

How pharmacy sales of OTC Medicines contribute to better public healthcare

Supporting Material

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Definitions

OTC Medicines. In the course of our research it became clear that there is no agreed definition of Over the Counter (OTC) medicines. For the purpose of this Paper, OTCs are defined as non-prescription medicines (NPMs) which the public can purchase from a licensed pharmacy and other non-pharmacy outlets (i.e. drug stores, petrol stations, etc.).

Pharmacy Medicines (P Meds). This definition will be new to some readers. Medicines in a P Med category are subject to stricter rules and sales criteria designed to ensure the public gets the most appropriate treatment for them. In addition P Med sales are conducted safely under the supervision of a pharmacist.

Some typical attributes of the P Med category

- This applies to the safe and professional sale of recognised medicine products or treatments as defined under national legislation.
- This is a product specifically referred to as a P Med in national legislation, for example, a product in a certain package / containing certain amount of pills / tablets.
- Medicines not the P Med category would be either prescription medicines, or non-medicinal products.
- If sold through an online pharmacy, strict questions and standards of sale will equally apply.
- A set of criteria typically applies to all P Med sales:
 - Sales conditions – Questions about whether the medicine was previously taken, symptoms, who the medicine is for etc.
 - Quantity criteria – Only one or two packs; for any more the pharmacist must use professional judgement
 - Display conditions – Not directly self-selectable without supervision, but can be displayed in the pharmacy in secure units
 - Safety conditions – P Meds will always include recently reclassified prescription medicines
 - Additional or fewer criteria may apply depending on the country in question.

For detailed examples please review the legislation applying to Pharmacy Medicines in the UK or Ireland.

General OTC safety concerns

Europe: A recent study on availability of paracetamol and reported enquiries to Poisons Information Centres found that:

'A significantly lower median frequency of paracetamol-related enquiries was found in countries without non-pharmacy outlet sales compared to those with such sales (median difference 2.2%, $p = 0.02$).'¹

Denmark: A recent study from Danish researchers found that the use of ibuprofen and other non-steroidal anti-inflammatory drugs (NSAIDs) was associated with increased health risks, including risk of cardiac arrest.²

Ireland: The pharmacy regulator (PSI) published updated guidelines for pharmacists in October 2017 on the safe supply of non-prescription medicines containing codeine, stating:

'The safety concerns around the misuse of non-prescription medicinal products containing codeine are well established. Consumption of quantities of these medicines in excess of the recommended dose, or over a prolonged period of time, may cause tolerance and dependence, as well as the risk of other adverse effects. Furthermore, the consumption of excessive quantities of 'combination products', i.e. those containing codeine and another analgesic such as paracetamol, aspirin or ibuprofen, also increases the risk of harm from these other medicinal products. This risk applies to both short and long-term use.'³

National examples of misuse of OTCs

Finland: A survey of over 700 pharmacists for the Association of Finnish Pharmacies published in January 2018 found that half of the respondents reported customers buying OTC medicines for the wrong purposes on a weekly basis, and one in four reported misuse at least once a day. Medicines which the respondents named as commonly misused included cough medicines, nasal decongestants, painkillers, drinks for treating flu symptoms, laxatives, cortisone lotions, antibiotic ointments, motion sickness medication and aspirin.⁴

Ireland: In 2016, paracetamol was used in 1,234 reported poisoning cases, out of a total of almost 5000 involving drugs.⁵

In 2014 the police asked pharmacists to practice caution in dealing with requests for pseudoephedrine, an active ingredient in non-prescription cough and cold medicines, as it was being used by criminal gangs for the production of methamphetamine.⁶

¹ *Availability of Paracetamol Sold Over the Counter in Europe: A Descriptive Cross-Sectional International Survey of Pack Size Restriction*; Morthorst BR et. al, *Basic Clin Pharmacol Toxicol*. 2018 Jan

² *Non-steroidal anti-inflammatory drug use is associated with increased risk of out-of-hospital cardiac arrest: a nationwide case–time–control study*; Kathrine B. Sondergaard et al., *European Heart Journal*, 2016
<https://academic.oup.com/ehjcvp/article/3/2/100/2739709>

³ *Non-Prescription Medicinal Products Containing Codeine: Guidance for Pharmacists on Safe Supply to Patients*, Pharmaceutical Society of Ireland, October 2017
http://thepsi.ie/Libraries/Folder_Pharmacy_Practice_Guidance/01_3_Safe_supply_of_Codeine_to_patients.sflb.ashx

⁴ *Finnish pharmacies list misused over-the-counter medicines*, yle.fi 14 January 2018
https://yle.fi/uutiset/osasto/news/finnish_pharmacies_list_misused_over-the-counter_medicines/10022291

⁵ Poisons Information Centre of Ireland, Annual Report 2016

Norway: A survey by the Norwegian Pharmacy Association conducted in 2015 on attitudes to paracetamol among 15-24 years showed that around half of the 400 respondents had a different opinion of medicines bought in groceries to those bought in a pharmacy – they perceived the former to be ‘milder’.

Poland: A 2016 study based on a survey of 680 pharmacists found a significant problem:

‘The misuse of OTC drugs is increasing in Poland from pharmacists point of view. The most popular substance was PSD followed by COD and DXM. The main reason of misuse of these drugs could be related to the use of Internet and free access to these medications. In respondents (58.2%) opinion OTC drugs containing analyzed substances should be moved into the prescription status.’⁷

Sweden: The medicines supervisor (Läkemedelsverket) ordered the removal of paracetamol pills from supermarkets in 2015 after an increase in cases of misuse – poisoning cases had increased by 40% since sales were liberalised in 2009.⁸

In 2014 oral medication with fluconazole was switched from Rx to OTC and only sold in pharmacies. In 2016 the Läkemedelsverket ordered the removal of oral medications with fluconazole from pharmacies as from June 2017, switching it back to Rx from OTC. The order was issued due to the correlation between use of antibiotics and antibiotic resistance.

UK: According to the research published in the Journal of Public Health, a fifth of the UK population may have misused NPMs in some way during their lifetime, either by taking a higher dose than recommended, using a product more often than recommended or by using a medicine beyond the recommended time limit.⁹

Public support for P Med category

Ireland: In January 2018, the Irish Pharmaceutical Healthcare Association (IPHA) and the Irish Pharmacy Union (IPU) published a market research report¹⁰ which they had jointly commissioned detailed market on attitudes towards self care in Ireland. This included the following observation regarding attitudes to pharmacy:

‘Focusing on those who made an OTC medicines purchase, arguably the group most focused on self care, the research highlights that they were much more likely to assess the following facets as being important contributors to their decision on what to buy: staff attitude, interaction with staff, past relationship with the pharmacy and advice from the counter staff or pharmacy assistants. All of these elements were more contributory for this group than they were for others.’

⁶ *Vigilance in the Sale of Pseudoephedrine- Garda Request*, The Pharmaceutical Society of Ireland, June 2014
http://www.thepsi.ie/gns/Pharmacy_Practice/PracticeUpdates/VigilanceintheSaleofPseudoephedrine.aspx

⁷ *Misuse of OTC drugs in Poland*, Zaprutko T et al, Health Policy. 2016 Aug;120(8):875-81

⁸ *Paracetamol tablets only available in pharmacies*, Swedish Medical Products Agency, 30 October 2015
<https://lakemedelsverket.se/english/All-news/NYHETER-2015/Paracetamol-tablets-only-available-in-pharmacies/>

Increased availability of paracetamol in Sweden and incidence of paracetamol poisoning: using laboratory data to increase validity of a population-based registry study, Gedeborg R et al., Pharmacoepidemiol Drug Saf. 2017 May;26(5):518-527

⁹ *Non-prescription medicine misuse, abuse and dependence: a cross-sectional survey of the UK general population*, Fingleton N A, Watson M C, Duncan E M et al., Journal of Public Health, 2016

¹⁰ *SELF CARE Taking charge of your health*, January 2018
<http://www.ipha.ie/IPHA/media/Documents/Self-Care-taking-charge-of-your-health.pdf>