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Original Research

General sale of non-prescription medicinal products: Comparing legislation in two European countries

Johanna Lind, M.Sc.[a], Ellen Schafheutle, Ph.D.[b], Annika Nordén Hägg, Ph.D.[a], Sofia Kälvemark Sporrong, Ph.D.[a,c,*]

[a]*Department of Pharmacy, Uppsala University, Box 580, S-751 23 Uppsala, Sweden*
[b]*Manchester Pharmacy School, The University of Manchester, Oxford Road, M13 9PT Manchester, UK*
[c]*Department of Pharmacy, University of Copenhagen, Universitetsparken 2, 2100 København Ø, Denmark*

Abstract

Background: The number of non-prescription medicines (NPMs) available for self-medication is increasing within the European Union (EU). This can enhance the autonomy of individuals but is also connected with risks. Under an existing EU Directive, Sweden has only recently deregulated and made NPMs available in non-pharmacy outlets; The United Kingdom (UK) is a more established NPM market; both are guided by the same EU directives.
Objective: The aim of this study was to compare specific requirements under the legislation, rationales and outcomes regarding the sale of NPMs through non-pharmacy outlets between Sweden and the UK.
Method: The main method was analysis of legislative text and policy documents, conducted in 2012.
Results: Both countries had specified medicines available to the public in non-pharmacy outlets, but with restrictions on different factors, e.g. placement and package size of the NPMs. The main rationales for legislation were quality and patient safety. NPMs for 51 ailments were available in the UK, compared to 35 in Sweden.
Conclusion: Sweden had more extensive requirements, probably due to the market being more recently deregulated, while the UK represented a more mature market. There is a difference in the balance between confidence and control, as well as availability and safety when it comes to NPMs in non-pharmacy settings that needs to be further discussed.

Keywords: Non-prescription medicines; Sweden; UK; EU directives; General sales medicines; Self-medication

Introduction

Pharmaceutical policy has been described as an on-going dynamic process with the overall goal to achieve rational drug usage. It is a global concern and therefore policymakers can learn from interventions made in other countries. The analysis of policies and their outcomes is one way of predicting the potential impacts of new policies.[1] Hence, it is important both to follow up changes in legislation, but also to compare different regulatory systems and their outcomes.

* Corresponding author. Department of Pharmacy, Section for Social and Clinical Pharmacy, University of Copenhagen, Universitetsparken 2, DK-2100 Copenhagen, Denmark. Tel.: +45 353 20009.
E-mail address: sofia.sporrong@sund.ku.dk (S.K. Sporrong).

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In the European Union (EU) directives should, in theory, give the same guidance to all member states. The purpose is to minimize conflicting regulatory decisions and instead harmonize them between the EU member states.[2] However, factors, such as different systems, traditions and customs, bring about varying needs for legislation.

NPMs are licensed medicines that are sold without a prescription; and for the purpose of this paper, they are defined as those NPMs available through non-pharmacy outlets. They are used for treating minor ailments for which patients are able to diagnose, treat and also evaluate outcomes. A trend of increasing the numbers of NPMs available for self-medication is seen all over Europe, and elsewhere.[3] This has the potential of reducing the cost burden on health care systems. Deregulation of a medicine to be sold without prescription can increase the autonomy and independency of individuals.[4,5] but is also connected with risks.[6]

An acceptable overall safety profile, including the lack of serious potential side effects, is essential for the deregulation of a medicine as an NPM. They must be appropriate for self-medication, without involvement of a prescriber, and the risks for abuse should be minimal.[7] All medicines might cause unwanted effects, and a drug sold without a prescription is not automatically harmless.[8,9] However, members of the public often consider NPMs to be less strong, and hence less dangerous than prescription-only medicines, a perception that can lead to the belief of NPMs being harmless.[10,11]

The use of NPMs by the public is associated with several potential risks. Examples are unawareness of drug–drug interactions[5] and contraindications.[12] It may also be that people who have not had their needs met by health care use self-medication as an alternative, which could be inappropriate.[13] If the patient's own diagnosis is incorrect it might lead to self-medication involving medical errors and prolonged time to get proper care, potentially impacting negatively on both the patient and the health care system.[5] Within the EU, member states are guided by the same main principles. However, the specific requirements under the legislation in the member states may differ.[14] Differences in the way this EU directive has been implemented have not yet been investigated, particularly one focusing on 2 countries, where this implementation was more recent, versus one where liberalization of the NPMs market is much more established.

Aim

The aim of this study was to compare similarities and difference between 2 countries; Sweden and the UK; in terms of legislation and practice regarding the sale of NPMs through non-pharmacy outlets. The study focused on the rationales, i.e. the motives of the legal requirement; the resulting and in some aspects specific legal requirements; and some of the practical outcomes.

Method

The settings

In 2008 and 2009 the Swedish pharmacy market was deregulated. Prior to the changeover NPMs were only sold in community pharmacies, where NPMs were available for self-selection but trained staff were available to provide pharmaceutical information. There was no age limit to sell NPMs, except for smoking cessation products for which customers had to be 18 years old.[15] After the regulatory change, some NPMs were made available for general sale, i.e. through non-pharmacy outlets.[16]

The UK, representing a more liberal and more established model of the NPM market,[17] has had a number of NPMs available for general sale for many years.[15] Legislation allowing the general sale of medicines has been in place since the Medicines Act in 1968,[18] with the latest, minor, changes in 2012.[19] Besides prescription only and general sales medicines, there is a third classification of Pharmacy medicines which are NPMs that can only be sold in community pharmacies under the supervision of a pharmacist.[18,19]

This study focuses specifically on those NPMs which are available for general sale, i.e. through non-pharmacy outlets.

Regulating documents

A documentary review was undertaken of actual primary and secondary legislation (acts and statutory instruments) relating to the availability and sale of NPMs in the 2 countries, together with other governmental, parliamentary and authority documents. The legislative documents and the rationale for these, encompassing information related to the general sale of NPMs in Sweden and in the UK respectively, were collected.

The general sale of NPMs in Sweden is regulated by The Swedish Code of Statutes: Law