

How and why are non-prescription analgesics used in Scotland?

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Background. UK Government policy increasingly encourages self-care of minor illnesses, including self-medication. Analgesics constitute a quarter of UK over-the-counter medicines sales, but concerns have been expressed about their potential for inappropriate use.

Objectives. To estimate the prevalence of recent use of non-prescription analgesics in Scotland, to describe by whom they are used, and to estimate inappropriate use.

Method. A cross-sectional postal survey consisting of a self-completed questionnaire that collected data on respondents' use of non-prescription and prescription medicines, as well as demographic and lifestyle data. The sample comprised 2708 subjects of 18 years and over, randomly selected from the Scottish electoral roll.

Results. The response rate was 55% ($n = 1501$). Some 37% (555/1501) of respondents had used a non-prescription analgesic in the previous two weeks. Analgesics accounted for 59% (636/1081) of all non-prescription medicines used in that period. After controlling for all other variables, age, sex, level of education, self-reported health status, prescription exemption status, and use of prescription analgesics, remained significant predictors of non-prescription analgesic use. There was evidence of possible inappropriate use of non-prescription analgesics including use of multiple analgesics ($n = 67$), use by individuals self-reporting conditions associated with cautious use of certain analgesics ($n = 51$), and potential drug–drug interactions ($n = 15$). A few respondents appeared to be using non-prescription analgesics to supplement medical treatment of chronic conditions ($n = 4$).

Conclusions. Our findings have demonstrated a high level of use of non-prescription analgesics amongst the general public, with significant potential for inappropriate use. As we move towards a culture of increased self-management of minor illness, this demonstrated need for improved pharmacovigilance of non-prescribed medicines must be addressed.

Keywords. Analgesics, pharmacoepidemiology, primary care, non-prescription drugs.

Introduction

Government policy in the UK encourages self-care of minor, self-limiting illnesses.^{1–3} This policy is supported by the continued re-classification of many drugs previously restricted to prescription-only use, allowing them to be purchased over-the-counter (OTC). However, the move towards increased self-care needs to be carefully assessed. Patients should not be exposed to increased risk through inappropriate use of non-prescribed medicines, or because symptoms or signs of serious conditions that require medical attention are misinterpreted as being trivial or self-limiting. To inform the appropriate self-management of minor illness, we

need to know more about: the extent and nature of current self-management practices; what influences patients when choosing between self-care and care based on advice sought from health professionals; the public's perception of risk when self-treating minor illness; what sources of information people use when practicing self-care and how accessible they are.

Analgesics constitute a significant proportion of OTC medicine sales—in the UK, 24% of the total £1.7 billion sales in 2001.⁴ Until now, there has been little research about non-prescribed analgesics in the UK. Most published pharmacoepidemiological studies on analgesic use have been carried out in Scandinavia and North America,^{5–9} but few studies have attempted to estimate whether non-prescription analgesics are being used in an appropriate way.

Concerns have been expressed about the potential for inappropriate use of non-prescription analgesics, although the extent of the problem is unknown.¹⁰ In the UK,

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analgesics that can be purchased without prescription are paracetamol, aspirin, and ibuprofen, with some products also containing low dose opiates such as codeine phosphate. Serious side effects could arise from the inappropriate use of such analgesics, for instance through use when contraindicated or through drug–drug interactions. Previous preliminary work has shown that non-prescription analgesics are not always used optimally, with evidence of drug interactions, excessive dosing, and instances of contraindicated use.¹¹ The consequences of these might be compounded if GPs do not consider use of non-prescription drugs when seeing patients,^{12–14} and patients do not volunteer such information.^{12,13}

In order to estimate across Scotland the prevalence of recent use of non-prescription analgesics, the characteristics of their users, and their patterns of medicine use, we have recently completed a large cross-sectional postal survey.

Methods

The postal questionnaire was developed from preliminary work examining the use of ibuprofen amongst pharmacy customers.¹¹ It asked about any use of non-prescription medicines [defined as ‘those which you have bought over-the-counter from a pharmacy (chemist), supermarket or garage, over the internet or from another retail outlet. They might also have been given to you by someone else (e.g. family member, friend)’] within the previous two weeks. For non-prescription analgesics, information was also collected on frequency of use, source of supply, and reasons for choosing this source. Other data collected included age, gender, marital status, education, smoking and alcohol use, exemption status for prescription fees, postcode [to estimate socio-economic status between 1 (most affluent) and 7 (least affluent)],¹⁵ self-perceived health status, selected medical history, and current use of prescription medicines.

The questionnaire was piloted on 300 adults randomly selected from a list compiled by a commercial sampling organization, from the Scottish electoral roll (maximum one name per household). The local research ethics committee advised that no ethical approval was required. Changes were incorporated into the final version (available at www.abdn.ac.uk/general_practice/research/drugs.hti). The questionnaire (and a reply-paid postage envelope) was mailed to another 3000 people randomly identified from the same list. Up to two reminders were sent to non-respondents. The survey was carried out between February and April 2002.

The Statistical Package for Social Sciences (SPSS) was used for data entry and analysis. In the descriptive analysis, the χ^2 test was used to examine univariate associations between categorical variables and use of non-prescription analgesics. Factors found to be statistically

significant ($P < 0.05$) were entered into a logistic regression model to produce unadjusted odds ratios. A stepwise procedure was then used to determine which of these factors were independently related to use of non-prescription analgesics (multi-adjusted odds ratios).

A template was drawn up to identify circumstances where use of certain non-prescription analgesics might need extra caution, or would cause concern. Such circumstances include: interactions between oral non-prescription analgesics and other drugs, classified in the British National Formulary¹⁶ as ‘potentially hazardous’, for example concurrent use of ibuprofen and diuretics; use of non-prescription non-steroidal anti-inflammatory drugs (NSAIDs) in the elderly; concurrent use of more than one analgesic, including those obtained on prescription (may indicate poor control of pain); conditions associated with contra-indicated or requiring cautious use of non-prescription analgesics (see Table 4 for full details). The template was used to identify all cases where one or more of these circumstances appeared to exist.

Results

Response

Of the 3000 people sent a questionnaire, 292 were excluded because the recipient was not known at the given address ($n = 257$), had died ($n = 28$), was no longer resident in Scotland ($n = 6$), or was under 18 years of age ($n = 1$). The corrected response rate was 55% ($n = 1501/2708$).

Compared to other statistics about the population of Scotland,^{17,18} the respondent group had fewer males, younger people, smokers, drinkers of alcohol, and people living in more affluent areas (Table 1). The differences however, tended to be relatively small.

Recent use of non-prescription analgesics

Almost 45% of respondents ($n = 673$) had used a non-prescription medicine of any type in the previous two weeks. Analgesics were the most commonly used non-prescription medicines; 37% ($n = 555$) of respondents had used a total of 636 recognised analgesic products, 59% of all non-prescription medicines used in the previous two weeks (Table 2).

The χ^2 test and unadjusted odds ratios indicated that some groups were more likely to have recently used non-prescription analgesics than others (Table 3). Thus, younger people, women, more educated people, alcohol users, those with good or very good health, those in more affluent socio-economic groups, people who pay for their prescriptions, and those not receiving prescription analgesics were more likely to be users of non-prescription analgesics. There was no significant association between use of non-prescription analgesics and smoking status. All significant factors were then entered into a multiple logistic regression model. Factors that remained

TABLE 1 Characteristics of respondents to the survey, compared with national statistics for Scotland

(n = 1501)	Survey respondents %(n)	Statistics for Scotland %
Sex		
Male	43 (648)	48 ^a
Female	56 (848)	52
Missing/invalid	1 (5)	–
Age range		
18–19	1 (12)	3 ^a
20–29	10 (145)	17
30–39	20 (306)	20
40–49	20 (298)	18
50–59	16 (245)	16
60–69	16 (239)	12
70+	16 (240)	14
Missing/invalid	1 (16)	–
Smoking		
Smoker	27 (411)	35 ^b
Never-smoker	44 (657)	38
Ex-smoker	27 (406)	27
Missing/invalid	2 (27)	–
Alcohol		
Yes	74 (1109)	90 ^b
No	24 (360)	10
Missing/invalid	2 (32)	–
Deprivation category		
Carstairs deocat ^c 1	6 (98)	9 ^d
2	15 (224)	17
3	21 (310)	23
4	25 (374)	23
5	15 (227)	12
6	9 (144)	10
7	6 (85)	6
Missing	3 (39)	–

Scottish data:

^a General Register Office Scotland—Population estimates for 2000.

^b Scottish Household Survey 1999.

^c Carstairs V, Morris R. Deprivation and Health in Scotland. *Health Bulletin* 1990; **48**: 162–175.

^d McCloone P, Buddy FA. Deprivation and mortality in Scotland, 1981 and 1991. *Br Med J* 1994; **309**: 1465–1470.

significant independent predictors of non-prescription analgesic use were age, sex, education level, health status, exemption status from prescription fees, and use of prescription analgesics.

The most common reason given for using non-prescription analgesics was to treat headache or migraine (59%, $n = 325$), followed by treatment of cold or flu symptoms (27%, $n = 151$), back pain (14%, $n = 77$), and joint pain (13%, $n = 70$). Of the 636 non-prescription analgesic products used in the previous two weeks, 43% were paracetamol alone ($n = 274$), 23% ibuprofen ($n = 150$), and 18% paracetamol in combination with other ingredients ($n = 116$).

When asked why they had chosen the last analgesic used, almost half of recent users said that they had used it before for a similar problem (49%, $n = 273$), and

two-fifths said that it was because they already had some of the analgesic available at home (39%, $n = 215$).

Nineteen percent of respondents ($n = 278$) reported taking prescription analgesics in the two weeks prior to completing the questionnaire. Just over half of respondents (51%, $n = 772$) had used an analgesic of some type during the previous two weeks, with 4% ($n = 61$) of the population using both prescribed and non-prescribed analgesics (Fig. 1).

Possible inappropriate use of non-prescription analgesics

A total of 146 instances of possibly inappropriate use were identified amongst 21% ($n = 115$) of non-prescription analgesic users (Table 4). Sixty-seven people used more than one analgesic in the two-week period and 17 of these used more than one paracetamol-containing product, 12 of which used both prescribed and non-prescribed preparations. Twelve respondents used more than one NSAID, in all cases both prescribed and non-prescribed preparations. Some 51 individuals (3% of all respondents) were identified as using NSAIDs in circumstances that would normally require caution, i.e. self-reported history of asthma, gastrointestinal ulcer, renal or hepatic impairment or allergy to aspirin.

Seventy-two respondents (13% of recent users) said that they used non-prescription analgesics continuously (i.e. every day). In most cases, this appeared to be a short-term situation, for example while treating a cold, although 16 respondents (3%) reported using non-prescription analgesics long-term (for several years or for an indeterminate period) to treat chronic conditions such as back or joint pain. Four of these individuals were also using prescription analgesics to treat the same or similar conditions (Fig. 1).

Source of analgesics

Respondents were asked where they usually obtained analgesics from (either non-prescription or prescription) and the reasons why they chose this source of supply. Valid responses were obtained from 1357 subjects, of whom 154 reported never obtaining analgesics. The most common source of analgesics was OTC from a community pharmacy (44%, $n = 530$), most often because of convenience (40%, $n = 211$) (Table 5). Free text responses indicated that respondents interpreted convenience in terms of geography i.e. proximity to home, work, GP surgery etc. Availability of advice from pharmacy staff was also seen as important to many respondents. Convenience was the most important reason for choosing to obtain analgesics from supermarkets and other retail outlets. Most of those who obtained analgesics from their doctor did so because they had a problem requiring medical consultation, because they preferred to get advice from their doctor about the use of analgesics, or because the analgesics were only available on prescription.

TABLE 2 Proportions (and numbers) of respondents using non-prescription medicines in the previous two weeks, and the distribution of preparations used

	Respondents using non-prescription medicines ^a % (n) of all respondents, n = 1501	Distribution of non-prescription medicines used % (n) of all non-prescription medicines, n = 1081
Analgesics (e.g. paracetamol, ibuprofen, aspirin, compound preparations)	37 (555)	59 (636)
Dietary supplements (e.g. vitamins, minerals, fish oils, garlic)	8 (117)	17 (189)
Complementary products (e.g. echinacea, glucosamine, ginkgo biloba, St John's Wort)	4 (65)	8 (88)
Gastrointestinal products (e.g. antacids, laxatives, anti-diarrhoeals)	4 (57)	6 (63)
Topical preparations (e.g. emollients, antiseptics, antifungals, rubefacients)	4 (55)	6 (61)
Cold/flu treatments (e.g. cough mixtures, decongestants, sore throat treatments)	2 (34)	3 (36)
Antihistamines	1 (7)	1 (7)
Nicotine replacement therapy	0.1 (1)	0.1 (1)
None	55 (828)	–

^a Some respondents used more than one non-prescription medicine, hence percentages do not add up to 100.

We found no statistically significant difference in the frequency of cases of possible inappropriate use of analgesics between respondents using different sources of supply. Forty-one cases of possible inappropriate use were identified amongst those who usually obtained analgesics from a pharmacy (41/530, 8%). A similar percentage of such cases were identified amongst those who usually obtain analgesics on prescription (19/240, 8%), and those who obtain analgesics from sources where professional health advice is not available (35/433, 8%).

Discussion

Study strengths and limitations

This study was conducted on a large, national sample representing a broad range of ages and socio-economic groups. Non-prescription medicines from all possible sources of supply were included.

The proportion of respondents in our survey differed from national statistics^{17,18} in terms of age, gender, smoking and drinking habits, and socio-economic status, however the absolute differences were relatively small. This suggests that our sample was broadly representative of the general population of Scotland. We were however, unable to compare directly the characteristics of respondents and non-respondents since our sample was from the electoral roll. With a relatively modest response rate of 55%, bias may have affected some of our findings, although low response rates do not automatically indicate the presence of bias.^{19,20}

Previous work has shown that people may be more likely to respond to questionnaires that they perceive as personally relevant.^{21,22} If this were the case here, our results may indicate a higher prevalence of non-prescription drug use than is the case in the general population.

The information collected through the postal survey was not sufficient to unequivocally identify clinically significant cases of inappropriate non-prescription analgesic use. Such cases probably need clinical review for validity. The cases described in this paper are those regarded as potentially hazardous by the British National Formulary, and those considered by ourselves to be most likely to lead to adverse events. Some might however be regarded as clinically insignificant when assessed by clinicians. Conversely, further cases of inappropriate use of non-prescription analgesics may exist that have been missed by the identification procedure used in this study. Reasons for this could be that some events are potentially less serious (and therefore not included in the template used to identify possible inappropriate use), or that respondents provided incomplete information about their medication.

Study findings and the existing literature

While several published studies have reported data concerning the prevalence of use of prescribed and, to a lesser extent, non-prescribed analgesics, few have considered the potential for inappropriate use of non-prescribed analgesics. Wherever possible, we compare our findings to similar studies from the literature, and

TABLE 3 Associations between use of non-prescription analgesics in the previous two weeks and various characteristics of the respondents

Variable	Users:non-users of non-prescription analgesics <i>n:n</i> (% users in group)	Unadjusted odds ratios ^a	95% CI	Multi-adjusted odds ratios ^b	95% CI
Age					
Under 60 years	444:562 (44)*	2.70	2.11–3.46	1.52	1.05–2.20
60 years and above	108:369 (23)	1.00			
Sex					
Male	208:440 (32)*	1.00			
Female	347:501 (41)	1.47	1.18–1.82	1.70	1.33–2.18
Marital status					
Married/living with partner	340:513 (40)**	1.32	1.07–1.64	–	–
Other	213:425 (33)	1.00			
Education					
Less than O-level	150:393 (28)*	1.00			
O-level or better	348:433 (45)	2.11	1.66–2.66	1.47	1.12–1.94
Alcohol status					
Does not drink alcohol	97:263 (27)*	1.00			
Drinks alcohol	448:661 (40)	1.84	1.41–2.39	–	–
Self-reported health status					
Excellent	43:105 (29)*	1.00			
Very good or good	417:596 (41)	1.71	1.17–2.49	1.94	1.28–2.94
Fair or poor	88:224 (28)	0.96	0.62–1.48	2.01	1.20–3.36
Deprivation category					
1	49:49 (50)***	2.69	1.45–5.01	–	–
2	83:141 (37)	1.59	0.92–2.75	–	–
3	123:187 (40)	1.77	1.04–3.01	–	–
4	128:246 (34)	1.40	0.83–2.37	–	–
5	79:148 (35)	1.44	0.83–2.49	–	–
6	53:91 (37)	1.57	0.87–2.82	–	–
7	23:62 (27)	1.00			
Prescription fee exemption status					
Does not pay prescription fee	198:522 (28)*	1.00			
Pays prescription fee	355:412 (46)	2.27	1.83–2.82	1.55	1.10–2.13
Use of prescription analgesics					
Yes	61:217 (22)*	1.00			
No	494:729 (40)	2.41	1.78–3.27	2.17	1.49–3.14

^a Factors found to be significant on univariate analysis (χ^2 test) were individually entered into a logistic regression model to produce unadjusted odds ratios.

^b Stepwise procedure was employed to produce multi-adjusted odds ratios.

* $P \leq 0.001$; ** $P \leq 0.05$; *** $P \leq 0.01$ (linear trend).

consider the possibility that non-prescription analgesics constitute a significant risk amongst users.

At 37%, the prevalence of recent use of non-prescription analgesics was much higher in this study than the 6% suggested by a survey carried out by the Proprietary Association of Great Britain in 1997.²³ Other international studies using the same time frame (non-prescription analgesic use within the previous two weeks) have reported prevalences of 25%²⁴ and 41%.²⁵

Our finding of different use of non-prescription analgesics amongst particular groups is also consistent with the results of others. Women are more likely to use non-prescription medicines in general,^{26,27} and analgesics in particular^{5,6,8,24,28} than men. Better educated people have been found to be more likely to

use non-prescription medicines.^{27,29} The finding of a greater use of non-prescription medicines, including analgesics, amongst younger people (under 60 years) is consistent with some studies^{24,26} but not others.^{6,8,27,28}

Several studies have shown an association between poor health and increased use of non-prescription medicines^{26,27} or analgesics²⁸ (where no distinction was made between prescribed and non-prescribed analgesics). One Swedish study reported that poor health was associated with increased use of prescription but not non-prescription analgesics.²⁴ In this study after multiple adjustment, respondents whose self-reported health status was 'good or very good' or 'fair or poor', were twice as likely to use non-prescription analgesics as those reporting 'excellent' health. However, there was

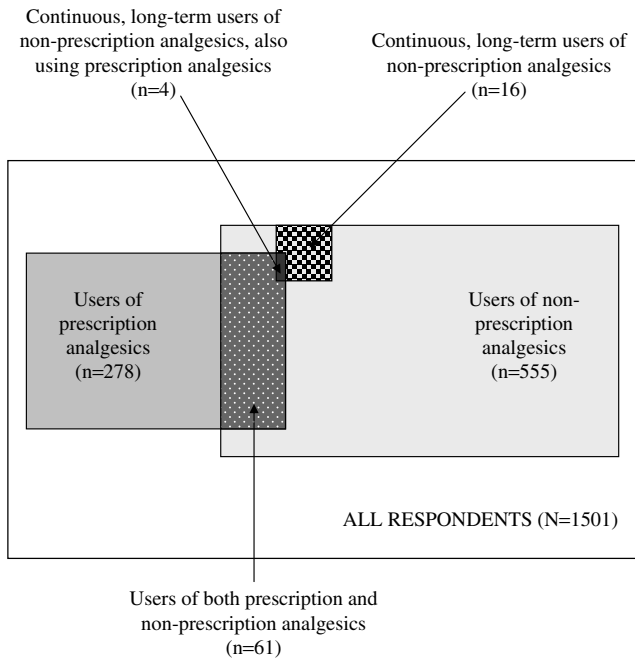


FIGURE 1 Diagram showing the distribution of users of non-prescription and prescription analgesics within the respondent group

TABLE 4 Cases of possible inappropriate use of non-prescription analgesics

Users of non-prescription analgesics who:	Non-prescription analgesics implicated	Cases identified
Were also using:		
Other analgesics/NSAIDs	Aspirin, ibuprofen, paracetamol	67
H2 antagonists/proton pump inhibitors	Aspirin, ibuprofen	8
Diuretics	Ibuprofen	7
Low dose aspirin (cardiovascular) ^a	Aspirin, ibuprofen	5
ACE inhibitors	Ibuprofen	2
Sulphonylureas	Aspirin, ibuprofen	1
Self-reported the following conditions:		
Asthma	Aspirin, ibuprofen	31
Gastro-intestinal ulcer	Aspirin, ibuprofen	10
Renal/hepatic impairment	Aspirin, ibuprofen, paracetamol	8
Allergy to aspirin	Aspirin, ibuprofen	2
Were 70 years or over:		
	Aspirin, ibuprofen	5
	Total cases	146

^a In cases where respondents specified that aspirin was used for 'cardiovascular' reasons e.g. 'to thin the blood', this was not classed as an analgesic. However, use of low dose aspirin concurrently with aspirin or ibuprofen was considered potentially inappropriate because of the increased risk of dose-related adverse events.

little difference in the use of non-prescription analgesics between respondents whose self-reported health status ranged from very good to poor.

Other studies, both in the UK and abroad, confirm our findings that analgesics are the most commonly used non-prescription medicines,^{23,25,27,30} that paracetamol is the most commonly used non-prescription analgesic,^{5,23,31} and that headache is the condition most frequently treated using non-prescription analgesics.²³

Some evidence of inappropriate use of non-prescription analgesics was found. Sixty-seven people (4% of all respondents) reported using multiple analgesics in the two-week period, although we do not have exact details of how they were using them. While knowledgeable users could conceivably use two analgesics concurrently in a safe manner, our findings suggest that some people may be placing themselves at risk, for example, the 12 cases using more than one NSAID and the 17 cases where multiple paracetamol products were being used. Concerns have been expressed about the potential for harm caused by intentional or unintentional overdose with paracetamol, although the true extent of poisoning through accidental incorrect dosing is not known.³²

That 11% ($n = 61$) of all non-prescription analgesic users were simultaneously using prescription analgesics is consistent with a previous study.²⁷ Of these, four individuals were continuously using non-prescription analgesics, on what appeared to be a long-term basis, for a condition similar to that being treated by the prescription analgesic. This suggests that a small proportion of non-prescription analgesic users may be supplementing medical treatment of chronic conditions, possibly without the knowledge of their doctor.

Our finding that 3% of the population appear to be using NSAIDs in circumstances that would normally require caution is of some concern. Clearly, not all the cases we identified are likely to lead to important clinical events. Nevertheless, we suggest that it would be advisable for clinicians to at least be aware of non-prescription medicine use when assessing individuals in the consulting room. It is of interest to note that the risk of inappropriate use appears to be similar, regardless of where users normally obtain their analgesics. However with 8% of the population apparently at risk from a potential adverse event, the case for improving pharmacovigilance of non-prescribed analgesics is a strong one.

The main influencing factor when choosing a source of analgesics was convenience, although cost and availability of advice were also important. While this is unsurprising, further investigation is required to attain a better understanding of the relative importance of factors associated with the term 'convenience', such as geographical proximity, hours of availability or waiting times to access health professional advice. It is also important to know if patients consciously trade between convenience and other aspects of obtaining

TABLE 5 Respondents' usual source of analgesics and reasons for choosing this source

(n = 1203)	% (n) of all respondents	Most common reasons for choice of source ^a			
		Convenience	Cost	Advice	Prescription/consultation required
OTC from pharmacy	44 (530)	40 (211)	4 (19)	22 (119)	–
Supermarket	26 (318)	77 (245)	16 (51)	–	–
Prescription from doctor/dentist/nurse	20 (240)	3 (8)	3 (8)	29 (69)	28 (68)
Corner/local shop	6 (67)	72 (48)	6 (4)	–	–
Someone else usually gets them for me	2 (26)	65 (17)	8 (2)	–	–
Other	1 (13)	–	–	–	–
Garage/petrol station	1 (9)	44 (4)	–	–	–

^a Not all respondents gave reasons for their choice of source, hence rows do not add up to 100%.

non-prescription analgesics which might influence safe usage, such as access to advice.

Implications for future work

This is the most comprehensive published survey of non-prescription analgesic use in the UK to date. Many findings are consistent with research in other countries. We have identified some potential risks associated with the use of non-prescription analgesics by the general public. As we move towards a culture of greater self-care, the range of non-prescribed drugs available and the number of people using them will increase. Our findings emphasize the previously recognized need for continued and improved pharmacovigilance of non-prescribed medicines.³³ Future work should include assessments of the extent of inappropriate use of other non-prescription medicines, methodological work into the pharmacovigilance of medicines sold in general sales outlets, and research into methods for providing advice to the public when they access medicines in settings without direct health professional input.

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Conflicts of interest: none.

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