McKesson Europe Policy Position

How pharmacy sales of OTC Medicines contribute to better public healthcare

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Introduction

OTC medicines[1] play a vital and possibly overlooked role in general population healthcare. When taken correctly OTCs are highly accessible and relatively inexpensive and enable patients to manage symptoms of common illnesses. This provides important benefits not only for patients, but also for healthcare systems and economies. McKesson's EU-owned pharmacies and those of our customers safely sell OTCs to millions of patients across Europe every day.

At McKesson Europe we believe that many common illnesses and symptoms can and should be addressed in a licensed pharmacy, where qualified pharmacists and their teams can select the right medicine and provide supporting professional advice. Critically, where a pharmacist or their trained staff do not consider an OTC intervention appropriate, they may instead offer an alternative intervention such as signposting the patient for non-pharmaceutical care. This kind of professional pharmacy intervention sets pharmacy transactions apart from non-medicine sales or OTC sales outside of a licensed pharmacy.

Recognising that medicines require special treatment, in this paper we call on national policy makers to ensure that their regulatory environment protects the public from harm whilst ensuring availability of OTC medicines when they are needed.

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[1] For the purpose of this document, Over the Counter (OTC) medicines 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.). Across Europe no agreed common definition of OTC exists.

Medicines are not ordinary products

Medicines can bring many benefits, but can also be harmful when not used properly. They must not be considered as ordinary commercial goods, but as highly regulated health products – an approach which has been explicitly recognised in EU legislation. [2] OTC medicines are typically used to manage symptoms of common illnesses. [3] They play an important role in the broader self-care agenda, which includes other non-pharmaceutical support[4] to deliver better overall health and well-being. Although beneficial however, OTC medicines are not without risks, as highlighted in the table below.

Table 1: OTC medicines – the risks and the benefits

Benefits	Risks
Low cost	Unforeseen side-effects and complications due to interaction with other medicines
Readily available - patients do not require GP appointment / prescription	Repeat sales less likely to be picked up if sold outside of a licensed pharmacy
Reduced pressure on healthcare professionals re minor complaints – freeing time for more serious ones	Inappropriate dosage and / or incorrect self-diagnosis
Highly accessible: quick relief of the medical problem	Medicine dependency and / or deliberate misuse
Individual can exercise more autonomy and choice	Unwanted hospital admissions due to Adverse Drug Reactions (ADRs)
	Additional GP or hospital visits if used incorrectly

Access to OTC medicines must be controlled to deliver all the benefits and manage the risks listed above. We believe that the rules regarding sales of OTC medicines should adequately reflect the special status of medicines. Accordingly, switching medicines from prescription status to another category needs to address potential abuse and misuse concerns as well as ADRs.[5] Patient safety must remain the top priority.

Our key messages

- *Medicines are unlike ordinary commercial goods: they provide enormous benefits to patients but can be harmful if not used properly*
- *Pharmacy personnel are best placed to provide professional, personalised advice to patients on the most appropriate use of medicines*
- *Sales of OTC medicines through non-pharmacy channels can, in certain cases, put patients at risk through lack of supervision and professional advice*
- *If Rx medicines are reclassified to non-prescription status, we recommend creating a Pharmacy Medicines category*

[2] This includes the Falsified Medicines Directive (Directive 2011/62/EU) Recital 22, which recalls that the Court of Justice of the EU 'has recognised the very particular nature of medicinal products (including NPMs)' and TFEU Article 168 paragraph 4c.

[3] Such as colds, coughs, pains or digestive conditions

[4] For example, medical devices, fitness and diet advice and coaching

[5] ADRs result in 6.5-10.9% hospital admissions and mortality rates of 0.15-2.9%. *Adverse Drug Reactions related to mortality and morbidity: Drug-drug interactions and overdoses*; Angella Angiji, Xendo, 2018

The professional and personal value pharmacies offer

McKesson Europe believes that the sale of OTCs is best conducted within the framework of licensed pharmacies under the professional supervision of qualified pharmacists or their teams operating under the pharmacy's quality control system, e.g. pharmacy technicians. Pharmacists have been practising a form of personalised medicine for years. Only they are best placed to:

- Advise patients on appropriate medicine and dosage, based on their personal needs / medication history;
- Provide special advice for OTC use by vulnerable patients [6];
- Warn about side-effects and interactions with other medicines, and the necessary precautions to take;
- Provide holistic advice to a patient about managing their medical condition.

Medicine Reclassifications – A Pharmacy Medicine

McKesson Europe welcomes the reclassifications of medicines from prescription only to non-prescription status where sufficient evidence exists to support patient safety claims.

In such cases, we recommend that these medicines should be considered across the EU as a special category – a **Pharmacy Medicine (P Med)**. This category already exists in some Member States where such medicines are not immediately accessible to patients without the supervision of a pharmacist. This status ensures that patients get professional support with their medicine purchases. We would encourage at Member State level a review and the possible translation of current OTC medicines and products into this newly defined P Med category. Some Member States may already consider their current OTC categorisation as sufficiently robust. In other countries the terms OTC and Pharmacy Medicines are interchangeable. We believe that these are unsustainable situations, as there is increasing pressure from non-healthcare outlets for liberalisation of the OTC sector. Their arguments are based predominantly on price and competition. The European Commission also broadly supports OTC liberalisation. [7]

We would strongly urge pharmacy regulators to create the Pharmacy Medicine category as a recognised subset of what is today called OTC medicines.

Uncontrolled sales through non-pharmacy channels

As discussed, Member States are reviewing OTC medicines currently thought to be of lesser risk, with a view to making them available through non-pharmacy channels[8], i.e. outside the pharmacy regulation framework. Recognising that staff at retail outlets have no medical training, that patients may be unaware of any risks, may be over-confident in their ability to navigate purchases on their own, or may return later for repeat sales, we believe that stronger controls are required to protect the public.

We recommend that where OTC medicines are reclassified, or sales are made possible through non-pharmacy channels, that these should be for a very limited number of medicines for immediate and short-term use only.[9] Furthermore, we believe that these medicines should not be available for self-selection and should be stored out of children's reach. We would also recommend that outlets selling these products should also be subject to additional controls to protect public health.

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[6] Such as children, pregnant women, the elderly or carers

[7] European Commission Communication and Staff Working Document: *A European retail sector fit for the 21st century*, April 2018

[8] Typically convenience stores or petrol stations

[9] In packs of four or less, while multiple pack sales should not be allowed thereby reducing the chance of accidental or deliberate overdosing.

Maintaining a comprehensive community pharmacy network

Licensed community pharmacies provide a public service role – not only do they supply medicines and free health advice, but they also relieve pressure on other primary and secondary care providers by providing advice immediately and without an appointment. This is very convenient for 98% of Europeans who live within 30 minutes of a community pharmacy[10] – often their first healthcare contact point.

In many countries, OTC medicine sales have historically formed a key part of a traditional 'bricks and mortar' community pharmacy's sales, ranging from 5% to over 50% of a typical pharmacy's income. [11] Removing these sales could undermine the financial sustainability of many community pharmacies, particularly in less populated areas. We strongly recommend that policy makers think cautiously about liberalising for short-term gains.

Our recommendations

- Policy makers, and in particular competition and anti-trust authorities, in all countries should recognise that **OTC medicines are not ordinary commercial goods**.
- McKesson Europe believes that increasing access to medicines is best enabled by increasing the reclassification of medicines from prescription-only status to pharmacy-only sales.
- Where sufficient evidence exists to support a medicine's reclassification from prescription to non-prescription status, we believe that such medicines must remain in licensed pharmacies under a **Pharmacy Medicine (P Med)** category. In this way, they remain under the appropriate supervision of pharmacists and their teams. Where this category does not exist, we are calling on pharmacy regulators to make the necessary changes to guarantee public access and safety through the creation of this category.
- **McKesson Europe does not believe it is necessary for non-healthcare policy makers to facilitate increased access to P Meds and OTC medicines as we consider this a public health matter.** Such decisions should remain the competence of medicines authorities. However if changes are sought to increase availability, we strongly advocate that this applies only to very small packs for limited symptomatic relief medicines with proven safety profiles.

About McKesson Europe

McKesson Europe is a leading international wholesale and retail company and provider of logistics and services to the pharmaceutical and healthcare sector. With about 39,000 employees, the group is active in 13 European countries. Every day, the company serves over 2 million customers – at more than 2,100 pharmacies of its own, at about 300 managed pharmacies and at over 5,700 participants in the brand partnership schemes. With 110 own and seven managed wholesale branches in Europe, McKesson Europe supplies more than 55,000 pharmacies and hospitals every day with up to 130,000 pharmaceutical products.

Facts and Figures

Please see our online Annex at http://www.mckesson.eu/mck-en/company/public-affairs/position-papers/otc-medicine-sales/24118

[10] Survey of Chain of Trust Project, under EC Public Health Programme (Grant Agreement N° 2009 11 13)

[11] From PGEU internal survey.