



**All Party Parliamentary Group on Drug Misuse  
Inquiry into the misuse of prescription-only and over-the counter medicines  
Response from Proprietary Association of Great Britain**

**EXECUTIVE SUMMARY**

PAGB is the trade association representing manufacturers of over-the-counter (OTC) medicines which enable people to practice self care. We are responding to the APPG inquiry on Drug Misuse on behalf of these manufacturers. Access to OTC medicines play a key part in self medication which is essential for effective management of healthcare costs in UK. A balance is essential in providing access to OTC medicines to encourage self medication while minimising the potential for inappropriate use. We hope that our contribution will assist understanding of the issue, provide information that sets it in context and shows what strategies have been employed to address what is generally considered as a serious but uncommon problem. We urge the All Party Parliamentary Group to consider the contribution that safe and effective OTC medicines make to public health in the UK in the recommendations that it makes.

The safe use of over-the-counter medicines is of paramount concern to the industry and manufacturers are fully committed to the support of programmes and activities to prevent misuse and abuse. Having conducted a comprehensive review of the available research on OTC misuse, it is apparent that there is awareness of the issue amongst pharmacists and the public. Awareness is not the same as evidence and we urge the APPG to strive for recommendations that are based on evidence.

The vast majority of people who use OTC medicines do so responsibly and virtually all researchers agree that the abuse of over-the-counter medicines is limited to a few ingredients. Most of the research into misuse and abuse has focused on awareness of the problem by pharmacists and their assistants, control of supply and the provision of information with products.

A one size fits all solution to the issue is unlikely and everyone involved needs to participate in the overall solution. While we sympathise with the perception of misuse/abuse, any recommended measures need to be founded upon good evidence, to do otherwise would be knee-jerk response. A multilateral team approach is the best way to manage drug misuse and abuse with a research approach which is focused on the individual and could include the following:

- A research model which focuses on the individual rather than on access and control of supply, to allow a true assessment of the scale of the problem to be established in the UK and provide an understanding of the psycho-social background which lies beneath inappropriate use.
- Information to people who are misusing medicines to enable them to realise that they may need assistance.
- A resource within the NHS to address OTC misuse within England; people who are concerned that they are misusing medicines need to be signposted to a resource available which can help them.
- Where the problems of misuse are linked to lack of understanding of what the product is for and how to use the medicine, appropriate label and leaflet information to improve this. For example product leaflets could include references to websites where more detailed or targeted information could be provided.

## 1. Self care and self medication with OTCs

OTC medicines are an important part of the nation's healthcare with over **930 million** packs sold for year ending 2006. Self care is recognised in UK health policy. It defines self care as a lifelong habit and culture. It is the action individuals take for themselves and their families to stay healthy and manage minor and chronic conditions, based on their knowledge and the information available and working in collaboration with healthcare professionals where necessary. Without self medication and access to OTC medicines the NHS would simply not be able to cope.

Successive government have supported policies to increase access to OTC medication which over the years has given people a greater choice, empowerment and ownership in managing their own self care and thus allowing the primary care services more time to deal with serious ailments and allowing the community pharmacists to function more effectively as an integral part of the primary health care system. This wider access to medicines is carefully managed and monitored to ensure that it does not result in increased harm to the public.

## 2. What do we mean by misuse and abuse of OTC medicines?

Various definitions have been used by researchers describing the inappropriate use of over-the-counter medicines. The terms "misuse" and "abuse" are often used interchangeably. Industry defines them as follows:

**Misuse** is the use of drug for a medical purpose but it is used incorrectly, usually in terms of dosage or duration (e.g. taking more of a painkiller than recommended to treat headache). This includes inappropriate medical use when the OTC is used to treat a medical condition but in a manner not supported by the manufacturer's instruction. Examples of this are the use of painkillers on a routine basis to prevent headache. It can lead to medical dependence if this practice becomes chronic.

**Abuse** is the use of a drug for a non-medical purpose (e.g. to experience its mind-altering effects). This includes mixing medicines with alcohol or street drugs to produce psychotropic effects.

## 3. How are OTC medicines regulated?

Pharmacy Sale Medicines and General Sale Medicines are collectively referred to as over-the-counter or OTC medicines. The Medicines Act 1968, which is the basis of medicines control in the UK, establishes the principle that medicines are "Pharmacy Sale" (restricted to sale in pharmacies) unless they are classified as prescription only (POM) or are considered safe enough to be supplied without pharmacy supervision in which case they are classified as General Sale Medicines which can be sold in any outlet. In practice, all new drugs are classified as prescription only medicines and generally remain in that classification until enough safety data is gained from use in the population at large. This managed access is a balance and a key part of self medication. Regulators, manufacturers, pharmacists, and retailers play a vital role in ensuring the safe supply of medicines.

Before any OTC medicines can be placed on the market, they are evaluated for safety and efficacy by the Medicines and Healthcare Products Regulatory Agency (MHRA). Some well known OTC medicines like aspirin, paracetamol, codeine, diphenhydramine and senna were on the market before the Medicines Act came into force. They were evaluated for safety and efficacy in the mid 1980s and deemed safe for continued availability as OTC medicines.

Some OTC medicines have newer ingredients which began life as prescription only medicines were released for use as OTC medicines after their safety was further assessed and established as satisfactory for this purpose. Part of the evaluation for release of ingredients for self medication is their potential to be abused.

Once marketed, safety evaluation continues with manufacturers holding responsibility for monitoring and reporting adverse events including reports of misuse to the MHRA. There are regular safety reviews of substances in the pharmacy and GSL categories. For example, in 2005, the Committee on Safety of Medicines (CSM) assessed the number of reports of abuse of OTC codeine and dihydrocodeine containing medicines. The MHRA reviewed this report and concluded that the number of reports of abuse of OTC codeine and dihydrocodeine medicines is exceedingly small, compared to volume of sales. From the report, the MHRA also concluded that the benefits of the availability of OTC medicines which contain codeine and dihydrocodeine outweigh any potential risks.

#### **4. How is misuse and abuse of OTC medicines handled now?**

##### **4.1 Classify medicines as prescription only or withdraw them from the market**

Safe use of OTC medicines is paramount to the Industry and companies work with the MHRA to introduce controls where this is necessary including voluntarily reformulating products or withdrawing them from the market if the risk outweighs the benefit. Some reviewers considering misuse and abuse of OTC medicines have speculated that wider availability may contribute to increase in misuse but there is no evidence to support this theory.

Any product which is frequently and to a wide extent misused must be prescription only and can be reclassified as prescription only, if any such problems arise at any time. More often, the issue is not abuse but misuse and it is tackled with improvements to label information and introducing pack size restrictions.

##### **4.2 Label and leaflet information**

In addition to control over the ingredient, The Medicines Act controls the information which is provided with every OTC medicine. Since these medicines will be taken by people without professional input, this information is vital to ensure safe use of the product. The label information sets out what the product is for, how much to take, how long to take it, who should not take it. It also gives advice on when to consult a doctor if the problem persists. This information is regularly reviewed and updated when new safety information becomes available.

Industry accepts the responsibility to ensure that medicines are used appropriately. The first way of addressing this responsibility is clear label and leaflet information. The information provided on labels and leaflets are controlled under EU and UK Medicines legislation and are checked for compliance by the MHRA before products are marketed. The information has to be provided in non-technical language which people can understand.

Clear labelling contributes to appropriate use of medicines. In 2005, in a joint decision between the Medicines and Healthcare products Regulatory Agency (MHRA) and the over-the-counter medicines industry it was voluntarily agreed that strengthened warnings, about the possible risk of addiction or medication overuse headache due to inappropriate use, was added onto packs of painkillers which contain codeine and dihydrocodeine.

As a result, additional warnings appear on the packs of painkillers which contain codeine and dihydrocodeine (see **Annex 2**).

A review of European Medicines legislation in 2001 led to the requirement all patient leaflets would be tested with groups of consumers to ensure it is legible, clear and easy to use, and this should lead to improvements in patient understanding and compliance. Manufacturers are required to test their leaflets with consumers. As a result, by July 2008 every pack of medicines in the UK will be required to include a leaflet which not only gives the information but does so in a way that consumers will understand.

Where problems of misuse are linked to lack of understanding of what the product is for and how to use the medicine, appropriate label and leaflet information can help. The leaflets are also allowed to include lifestyle information and references to other sources of health information and this leaflet review is an opportunity to design leaflets to address some misuse problems. For example, leaflets could include references to websites where more detailed or targeted information could be provided.

#### **4.3 Pack size restrictions**

Pack size restrictions have also been introduced when safety or misuse problems arise. In the 1970s GSL pack sizes of paracetamol and aspirin products were reduced from 100 tablet packs to 25 tablet packs to reduce accidental poisoning in children. They were further reduced to 16 tablets a few years ago in an effort to reduce their use in suicide attempts.

The industry voluntarily agreed to a maximum pack size of 32 tablets for all over-the-counter containing codeine or dihydrocodeine which was implemented in 2006. Recently, pseudoephedrine (PSE) was reviewed by the MHRA as it could be used to manufacture illicit methylamphetamine. Industry again instigated a voluntary agreement to reduce pack sizes to 720mg equivalent of pseudoephedrine and the pharmacy bodies all worked collaboratively to produce training packs for pharmacists and guidelines on the sale of PSE containing products.

#### **4.4 Role of Pharmacists**

Pharmacists play an important role in monitoring safety in use. Two thirds of all medicines are sold in pharmacies in the UK, unlike the United States and Canada where medicines can be sold in any outlets. It is often their experience and observations which identify products which could cause problems and industry often works with pharmacy bodies to respond. PAGB has funded research into the behaviour of patients with headache and their treatment options and also funded a study among community pharmacists designed to develop protocols for the identification and prevention of deliberate abuse of OTC medicines.

In another study a number of independent experts looked at the role played by the primary care team in counseling patients, in particular the role of pharmacists as the first point of interaction with people who are buying excessive amounts of medicines. The aim was to establish a protocol for pharmacists to use when interacting with people that they suspected were misusing medicines. This resulted in 2004, in the launch of an OTC medicines support service, funded by industry, to help consumers use their OTC medicines correctly. The service included an [education leaflet](#)<sup>1</sup> and an OTC medicines advice line. Although a million leaflets were distributed by pharmacists, the number of people accessing the helpline over a year was less than 300 and it was discontinued. With hindsight, there could be a number of reasons for the lack of success but it is notable that it was based on manufacturers and pharmacists' views of what might be helpful, not on patient research. If it is to be attempted again, then doing a baseline survey with those people who might need this service is of paramount importance.

---

<sup>1</sup> URL: <http://www.chic.org.uk/chicmco/docschic/adviceline.pdf>

Training of pharmacy staff has been rated the most important and effective means of reducing inappropriate sales of OTC drugs<sup>2</sup> and The Royal Pharmaceutical Society of Great Britain publishes a list of medicines and substances that might be subject to misuse and abuse to alert pharmacists and help them manage their sales. Community pharmacists and their staff are best placed to advise at point of sale without impeding appropriate requests for OTCs but there are reservations concerning the professional and financial implications of possible indiscriminate imposition of “blanket” policies.

#### 4.5 Role of Doctors

GPs have asked for a resource to be available under the NHS to enable them to counsel and provide advice for people who are misusing OTC medicines. In practice, doctors are supposed to include OTC medicines use when they take a patient history but it is by no means certain that the majority of doctors do this or that patients would readily reveal high levels of use, even if asked. A recent letter published in the *BMJ*<sup>3</sup> described the limited experience of a few GPs who had realised that a very small number of their patients were taking long term codeine products for pain relief. Their main concern was that the patients were increasing their doses when they should have been seeking more appropriate treatment.

There is no doubt that doctors could play a greater role and pharmacists try to refer patients to doctors when they suspect that they are taking medicines inappropriately. But without an available resource, this process stalls, preventing people getting the help that some undoubtedly need. There is little reliable knowledge concerning prevalence, what is driving misuse/abuse, and who is abusing the products and without this information providing help or developing an overall approach or strategy is impossible.

The main areas of research required seem to be:

- The obtaining of continuous good quality information on patterns of OTC abuse/misuse, at both national and local level.
- Establishing the needs of, and treatment options for, those individuals who are dependent on OTC products.
- Establishing whether there are identifiable at-risk groups such as those with affective disorders, histories of drug or alcohol problems, the elderly, adolescents or the unemployed.

#### 5. Responsible use of OTC medicines

There is plenty of evidence to show that the vast majority of people who use OTC medicines, do so responsibly.

The issue of abuse and misuse of over-the-counter medicines has to be considered in the context of a pattern of very cautious use of medicines by the majority of the population. PAGB has undertaken substantial consumer research into self medication. In 1986, the British Market Research Bureau was commissioned to conduct the first national survey of everyday healthcare in Britain. In 1996/97 the study was repeated using the same methodology and a further study conducted in 2005. Together these studies show how

---

<sup>2</sup> McBride AJ, Pates R, Ramadan R, McGowan C. Delphi survey of experts' opinions on strategies used by community pharmacists to reduce over-the-counter drug misuse *Society for the Study of Addiction to Alcohol and Other Drugs Addiction* 2003, **98**, 487–497

<sup>3</sup> Ford C, Good B. Good Over the counter drugs can be highly addictive *BMJ* 2007;**334**:917-918 (5 May); URL: <http://www.bmj.com/cgi/content/full/334/7600/917-b?ck=nck>

people in Britain view their health, their sources of advice and information and how they treat minor ailments. Results of these studies underpin the understanding of self care in Britain.

The general population experiences the symptoms of minor ailments almost every day and the most common response is to self care and to practice self medication in a responsible and cautious way. Self care occurs in over 80% of episodes of common ailments, indeed it has been estimated that self care accounts for as much as 80-90% of *all* care that people need. Nearly 9 out of 10 people often treat minor ailments themselves – 42% do it all the time.

PAGB research<sup>4</sup> clearly shows that consumers, when they experience a minor ailment, see it as important to have access to suitable medicines over-the-counter and that they are confident in their ability to select what to treat themselves with. Most of the ailments are experienced frequently and people recognise the problems and how to treat them. However if they are at all unsure about a health problem they consult a health professional, usually a doctor.

The UK population uses medicines cautiously and only when necessary

- Over 80% of the population said they read the instructions carefully before using the OTC medicine for the first time
- Almost two thirds of OTCs (64%) used for a day or two or less, 24% used only once
- By far most common reason for stopping was improvement:
  - The problem got better (81%)
  - OTC medicine was only taken when really bad (11%)

This is supported by an independent study conducted by Wazaify, McElnay *et al*<sup>5</sup>

- 74.5% reported that they *always* followed the directions on the OTC drug package, while 11.9% said they *often* followed the directions.
- 40.8% reported that they would stop and go to their GP if their OTC medicine did not work within the recommended period of time.
  - Almost a quarter (24.3%) said they would stop using the product and return to the pharmacy
  - 22.1% said they would decrease the dose or stop the medication.
  - Less than 9% indicated that they would increase the dose
  - Only 2.3% and 2.2% respectively would use the product more often or for a longer time than recommended.

Recent research carried out by IPSOS/MORI<sup>6</sup> on behalf of the MHRA explored perception of risk associated with medicines. It tested the theory that people might think that they need not worry about the safety of a medicine that they bought over-the-counter. 33% of responded tended to agree with that suggestion but 44% had the same attitude to the supply of medicines on prescription and overall the majority of people (69%) feel that the benefits of medicines outweigh the risks.

Qualitative research carried out on behalf of PAGB some years ago showed that some people worry about becoming addicted to medicines and are worried that if they take medicines when they do not really need them then they will not work when they are needed. These attitudes need to be taken into account in any communication programmes which

<sup>4</sup> PAGB Everyday Healthcare Study 1997

<sup>5</sup> Wazaify M, Shields E, Hughes CM and McElnay JC. Societal perspectives on over-the-counter (OTC) medicines. *Family Practice* 2005; 22: 170–176. URL: <http://fampra.oxfordjournals.org/cgi/reprint/22/2/170>

<sup>6</sup> Risks and benefits of medicines and medical devices – Perceptions, Communication & Regulation. Ipsos MORI research conducted for the Medicines and Healthcare products Regulatory Agency research study for MHRA March 2006. URL: [http://www.mhra.gov.uk/home/idcplg?ldcService=SS\\_GET\\_PAGE&nodeId=1017](http://www.mhra.gov.uk/home/idcplg?ldcService=SS_GET_PAGE&nodeId=1017)

address misuse and abuse to ensure that they tackle the issue in a targeted way and do not add to the concerns of the majority of people who are using medicines appropriately. People who are worried tend to go to the doctor instead of self treating and this will increase the burden on the NHS.

## 6. Scale of misuse of OTCs

Virtually all researchers agree that misuse of OTC medicines is a small problem but some express concern that it might be a growing problem possibly linked to the availability of more medicines which were prescription only but are now available for use in self medication products. In fact the substances which are most associated with misuse contain ingredients which have always been OTC. These include:

- opioid containing analgesics
- sleep aids containing sedating antihistamines
- cough and cold remedies containing opioid analgesics and sedating antihistamines
- laxatives

Obtaining reliable information about misuse or abuse behaviour from people is difficult as some individuals consciously or unconsciously underestimate how much of a substance they consume. In addition, the definitions of misuse that health care professionals use may not match the patient definitions – this is probably the case where the medicines used are within or below the normal dose range but the medicine is used more often than appropriate. Recent research in Canada shows that some people who take higher than average doses were advised to do so by their doctor and in the UK many people who take codeine containing products every day, do so, were prescribed the medicines by their hospital or general practitioner to treat pain when they do not tolerate alternative treatments such as non steroidal anti inflammatory drugs (NSAIDs).

### 6.1 Literature Review

PAGB has identified 50 papers and out of that 39 were relevant to this issue. PAGB commissioned an independent analysis of all the available data and it is presented as a report (see **Annex 1**). This analysis reviews the UK literature on abuse/misuse of OTC medicines, and relates it to the wider literature available in the field. PAGB is able to supply a copy of the report on request from academics researching in this field.

There is a body of peer reviewed literature addressing the abuse/misuse in the UK, but it is relatively narrow in its approach. Research in the UK has tended to focus on identifying the OTC products that are potentially abused/misused and on events at the point of sale. This contrasts with research in North America (USA and Canada), which has been more broadly based and has mirrored the much larger body of research on other problem activities such as the use of alcohol and nicotine, gambling, internet usage and even shopping. UK literature search reveals little about the characteristics of abusers/misusers, risk factors for abuse/misuse, the potential for OTCs to provide a gateway to other drugs, the different ways in which psychoactive drugs are abused nor does it reveal the scale of OTC abuse/misuse in quantitative terms. Consequently there is little understanding of the problem or its scale in the UK.

The data that do exist, however, provide valuable information regarding the experience built up by pharmacists and related staff in the handling of abuse/misuse issues. There is an awareness of products and product classes prone to abuse/misuse, and the existence of strategies to manage the sale of these to suspected abusers/misusers. The consensus is

that managing the sale of such products is generally under control although there may well be a case for a more coordinated approach. In contrast, if a purchaser requires specialist help that the pharmacy is unable to provide, there is no clear path to specialist help for the individual. This includes help for those who may have developed a dependency, and those who may have co-existing psychosocial factors. It is important to remember that awareness of a problem is not necessarily evidence of the problem and evidence needs to be gathered before action is taken.

The scale of dependency linked to OTC products in the UK is not known. Canadian evidence suggests that only a proportion of those who believe they are dependent on codeine satisfy clinical criteria for dependence. Evidence from studies with unlicensed (illegal) and prescription drugs suggests a significant co-morbidity between psychological and psychiatric conditions and both dependency and regular usage. This does not reduce the importance of any dependence, but informed opinion suggests that this should influence the way the problem is tackled.

There seems to be a need for further research in the UK focused on obtaining good quality national and local information on patterns of OTC abuse/misuse; the needs of, and treatment options for, those who are dependent on OTC products; and on establishing whether there are identifiable at-risk groups who can be especially targeted for support and education to prevent OTC abuse/misuse.

The UK research literature leaves many questions unanswered and many issues have not yet been fully understood. The main deficits seem to be:

- *Lack of reliable information concerning the extent of OTC abuse in the UK.*  
Anecdotal evidence, along with concern expressed by the medical profession, suggests there is a genuine problem that is changing in character or size. The figure of 30,000 abusers/misusers of OTC medicines in the UK is frequently quoted, but the basis of this estimate seems obscure.
- *Little understanding of who is abusing/misusing products*  
Attempts have been made to analyse the available data on the basis of age groups, gender, socioeconomic class etc but this has not led to much understanding. Attempts have been made to identify misusers and abusers at the point of product sale, but with limited success.
- *Little understanding of why products are being abused/misused*  
Much of the research to date has been descriptive, and has not attempted to investigate the nature of the abuse/misuse problem. For example, there is no research that establishes what proportion of those misusing psychoactive OTCs are willfully using them for recreational purposes and what proportion are misusing them because of a dependency resulting from use for a legitimate purpose. It is impossible to judge from the available anecdotal self-reports what the proportions are.
- *Some risk of misinterpretation*  
Although the findings of UK peer-reviewed research reports are objective, their presentation sometimes invites misinterpretation. Much of the research involves the gathering of opinions from health professionals and/or the public, but the way the opinions are reported can mask the findings of that research. For example, studies tend to present their findings in terms of how respondents describe them, rather than in objective terms. The naming of certain brands is common in research reports. This can lead to the perception that these specific products play a more significant role in the abuse/misuse problem than the reports actually show or claim.

In summary, there is a body of research regarding abuse/misuse of OTCs in the UK, but it is small and relatively narrow in scope. Most UK studies have had specific objectives, and the research has been targeted towards those objectives. Consequently, it is important not to misuse the information gathered in this research merely because of a paucity of information in the field as a whole.

## 6.2 Other Data Sources

### Overcount

The figure of 30,000 potential misusers is often quoted on the website<sup>7</sup> of Overcount based in Dumfries, Scotland which provides information to users of OTCs who have developed dependence problems. Overcount has explained to PAGB that their records are not complete but they believe that over a number of years around 15,000 people have contacted them. They doubled that figure to get an estimate of the scale of the problem. Overcount has been asking people who contact them to complete a questionnaire and although the information is anecdotal rather than fully validated, it offers a source of information about the people who misuse drugs.

### National Statistics Drug Misuse Data Base

The same figure of over 30 000 users<sup>8</sup> appears in the National Statistics Drug Misuse Database but there is no information about whether this is prescription, OTC or illicit use.

### Regional Drug Misuse Database

The Regional Drug Misuse Database Return (RDMD) used statistical collection<sup>9</sup> (up to March 2001) to provide the Department of Health (and others) with information about people in contact with drug treatment services, and about patterns and trends in drug misusers presenting for treatment. The data was used to monitor the objectives for treatment set out in the Government's drugs strategy '*Tackling Drugs to Build a Better Britain*'. It was also used to supply information to bodies such as the Advisory Council on the Misuse of Drugs (ACMD) (which provides advice to Ministers on all aspects of drug misuse) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Drugs quoted in the [statistics](#) relating to these users do **not** include OTC drugs.

The RDMD database was closed on 31 March 2001. PAGB has requested information from NTA lead for this database to work out the incidence of OTC abusers/misusers.

### Manufacturers and MHRA Databases

Surveillance of marketed drugs is a shared responsibility between regulatory authorities and manufacturers. Manufacturers carry out routine signal detection and trend analysis and address all safety information when they submit a Periodic Safety Update Review (PSUR) to the UK regulatory agency, MHRA. The PSUR is a practical mechanism for summarising the overall safety evaluation of a product. The report also explicitly addresses any new safety issue and the lack of significant new information is mentioned for each of the following:

- Experience with overdose, deliberate or accidental, and its treatment.
- Drug abuse or misuse.

---

<sup>7</sup> URL: <http://myweb.tiscali.co.uk/overcount/index.htm>

<sup>8</sup> URL: <http://www.statistics.gov.uk/STATBASE/Source.asp?vlnk=910&More=Y#general>

<sup>9</sup> URL: [http://www.dh.gov.uk/en/Publicationsandstatistics/Statistics/StatisticalWorkAreas/Statisticalpublichealth/DH\\_4015620](http://www.dh.gov.uk/en/Publicationsandstatistics/Statistics/StatisticalWorkAreas/Statisticalpublichealth/DH_4015620)

From the information gathered from individual OTC manufacturers the number of reports is very low and MHRA will be able to provide further details on this.

## 7. Tackling misuse

### 7.1 Control of supply of medicines

In the absence of detailed information about the reasons people practice OTC drug misuse, the methods used to tackle the issue have focused on control of supply in pharmacies. A variety of strategies are implemented by community pharmacists when dealing with “suspicious” requests and there are many similarities between the findings of investigations<sup>10</sup>.

In a typical case, pharmacists and their staff become aware that some customers are asking for large quantities or are purchasing more frequently than normal, are asking for specific combinations of products or are behaving in an unusual way. The reaction is to refuse a sale and/or remove the products from display and/or refuse to stock products which are known to be abused although different pharmacists apply different criteria in making decisions to control sales.

A research project study looking at a harm minimisation model<sup>11</sup> for identification and treatment of OTC drug misuse and abuse conducted by Queen’s University Belfast indicated a wide range in the numbers identified as misusers/abusers between pharmacies. This indicated that the large variance in suspected misusers/abusers in other published papers could also be due to the criteria for identifying a misuser/abuser being very subjective rather than to geographic or demographic differences.

Pharmacists have shown they are responsible in dealing with inappropriate requests. Kaolin and morphine, Gees linctus, Codeine linctus, cyclizine, promethazine, pseudoephedrine were all identified by pharmacists as either drugs of abuse or misuse. They were never reclassified as a prescription only medicine simply because their intervention stopped this taking a firm hold. To help pharmacists, RPSGB produces a code of ethics and professional standards for pharmacists<sup>12</sup> which lists medicines and substances where pharmacists should practice increased vigilance in sales. This needs to be developed further with more thorough standardised policies on the sale of particular OTC products, methods of identifying OTC misusers and effective interventions<sup>13,14</sup>

Innovative strategies need to be developed and formally implemented to help pharmacists and retailers to identify and prevent inappropriate sales of OTCs. These should be practiced uniformly in all pharmacies to avoid the situation where customers go from shop to shop to get the quantities they need. A new model of training has just been introduced for the sale of pseudoephedrine medicines which could be the basis for training for other medicines that can be abused.

---

<sup>10</sup> Pates-R; McBride-AJ; Li-S; Ramadan-R. Misuse of over-the-counter medicines: a survey of community pharmacists in a south Wales health authority. *Pharmaceutical Journal* 2002;**268** (Feb 9):179-82.

URL: [http://www.pjonline.com/pdf/papers/pj\\_20020209\\_otc.pdf](http://www.pjonline.com/pdf/papers/pj_20020209_otc.pdf)

<sup>11</sup> Wazaify M, McElnay J, Hughes CM. *Int J Pharm Pract* 2002;10 (suppl):R92. The implementation of a harm-minimisation model for the identification and treatment of over-the-counter drug misuse and abuse in community pharmacies.

URL: [http://www.pjonline.com/IJPP/bpc2002/ijpp\\_bpc2002\\_r92.pdf](http://www.pjonline.com/IJPP/bpc2002/ijpp_bpc2002_r92.pdf)

<sup>12</sup> URL: <http://www.rpsgb.org.uk/protectingthepublic/ethics/>

<sup>13</sup> Pates-R; McBride-AJ; Li-S; Ramadan-R. Misuse of over-the-counter medicines: a survey of community pharmacists in a south Wales health authority. *Pharmaceutical Journal* 2002;**268** (Feb 9):179-82.

URL: [http://www.pjonline.com/pdf/papers/pj\\_20020209\\_otc.pdf](http://www.pjonline.com/pdf/papers/pj_20020209_otc.pdf)

<sup>14</sup> Harrison, I. Sale of medicines liable to abuse. *Pharmaceutical Journal* 1998 :**240**, 600.

## 7.2 Supporting the individual

The general consensus is that tackling abuse/misuse requires involvement of many different professionals, and to some extent involvement of retail organisations and manufacturers. The view tends to be, however, that the predominant current problem is how to deal with abusers/misusers, rather than how to control their access to products.

GPs have expressed a preference for a team approach to managing OTC abuse/misuse, and have recognised the role of pharmacists. Delegates at a BMA conference<sup>15</sup> have called for the Department of Health to take responsibility for coordinating a strategy that would include a role for drug addiction services.

Pharmacists have identified the need for improved systems for referring abusers/misusers to addiction services, and have identified a need for support. It has been suggested that the Royal Pharmaceutical Society of Great Britain could have a role in coordinating or implementing guidelines for managing pharmacy-based aspects of the problem. This arises because nearly all of the OTC products that are misused are Pharmacy medicines and have to be sold under the personal supervision of a pharmacist or trained assistant.

The problem in providing support is identifying the person who is misusing the medicines and identifying strategies which will work for different people. It is difficult to identify any particular group of individuals as “typical” suspected misusers.

This suggests that a one size fits all solution to the issue is unlikely,

- A research model needs to be agreed which focuses on the individual rather than on access and control of supply to allow a true assessment of the scale of the problem to be established in the UK and an understanding of the psychosocial background which lies beneath inappropriate use.
- In order to provide support people who are misusing medicines need to be provided with information to enable them to realize that they need assistance.
- People who are concerned that they are misusing medicines need to be directed to sources of that assistance, for example signposting to a resource available with the NHS
- NHS funding needs to be provided to develop and sustain this model

The APPG Inquiry on Misuse of Drugs has for the first time in the UK brought together information and expertise in this field and we look forward to participating fully in the Inquiry.

---

<sup>15</sup> *Pharmaceutical Journal* 2004:273:44 (Jul 10)  
URL: <http://www.pjonline.com/Editorial/20040710/news/p44addictionwarning.html>

**Annexes**

**Annex 1**

**Report on abuse and misuse of OTC Products in the UK  
October 2007**

**Christine E. Heading PhD, BSc, M.R.Pharm.S**

## Executive Summary

This report reviews the UK literature on abuse/misuse of OTC medicines, and relates it to the wider literature available in the field. The terms misuse and abuse are used here to refer to: use for a proper purpose but at an inappropriate dose (misuse), and use for an inappropriate purpose or in a way inconsistent with medical practice (abuse).

There is a body of peer reviewed literature addressing the abuse/misuse in the UK, but it is relatively narrow in its approach compared with literature from North America. UK literature focuses on events around the point of sale, and reveals little about: the characteristics of abusers/misusers; risk factors for abuse/misuse; the potential for OTCs to provide a gateway to other drugs; the different ways in which psychoactive drugs are abused; or the scale of OTC abuse/misuse in quantitative terms. Consequently there is little understanding of the problem or its scale in the UK.

The data that do exist, however, provide valuable information regarding the experience built up by pharmacists and related staff in the handling of abuse/misuse issues. There is a broad awareness of products and product classes prone to abuse/misuse, and widespread existence of strategies to manage the sale of these to suspected abusers/misusers. The consensus is that managing the sale of such products is generally under control although there may well be a case for a more coordinated approach. In contrast, if a purchaser requires specialist help that the pharmacy is unable to provide, there is no clear path to specialist help for the individual. This includes help for those who may have developed a dependency, and those who may abuse laxatives because they have an associated disorder such as anorexia.

The major drug classes that seem to be abused/misused in the UK are opiates (especially codeine), antihistamines (usually in sleep inducing products), and laxatives. Different OTC products seem to be involved in deliberate or accidental overdose incidents resulting in hospital admissions.

The scale of dependency linked to OTC products in the UK is not known. Canadian evidence suggests that only a proportion of those who believe they are dependent on codeine satisfy clinical criteria for dependence. Evidence from studies with unlicensed (illegal) and prescription drugs suggests a significant co-morbidity between psychological and psychiatric conditions and both dependency and regular usage. This does not reduce the importance of any dependence, but informed opinion suggests that this should influence the way the problem is tackled.

The scale of recreational use of OTC products in the UK is also unknown. Research in North America suggests that because adolescents are attracted to risk-taking, they may be more likely than adults to abuse OTCs recreationally.

There seems to be a need for further research in the UK focused on: obtaining good quality national and local information on patterns of OTC abuse/misuse; the needs of, and treatment options for, those who are dependent on OTC products; and on establishing whether there are identifiable at-risk groups who can be especially targeted for support and education to prevent OTC abuse/misuse.

# TABLE OF CONTENTS

## EXECUTIVE SUMMARY

### **1. OBJECTIVE, DEFINITIONS AND METHODOLOGY**

### **2. INTRODUCTION**

### **3. SCALE OF THE PROBLEM**

3.1 WHAT IS THE CURRENT SCALE OF THE MISUSE OF OTC SUBSTANCES IN THE UK?

3.2 HOW MANY PEOPLE ARE CURRENTLY DEPENDENT ON OTC SUBSTANCES?

3.3 HOW MANY PEOPLE CURRENTLY USE OTC SUBSTANCES IN A RECREATIONAL MANNER?

3.4 WHAT ARE THE MAJOR DRUGS OF MISUSE IN OTC SUBSTANCES?

3.5 WHAT IS THE CURRENT LEVEL OF PUBLIC AWARENESS OF THE PROBLEM OF OTC SUBSTANCE MISUSE?

3.6 WHAT ARE THE PHYSICAL, SOCIAL, PSYCHOLOGICAL AND ECONOMIC HARMS OF OTC DRUG MISUSE?

3.7 WHAT ARE THE PHYSICAL, SOCIAL, PSYCHOLOGICAL AND ECONOMIC HARMS OF OTC DRUG MISUSE?

3.8 WHAT RELATIONSHIP DOES THE MISUSE OF OTC DRUG MISUSE HAVE TO THE MISUSE OF ILLICIT DRUGS?

3.9 GEOGRAPHY, DEMOGRAPHICS AND SOCIO-ECONOMIC GROUPS AFFECTED

### **4. TACKLING THE PROBLEM**

4.1 OVERVIEW

4.1.1 Current position

4.1.2 Broader issues regarding accessibility of substances with psychoactive properties

4.2 WHAT CAN BE DONE TO TACKLE TH PROBLEM OF DEPENDENT USE OF OTC SUBSTANCES?

4.3 WHAT CAN AND SHOULD BE DONE TO TACKLE THE PROBLEM OF RECREATIONAL USE OF OTC SUBSTANCES?

4.4 WHAT CAN AND SHOULD BE DONE TO TACKLE THE PROBLEM OF RECREATIONAL USE OF OTC SUBSTANCES?

4.5 WHO SHOULD TAKE RESPONSIBILITY FOR TACKLING MISUSE OF OTC SUBSTANCES?

### **5. CONCLUSIONS**

### **6. REFERENCES**

## **1. OBJECTIVE, DEFINITIONS and METHODOLOGY**

### 1.1 OBJECTIVE

To address the anecdotal information and misinformation on abuse and misuse of OTC medicines by carrying out a comprehensive literature search and producing an independent overview report which will underpin the PAGB response and inform the discussion.

### 1.2 DEFINITIONS

APPGDM have explained that they are using the term ‘misuse’ to include situations where there may have been poor prescribing practices (that may have led to dependency or other problems for the patient), as well as any use for which the medication was not originally intended.

Within the UK there are several points of view concerning the distinction between *abuse* and *misuse* of OTC products. Commonly, in pharmaceutical literature, OTC misuse is defined as using a product for a legitimate medical reason but in a higher dose or for a longer period of time than recommended. OTC abuse is defined as the non medicinal use of drugs, for example for recreational purposes [See 1, 2, 3, 4]. This is broadly consistent with the definition published in 1969 by the WHO Expert Committee on Drug Dependence that referred to abuse as ‘persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice’ [see Appendix .

This classification works tolerably well and will be used in this report whenever it is necessary to distinguish between different types of inappropriate use. On most occasions, this report will be discussing abuse and misuse together (abuse/misuse). Two areas of classification difficulty are the inappropriate use of laxatives to try and lose weight and the issue of overdoses. Some groups would define laxative use for weight loss as abuse, but WHO describe this as misuse. Accidental overdose may be misuse, but deliberate overdose would be abuse.

Medical literature often fails to make any clear distinction between abuse and misuse.

### 1.3 SCOPE OF THE LITERATURE SEARCH

A systematic literature search was conducted covering the period 1996-2007 using three electronic pharmacy databases (EPIC, Silver Platter and IPA). In addition, less structured searches were conducted using the Web of Science and Science Direct databases (1997-2007). All searches used key words relevant to the topic of abuse/misuse of OTC medicines. The references generated were checked for relevance on the basis of the title or abstract and follow-up references from the papers were identified. A Google search was used to seek any relevant anecdotal or informal material, and several relevant websites were also examined.

## **2. INTRODUCTION**

There is a body of research regarding abuse/misuse of OTCs in the UK, but it is small and relatively narrow in scope. Most studies have had specific objectives, and the research has been targeted towards those objectives. Consequently, it is important not to misuse the information gathered in this research merely because of a paucity of information in the field as a whole.

Research in the UK has tended to focus on identifying the OTC products that are potentially abused/misused and on events at the point of sale. This contrasts with research in North

America (USA and Canada), which has been more broadly based and has mirrored the much larger body of research on other problem activities such as: use of alcohol and nicotine, gambling, internet usage and even shopping. North American OTC research has included study of:

- the characteristics of abusers/misusers
- risk factors for abuse/misuse
- the potential for OTCs to provide a gateway to other drugs
- the different ways in which psychoactive products are abused
- attempts at quantifying some aspects of OTC abuse/misuse

Although this report focuses on research into UK events, information from North American studies enables informed evaluation of the UK research base. It is clear that the UK research literature leaves many questions unanswered and many issues not yet understood. Overall, psychological and behavioural aspects of the abuse/misuse issue have received little attention in the UK. The main deficits seem to be:

*Lack of reliable information concerning the extent of OTC abuse in the UK.*

Anecdotal evidence, along with concern expressed by the medical profession, suggests there is a genuine problem that is changing in character or size. The figure of 30,000 abusers/misusers of OTC medicines in the UK is frequently quoted, but the basis of this estimate seems obscure.

*Little understanding of who is abusing/misusing products*

Attempts have been made to analyse the available data on the basis of age groups, gender, socioeconomic class etc but this has not led to much understanding. Attempts have been made to identify misusers and abusers at the point of product sale, but with limited success.

*Little understanding of why products are being abused/misused*

Much of the research to date has been descriptive, and has not attempted to investigate the nature of the abuse/misuse problem. For example, there is no research that establishes what proportion of those misusing psychoactive OTCs are wilfully using them for recreational purposes and what proportion are misusing them because of a dependency resulting from use for a legitimate purpose. It is impossible to judge from the available anecdotal self-reports what the proportions are.

*Some risk of misinterpretation*

Although the findings of UK peer-reviewed research reports are objective, their presentation sometimes invites misinterpretation. Much of the research involves the gathering of opinions from health professionals and/or the public, but the way the opinions are reported can mask the findings of that research. For example, studies tend to present their findings in terms of how respondents describe them, rather than in objective terms. Laxatives are identified in virtually all research as a problem class, but brands or even types of laxative are rarely specified or tabulated. In contrast, within other product classes, the naming and tabulating of high profile brands is common in research reports. This can lead to the perception that these specific products play a more significant role in the abuse/misuse problem than the reports actually show or claim.

The sections that follow address the specific issues raised by APPGDM.

### **3. SCALE OF THE PROBLEM**

#### **3.1 WHAT IS THE CURRENT SCALE OF THE MISUSE OF OTC SUBSTANCES IN THE UK?**

The scale of OTC abuse/misuse in the UK is very hard to judge because of the many gaps in the available information, especially on abuse. For example, so far as quantitative information is concerned, very little has been reported concerning: the actual dose of active substance being taken, the frequency of use or the time span over which substances are being taken. All of these factors are well known to influence harm and the development of dependency, and without having this quantitative information it is hard to assess the scale of the problem.

In turn, the absence of this information means that qualitative characteristics of abusers/misusers are often unknown, since there is no way of classifying users accurately as occasional, regular, recreational, dependent, co-dependent, or users with co-morbid conditions. Consequently, notional figures of the number of abusers/misusers mean very little.

Turning to the literature that is available, most quantitative data in the literature reflect *awareness* of the problem by health professionals or the public, and can not be interpreted as reflecting *usage* patterns. There is, nevertheless, some information in the literature regarding the scale of abuse/misuse.

A study in Northern Ireland [2] suggested that over a six month period between 2 and 87 abusers/misusers visited the six pharmacies involved during the study over the period. The total number of abusers/misusers was 196. An interim report of the study put the average number of abusers/misusers visiting pharmacies as two per week. In a Scottish study, the average was quoted as 5.63 per week, although most pharmacies (52%) saw no more than two. A further 18% saw no more than four [7]. These figures could be used to estimate a national total, but the figure would include those misusers whose problem is a poor understanding of how a product should be used, as well as those deliberate abusers whose have a significant drug use problem. The NI study estimated that the proportion of misusers represented 39% of the total number of abuser/misusers identified. [2]. Another difficulty with estimates is that they cannot necessarily take account of locality-based differences, of the type identified in Scottish studies of 1995 and 2000 [8] [7]. Consequently, although the Northern Irish and Scottish studies provide numerical data that are useful for designing management strategies for pharmacies, they do not necessarily provide data that indicate the prevalence of problematic drug abuse/misuse.

In another Northern Ireland study [1], members of the public commented on their personal knowledge of cases of drug abuse/misuse. About one third of the 848 members of the public reported having encountered drug abuse or misuse. About 27% claimed to know of someone 'addicted' to an OTC, about 2% knew of individuals taking too high a dose for no particular reason, about 19% knew of someone taking it for a 'rush', about 14% for an overdose, about 8% deliberately mixing an OTC with alcohol and about 6% to lose weight. It should be remembered, that these are subjective classifications by members of the public.

GPs have highlighted their concern during 2007 and in preceding years, and anecdotal evidence from agencies such as the Dumfries-based non-statutory agency Over-Count claim that the problem is significant. A figure of 30,000 abusers/misusers is frequently attributed to

Over-Count [5], [6], but hard evidence needs to be produced to support this claim. Even when obtained, as already mentioned, total figures will be of limited value unless accompanied by information regarding the qualitative characteristics of abusers/misusers recorded (e.g. occasional, regular, recreational, dependent, co-dependent, co-morbid etc).

Data entered into the Scottish Drug Misuse Database 2006, which draws its information from individuals attending centres for help, included no obvious mention of OTC abuse [34]. Similarly, in its 2005 report to the European Monitoring Centre for Drugs of Addiction, the UK Department of Health did not identify OTC products for any specific comment [35]. The website of EMCDDA itself does not seem to include any information on OTC medicines [36].

### 3.2 HOW MANY PEOPLE ARE CURRENTLY DEPENDENT ON OTC SUBSTANCES?

It is impossible to say how many people are dependent on OTC substances in the UK. Furthermore, there is evidence that those who regard themselves as dependent do not always meet recognised criteria such as those of DSM-IV. In a Canadian study conducted in 1997, of 339 individuals with a self-diagnosis of codeine dependency, only 37% met DSM-IV criteria for codeine dependence and 4% met the criteria for codeine abuse. Similar proportions met ICD-10 criteria. In this Canadian study, nearly all individuals had started taking codeine products for pain, and 66% received codeine on prescription from one physician only while 54% acquired codeine as an OTC (exclusively, or in addition to other supplies). Other sources were friends (32%), relatives (11%), off the street (19%), and on prescription from more than one physician (11%) [9].

### 3.3 HOW MANY PEOPLE CURRENTLY USE OTC SUBSTANCES IN A RECREATIONAL MANNER?

There are no reliable data for the UK. English language internet websites give the impression that there is a well-established culture of experimentation and use, but often these sites are international [for example, 10]. Personal-experience information does appear on numerous 'blogs' and message boards, and on sites with UK addresses [for example, 11], but the reliability of information on these sites regarding users and their experiences cannot be tested. The impression is given that users experience a range of good and bad experiences. Taking more than one drug at a time and using a drug alongside alcohol, nicotine or an unlicensed (illegal) substance is often reported.

Information from the general public collected in academic studies is broadly consistent with the internet material. As already mentioned (section 3.1), in one study conducted in 2002, awareness of specific individuals who were using OTCs 'for a rush' was found to be about 19% of a sample of the general public, and about 9% for mixing OTCs with alcohol [1].

In the absence of any UK data, data from the USA may help to give a flavour of the problem. However, even from this data it is hard to determine how much usage is occasional, how much is frequent and how much is in-between. It should be noted that most of these studies acknowledge their limitations and suggest that their findings are indicative rather than absolute.

A 2006 US report claimed that of nearly 40,000 high school students, 4.7% occasionally used OTC products to get euphoric, while an additional 2.1% had used a product in the previous month (total 6.8%). Use was associated with the existence of some depressed mood, abuse of other drugs and of alcohol [12]. In 2005, one report stated that dextromethorphan was used

by an 'unknown' number of US adolescents [13]. It was claimed that supplies in multiple of 1g were available via the internet including eBay. The drug was taken to produce intoxication at parties, after and even before school. A 2007 review of US trends in recreational drugs has drawn attention to the trend of 'pharming', which involves use of cough and cold remedies for obtaining euphoria or 'highs'. Products containing dextromethorphan are particularly popular and both OTC and prescription products are used. The study claimed that dextromethorphan OTC abuse has been rising alarmingly, and is accompanied by so-usage with alcohol and illicit drugs. [14].

In 2004, a US study of intentional drug abuse covering the period 1990-199 was reported. This was based on reports of child and teen OTC misuse made to a regional poison centre. Of 2214 reports, 38.1% involved OTCs, but the number of reports decreased each year. The most common classes of abused substances were anticholinergic drugs, caffeine and OTC stimulants [15].

### 3.4 WHAT ARE THE MAJOR DRUGS OF MISUSE IN OTC SUBSTANCES?

This too is not an easy question to answer, because of lack of definitive UK data and because the word 'major' requires defining. As already explained, quantitative data are lacking, but it is possible to say that the drugs are predominantly used orally, although sometimes by nasal or oral inhalation. The available data tend to be based on awareness by the public and health professionals rather than on usage. It should also be stressed that there should not be any assumption that notoriety of a class or product correlates with prevalence of usage on either a regular or an occasional basis.

The limited information available from studies conducted since 1998 is presented in this report. There appears to be a considerable mismatch between individual products named by pharmacists and by the public, but rather more agreement regarding product classes. However, even for product classes, the match is not good. Analgesics (painkillers) were mentioned by the public most often as a product class linked to abuse, but this did not necessarily include codeine (opiate) containing products. By far the most frequently named individual product by the public was paracetamol. In contrast, pharmacists did not refer to analgesics as a class, and only mentioned paracetamol on its own in one of the studies. Mostly, when identifying problem analgesics, pharmacists only referred to analgesics that included codeine. Sleeping aids and cough/cold remedies were mentioned by both pharmacists and the public as products prone to abuse. Laxatives were identified by pharmacists as a problem class, and in a study of laxative abuse published in 2005, nearly all the 19 English pharmacies surveyed considered that there was a problem with laxative abuse/misuse [17]. The public did not mention this class directly when surveyed, but in another context, 6% of a random sample did indicate they knew of individuals who abused laxatives [1].

Some additional information comes from a harm-minimisation study conducted in Northern Ireland [2], which compared drug use in individuals tentatively classified as either misusers (using for medicinal purposes in an incorrect manner) or abusers (using for non-medical purposes). The spectrum of products used was not very different in the two groups, but the percentages of abusers to misusers using opiates were 57% versus 47%; the percentages for antihistamines 23% versus 32%; and the percentages for laxatives 20% versus 19%.

It should be noted that most of the studies described in this section were all undertaken between 1998 and 2001, and it is possible that new trends have developed since that time.

There is little UK information concerning recreational use of OTC products, which several US studies suggest have increased in fashion, as discussed in the previous section (3.3).

Looking at usage patterns, rather than at the drugs or products involved, the consensus seems to be that any product has the potential to be misused by the public because of, misunderstanding, carelessness, or failure to follow guidance on usage. In contrast, those individuals who are abusing OTC medicines by deliberately using them inappropriately are likely to be:

- using medicines with psychoactive properties for recreational purposes
- using medicines with psychoactive properties because they believe they have become dependant on them
- abusing laxatives for weight loss
- intending to take a life-threatening overdose.

### 3.5 WHAT IS THE CURRENT LEVEL OF PUBLIC AWARENESS OF THE PROBLEM OF OTC SUBSTANCE MISUSE?

In a study of awareness by the public conducted utilising a random sample of the public in Northern Ireland in 2002, 85% of public were aware of abuse potential of OTC medicines [1]. Of 637 respondents who identified products or product classes, painkillers were mentioned by 501, sleeping aids by 83 cough mixtures by 81.

As already mentioned, by far the most commonly mentioned product was paracetamol, followed by five other analgesic products, four of which contained codeine. Of the 18 products mentioned, not one was a laxative although about 6% of 298 respondents claimed they knew of instances of laxative misuse.

The extent to which members of the public have encountered drug abuse/misuse was also determined, and has been described earlier (section 3.1). About one third of a random sample of the public surveyed in Northern Ireland in 2002 had encountered an episode of drug abuse/misuse [1].

### 3.6 WHAT ARE THE PHYSICAL, SOCIAL, PSYCHOLOGICAL AND ECONOMIC HARMS OF OTC DRUG MISUSE?

This varies with drug class and form of usage, as well as with the frequency with which an individual uses the product.

#### **Overdose issues:**

- As with most medicines, acute OTC overdoses can result in direct temporary damage, direct permanent damage, or death. It is clear that OTC products are implicated in many instances of deliberate overdose, as well as accidental overdose. In a 12 week Northern Ireland study, of 616 overdose cases, OTCs featured in 40% of cases. In more than half of these cases OTC products were the only products used. In other cases, OTCs were used in combination with prescription drugs, or other substances and methods. Most, but not all, OTC overdoses were intentional, and the drug most often involved in both accidental and deliberate overdosing was paracetamol. The actual number of tablets used in overdoses ranged from 1-100, but when OTC-only cases involving paracetamol, aspirin or ibuprofen the number of tablets was no more than 32. More than one-third (38.9%) of those presented with overdose had a previous history of overdosing [18].

- Non-lethal overdose with OTCs can also result in indirect damage to an abuser/misuser or bystander, for example from car accidents when the driver is drowsy or sedated.
- Chronic overdose with OTCs can result in effects that could be classified as toxicity effects (kidney damage, stomach bleeding, weight changes etc) and also in psychological changes. Psychological changes are likely to take the form of the development of dependence or the belief that dependence has developed.

### **Social, psychological and economic issues:**

- Evidence from other countries and from studies of prescription and unlicensed drugs suggests that psychological and psychiatric difficulties are quite commonly associated with both dependency and recreational drug use [see 37, 9 and 12]. The prevailing view seems to be that, in the first instance, such difficulties predispose to drug abuse/misuse.
- So far as OTC dependency is concerned, many of the issues are potentially similar to those that apply to abuse/misuse of prescription drugs and abuse/misuse of illegal (non-licensed) drugs. The crime element is usually absent in OTC dependency, but the need for treatment is the same and appears to be being ignored. Too little information is available to quantify the issues.
- Regarding recreational OTC use, too little is known about trends and usage in the UK for much comment to be made, but evidence from the USA suggests that recreational use of OTCs can lead to abuse/misuse of other more potent substances, as discussed below (section 3.7).

### **3.7 WHAT RELATIONSHIP DOES THE MISUSE OF OTC DRUG MISUSE HAVE TO THE MISUSE OF ILLICIT DRUGS?**

Again there are insufficient data. In terms of opiate drugs, it seems probable that the move between P, POM and illicit usage could be in both directions and between any of the three groups. Anecdotal cases reported on websites such as <http://www.codeinefree.org.uk> support this view. Some individuals seem to start with OTCs and move to illicit supplies because of tolerance and desire for an enhanced effect, whilst there seem to be others who move from prescribed products to OTCs. The prescribed drugs will normally have been prescribed either for a diagnosed dependency or for a pain condition. The Canadian study of codeine usage [9] gives some details concerning how codeine-dependent users sometimes utilise a range of legitimate and illicit sources.

So far as recreational use in adolescents is concerned, it does seem likely that use of novel products may be a manifestation of risk taking, and will be followed by a move to others substances. There is a substantial body of evidence from other countries that, as a general rule, abuse of OTC products for non-medical purposes is associated with an increased risk of polysubstance abuse with alcohol or other drugs. In turn, this can lead to addiction if addictive drugs are involved [see 14].

An unusual association was reported in one US study (reported in 2006) involving 2,006 adolescents. The study [19] found an association between the use of herbal products by

adolescents, and usage of a range of additional substances including alcohol, marijuana, cocaine and crack cocaine, LSD, IV injection drugs, steroids, inhalants, methamphetamine, and heroin. All usage was seen as evidence of adolescent risk-taking activity; an activity widely associated with improper drug usage. A total of 25% of the sample used herbal products. Again referring to the USA, a 2007 study in the USA (mentioned previously) claimed that dextromethorphan OTC abuse is accompanied by co-usage with alcohol and illicit drugs [14], while a 2006 report (also mentioned previously) claimed that use of OTCs to induce euphoria was associated with abuse of other drugs and of alcohol [12].

### 3.8 HAS THERE BEEN SUFFICIENT RESEARCH INTO THE SCALE AND NATURE OF OTC DRUG MISUSE?

Clearly there has been insufficient research into the scale and nature of OTC drug misuse.

The willingness of pharmacists, other health professionals and general retailers to help to address the issue has already been investigated. Their willingness is not in doubt and potential strategies exist to manage availability, as discussed in subsequent sections. Overall though, the amount of research in the UK has been very small and is too small to answer many questions. The key issue is to identify what questions need to be answered. These seem to include:

**Obtaining continuous good quality information on patterns of OTC abuse/misuse.** This would allow rapid and appropriate action by health professionals in response to those trends and fashions prevailing at any particular time.

**Establishing the needs of, and treatment options for, those individuals who are dependent on opiate OTC products.** There is significant anecdotal evidence that OTC opiate-dependent individuals are not receiving appropriate health care. These individuals will not be in touch with health professionals in the way that those receiving prescription opiates are, and they probably differ significantly from those who are dependent on illicit opiates. More information should improve the care of these individuals, make the overall issue manageable and probably reduce its scale considerably.

**Establishing whether there are identifiable at-risk groups such as those with affective disorders, histories of drug or alcohol problems, the elderly, the unemployed etc.** This could allow targeting of educational/warning messages and facilitate better support of vulnerable individuals by appropriate agencies with which they are in contact.

### 3.9 GEOGRAPHY, DEMOGRAPHICS AND SOCIO-ECONOMIC GROUPS AFFECTED

The information regarding relevance of age, gender, socio-economic circumstances or health status for substance abuse/misuse in the UK is inconclusive. Generally, no clear pattern has been observed regarding gender, except in the case of laxative use and suicides. There is evidence to support the view that women are more prone to this than men and the motivation is thought to often be that of seeking weight loss. Some individuals are thought to be suffering from anorexia nervosa. Some gender differences were found in Northern Ireland studies: amongst A&E admissions, overdoses involving OTC arose predominantly in women (62.3%) [18], and slight differences were found regarding opiate misuse with men being more prone to use of OTC medicines than women [2].

Regarding age, there is a wealth of information from North America that suggests that younger individuals (adolescents in particular) are especially likely to abuse OTCs for

recreational purposes. This is portrayed as a manifestation of risk-taking behaviour that is thought to prompt and maintain substance abuse in many individuals.

Older individuals too are known to abuse/misuse drugs, and a 2005 UK study claimed it was 'overlooked and under-reported' [20]. In a Canadian study of codeine abusers who considered themselves dependent, those who met DSM-IV criteria were older than those who did not. However, the overall mean age was 43.5 years and the mean age of starting codeine use was 26 years. These individuals accessed codeine via prescription, OTC products and other means and all claimed to have started usage for pain relief. There was evidence of widespread usage of other psychoactive agents at some time, and family histories of some substance abuse [9].

Concerning geographical distribution within the UK, there is neither strong evidence for, nor strong evidence against, any difference between the four UK nations. However, there is some evidence, from the studies in Scotland, that there may be differences between rural and other areas. In one study [8], within most Scottish Board regions, 50-75% of pharmacists reported that there was abuse/misuse of OTCs, but reporting tended to be lower in rural areas. A similar finding was reported in another study [7].

## **4. TACKLING THE PROBLEM**

### **4.1 OVERVIEW**

#### **4.1.1 Current position**

Published studies suggest that the vast majority of UK pharmacies have some protocols, techniques and/or procedures for dealing with suspected abusers/misusers, and try to provide appropriate support. These strategies include the twin approaches of harm reduction (by managing access to the medicines) and addressing underlying problems (by providing relevant support).

A major difficulty is that, before support can be offered, though, some way of engaging with the abuser/misuser has to be achieved. This can be very difficult [2], [21] and it is acknowledged that genuine customers could react badly to encroachment on their expectations of product access and confidentiality [21].

Most UK studies of abuse/misuse of OTCs have identified ways for tackling some of the problems. The greatest emphasis has been on managing the availability of the products, but the need for providing support to abusers/misusers has also been widely considered. Most recommendations regarding support go little further than recommending training of staff, development of better protocols, participation in awareness campaigns and liaison with other agencies or professionals.

In contrast, recommendations concerning managing availability include many well-supported, practical and specific recommendations. Widely supported measures to reduce the inappropriate supply of products to abusers/misusers include:

- Having a proactive approach
- Awareness by pharmacists and pharmacy staff of the most widely abused classes
- Training of pharmacists and staff in how to handle suspected abuse/misuse
- Use of in-store protocols for suspected instances of abuse/misuse
- Development of national guidelines for handling of OTC abuse
- Refusal of sales where appropriate

- Limiting display of potentially abused/misused products
- Monitoring, recording and intervening where appropriate

#### 4.1.2 Broader issues regarding accessibility of substances with psychoactive properties

Whilst it is obvious that restricting access to a substance of potential abuse/misuse will influence the usage of the substance, it is less obvious that restriction will benefit the would-be user or the public at large. For those users who are willing to accept advice, a combination of restriction, guidance and support is likely to be helpful. For others, restricting access to a particular substance may merely shift the problem to another substance or activity.

This view is supported by literature regarding:

- substance choice
- source of supply
- factors predisposing an individual to become or remain a drug abuser

Regarding choice of substance, there is a considerable body of literature indicating that, at any one time in their lives, those abusing substances may abuse multiple substances. Some users will switch between substances over time. This is supported by a recent study by the US National Institute on Drug Abuse, National Institutes that showed widespread usage and dependency on more than one substance. [37]. These observations are consistent with older studies [see 9]. Recent New Zealand and Australian studies of drug use for recreational use have also reported that amongst adolescent recreational users, many use multiple substances [see 38], as have studies in the USA [12].

Concerning supply, most literature focuses on drugs that are acquired illegally. However, one 1997 Canadian study that is particularly relevant to OTC products examined characteristics of dependent and non-dependent regular users of codeine. The study revealed that users often obtained supplies from several different sources of supply and would switch between them as required. Users obtained products OTC, on prescription from one or more doctor, illicitly, and from family and friends [9]. A more recent study (published in 2007) that focused on prescription and OTC recreational drugs in the USA, also reported that substances were accessed from a variety of sources [14].

Regarding the risk factors linked to becoming a substance abuser, the consensus view held by scientists, psychologists and healthcare professionals working in the field of addiction is that the development of dependence is as much influenced by personality, environmental and genetic factors as it is by availability [see 24, 25, and 26]. In adolescents, enthusiasm for experimentation [19], [26], and low mood [12] seem especially relevant to recreational use. Additionally, across age groups, the existence of underlying psychiatric disorders is well known to be associated with both repeated substance abuse and dependency [37].

The factors outlined above, combined with a documented lack of willingness by regular users to seek help [37], indicate a need for provision of specialist support for these abusers rather than the need for any further restriction on substance or product availability.

#### 4.2 WHAT CAN AND SHOULD BE DONE TO TACKLE THE PROBLEM OF DEPENDENT USE OF OTC SUBSTANCES?

For OTCs, very little UK research has been published that has tackled dependency and recreational use as separate issues. It is acknowledged that some individuals are dependent in a way that match relevant DSM-IV and/or ICD-10 criteria, but as already mentioned, not all

those who may consider themselves dependent would be diagnosed as such. Nevertheless, such individuals require help and there is a widespread view that they are not able to get it [see 22, 23]. There seems to be a consensus that the immediate priority is to establish guidelines for NHS addiction services on how to treat OTC addictions, and to provide treatment for dependent individuals. If, additionally, there were national guidelines on how pharmacies should deal with potential OTC abusers/misusers, this could consolidate and spread the good practice that already exist.

Probably there are educational issues that could be tackled, but until more information is available concerning who is becoming dependent, why and on what, education cannot be selectively targeted at at-risk individuals.

#### 4.3 WHAT CAN AND SHOULD BE DONE TO TACKLE THE PROBLEM OF RECREATIONAL USE OF OTC SUBSTANCES?

Without knowing more about who is using OTCs, it is not easy to devise comprehensive strategies. In the absence of information, national guidelines could consolidate and extend existing good practice regarding display, stocking levels, limits on sales, liaison with other pharmacies etc. The information and experience that could support these guidelines seems to exist already.

#### 4.4 WHAT CAN AND SHOULD BE DONE TO IMPROVE THE CURRENT LEVEL OF PUBLIC AWARENESS OF THE POTENTIAL FOR MISUSE OF OTC SUBSTANCES?

There is general support for increasing the awareness of the public of the risks of inappropriate use of medicines, but some lack of conviction that it will achieve the intended result of reducing abuse/misuse. The idea of education campaigns has limited support [21]. BMA delegates have called for amending labelling and patient information [5], which was put in place for codeine and dihydrocodeine products in 2005 after an MHRA review. There is no strong evidence that this would achieve very much. Pharmacists tend to believe that highlighting the misuse potential of particular OTC products could boost abuse/misuse and should be avoided. [5], [7]. Restricting advertising and making warnings easier to understand are regarded as low priority measures by pharmacy experts [21].

Regarding compliance with advice and warnings, evidence is conflicting. A 2007 report [27] drawn up on behalf of Tesco indicates that 32% of customers never read the instructions on analgesic packs. In contrast, a study conducted in 2002 reported that 75% of the public claimed that they always followed directions for use of OTC products, and a further 12% often followed directions [1].

#### 4.5 WHO SHOULD TAKE RESPONSIBILITY FOR TACKLING MISUSE OF OTC SUBSTANCES?

The general consensus is that tackling abuse/misuse requires involvement of many different professionals, and to some extent involvement of retail organisations and of manufacturers (e.g. change to codeine and hydrocodeine labelling changes in 2006). The view tends to be, however, that the predominant current problem is how to deal with abusers/misusers, rather than how to control their access to products.

GPs have expressed a preference for a team approach to managing OTC abuse/misuse, and have recognised the role of pharmacists [30]. Delegates at a BMA conference have called for the Department of Health to take responsibility for coordinating a strategy that would include

a role for drug addiction services [5]. Pharmacists have identified the need for improved systems for referring abusers/misusers to addiction services, and have identified a need for support. It has been suggested that the Royal Pharmaceutical Society of Great Britain could have a role in coordinating or implementing guidelines for managing pharmacy-based aspects of the problem [5], [21].

From literature searches, the Welsh Assembly seems to be the only authority within the UK that has specifically included management of OTC products in its drugs abuse management strategy [39] [35].

## **5. CONCLUSIONS**

There is a high level of awareness of the problem of OTC abuse/misuse by pharmacists. Managing the access of abusers/misusers to OTC products is not simple, but is regarded as manageable and broadly under control.

In contrast, GPs and pharmacists believe that more help needs to be provided for those for whom support within pharmacies does not prove effective. This applies especially to those who are dependent on OTC products.

The present knowledge of the extent of abuse/misuse of OTC products in the UK is poor. There is little reliable knowledge concerning prevalence, what is driving abuse/misuse, and who is abusing the products. By focussing excessively on the specific drugs or products involved, there is a risk that a proper understanding of the problem will not be achieved.

The main areas of research required seem to be:

- The obtaining of continuous good quality information on patterns of OTC abuse/misuse, at both national and local level.
- Establishing the needs of, and treatment options for, those individuals who are dependent on OTC products.
- Establishing whether there are identifiable at-risk groups such as those with affective disorders, histories of drug or alcohol problems, the elderly, adolescents or the unemployed.

## **6. REFERENCES**

1. Wazaify M, Shields, E, Hughes, CM, McElnay, JC Societal perspectives on over-the-counter (OTC) medicines. *Fam-Pract.* 2005 Apr; 22(2): 170-6
2. Wazaify M, Hughes, CM, McElnay, JC The implementation of a harm-minimisation model for the identification and treatment of over-the-counter misuse and abuse in community pharmacies in Northern Ireland. *Patient-Educ-Couns.* 2006 Dec; 64(1-3): 136-41
3. Fleming-GF, McElnay JC, Hughes, CM Development of a community pharmacy-based model to identify and treat OTC abuse/misuse: a pilot study. *Pharmacy-World-and-Science* 2004 Oct;26(5):282-288
4. Wazaify-M; McElnay-JC; Hughes-CM The implementation of a harm-minimisation model for the identification and treatment of over-the-counter drug misuse and abuse in community pharmacies. *International-Journal-of-Pharmacy-Practice* 2002:Sep Sup:10:R92
5. Doctors call for addiction warning labels on OTCs *Pharmaceutical-Journal* 2004 Jul 10:273:44
6. BMA Science Board June 14 2005 Over the counter Medication  
<http://www.bma.org.uk/ap.nsf/content/OTCmedication>
7. MacFadyen L, McGowan ET Community pharmacists experience of over-the-counter medicine misuse in Scotland. *The Journal of the Royal Society for the Promotion of Health* 2001;121:185-192
8. Matheson C, Bond C, Pitcairn J Misuse of over-the-counter medicines from community pharmacies: a population survey of Scottish pharmacies. *Pharmaceutical Journal* 2002:July 13: 269:66-68
9. Sproule BA, Bust UE, Somer G, Romach MK, Sellers EM Characteristics of dependent and nondependent users of codeine. *J Clin Psychopharmacol.*1999; 19(4) 367-372
10. <http://www.erowid.org/>
11. <http://board.dogbomb.co.uk/>
12. Steinman KJ High school students' misuse of over-the-counter drugs: A population-based study in an urban county. *Journal of Adolescent Health* 2006;38 445–447
13. Schwartz RH Adolescent abuse of dextromethorphan *Clin Pediatr (Phila).* 2005 Sep;44(7):565-8
14. Levine DA 'Pharming': the abuse of prescription and over-the-counter drugs in teens. *Current Opinion in Pediatrics* 2007, 19:270–274
15. Crouch BI, Cravati EM, Booth J Trends in child and teen nonprescription drug abuse reported to a regional poison control center *Am J Health Syst Pharm.* 2004 Jun 15;61(12):1252-7
16. Pates R, McBride AJ, Li S, Ramadan, R et al Misuse of over-the-counter medicines: a survey of community pharmacies in a South Wales health authority. *Pharmaceutical-Journal* 2002:Feb 9: 268:179-82
17. Bryant Waugh R, Turner H, East P Over-the-counter laxatives and eating disorders – a survey of pharmacists' and other retailers' views and practice. *Pharmaceutical-Journal* 2005 July 16:275:87-91
18. Wazaify M, Kennedy S, Hughes CM, McElnay JC Prevalence of over-the-counter drug-related overdoses at Accident and Emergency departments in Northern Ireland – a retrospective evaluation. *J Clin Pharm Ther;* 2005; 30(1):39-44
19. Yussma SM, Wilson KM, Klein JD. Herbal products and their association with substance use in adolescents. *Journal of Adolescent Health* 2006; 38 395–400
20. McGrath A, Crome P, Crome IB Substance misuse in the older population *Postgrad Med J* 2005 Apr;81(954):228-231.
21. McBride AJ, Pates, R, Ramadan R, McGowan C Delphi survey of experts' opinions on strategies used by community pharmacists to reduce over-the-counter drug misuse. *Addiction* 2003 April: 98(4) 487-497
22. Ford C, Good, B Over the Counter drugs can be highly addictive (Letter) *BMJ* 2007 May 5 334:917-918
23. *BMJ* Rapid responses to Ford and Good Letter May 5 2007 (8<sup>th</sup>, 10<sup>th</sup> and 16<sup>th</sup> May, 2007)

24. [Kelly TH](#), [Robbins G](#), [Martin CA](#), [Fillmore MT](#), [Lane SD](#), [Harrington NG](#), [Rush CR](#). Individual differences in drug abuse vulnerability: d-amphetamine and sensation-seeking status. [Psychopharmacology \(Berl\)](#). 2006 Nov;189(1):17-25. Epub 2006 Sep 14.
25. [Scherrer JF](#), [Xian H](#), [Shah KR](#), [Volberg R](#), [Slutske W](#), [Eisen SA](#). Effect of genes, environment, and lifetime co-occurring disorders on health-related quality of life in problem and pathological gamblers. [Arch Gen Psychiatry](#). 2005 Jun; 62(6):677-83
26. [Fowler T](#), [Lifford K](#), [Shelton K](#), [Rice F](#), [Thapar A](#), [Neale MC](#), [McBride A](#), [van den Bree MB](#). Exploring the relationship between genetic and environmental influences on initiation and progression of substance use. *Addiction*. 2007 Mar;102(3):413-22.
27. (News Item) *Pharmaceutical Journal* 2007; May 12; 278: 543
28. McCarthy M Prescription drug abuse up sharply in the USA. *Lancet* 2007 May 5 369:1505-1506
29. Scottish Specialists in Pharmaceutical Public Health and Trust Chief Pharmacists Drug Misuse in Community Care: Issues for pharmaceutical care. March 2004  
[http://www.ssiapph.scot.nhs.uk/public\\_health\\_scotland/priority%20topics/drug%20misuse/drug\\_misuse\\_and\\_community\\_pharmacy\\_full.pdf](http://www.ssiapph.scot.nhs.uk/public_health_scotland/priority%20topics/drug%20misuse/drug_misuse_and_community_pharmacy_full.pdf)
30. Hughes GF, Bell HM, McElnay JC General practitioners' awareness of the appropriate and inappropriate use of over-the-counter products *Pharmaceutical-Journal* 1999 Sep 18:263; *Pharmacy Practice Research Supplement* R29
31. Downie G, Hind C, Kettle J The abuse and misuse of over-the-counter medicines. *Hospital-Pharmacist* 2000: Oct: 7(9):242-250.
32. Temple, DJ A 'harm reduction' model for community pharmacy. *Chemist-and-Druggist* 1996:245:730-731
33. Cone EJ. Ephemeral profiles of prescription drug and formulation tampering: Evolving pseudoscience in the internet. *Drug and Alcohol Dependence* 2006 ; 83(S1) S31-S39
34. [www.drugmisuse.isdscotland.org](http://www.drugmisuse.isdscotland.org)
35. Dept of Health Annual Report to European Monitoring Centre for Drugs and Addiction 2005
36. [www.emcdda.europa.eu](http://www.emcdda.europa.eu)
37. [Compton WM](#), [Thomas YF](#), [Stinson FS](#), [Grant BF](#). Prevalence, correlates, disability, and comorbidity of DSM-IV drug abuse and dependence in the United States: results from the national epidemiologic survey on alcohol and related conditions [Arch Gen Psychiatry](#). 2007 May;64(5):566-76.
38. Sheridan J, Butler R, Wilkins C, Russell B. Legal piperazine-containing party pills - a new trend in substance misuse *Drug and Alcohol Review*, 26:3, 335 - 343
39. [www.wales.gov.uk](http://www.wales.gov.uk)

**Biog details about the author of expert report:**

Christine E. Heading PhD, BSc, M.R.Pharm.S

Dr Heading is a pharmacist and pharmacologist with a background in academia and the pharmaceutical industry. Her principal expertise is in the central nervous system, and she has worked in the fields of drug dependence, drug tolerance, and pharmacokinetics for many years. Between 1970 and 2007 she has published more than 50 articles in these broad subject areas.

Since 2000 she has been an Associate Lecturer at the Open University, with a particular involvement in interdisciplinary courses specialising in addiction and in the neurobiological basis of psychology. Additionally she works freelance for scientific publishers and the pharmaceutical industry, with a focus on the development of new drugs and medicines.

Between 2001–2003 and 2006-2007 she was president of the UK National Association of Women Pharmacists, and is a member of its national Executive Committee. She is a member of the British Pharmacological Society and the UK Psychiatric Pharmacists Group.

Address for contact:  
11 Kingsend, Ruislip, Middx HA4 7DD.  
[moore11@globalnet.co.uk](mailto:moore11@globalnet.co.uk)

## Appendix

### Lexicon of alcohol and drug terms published by the World Health Organization

[http://www.who.int/substance\\_abuse/terminology/who\\_lexicon/en/](http://www.who.int/substance_abuse/terminology/who_lexicon/en/)

**abuse** (drug, alcohol, chemical, substance, or psychoactive substance) A group of terms in wide use but of varying meaning. In DSM-III-R\*, "psychoactive substance abuse" is defined as "a maladaptive pattern of use indicated by ...continued use despite knowledge of having a persistent or recurrent social, occupational, psychological or physical problem that is caused or exacerbated by the use [or by] recurrent use in situations in which it is physically hazardous". It is a residual category, with dependence taking precedence when applicable. The term "abuse" is sometimes used disapprovingly to refer to any use at all, particularly of illicit drugs. Because of its ambiguity, the term is not used in ICD-10 (except in the case of non-dependence-producing substances- see below); harmful use and hazardous use are the equivalent terms In WHO usage, although they usually relate only to effects on health and not to social consequences. " Abuse" is also discouraged by the Office of Substance Abuse Prevention (OSAP, now CSAP - Center for Substance Abuse Prevention) in the USA, although terms such as "substance abuse" remain in wide use in North America to refer generally to problems of psychoactive substance use.

\* Diagnostic and statistical manual of mental disorders, 3rd ed.(revised).Washington, DC, American Psychiatric Association,1987.

In other contexts, abuse has referred to non-medical or unsanctioned patterns of use, irrespective of consequences. Thus the definition published in 1969 by the WHO Expert Committee on Drug Dependence was "persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice"\*(see, misuse drug or alcohol).

\*WHO Expert Committee on Drug Dependence. Sixteenth report. Geneva, World Health Organization ,1969 (WHO Technical Report Series, No.407

**abuse liability** The propensity of a particular psychoactive substance to be susceptible to abuse, defined in terms of the relative probability that use of the substance will result in social, psychological, or physical problems for an individual or for society. Under international drug control treaties (see conventions, international drug) WHO is responsible for determining the abuse liability and dependence potential, as distinct from therapeutic usefulness, of controlled substances. *See also:* abuse; dependence potential; harmful use

abuse of non-dependence-producing substances (F55) Defined in ICD-10 as repeated and inappropriate use of a substance which, though the substance has no dependence potential, is accompanied by harmful physical or psychological effects, or involves unnecessary contact with health professionals (or both). This category might more appropriately be termed "misuse of non- psychoactive substances" (*compare* misuse, drug or alcohol). In ICD-10, this diagnosis is included within the section "Behavioural syndromes associated with physiological disturbances and physical factors" (F50-F59).

A wide variety of prescription drugs, proprietary (over-the-counter) drugs, and herbal and folk remedies may be involved. The particularly important groups are

(1) psychotropic drugs that do not produce dependence, such as antidepressants and neuroleptics;

(2) laxatives (misuse of which is termed the "laxative habit");

(3) analgesics that may be purchased without medical prescription, such as aspirin (acetylsalicylic acid) and paracetamol (acetaminophen);

(4) steroids and other hormones;

(5) vitamins; and

(6) Antacids.

These substances do not typically have pleasurable psychic effects, yet attempts to discourage or forbid their use are met with resistance. Despite the patient's strong motivation to take the substance, neither the dependence syndrome nor the withdrawal syndrome develops. These substances do not have dependence potential in the sense of intrinsic pharmacological effects, but are capable of inducing psychological dependence.

## **Annex 2**

In 2005, in a joint decision between the Medicines and Healthcare products Regulatory Agency (MHRA) and the over-the-counter medicines industry it was voluntarily agreed that strengthened warnings, about the possible risk of addiction or medication overuse headache due to inappropriate use, was added onto packs of painkillers which contain codeine and dihydrocodeine. As a result, the additional warnings appear on the packs of painkillers which contain codeine and dihydrocodeine are as follows:

- If you need to use this medicine for more than three days at a time, see your doctor, pharmacist or health care professional.
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.