, as yet, a large enough bank of research in this area.³²

Tackling the problem

The two main themes in tackling this problem must be to raise awareness in order to prevent new patients becoming addicted, and to provide support for those who are already addicted. The Council for Information on Tranquillisers and Antidepressants (CITA), in its submission to the inquiry, detailed the work it does with Primary Care Trusts (PCTs) in the North West, such as St Helens, Wigan and South Manchester, in helping them to reduce the number of people on benzodiazepines in their areas.

The value of the work that CITA has done with PCTs can be seen in the reduction of the number of prescriptions for benzodiazepines in the PCT area. For example, working closely with four GP practices in St Helens PCT, they have had a 67% success rate in helping patients withdraw from benzodiazepines. CITA works with PCTs in a variety of different ways, usually liaising with surgeries to educate the prescribers, and working with individuals who want to reduce their benzodiazepine usage. By working with individual surgeries, they are able to target their resources where they are most needed, and are able to access a wide range of patients, from patients who have only just begun taking benzodiazepines to those who have been on them for a number of years.

Something that particularly comes across in the submissions from support groups, such as CITA, is the low level of knowledge about this issue amongst some GPs. Despite the fact that the guidelines have been made quite clear in the BNF and, the fact that GPs have received correspondence about prescribing benzodiazepines from the Chief Medical Officer (CMO), repeat prescriptions for longer than the 2-4 week period continue to be allowed and, conversely, some GPs continue to try to reduce the benzodiazepine usage of their patients too fast.

Clearly there must be a more joined-up approach to educating all health professionals, from pharmacists to nurses and doctors, to ensure that they are able to help vulnerable patients

Campaigners within the benzodiazepine movement have been working for a number of years to get recognition for the problems that benzodiazepines have caused and continue to cause the individuals who take them. Parliamentary Questions (PQs) tabled by Jim Dobbin MP, Chair of the All-Party Parliamentary Involuntary Tranquilliser Addiction Group,²⁶ demonstrate that the DH has been aware of the problems for some time, but that they are unwilling to take decisive action, as they believe that the information is there for doctors, and that support can be accessed. However, as we have seen in our case studies, some GPs ignore the guidelines, and patients can find it very difficult to access the support they need to withdraw.

The lack of awareness of this issue amongst some GPs is extremely concerning. GPs in the UK enjoy a great deal of autonomy, and a lot of trust is put in their capacity to make complex clinical judgments. However, we need to feel reassured that the GPs making those decisions are keeping up-to-date with the latest research on, for example, the complexities involved in withdrawing from certain mind-altering prescription drugs. It is also important to remember that their patients are vulnerable people, often with co-morbid mental health problems.

There needs to be clearer, strategic, long term thinking from the DH and NHS about the issue of benzodiazepine prescribing. Taking benzodiazepines for long periods of time is likely to cause the patient associated ill-health,²⁴ which, in addition to the cost of prescriptions, can be an expensive way for the NHS to maintain such patients. It is surely more cost effective and more in line with the Government's policy of preventative health care, to act to avoid prescribing benzodiazepines in the first place or to provide support services to help patients to withdraw. Would having nurse or counsellor-led support in GP practices to undertake early intervention and reduce the number of prescriptions really be as costly as having large numbers of repeat prescriptions? The inquiry received evidence from a nurse working specifically on prescribed drug dependence in Northern Ireland. Patients are referred to him by GPs' surgeries, and engagement with the service he provides has

been high, at 65%. Although he was employed to lower the rates of benzodiazepine prescribing, he has also noted the growth of groups dependent on both benzodiazepines and analgesics and on analgesics alone. It is clear that the work he is doing is proving useful to GPs' surgeries.

We also need greater understanding about why some GPs continue to prescribe outside the BNF guidelines. In oral evidence to the APPDMG, Dr Stephen Willotts from the Royal College of GPs was honest about how the time pressures on GPs and their need to work through the patient load, as well as the paperwork and patient expectation, resulted in a prescription rather than talking more to the patient. Although the DH has recently announced more funding for 'talking therapies', there are still long waiting lists, and referral for cognitive behaviour therapies may take too long and it will take time before the effects of this investment are felt in clinical practice.³³

During clinical trials there must be greater follow up on those who underwent the trial and details of how to withdraw from the drugs should be made available both on the Patient Information Leaflet (PIL) and on the computer systems used by doctors.

BENZODIAZEPINES – MISUSE

Defining the Problem

In 1998, the Advisory Council on the Misuse of Drugs (ACMD) recommended that all benzodiazepines should be rescheduled to Schedule 3 to reflect their harm potential.³⁴ Whilst benzodiazepines are available on prescription only, they are also Class C drugs in the ABC classification of controlled drugs. If a person is caught in possession of these drugs (without a prescription), they face up to 2 years in prison and, if caught dealing in them, they would face up to 14 years in prison.³⁵

Benzodiazepines, which are used and abused recreationally, activate the dopaminergic reward pathways in the central nervous system. Current NHS

figures show that there are 200,000 illicit benzodiazepine users in the UK.³⁶ Up to 90% of problem drug users also use benzodiazepines as part of a cycle of polydrug misuse, usually with cocaine or crack. This is because they can alleviate the comedown effects from the highs of crack or cocaine.^{37, 38}

Benzodiazepines are not just misused within a polydrug misuse cycle. Flunitrazepam (trade name Rohypnol) has been linked to drug-assisted sexual assaults.

The sources of illicit benzodiazepines range from diverted prescriptions as well as warehouse and pharmacy thefts and forged prescriptions.³⁶ New evidence from the recent Drug Trends Study undertaken by Drugscope, as discussed above, shows that the problem of smuggling benzodiazepines into the country is increasingly becoming a problem in some cities.²⁵

It is also fairly easy to purchase benzodiazepines on the Internet. However, it would be wrong to suggest that everyone who buys benzodiazepines online does so with a desire to misuse them recreationally. Anecdotal evidence from support groups such as CITA and Battle Against Tranquillisers (BAT) would suggest that buying benzodiazepines from online pharmacies can sometimes be the only way a patient can manage their withdrawal, for example if their GP has withdrawn their prescription too quickly. However, there are considerable risks in buying drugs online as they may be counterfeit drugs whose safety cannot be assured.

However, the inquiry has received submissions from people who choose to buy benzodiazepine drugs online to top-up the prescription they receive from their doctor. In addition, there are instances of diversion of prescriptions. Although the inquiry did not receive formal evidence of this happening, it is documented in other research.

In evidence to the inquiry, Ashton²⁶ estimates that 50% of alcoholics also use benzodiazepines to reduce alcohol induced anxiety and because the mix of alcohol and benzodiazepines gives a buzz. Paradoxically, benzodiazepines

are also used in treatment for alcoholics when they are trying to cut down. A number of the individual submissions to the inquiry make reference to the fact that they were alcohol misusers who were prescribed benzodiazepines to help them withdraw from alcohol, or after they had withdrawn to help them to cope. These individuals then became dependent on benzodiazepines.

Tackling the problem

As discussed, those who choose to misuse benzodiazepines illicitly often do so as part of a polydrug use cycle as 'downers' to counteract the 'uppers' they have taken. It is vital that these people are able to access the support they need to help them to address their drug problems. This would take the form of traditional DAAT intervention and drug treatment in the appropriate facility. For those continuing with their drug misuse, reducing the potential harm is most important.

Some organisations such as BAT, run by Una Corbett in Bristol, have facilities for people who are addicted to benzodiazepines through illicit means, as well as those addicted involuntarily. Evidence received from BAT indicates that this approach can prove successful in helping those with dependence.

An important component of tackling drugs misuse has to be addressing the route of supply for the drug. As benzodiazepines come from a wide range of sources, procedures must be put in place to make prescription diversion more difficult. In May 2008, the European Federation of Pharmaceutical Industries and Associations revealed that they were planning to pilot a bar code system to allow them to monitor the authenticity of drugs as they are dispensed. The announcement was made following a European Commission Consultation on how to tackle counterfeit products.³⁹

The scheme, which is currently being developed and trialed in California, will give each product an electronic pedigree, which should allow manufacturers to trace their products.³⁹

However, there are some concerns over whether this approach would actually work in Europe, as the EU allows the parallel trade of pharmaceuticals and the repackaging of products. The MHRA has expressed concerns that a unique seal on pharmaceutical packaging would restrict importers from complying with UK specific regulations on medical leaflets and labeling.

This bar code pilot across Europe is only one of many ways that the pharmaceutical industry is looking at to reduce the amount of counterfeit products in circulation. According to the WHO, around 10% of medicines sold in the world are counterfeit, this ranging from less than 1% in developed countries to around 30% in Africa. This is an especially pertinent issue when considering medicines bought over the Internet.³⁹

In terms of the accessibility of prescription drugs on the Internet, this is a topic that our report will look at in greater depth in the section on over-the-counter drugs.

ANTIDEPRESSANTS

Defining the Problem

In 2004, the National Institute for Clinical Excellence (NICE) issued new guidance on the treatment of depression. It recommended that those who present to their GP with mild depression should be put in the “watchful waiting” category, meaning they should have a follow-up appointment within 2 weeks to reassess their condition. This approach has recently been backed up by a study conducted by a research team at the University of Hull, which concluded that antidepressants only help a small group of the most severely depressed patients.⁴⁰

The Hull Group looked at the results of 47 clinical trials and, whilst they accept in their conclusions that many people believe the drugs do work for them, the researchers argue that this could be a placebo effect. Manufacturers GlaxoSmithKline and Eli Lilly dispute their findings, saying that scientific and medical experience has proven these drugs to be effective antidepressants.⁴⁰

Plant and Stephenson⁴¹, support the NICE guidance on the treatment of depression and advocate a combination of alternative therapies and lifestyle changes, which can be more effective at treating depression than the traditional chemical route. This work is backed up by the Hull Study⁴⁰ and the London School of Economics ‘Depression Report’, which looked in detail about how best to organise cognitive behavioural therapies in this country so the greatest number of people could access support.⁴²

Despite this guidance and research, the number of prescriptions to treat depression has been steadily increasing. By 2007, there were 33.8 million prescriptions in the community, an increase of over 2 million on the previous year.²⁷

This inquiry received a number of submissions from individuals who had been prescribed antidepressant drugs; usually Seroxat, Prozac, Venlafaxine or Paroxetine. These are similar to the accounts received from benzodiazepine involuntary addicts. They presented to their GP, sometimes with depression, others with Myalgic Encephalomyelitis (ME), or suffering from obsessive compulsive disorder and mental health difficulties, others simply feeling “a bit low.” Many of these individuals were then left on the antidepressants with little or no extra support that might enable them to tackle the problems that had led them to a prescription for antidepressants in the first place.

Many of the submissions to this inquiry detail the horrible side-effects patients experienced whilst taking the drugs, such as insomnia, dizziness, disorientation and flu-like symptoms. As with the involuntary benzodiazepines addicts, these are symptoms the patients might well have been experiencing before they began taking the drugs. For many of those who made individual submissions to the inquiry, the ill-health they suffered was merely a continuation of the way they were feeling before they went on the drugs. As they tried to withdraw from the drugs, the symptoms remained or got worse.

The main body of our information on the mis-prescribing of antidepressants came from the Seroxat Users Group, with additional information from CITA. Whilst CITA began as a benzodiazepine support group, they have widened their remit to allow them to help those affected by antidepressants – including the ‘Z-drugs’ because of demand for their services.

The main concerns about Seroxat in particular are largely outside the remit for this inquiry, which really seeks to focus on the misuse and addiction to prescription and over-the-counter medications. However, the impact that Seroxat in particular has had on people’s lives has at times been so devastating that the APPDMG wanted to make reference to it as part of this report.

The first Selective Serotonin Reuptake Inhibitor (SSRI) (Prozac) was launched in 1988. Acting on various scientific reports and an ongoing correspondence

with psychiatrist Dr David Healey, the MHRA conducted four investigations into antidepressants. Each concluded that antidepressants were safe, effective and non-addictive. However, by 2002, concerns were growing about the safety of this class of drugs and the BBC programme Panorama conducted the first of their investigations into the drug. They reported side-effects of addiction, aggression and suicide. In a follow-up programme a year later (based on the responses they received to the first programme – over 1,500 emails detailing individuals concerns) Panorama concluded that Seroxat was addictive and, in some patients, could increase the risk of suicide.⁴³

As a result, the MHRA issued new guidelines on antidepressants.⁴⁴ It now advises against prescribing antidepressants (excluding Prozac) to children under the age of 18. GlaxoSmithKline has removed the statement “this drug is not addictive” from their packaging and issued a warning about the difficulties of stopping taking the drug.

The Seroxat Users Group gave oral evidence to the inquiry and provided us with a large number of testimonies from individuals who have suffered whilst taking this drug. Like those who submitted individual evidence to our inquiry, they range from the side-effects whilst taking it, the difficulties of withdrawing from the drug and, sadly, cases of suicide attempts and actual suicide whilst taking this drug.

Case Study 1

Mr G had recently retired and, whilst having a fairly positive outlook on life and much to look forward to in the future, he was experiencing anxiety and nervousness. Friends and family have described him as not quite being himself. His GP prescribed him fluoxetine.

His symptoms of anxiety and ‘nerves’ were not alleviated by the drug; if anything they became worse and he seemed less connected to those

around him. Despite not displaying any signs of depression or suicidal tendencies before taking the drugs, Mr G hung himself within 2 weeks of starting the course of antidepressants.

This is not the only submission the inquiry has received detailing such tragic loss of life.

The APPDMG is aware of the campaign work being undertaken by the Seroxat Users Group and others against the manufacturers of this drug about the results of clinical trials and, consequently, does not want to prejudice any civil action there may be.

This inquiry did not receive evidence from individuals about their misuse of antidepressant drugs, but there is anecdotal evidence of these drugs being used in this way as part of a cycle of illicit drugs misuse. Different kinds of antidepressants can be misused alone for their amphetamine-like effect or alongside ecstasy to alleviate the post ecstasy come-down.⁴⁵

Tackling the Problem

To tackle the problem effectively, more research must be conducted into depression and the best forms of treatment, as well as an assessment of the effectiveness of antidepressants which accurately factor in the side-effects and withdrawal symptoms some people can suffer from when they take these drugs. This could be made considerably easier if the results of all clinical trials were made public, not just the results of supportive clinical trials. When the researchers at the University of Hull were conducting their research into the effectiveness of antidepressants, they were able to look at only some of the clinical trial data after freedom of information requests.⁴⁰ Greater information would allow patients and doctors alike to make the right decisions regarding treatment.

There is also concern that clinical trials may not be representative of those who take the drugs. For example, women, older people and those from ethnic minority groups are often under-represented in clinical trials, so it is difficult to know whether they will react to the drug in different ways. This becomes increasingly pertinent considering that increasingly more and more drugs will be biological drugs, so genetics will play an important role in how the body reacts to them.

There needs to be an acceptance amongst the medical profession that these drugs can not only have serious side-effects but that the withdrawal symptoms can, for some people, be so difficult to manage that they are unable to stop taking the drug. Professor Healey, who first raised concerns about the safety of Seroxat, has devised a withdrawal protocol for patients wanting to come off antidepressants.⁴⁶ As with the Ashton Protocol,²⁹ it is important that all GPs have access to this document as it would allow them to provide their patients with greater support if they need it. Making such protocols available to GPs is common practice in places like Canada.

Many of the problems associated with antidepressants (and other prescription drugs) could have come to light earlier if the side-effects and withdrawal difficulties had been brought to the attention of clinicians earlier. Obviously, this ties in with the need to make clinical trial data more transparent, but there is also a need to ensure that adverse reactions to drugs are reported and acted upon.

The APPDMG received written and oral evidence from the charity APRIL (Adverse Psychiatric Reactions Information Link), run by Millie Kieve, which campaigns to raise awareness about the issues surrounding adverse drug reactions. The charity plays an important role in bringing the risk of addiction and the associated withdrawal symptoms to the attention of policy-makers and health professionals. Although there is a growing awareness of the problems associated with taking benzodiazepines and antidepressants and, to some extent, the 'Z-drugs', various new drugs become available every year, and it is

vitaly important that any adverse reactions to them are reported and monitored.

There has been a lot of debate about the strength and efficacy of the current “Yellow Card” system being run by the MHRA. According to a survey conducted by APRIL, on one hospital shift, 50% of doctors and over 90% of nurses claimed never to have heard of the “Yellow Card” scheme. This was not a scientifically rigorous study but it does give an indication of the level of ignorance there may be in the medical profession regarding this scheme.⁴⁷

APRIL has raised concerns about the sort of training that doctors receive and whether doctors learn the skills to understand how medicines are metabolised and interact with each other. By not being able to diagnose and report an adverse reaction, doctors will continue to put patients at risk. As drugs become more advanced and more gene specific, there will be a need for even greater rigor in prescribing and reporting as adverse reactions may be irreversible.⁴⁸

In 2005, the Health Select Committee conducted an inquiry into the influence of the pharmaceutical industry. The Committee found that the MHRA had a conflict of interest in its remit to promote the pharmaceutical industry and to regulate the safety of medicines. There have long been concerns over the pharmaceutical industry’s attempts to encourage doctors to prescribe in a certain way and to discount adverse reactions.⁸

In October 2007, the Secretary of State for Health, Alan Johnson, announced more funding for “talking therapies.” Currently, patients can be waiting for alternative therapies, such as cognitive behaviour therapies, for up to 18 months. This is far too long. “Talking therapies” have been shown to have some success in tackling depression, so the APPDMG was very pleased to see the announcement of a £170 million increase in funding for this area and an announcement that 3,600 more therapists will be recruited by 2010. The APPDMG very much hopes that this will result in a reduction in the number of prescriptions for antidepressants.³³

The importance of using all avenues for gathering research cannot be underestimated, so the APPDMG would advocate that, where possible, the drugs being taken at time of death should be included in the coroner's report and that the records should be available, anonymised, to researchers. This course of action has been recommended by a number of coroners dealing with suicide cases recently and would allow data to be collected that would help researchers investigating the link between Seroxat and suicide.

OVER-THE-COUNTER MEDICATION

Defining the problem

There are no reliable figures which would allow the APPDMG to put a precise figure on the scale of addiction to and misuse of over-the-counter medication in the UK. However, the inquiry has received a diverse range of evidence from various sources which allows us to conclude that the problem does exist and does affect enough people for action to be required to address and combat it.

The majority of the evidence the inquiry received in this area relates to addiction to over-the-counter products containing codeine. However, anecdotally, and through other research, the inquiry has uncovered evidence of misuse of performance enhancing drugs, such as steroids (usually obtained illegally), Ritalin for increased mental capacity and also as an appetite suppressant, laxatives for weight loss, and caffeine tablets as appetite suppressants and for increased mental alertness.

In March 2004, the Scottish Specialists in Pharmaceutical Public Health, together with Trust Chief Pharmacists produced a report looking at the issues of drug misuse and the rôle community pharmacies can play in helping people manage their drug misuse. Although the majority of the report looks at the rôle for the pharmacists in caring for illicit drug misusers, it does acknowledge that over-the-counter and prescription drugs may be “the cause of drug misuse.” The report devotes an entire chapter to looking at this issue.⁴⁹

The chapter entitled “The Recreational User” looks in detail at the sort of drugs being misused, the prevalence of such activity and ways to tackle the problem. The report’s assessment of the drugs of misuse is similar to evidence given to the inquiry and from that uncovered by additional research. Drugs of misuse include antihistamines, opiate-containing painkillers, laxatives and stimulants.⁵⁰

The report makes reference to surveys conducted in community pharmacies across Scotland, which have reported a high level of suspected misuse of over-the-counter medication. In 1995, 67.8% of community pharmacists suspected over-the-counter misuse was occurring in their area. By 2000, this figure had risen to 69%. These surveys revealed that Nytol was particularly a drug of suspected abuse.⁵⁰ However, the APPDMG did not receive any evidence from an individual detailing misuse of this particular drug.

Although few academic studies have been conducted in this area the inquiry uncovered two studies which had looked at the perceived prevalence of this problem in community studies, one in Northern Ireland⁵¹ the other in Scotland.⁵² The Northern Ireland study concluded that, on average, two people per week using the pharmacy were potential misusers. In the Scottish study, the figures for reported misusers was higher, with community pharmacists estimating the number to be over 5 misusers per week.

However, the studies that have been undertaken have focused on the perception amongst either pharmacists, or members of the public, of the scale of misuse, and the criteria for making this decision has been fairly narrow. This makes it extremely difficult to determine the real scale of this problem.

'Over-Count', the online support group and campaigning charity for the issue of over-the-counter addiction and misuse, run by David Grieve, a former codeine addict, estimates that, in the period 1993-2007, they have helped 16,000 people who have approached them with a problem about dependency to an over-the-counter product.⁵³ When the figure of 30,000 addicts is quoted in the media, it is usually an extrapolation of this figure.

'Over-Count' recently conducted a survey⁵⁴ amongst their online community about the nature of people's dependency on codeine-containing medication. The survey found that Solpadeine and Nurofen Plus are the most commonly misused products followed by generic co-codamol (available extremely cheaply) Syndol and Feminax.

The survey conducted by 'Over-Count' revealed that the majority of misusers are female and that there is an increasing trend for people to buy over-the-counter products from the Internet. Most respondees said they had first bought the product to treat a minor ailment. In submissions to the inquiry, other individuals report that they "didn't want to bother the doctor." Whilst most of the responses to Grieve's survey indicated that when they had approached their GPs for help after becoming concerned about a developing dependence, few had received the support they were looking for.⁵⁴

Grieve's survey results are backed up by statistics from the Republic of Ireland which, in May 2008, revealed that the numbers of patients addicted to Solpadeine and Nurofen Plus, who required treatment in a rehabilitation centre, had more than doubled in two years. In response to these figures, Dr John O'Connor, Clinical Director at the Drug Treatment Centre Board, called for codeine to be made prescription only, as the Republic of Ireland was facing "serious problems" with rising rates of addiction to this drug.^{55,56}

In the State of Victoria, Australia, Dobbin and Tobin⁶ have conducted an inquiry and produced a report for the Drugs Policy and Services Branch, Department of Human Services, Victoria. The report, published in May 2008, entitled "Over-the-counter ibuprofen/codeine analgesics: misuse and harm" looks at the prevalence of this problem in the State of Victoria. The report also contains a review of the literature available on this topic.

Dobbin and Tobin⁶ conclude that drugs such as Nurofen Plus and Panafen Plus (both codeine-containing) are drugs of misuse, but that the profile of the user is one of an individual who has no previous history of illicit drug dependence, but one who may well have a co-occurrence of a mental health disorder. They state that there is an "urgent need to limit the misuse of over-the-counter ibuprofen/codeine products."

The Australian report⁶ recommends that the pack size be reduced from 32 tablets to make the drugs less attractive for misuse. A pack size of 18 tablets

would allow treatment at the recommended dosage for the recommended time frame (6 tablets a day for 3 days). This report also recommends that drugs containing the highest codeine dosage, such as Nurofen Plus, should be reclassified as prescription only medicines and that clearer and more accessible information should be provided to help the patient make informed decisions.

Due to the covert nature of this type of addiction it is very hard to devise a profile for over-the-counter drug misuse. The stereotype image, based on reports and anecdotal evidence, is of a middle aged female. However, evidence to this inquiry suggests that many people become dependent on codeine-containing painkillers because of chronic pain and a lack of an appropriate pain management strategy. This means that having a stereotypical view of the sort of person who may become addicted is unhelpful in trying to ensure as many people as possible are able to recognise and get help for their misuse. For example, Mark Edwards, who runs the online support website for codeine misusers called 'CodeineFreeMe', is a former codeine addict. He became addicted to codeine following a painful operation and believes that, if an effective pain management strategy had been put in place, he would have been able to avoid becoming dependent on codeine.⁵⁷

It is hard to determine the profile of an over-the-counter drug misuser because they are likely to want to keep their misuse a secret, for example misuse of painkillers may only come to light when the sufferer is hospitalised through overdose – either deliberately or accidentally. Evidence from the British Pain Society, the RCP and individual submissions to our inquiry suggests that those who become dependent on codeine often have co-morbid mental health problems too. In some cases it can be hard to find the dividing line between prescription drug misuse and over-the-counter drug misuse as, with many other drugs, there may be a polydrug cycle that the misuser gets into, often involving alcohol. In other cases dependence on opioids develops as someone with a mental health disorder tries to self-medicate the feelings they are experiencing.

Many of those who become addicted to over-the-counter medication may become so due to a lack of effective pain management. In oral evidence to the inquiry, Dr Cathy Stannard, Chair of the Working Party on Pain and Substance Misuse at the British Pain Society, detailed her concerns about the risks for patients of a lack of an effective pain management strategy. In the period 2003-06, there was a 50% increase in the prescription of opioids. Stannard attributed this to changes in prescribing practices of doctors who are encouraged to try to alleviate pain where possible. Stannard suggested that guidelines devised to “help” doctors also undermine their ability to make individual decisions based on patients specific circumstances. She believes that prescribing guidelines can lead to increased prescribing, as doctors are too quick to write a prescription or issue a repeat prescription without investigating what is causing the pain or whether the drugs are actually tackling the problem.⁵⁸

Another reason behind increased prescribing is the push from the pharmaceutical industry for doctors to use their products to alleviate pain rather than to address the original problem. Stannard felt that greater scrutiny of the medical profession in this regard is essential to prevent patients being placed on pain relief for years without the question of whether the painkillers were actually working being asked.⁵⁸

However, there are also those who actively seek out codeine-containing products “for the buzz”. We have received anecdotal evidence from those working in the drugs field that the American teenage craze of “pharming,” i.e. taking a mixture of drugs available at home in the medicine cabinet, may be coming over to the UK. Obviously, different types of drugs are available in the USA and they may be more accessible due to the nature of the different healthcare system there.

Some of those who made individual submissions to the inquiry detailing their problems in withdrawing from benzodiazepines, also detailed their problems with codeine-containing drugs that they used whilst on the benzodiazepines and during the withdrawal process. In many of the cases there is an element

of just shifting the dependency rather than actually solving the problem behind the original prescription.

Currently, it would seem that the crime element in the misuse of over-the-counters drugs is at a fairly low level, as many of these products are available at a relatively low cost. However, there could potentially be a criminal element in the diversion of prescriptions, especially of codeine, or in thefts from pharmacies.

Stannard explained that because the body develops tolerance to opioids a person has to keep increasing the dosage in order to keep feeling the effects. This is why people have to increase their dosage of, for example, Nurofen Plus so they can continue to feel the benefit. Canadian evidence suggests only a proportion of those who think they are dependent on codeine actually satisfy the clinical criteria for physical dependence. However, there are many different types of dependence including, importantly, psychological dependence that cannot be underestimated, especially with people experiencing co-morbid mental health difficulties.⁵⁸

Case Study 1

Ms W was prescribed codeine-containing painkillers after an operation. After a while she found that the pain killers no longer alleviated her pain, so she began to buy more painkillers online to supplement her prescription. After missing a couple of tablets and feeling extremely unwell, Ms W conducted some research on the Internet and realised she had become dependent on these drugs.

Her doctor was unable to give her advice other than to cut down gradually, but this made her feel unwell. She contacted a local drug addiction charity who were unable to give her any support as they had no experience of codeine addiction. Eventually, she was able to find support through the online forum 'CodeineFreeMe', and was prescribed Subutex to help her

withdraw from the codeine.

As she was holding down a full time job and was addicted to an over-the-counter product that was readily available, and had been prescribed to her, Ms W felt that it was insensitive that she had to go through the same procedures for receiving Subutex as those who are prescribed it for illicit drug misuse do. Ms W was required to attend the same pharmacy at the same time every day and take the drug in the presence of the pharmacist.

After gradually withdrawing from the Subutex she is now free from her codeine addiction.

Case Study 2

Ms P has been taking Nurofen Plus for 15 years. She began taking ibuprofen, then Feminax for painful periods. She switched to Nurofen Plus when she realised that it contained 12.8mg of codeine per tablet compared to the 8mg per tablet in Feminax. Ms P admits that she enjoyed the lift that she got from taking the Feminax; soon she was taking Nurofen Plus to “help her along.” By 2004 she was taking between 48-60 tablets a day.

Whilst living in the USA for a brief period, she had friends post her boxes of Nurofen Plus out to her to keep her supplied with them. By 2004, she was experiencing severe pain and was diagnosed with ulcers caused by the amount of ibuprofen she was taking. Ms P began to cut back on the Nurofen Plus but felt that, without Nurofen Plus, her “life was dreadful and depressing,” and she didn’t want “such a grey flavourless existence.”

By June 2007, she felt ready to stop taking the drug and, with the aid of hypnotherapy and support from her local DAAT, she moved into a detox programme, and has now stopped taking the drug completely.

Both these case studies have common elements in that both women began taking the drugs and misusing them without realising the potential harm it could cause them. Both were suffering pain which was not being alleviated through other mechanisms and, clearly, neither of the women was challenged about their habits by health professionals or those around them. This is indicative of why it has been hard to reach so many of those affected by this issue. They may well be keeping their misuse a secret, and are unaware of the potential harm it could be causing them. Ms P, however, does mention the 'buzz' she got whilst taking Nurofen Plus and the feeling of calmness and control it gave her. The element of pleasure being experienced by the patient after taking the tablets cannot be ignored as a driver within the misuse cycle.

Other submissions to the inquiry detail tales of misuse of over-the-counter painkillers to treat chronic pain, sometimes in addition to the tablets prescribed by doctors. In addition, some individuals have turned to over-the-counter medication as part of a polydrug cycle of misuse, often involving alcohol.

There have been recent reports in the press of people dying after mixing over-the-counter medication and alcohol. In January 2008, a 41 year-old man died after taking dihydrocodeine and then drinking alcohol. The coroner said "this should be a lesson to us all. I am sure that many people do not think about the consequences of mixing painkillers with alcohol".⁵⁹

In another case, reported in July 2008, a 17 year-old student died after mixing painkillers and alcohol. She had been taking painkillers for her bad back and had been using another person's prescription of another painkilling drug too; this led to breathing difficulties and a heart attack from which she later died.⁶⁰

The above cases demonstrate two very important points. Firstly, that the public, as a general rule, are unaware of the potential harm mixing over-the-counter drugs can do to their health and, secondly, that diversion of

prescriptions to family and friends does occur and should not be ignored as a potential source for misuse.

Case Study 3

Mr M, an alcoholic, began taking Solpadeine, then Paramol for his headaches. He enjoyed the feeling of calmness, happiness and control they gave him. Eventually, he was taking 32 Paramol tablets a day and, when he lost his job, he was spending most of his benefits on Paramol.

Mr M approached his GP for help but neither he nor the local DAAT were able to give him much help. The drug service offered him a place in a residential detox facility, but he was unable to stay there. The quantity of paracetamol he was taking (alongside the codeine in the Paramol tablets) was adversely affecting the functioning of his liver and kidneys.

Eventually, Mr M was offered methadone replacement for his codeine addiction, which would allow his liver and kidneys some respite from the amount of paracetamol he was taking. Mr M is now withdrawing gradually from methadone and has not taken any Paramol since beginning the methadone prescription.

Tackling the Problem

It is clear from the submissions to this inquiry and the growing body of evidence from academic studies that the problem of addiction to and misuse of over-the-counter products does exist. The case studies show that it can be tackled and people can withdraw successfully from over-the-counter codeine-containing products. Crucial in the cases detailed has been the desire from the patient to stop taking the codeine and their doctor's response to this. In these cases, whilst the patients have had to fight to access the support they need, it has been available and possible. The APPDMG is convinced that, if doctors were aware of the problems caused by taking excessive amounts of

codeine, they would be better able to help patients who present with dependence to withdraw from it.

There needs to be greater awareness of this problem amongst GPs, other health professionals and nurses. The website “Substance Misuse Management in General Practice” contains some advice in their frequently-asked questions section for GPs dealing with patients who present with an addiction to codeine-containing products. In this case, the patient was addicted to the codeine in her painkillers, but the ibuprofen part of the painkiller was giving her a stomach ulcer. The advice was the gradual reduction in the amount of codeine she took in order to reduce her dependence.⁶¹ Letters have also been published in the British Medical Journal (BMJ) highlighting the risk of misuse of over-the-counter codeine-containing products.⁶² This is important in raising the profile of these issues amongst doctors, who may well be seeing similar problems and not do know how to deal with them.

It is hard to tell if making codeine-containing products and other products available over-the-counter has resulted in an increased number of people addicted to codeine, because we do not know how many were affected before the products were so easily available. However, it is logical to assume that, if a product is more accessible, then there is a greater likelihood of a patient being able to access it and the potential for misuse is greater. Making it easier to access these drugs has long been part of the Government’s strategy to encourage self-care of common conditions. This has the effect of reducing the burden on primary care and, whilst the APPDMG does support this policy, it is also important to note that giving appropriate and accessible information is vital. The writing on the PIL or the packaging is often very small, so it is easy for the industry to hide away warnings they would rather not draw attention to. It is not enough for manufacturers to just refer patients to their website for further information.

Codeine, of course, is also available on prescription and it is readily acknowledged that GPs are very busy and often do not have enough time to

really talk to a patient about the problems they are experiencing. In their turn patients usually attend a GP looking for a pill to make them feel better. This means that it is quicker and easier for a doctor to write a prescription, and it has the added advantage of meaning the patient leaves satisfied with the consultation. Doctors need to be bold enough not to prescribe, and pharmacists need to be bold enough to challenge sales. They also need to be able to respond more to an individual's needs, particularly with regard to those who would simply benefit from a GP's time. This aspect will hopefully be addressed in part by the increase in funding announced for cognitive behavioural therapies.³³

Many people who submitted evidence to the inquiry about over-the-counter product misuse have said that they had no idea they could become dependent on something that was available so readily. In the introduction to this section we discussed the reasoning behind why some drugs are allowed to become available over-the-counter. In some countries, such as the USA, codeine is not available over-the-counter. However, they have different problems, for example with prescription painkillers such as Percocet or Vicodin because of the different way their medical system works.

The availability of codeine-containing over-the-counter products is a cause for concern to the APPDMG as we believe that there is substantial risk of misuse and that other painkillers without the same addictive qualities as codeine could take its place. Whilst a dependence and addiction to codeine can develop, it is not known whether an addiction to codeine would lead to a dependence on other opiates, for example, heroin. There was a recent case in Sheffield of nurse who became addicted to heroin following a dependence on codeine; she claimed she needed the heroin to help her with the withdrawal symptoms from the codeine.⁶³ However, the APPDMG did not receive any evidence that codeine addiction had led on to addiction to other opiates.

Studies have also been conducted which doubt the efficacy of codeine, particularly as a cough reliever. In 2002, Schroeder and Fahey conducted a review of the literature on the effectiveness of over-the-counter cough

medicines for acute cough in adults.⁶⁴ Currently GPs and health professionals are advised to recommend over-the-counter cough medicines for cough in adults. However, the review questioned the effectiveness of over-the-counter medicines for this treatment. The researchers looked at a number of studies comparing and contrasting the use of a particular medication for the relief of cough symptoms. Two studies tested codeine-containing cough mixture and found it to be no more effective than the placebo.⁶⁴

This is significant for the inquiry as we have received evidence of people becoming addicted to over-the-counter codeine-containing cough medicine and, if it is ineffective at treating the problem, then we would question the advisability of having it available over-the-counter. The authors of the literature review⁶⁴ concluded that a judgment could not be made as to whether codeine-containing cough medicines available over-the-counter were actually effective in treating coughs. Therefore, with an eye to consumer health and cost to the consumer, they would not support the recommendations given for adults to take over-the-counter cough medicine to treat the common cough.⁶⁴

The decision on whether codeine is available over-the-counter in the UK ultimately lies with the MHRA. There have been some cases where there has been cause for concern over safety where the MHRA has taken action, for example with the painkilling drug co-proxamol. A number of studies implicated co-proxamol over a period of years with a high rate of fatal overdose. Professor Bateman from Edinburgh University, who conducted some of the studies into this drug, said that, over the last 10 years or so, between 300-400 people have been dying every year from accidental ingestion or overdose. Co-proxamol accounts for a fifth of all drug-related suicides.⁶⁵

This led the MHRA to remove the drug's licence (from January 2008). The removal of a drug licence does not mean a GP cannot prescribe it; rather that it makes it much harder for the GP to prescribe as they must be able to give reasons why only this painkiller is appropriate for the patient. However, its withdrawal has left many individuals who suffer from severe pain without a drug they have relied on. A campaign has been led in Parliament by Aberdeen

South MP Anne Begg calling for the drug to be allowed back on prescription, as for some arthritis sufferers it may be the only relief from pain they have.⁶⁶

The MHRA has acted before in the field of painkiller misuse. In 1998, a change in the pack size of paracetamol was due, in part, to a growing body of evidence that suggested that those wishing to overdose would often use products found within the home. The pack sizes for any analgesic were reduced considerably, whilst still supplying enough for a person who wished to self-medicate a minor condition to receive the pain relief they needed. A follow up study in 2004 reported a gradual reduction in suicide deaths from paracetamol and salicylates, such as aspirin, over the years following the change in pack sizes.⁶⁷

It is useful to note that the MHRA is willing to take action in this area. The MHRA says that it keeps a ‘watching brief’ on all drugs. In July 2005, following reports of concerns over potential misuse and “medication overuse headache”, the MHRA reached a voluntary agreement with the pharmaceutical industry for packaging to contain warnings about potential addiction and “medication overuse headache”. It was also agreed to reduce pack sizes to 32 tablets maximum. However, on their glossy website for Nurofen Plus, GSK do not mention either dependence risk or medication overuse headache in their “advice on use” section.⁶⁸

Medication overuse headache is a noteworthy side-issue to the misuse of painkillers and feeds in very strongly to the problem of a lack of effective pain management mentioned earlier in this section. Medication overuse develops when a patient chooses to treat their recurring headaches with over-the-counter painkillers. Over time the ever-present analgesic causes the body’s pain receptors to become oversensitive, meaning a feeling of pain frequently or even constantly. This problem can develop with any type of painkiller and the only way to solve the problem is to stop all analgesia. Of course if the patient has been using codeine-containing painkillers then there may be a need to withdraw from the codeine too.⁶⁹

The APPDMG is sceptical about the value of these warnings on PILs as they are usually in extremely small print, and there is considerable evidence to suggest that few patients actually read the leaflets in detail. Grieve's study of his clients on the 'Over-Count' website found that only a minority had ever read the PIL and even fewer had taken any notice of the warnings.⁵⁴

The front line in tackling this potential misuse lies with the pharmacist. However, studies have shown that pharmacists can find it difficult to spot a misuser and find it even harder to tackle them about their misuse. In oral evidence to the inquiry Jeremy Clitherow, Chairman of the Community Pharmacists Group at the Royal Pharmaceutical Society of Great Britain (RPSGB) and a pharmacist in Liverpool, gave details of a lecture on substance misuse he gives to pharmacy students during the course of their studies. However, it is unlikely that one lecture is enough to cover all the aspects of substance misuse within a community pharmacy setting. The pharmacy white paper, published by the Government in April 2008¹⁴ expressed a desire for pharmacies to become "healthy living centres that support self-care." As pharmacists become more involved in actually giving advice on medicines, rather than spending their time in the back room dispensing, they may well become more aware of misuse taking place.⁵⁸

If they suspect misuse, pharmacists do have a number of options, for example removing the product from view and making it only available on request. This would mean the pharmacist having to talk directly to the person buying the product. The RPSGB provides pharmacists with a list of drugs which could potentially be misused to help them monitor sales. In addition to this, an inspectorate from the RPSGB goes around pharmacies across the country talking to pharmacists about any issues they might have with regards to sales. The inspectorate is there for support; rather than carrying out a critical audit.

Whilst it is extremely important for pharmacists to monitor sales of certain products, and to challenge and act where necessary, the APPDMG has concerns about making access to codeine-containing drugs in pharmacies too difficult because of the risk of displacing the problem onto the Internet.

There are thousands of Internet sites selling medicines and, in evidence the inquiry received, some people did admit to buying both prescription and over-the-counter medication online. Legitimate online pharmacies can make it easier for people to have their prescription delivered or to access pharmacy drugs without having to go to the pharmacy.

The RPSGB estimates that 2 million Britons access medicines through online pharmacies.⁷⁰ In an attempt to ensure that these pharmacies are operating legitimately, the RPSGB has devised a logo for online pharmacies which conform to their code of conduct to use. This is designed to make it easier for consumers to pick out the genuine pharmacies. This logo programme has not been in place long enough for a real assessment of its success to be undertaken, but the APPDMG welcomes the move by the RPSGB to tackle the problem of fraudulent Internet sales.

Whilst the MHRA does not collect figures for the amount of electronic sales of medicines to UK residents, it does undertake monitoring of the quality of the products available on the Internet. Although the MHRA does not have the power to close websites down, it does work with Internet service providers to force closure of websites selling drugs illegally. In evidence to the inquiry, Mike Deats, Enforcement and Intelligence Manager at the MHRA, reported that, since it began patrolling websites in 2003, there have been 14 prosecutions; 14 cases are currently before the courts and 22 websites have been shut down.⁷¹

Of course, the MHRA only has jurisdiction in the UK and, by its very nature, the Internet is global. Much of the problem with online sales is the quality of the medication being sold. The MHRA focuses its campaigns on making sure the public can make an informed choice about whether to buy drugs online. It works closely with the police and media to ensure that the public is aware that, whilst many of these websites may look flashy, the operations behind them may be extremely dubious and potentially fraudulent.

The inquiry received written and oral evidence from Professor Schifano from the Royal College of Psychiatrists. He runs an addiction clinic in South London and has conducted research into the impact of online pharmacies. In giving oral evidence, Schifano said that, in his opinion, the numbers of people addicted to over-the-counter medication were rising and that this could be attributed to the growth of the Internet. He and his research team concluded that there were sites online which could sell you anything, the advantage being lower costs and ease of access.⁷² Advice from the MHRA compliance unit suggests that, currently, those buying drugs without prescription, or in large quantities, are not breaking the law; it is the website that is breaking the law.⁷¹

There does need to be a multi-faceted approach in tackling this problem, and the APPDMG would strongly suggest a reduction in the pack size for codeine-containing over-the-counter drugs. This would make it more difficult for patients to access large quantities of the drug as if, for example, they were only able to buy 12 or 18 tablets at a time they would have to make a number of trips to various pharmacies to acquire the quantities they wanted. Closer working between pharmacies about patients who frequently ask for supplies of these products would allow pharmacists to monitor behaviour and act where necessary.

For any of these proposals to be successful in reality, there must be support available for the addict when they present with this problem. If the pharmacist or doctor has no expertise in this area and nowhere to refer the patient for support, all these schemes to reduce availability will have little effect on the problem.

In the case studies detailed above and in the individual submissions to the inquiry, many of the cases of misuse were so severe that the patients needed to be prescribed opiate substitute drugs, such as Subutex or methadone, to allow them to withdraw. In these cases it is necessary to involve the DAAT to allow these prescriptions to take place. In other cases a tapering down of the drug, done with the support of the GP may be successful. However, as with all

addiction, flexibility of approach is vital to allow health professionals to respond to the individual's needs. We do believe that services to help those who become addicted to these products can be available in a primary care setting, particularly as polyclinics develop.

Another vital component of treating this misuse is the availability of support groups. Because many of those who become addicted are often ashamed and embarrassed, online support groups can be very effective.

RECOMMENDATIONS

1. Training for Medical Professionals

1.1 That the British Medical Association (BMA), the GMC and the Royal College of Nursing (RCN) should ensure that all medical students and nurses are trained to recognise the symptoms of physical dependence and addiction to drugs including over-the-counter and prescription medications.

1.2 That the BMA, GMC and RCN should make training in substance misuse part of the continuing professional development of GPs and nurses, as information on this topic is being uncovered all the time.

1.3 That the BMA and GMC should ensure that medical students receive comprehensive training in good prescribing practice and are taught the skills to help them to deal with anxious or depressed patients to allow them to move away from the “pill for every ill” prescribing attitude.

2. Awareness

2.1 That the MHRA, working with the professional associations, must promote better awareness amongst doctors and other health professionals about the guidelines on prescribing and encourage them to work together to try to reduce the number of people taking these potentially problematic drugs.

2.2 That, when GPs prescribe drugs which are known to have the potential to cause physical dependence or addiction, they must explain these potential risks to the patient.

2.3 That the MHRA and the pharmaceutical industry must put warnings about potential dependence on the boxes of products containing over-the-counter codeine as well as prominently in the PIL.

2.4 That the MHRA and the DH should seek to raise awareness about the risk of developing dependence problems with codeine-containing painkillers, either over-the-counter or on prescription.

2.5 That the advertising and promotion of codeine-containing products must end.

2.6 That the DH must undertake a campaign to encourage patients to take more responsibility for their own health and prescription choices. This campaign must also extend to the use of online pharmacies and the potential risks people expose themselves to when they buy from fraudulent online pharmacies.

2.7 That the MHRA, DH, RPSGB and other interested parties must work together to tackle fraudulent online pharmacies. An assessment of online pharmacy usage and the impact of the RPSGB logo for legitimate sites needs to be undertaken.

2.8 A joined-up approach between Customs, Police and Internet Service Providers must be taken to tackle the problem of fraudulent drug sales globally.

3. Prescribing and Monitoring

3.1 That the MHRA must be rigorous in ensuring that all pharmaceutical companies monitor their products through clinical trials and after their introduction into general practice, and report to the MHRA problems of physical dependence and addiction. Full information about clinical trials, including those abandoned, should be publicly available.

3.2 That the DH sets up procedures to monitor the prescribing habits of doctors, particularly with a view to preventing prescribing outside the BNF and DH guidelines. GPs who prescribe outside the guidelines must be required to

justify their decision to the PCT. Pharmacists should be encouraged to flag up to PCTs doctors who are regularly prescribing to their patients outside these guidelines.

3.3 That, when GPs prescribe drugs that are known to have the potential to cause physical dependence or addiction, such as opiate-containing products and benzodiazepines and related classes of drugs, they should set up procedures to monitor the patient. Monitoring could, for example, be carried out by a practice nurse or a pharmacist working within or alongside the practice. The practice of repeat prescription without review for these drugs must end.

3.4 That the MHRA should restrict access to codeine-containing painkillers, such as Nurofen Plus, by reducing pack sizes (to 18) and making them only available after consultation about the problem with a pharmacist.

3.5 That PCTs should play a greater role in ensuring doctors, healthcare professionals and patients are all aware of the ways to report adverse drug reactions. For example, the BMA publication “Reporting adverse drug reactions: a guide for healthcare professionals” should be made available to every healthcare professional.

4. Recognition and Research

4.1 That more research must be undertaken in the field of dependence to prescription and over-the-counter medication to determine the scale and related implications of the problem.

4.2 That more research must be undertaken into anxiety, depression and pain control to ensure that appropriate treatments are being offered to patients.

4.3 That more research is undertaken in the field of dependence and addiction to both licit and illicit drugs to ensure that lessons are being learned and that appropriate help and support can be provided.

4.4 That better records, particularly with regard to suicides and drugs being taken, are kept to allow research and monitoring to be undertaken in this area.

5. Treatment

5.1 That, for patients who are already physically dependent or addicted to a prescription or over-the-counter medicine, GPs should be required to assess the situation and help the patient whenever possible to withdraw from the drug using the available guidance, or should refer them on to a support organisation or a treatment centre.

5.2 That the DH should require PCTs to provide appropriate treatment for those addicted to these drugs. We believe that it would be inappropriate to refer patients for treatment to DAATs for the reasons given in this report. We recommend that a centre be established in each region and that these should work on a 'hub and spoke' model so that patients in each PCT area can be referred to clinics where specialist advice is available.

5.3 That PCTs should ensure that pathways for treatment of patients presenting with a dependency should be as flexible as possible and accessible. Patients should be able to refer themselves to these treatment centres. The APPDMG encourages PCTs to undertake preventative action in reducing the number of addicts in their area, as well as working with those who become dependent.

5.4 That the value of local support groups for those who have become physically dependent or addicted to prescription or over-the-counter medication should be recognised by Government and its agencies. Online support groups and those providing 24-hour services are particularly valuable in our opinion and should receive appropriate funding.

ACKNOWLEDGEMENTS

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ALL-PARTY PARLIAMENTARY DRUGS MISUSE GROUP LIST OF OFFICERS

Chair	–	Dr Brian Iddon MP (Bolton South East)
Vice Chairs	–	Paul Flynn MP (Newport West) Lord Mancroft Baroness Masham of Ilton Lord Rea
Treasurer	–	Dai Davies MP (Blaenau Gwent)
Secretary	–	David Burrowes MP (Enfield Southgate)

ACRONYMS

ACMD	-	Advisory Council on the Misuse of Drugs
APPDMG	-	All-Party Parliamentary Drugs Misuse Group
APPGITA	-	All-Party Parliamentary Group for Involuntary Tranquilliser Addiction
APRIL	-	Adverse Psychiatric Reactions Information Link
BAT	-	Battle Against Tranquillisers
BMA	-	British Medical Association
BMJ	-	British Medical Journal
BNF	-	British National Formulary
CHM	-	Commission on Human Medicines
CITA	-	Council for Information on Tranquillisers and Antidepressants
CMO	-	Chief Medical Officer
CSM	-	Committee on the Safety of Medicines
DAAT	-	Drugs and Alcohol Action Team
DH	-	Department of Health
GMC	-	General Medical Council
GSK	-	GlaxoSmithKline
GSL	-	General Sale Licence
GP	-	General Practitioner
HSC	-	Health Select Committee
IM	-	Intramuscular (injection)
INCB	-	International Narcotics Control Board
IV	-	Intravenous (injection)
ME	-	Myalgic Encephalomyelitis

MHRA	-	Medicines and Healthcare products Regulatory Agency
NAO	-	National Audit Office
NHS	-	National Health Service
NICE	-	National Institute for Clinical Excellence
NTA	-	National Treatment Agency
P	-	Pharmacy
PCT	-	Primary Care Trust
PIL	-	Patient Information Leaflet
POM	-	Prescription Only Medication
PQs	-	Parliamentary Questions
RCGP	-	Royal College of General Practitioners
RCN	-	Royal College of Nursing
RCP	-	Royal College of Psychiatrists
RPSGB	-	Royal Pharmaceutical Society of Great Britain
SC	-	Subcutaneous (injection)
SSRI	-	Selective Serotonin Reuptake Inhibitor
WHO	-	World Health Organisation

WRITTEN EVIDENCE RECEIVED FOR INQUIRY

Professional Organisations and Trade Associations

AAH Pharmaceuticals

ABPI

Citizens Commission on Human Rights

European Association for the Treatment of Addiction

MHRA

National Pharmacy Association

PAGB

Perrigo Pharmaceuticals

Royal College of GPs

Royal College of Psychiatrists

Royal Pharmaceutical Society of Great Britain

Schering Plough Pharmaceuticals

Charities and Support Organisations

APRIL

Battle Against Tranquillisers

Beat the Benzos

Benzodiazepines, Cooperation Not Confrontation

Benzact

CITA

CodeineFree

Overcount

Seroxat Users Group

Individuals

Brendan Georgeson – treatment co-ordinator

Professor Hamid Ghodse – academic

Dr Adam Mackridge - academic

Plus a large number of individual submissions detailing personal addiction and experience of caring for those with addiction problems, who wished to remain anonymous.

ORAL EVIDENCE WITNESS PANELS

Oral Evidence Session One

ABPI – John Ferguson, Commercial Affairs Manager.

British Pain Society – Dr Cathy Stannard, Chair of the Working Party on Pain and Substance Misuse.

MHRA – Dr June Raine, Director of Post Licensing and Mick Deats, Enforcement and Intelligence Manager.

PAGB – Sheila Kelly, Chief Executive, Dr Christine Harding (CH) author of PAGB written submission, Eric Teo – Reckitt Benckiser, PAGB Member Company and Liz Bamford – GlaxoSmithKline, PAGB Member Company.

Perrigo – Richard Egglestone, Director of Research and Development.

RPSGB – Jeremy Clitherow, pharmacist in Liverpool and Charles Willis, Head of Public Affairs.

Royal College of GPs – Dr Stephen Willott, Drugs Lead for the RCGPs Sex, Drug and HIV Group and a GP in an inner city practice in Nottingham.

Royal College of Psychiatrists – Professor F. Schifano, member of the Addiction Faculty at the Royal College of Psychiatrists and runs an addiction clinic in South London.

Schering Plough – Andy Stewart, Senior Product Manager and Dr Gary Lapham, Senior Medical Officer.

Oral Evidence Session Two

Rehab Treatment Centre, Bristol, Brendan Georgeson, Treatment Coordinator

APRIL, Millie Kieve, Founder and Chair

Seroxat User Group, Janice Simmons, organiser and Dr Paul Duckett, organiser.

CITA - Pam Armstrong, consultant, trainer and practising nurse.

Benzodiazepine, Co-operation not Confrontation – Allan Weatherburn, organiser and carer.

Battle Against Tranquillisers - Una Corbett, coordinator.

All-Party Parliamentary Group for Involuntary Tranquilliser Addiction, Professor Heather Ashton, Emeritus Professor of Clinical Psychopharmacology at the University of Newcastle, Michael Behan, former benzodiazepine addict, now organiser and campaigner and Barry Haslam, former benzodiazepine addict, now organiser and campaigner.

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