Starter packs: a good start to therapy?

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Summary

Samples of drugs are often given to doctors by pharmaceutical representatives as part of a marketing strategy. Despite the well described advantages of drug samples, little has been published on the potential adverse outcomes. A series of consumer calls to the Adverse Medicine Events Line has highlighted concerns regarding the quality use of medicines associated with drug samples. The most commonly reported problems were drug samples being supplied to patients with inadequate information regarding dosage, administration, storage and possible adverse effects. In addition, some patients were given excessive quantities of a drug. To reduce such adverse outcomes, the drug industry, health professionals and consumers should be aware of the potential problems associated with starter packs.

Key words: Adverse Medicine Events Line, consumer information, drug industry.

(Aust Prescr 2007;30:14–16)

Introduction

Starter packs are samples of drugs given to doctors by pharmaceutical representatives, often as part of a marketing strategy. Medicines Australia's Code of Conduct states that starter packs are '… a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists'.[1]

The pros and cons of starter packs

There are both advantages and disadvantages in the provision of starter packs. From a manufacturer's perspective, starter packs provide an avenue to introduce new or unique products to the marketplace. Evidence suggests that drug samples influence prescribing behaviour and increase prescribing of a particular product.[2,3,4,5] Advantages for doctors include being able to assess the efficacy or tolerability of new treatments and to provide immediate treatment such as antibiotics after hours. This is especially beneficial in remote or rural populations. Likewise, patients can try a new drug before having to pay for a prescription and may be able to access drugs that are not yet available on the Pharmaceutical Benefits Scheme (PBS).

These advantages must be weighed against significant, but less well described, disadvantages. These include unregulated supply and the potential for:

- use of expensive medicines when effective and less expensive alternatives are available[4,6]
- increased demand for drugs not listed on the PBS
- issue of expired or poorly stored stock[7]
- inability to track or recall the product[7]
- medicine issued without a label or accompanying consumer medicines information.[8]

Samples are big business. Marketing expenditure on drug samples by American pharmaceutical companies has increased annually since 1996, with a total estimated allocation of US$10.5 billion in 2001.[9] Yet a recent literature review identified only 23 papers that had studied the impact of sampling in any capacity. The primary focus of these studies was the influence of drug samples on prescribing behaviour. Very little has been published on the potential adverse outcomes associated with samples.[10]

Consumer calls to the Adverse Medicine Events Line

The Adverse Medicine Events Line is a national consumer hotline for reporting 'when things go wrong with medicines'. This two-year project, funded by the Australian Council for Safety and Quality in Health Care and operated by Mater Pharmacy Services, identified a series of calls from consumers where provision of starter packs by doctors resulted in either poor quality use of medicines or an adverse outcome. The motivation for these consumer calls was primarily inadequate drug information. None of the samples had been labelled, none was accompanied by consumer medicines information or simple written instructions regarding dosage, administration, indication, storage, possible interactions or adverse effects. The nature of these events and the related quality use of medicine problems are described in Table 1.

> Lack of information accompanying starter packs can cause medicine misadventure

Table 1

Patient reports of problems involving drug samples given without labelling or written information

Case	Problems
1. A 78-year-old male was given a rofecoxib sample (25 mg/day). A celecoxib prescription (200 mg/day) was given at the next visit. On the third visit, the patient took an empty starter pack of rofecoxib and asked for a refill.	Lack of documentation led to the doctor being unaware of the patient using both COX-2 inhibitors for one month. Patient was not aware that both medicines were for osteoarthritis.
2. A 75-year-old female was given a rofecoxib sample for osteoarthritis. She had no recollection of dosage or administration with regard to food.	Anxious patient had failed to initiate the starter pack. A previous reaction to an unrelated drug had heightened her anxiety.
3. A 66-year-old male was given pravastatin samples. No information was provided on dosage or administration with regard to food.	Patient did not commence medicine because of lack of counselling. He could not recall being given any information.
4. A 50-year-old female was given quetiapine samples. She rang to clarify the indication for the new medicine. She thought it was for pain relief since her consultation was for pain and her previous medicine was celecoxib.	Patient was unaware that she had been given an antipsychotic medicine and intended to commence quetiapine 'as required'.
5. A 47-year-old female rang because she had forgotten the dose of her new medicine. She had been given one month's supply of meloxicam samples at two doses (7.5 mg and 15 mg) for osteoarthritis.	One week treatment delay due to patient's concern with regard to lack of directions from the doctor and lack of medicines information or label.
6. A 53-year-old female was given a sample of 10 indapamide tablets.	Patient was unsure if she could drink alcohol with the new medicine.
7. A 32-year-old female was given multiple samples of fluoxetine (60 mg/day), clonazepam (4 mg/day) and quetiapine (200 mg/day).	Patient took the drugs for three weeks concurrently, before questioning how best to take them and what the potential adverse effects were.
8. A 50-year-old female was given one month's supply of fluoxetine samples for premenstrual tension.	Patient experienced insomnia, nausea, diarrhoea and palpitations and was unaware that these were probably drug-induced.
9. A 63-year-old male was given samples of imiquimod cream for solar keratosis.	Patient experienced severe erythematous lesions 48 hours later. He was concerned that the lack of consumer medicines information delayed him linking the symptoms with the new medicine.
10. A 48-year-old female was given a few glyceryl trinitrate tablets in a clear plastic specimen container after hospital discharge for a suspected heart attack. She was told to swallow half a tablet with water for chest pain.	Possible loss of drug efficacy due to incorrect information about its administration and storage.
11. A 28-year-old male was given four fluvoxamine starter packs to 'take the edge off'.	Patient did not take the drug due to inadequate medicines information. Large quantities of starter packs provided.
12. A 39-year-old male was given 80 risperidone tablets (2 mg) as samples.	Dose of half tablet daily equated to 160 days supply.
13. An 89-year-old female was given esomeprazole 40 mg samples to take twice daily. Written medicines information she obtained from another source gave different instructions (40 mg daily, reducing to 20 mg daily after one month). She was confused about correct dosing.	Patient did not want to start medicine until correct dose was clarified.

This series of cases shows that lack of information accompanying starter packs can cause medicine misadventure, specifically:

- increased patient anxiety
- treatment delay
- unintended doubling-up of similar medicines
- inadvertent use of two strengths of the same medicine
- inappropriate use due to patient confusion.

In addition, this case series highlighted the fact that some patients were being given excessive quantities of a drug. With starter packs, there is also an increased potential for medication error when the same health professional prescribes, dispenses and possibly administers the drug without any checks on the process.

Regulation of starter packs

The provision of starter packs by primary health carers requires that medicines be appropriately labelled and accompanied by consumer medicines information or equivalent. Failure to label starter packs contravenes some state and territory legislation. A legislative review[11] led to agreement that labelling of prescription starter packs will be regulated.[1] The feasibility of this remains to be determined.

Conclusion

To minimise medicinal misadventure, the drug industry, health professionals and consumers need to be aware of the potential consequences for the quality use of medicines when starter packs are provided.

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Conflict of interest: none declared

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