



14 January 2005

Response of the National Pharmaceutical Association to [ARM 26](#)

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 26 on proposals to raise the GSL pack size limit for Dulco-Lax tablets (bisacodyl 5mg).

We wish to raise the following concerns regarding the proposed increased availability of this product.

Role of the pharmacist

When Dulco-Lax tablets are supplied through a pharmacy, pharmacists and their staff will provide information to the patient that is important for the appropriate treatment of constipation. The long term use of stimulant laxatives has been reported to be associated with electrolyte disturbances and atonic colon. According to current Prodigy guidance chronic use of stimulant laxatives is therefore not recommended. Pharmacists and their staff are aware that laxatives are commonly abused and misused and will advise and question patients to ensure that the product will be used safely and appropriately. The sale may even be refused if the product is considered inappropriate for the patient. The chronic use of laxatives can also indicate the presence of underlying disease. In the pharmacy, the pharmacist and their staff will provide professional advice and prompt referral in the presence of any alarm symptoms. Such guidance will not be available in a non-pharmacy outlet. The pharmacist can also advise if the constipation may be aggravated by other medication, for example drugs such as analgesics that can cause constipation as a side effect. As patients consider constipation to be an embarrassing condition patients may decide to self treat without seeking medical advice and more serious conditions may be masked without the involvement of the pharmacist.

In addition lifestyle advice is important in the treatment and prevention of constipation. The pharmacist is able to offer advice on increasing fibre and fluid intake in the diet and self care to help prevent and treat constipation. This advice will not be available to patients who purchase the product without the pharmacist's supervision.

Convenience to the purchaser

We are not aware of any evidence which suggests that this product is difficult to access by the public and do not believe that patient care will be improved by the availability of an increased pack size of the GSL product. The long term implications and complications associated with inappropriate use of the product may increase the burden on healthcare rather than reducing it, due to continued long term use of the product rather than seeking professional advice.

Risk of misuse

In our opinion it is misleading to quote an independent report from 1992 on the incidence of laxative abuse and bisacodyl abuse. This report does not provide information on the levels of

laxative abuse in the UK today and is particularly misleading since Dulco-Lax only became a GSL medicine in 1990. Pharmacists and their staff currently help to restrict the misuse of laxatives by careful questioning of patients and monitoring of sales. In addition it is widely recognised that laxative abuse is under – reported. For example the Eating Disorders Association estimates that there are over a million people in the UK suffering from eating disorders, many of these will be using laxatives long- term.

Support for reclassification

Dulco-lax tablets are only indicated for the short term relief of constipation. In our opinion there is no clinical justification for a larger pack size to be made available as a GSL product. The current pack size of 20 tablets provides sufficient tablets for 10 days treatment. The availability of a larger pack size undermines the message that the product should only be used short- term. We believe that the increased availability of larger pack sizes of Dulco-lax is likely to increase the inappropriate use of this product and may lead to laxative abuse. A GSL product is freely available for purchase by any age group so the availability of a larger pack size may encourage misuse by teenagers, the age group most at risk of developing eating disorders.

We hope you take our comments on board.