

Paracetamol pack size restriction: the impact on paracetamol poisoning and the over-the-counter supply of paracetamol, aspirin and ibuprofen

Christopher L. Sheen^{*·1}, John F. Dillon², D. Nicholas Bateman³,
Kenneth J. Simpson⁴ and Thomas M. MacDonald¹

¹Medicines Monitoring Unit, Ninewells Hospital, Dundee, Scotland, UK

²Department of Gastroenterology, Ninewells Hospital, Dundee, Scotland, UK

³Scottish Poisons Information Bureau, Royal Infirmary, Edinburgh, Scotland, UK

⁴Scottish Liver Transplant Unit, Royal Infirmary, Edinburgh, Scotland, UK

SUMMARY

Purpose Self-poisoning occurs with over-the-counter (OTC) drugs, particularly paracetamol (acetaminophen). In 1998, OTC pack sizes of paracetamol were reduced. We have studied the effect of this pack size restriction on OTC supply of paracetamol, aspirin and ibuprofen.

Methods IMS Health UK provided data on the UK sales of paracetamol, aspirin and ibuprofen. The total mass and number of packs of each drug supplied were compared for the years 1998, 1999 and 2000.

Results The mass of aspirin and paracetamol sold fell, that of ibuprofen increased. The number of paracetamol packs sold was unchanged, the analgesic dose of aspirin fell and ibuprofen supply increased.

Conclusions It seems that the paracetamol pack size reduction has not achieved as large an overdose rate reduction as might have been expected. Instead, a shift to the use of ibuprofen may lead to an increase in gastrointestinal adverse events and continue the burden on healthcare resources. Copyright © 2002 John Wiley & Sons, Ltd.

KEY WORDS — paracetamol; aspirin; ibuprofen; over-the-counter; poisoning

INTRODUCTION

Self-poisoning, using drugs either prescribed or purchased without a prescription (over-the-counter, OTC), including paracetamol (acetaminophen), is an increasingly common reason for hospital admission.^{1,2}

In September 1998 legislation was enacted to limit the number of tablets of paracetamol that could be

purchased OTC. Prior to September 1998 pharmacies could sell unlimited amounts of paracetamol, generally sold in packs of 100 and this was restricted to 32 tablets. Other outlets can sell up to 16 tablets. Since this restriction there has been a reduction in the number of paracetamol overdoses in England, Wales and Northern Ireland.^{3–6}

Aspirin has been available OTC since before 1970. In 1997 the pack size was limited to 16 tablets for sale from general outlets and 32 tablets from pharmacies. Ibuprofen has been available for sale OTC both from pharmacies since 1983 with a maximum pack size of 32 tablets and other outlets since 1996. Until March 1999 the maximum number of tablets per pack that could be sold in general stores was 12, 400-mg tablets. It is now 16, 400-mg tablets per pack. However, under a

* Correspondence to: Dr C. L. Sheen, Clinical Research Fellow, Department of Clinical Pharmacology, Ninewells Hospital and Medical School, Dundee DD1 9SY, Scotland, UK. Tel: +44 (0) 1382 660111 ext. 33452. Fax: +44 (0) 1382 644972. E-mail: chris@memo.dundee.ac.uk

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pharmacist's supervision larger numbers of tablets may be sold.

This paper examines the OTC supply of paracetamol, aspirin and ibuprofen and the impact of the paracetamol pack size restriction in 1998 on the OTC sale of these drugs.

METHODS

IMS Health is a commercial company that supplies census data on OTC drug sales from wholesalers into pharmacy and grocers in the UK and Northern Ireland. Over 97% of the data are actual sales data from manufacturers and wholesalers. The remaining data is estimated from general practitioner and pharmacy panels to compensate for the small number of drugs prescribed in OTC packs and those drugs not obtained via the wholesale system (source: IMS Health UK National OTC Report December 2000 Dataset).

The data were provided as number and size of packs of paracetamol, aspirin and ibuprofen. Using the data from IMS Health, OTC sales of these drugs for the whole of the UK for the years 1998, 1999 and 2000 were obtained as grams of drug. The numbers of packs of paracetamol 500 mg, ibuprofen 200 mg and 400 mg and aspirin 75 mg and 300 mg tablets supplied were also totalled.

RESULTS

Table 1 shows the mass of paracetamol, aspirin and ibuprofen supplied in 1998, 1999 and 2000. The numbers of packs supplied OTC, in sizes for general and pharmacy sale, are shown in Table 2.

Paracetamol

The total amount of paracetamol supplied OTC has fallen. In 1999, 48.5% as much paracetamol by mass was sold as in 1998, a time when the amount of paracetamol in each pack was reduced. In 2000 the OTC

Table 1. United Kingdom OTC supply of analgesic doses of paracetamol, aspirin and ibuprofen (in grams)

	1998	1999	2000
Total annual OTC supply in UK (g)			
Paracetamol	409 054 172	198 566 850	166 456 260
Aspirin	66 465 780	21 943 740	15 448 710
Ibuprofen	26 453 320	29 616 100	45 929 400

Table 2. Number of packs (thousands) of paracetamol, aspirin and ibuprofen sold over the counter in the United Kingdom

	1998	1999	2000
Paracetamol (500 mg)			
≤16 tablets	1061.4	1935.3	1781.6
>16 and ≤32 tablets	4564	11283	9236.1
100 tablets	5633.8	0	0
Total packs	11259.2	13218.3	11017.7
Ibuprofen 200 mg			
≤16 tablets	4157.2	3556.8	4608.1
>16 and ≤32 tablets	878.6	606.2	648.6
>32 tablets	483.1	496.9	424.2
<i>Subtotal</i>	<i>5518.9</i>	<i>4659.9</i>	<i>5680.9</i>
400 mg			
≤16 tablets	2	1.3	69.5
>16 and ≤32 tablets	646.5	643.8	927.2
>32 tablets	0.1	178.4	649.3
<i>Subtotal</i>	<i>648.6</i>	<i>823.5</i>	<i>1646</i>
Total packs	6167.5	5483.4	7326.9
Aspirin 75 mg			
≤16 tablets	0.5	6.6	8.5
>16 and ≤32 tablets	892.2	3043.8	4525.9
>32 tablets	1951.4	0	2.6
<i>Subtotal</i>	<i>2844.1</i>	<i>3050.4</i>	<i>4537</i>
300 mg			
≤16 tablets	195.8	282.8	218.8
>16 and ≤32 tablets	1242.5	2193.9	1514.1
>32 tablets	1946.4	0	0
<i>Subtotal</i>	<i>3384.7</i>	<i>2476.7</i>	<i>1732.9</i>
Total packs	6228.8	5527.1	6269.9

sales by mass fell further to 40.7% of the 1998 supply. The total number of packs of paracetamol supplied for OTC use in 1999 increased but in 2000 the total number reduced to similar quantities as in 1998 in pack sizes available in both general stores and pharmacies. After 1998 no packs containing 100 tablets were supplied for OTC use.

Aspirin

There has been a fall in the total amount of aspirin supplied OTC; 33.9% as much aspirin by mass was supplied in 1999 as compared to 1998. In 2000 the OTC sales by mass fell further to 29.6% of the 1998 supply. The number of packs of low dose (75 mg tablets) supplied OTC has steadily increased from 1998 to 2000, whereas the supply of higher dose packs (300 mg) has fallen. At both doses almost all aspirin is now supplied in packs of 32 tablets or less.

Ibuprofen

Ibuprofen sales by mass were 112 and 173.6% of the 1998 OTC amount in 1999 and 2000 respectively. The number of packs of 200 mg-tablet size ibuprofen supplied fell between 1998 and 1999, but in 2000 the number of packs sold increased. The 400 mg-tablet size packs have steadily increased with the most marked increase seen in packs of more than 32 tablets.

DISCUSSION

Between 1998 and 2000, the pack size restrictions have had the effect of reducing the total mass of over-the-counter sales of paracetamol and aspirin with a concomitant rise in the mass of ibuprofen sold. As expected there has been a change in the number of paracetamol tablets per pack supplied following the change in licensing with the number of smaller packs increasing. The increasing OTC supply of the low dose (75 mg) of aspirin, used for cardiovascular prophylaxis, may reflect the increasing use of aspirin in the management of cardiovascular disease. At the analgesic dose of 300 mg the total number of packs sold over the counter decreased. OTC sales of ibuprofen have increased. This is seen particularly with the higher dose (400 mg). This may be due to its availability in larger pack sizes suggesting it may be being purchased in place of aspirin or paracetamol.

The paracetamol overdose rate in other studies has shown a mean reduction of 20% (95% confidence limits 1.7 to 39%).³⁻⁶ We have shown that the total mass of paracetamol sold OTC over the same period fell by 51.5%, although the number of packs sold did not change. The reduction in OTC supply by mass is considerably greater than any estimate of the fall in the number of overdoses. It might have been expected that with such a large fall in the mass of paracetamol sold OTC the number of paracetamol overdoses would have been reduced by more than 20%. This disproportionate change suggests that the reduced overdose rate may not be related directly to the pack size restrictions. The restriction has not been as effective in limiting the burden to the healthcare system of paracetamol overdoses as might have been anticipated or suggested by the change in mass of paracetamol sales. The more limited availability of paracetamol may have had a greater impact on those using the drug appropriately, for example, those with chronic pain conditions, making them purchase more packs or shift to using ibuprofen. A potential effect of a change to an increased use of ibuprofen is an increased risk of adverse events, in particular, gastrointestinal haemorrhage.

KEY POINTS

- Paracetamol pack sizes have been restricted for over-the-counter sale in the UK
- The pack size reduction has not reduced poisoning as much as might have been expected
- Ibuprofen supply has increased
- The paracetamol pack size restriction may have shifted analgesic use to ibuprofen, with an increased risk in adverse gastrointestinal events

CONCLUSION

The pack size restriction in September 1998 has reduced the total mass of paracetamol and aspirin sold over the counter whilst that of ibuprofen sold has increased. If this reduction in OTC supply of paracetamol was directly related to overdose, the rate reduction achieved would have been expected to be greater than observed. The shift to using ibuprofen may lead to an increase in adverse gastrointestinal events, and change the pattern of health burden from OTC analgesic supply in a way not expected by the instigation of the original licence change.

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