ACCESS TO NON-PRESCRIPTION MEDICINES – THE KEY ROLE OF PHARMACY IN SELF-CARE GIRP Position Paper

1. Background

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Non-prescription medicines (NPMs), also referred to as "Over-the-Counter" medicines (OTCs), are medicines that can generally be purchased without a medical prescription. NMPs must be registered as medicines either through the European Medicines Agency (EMA) or through national bodies. At the European level, NPMs are covered by Directive 2001/83/EC, the Community code relating to medicinal products for human use.

Today, patients are increasingly managing many of their ailments through the selection of NPMs without consulting either a doctor or pharmacist. This practice, commonly referred to as 'self-medication', however, entails a number of risks for patients that could be easily avoided by consulting a healthcare professional prior to administration of the product. Especially where doctors are not easily accessible, pharmacists play a key role in helping patients to make informed self-care choices. By asking their patients relevant and appropriate questions, pharmacists help to ensure that patients select NPMs that are appropriate, safe and effective to their needs.

Traditionally available via community retail pharmacies, today NPMs can, in some countries, be purchased at a variety of additional outlets, such as grocery stores, gas stations etc. As these outlets typically do not have trained staff capable of providing on-site consultations on usage, substance interactions etc., the purchase of NPMs via these outlets can pose serious health risks to patients. This paper seeks to examine the consequences of NPM dispensation via non-pharmacy outlets, to provide important arguments in favour of NPM dispensation/sale via the pharmacy, and to highlight the integral role of the pharmacist in safeguarding patients' health and the public's access to medicines.

2. Consequences of non-pharmacy dispensation of non-prescription medicines

In some countries, NPMs are available via a number of sales channels and are not exclusively dispensed via the retail pharmacy. Through market deregulation, or changes in classification of NPMs, or the reclassification of medicines into lesser restrictive classes by the regulatory authorities in some countries, NPMs are commercially available in such outlets as general stores, supermarkets and gas stations.

Patients are often over-confident in making self-medication choices when it comes to NPMs¹. Numerous studies have shown, however, that publicly available NPMs, when taken without adequate advice of trained staff, are not only among the medicines most associated with potentially preventable medication-related hospital admissions, but can also result in medicine intoxication, harmful medicine interactions, side effects, medicine abuse, medicine dependency and increased healthcare costs as a consequence of additional visits to physicians or hospitals.²⁻⁷



As NPMs are publicly available, patients often consider these products as 'safe' ⁸⁻⁹ and 'too weak to cause any real harm' ⁶, yet patients' confidence in using NPMs for self-medication purposes does not imply that the use of NPMs is always optimal or appropriate¹⁰. Patients are oftentimes unaware of potential medicine interactions with their other medications, medicine toxicities, or dependencies resulting from the use or misuse of non-prescription medicines.²

Studies have shown that despite high patient knowledge and confidence in choosing the appropriate NPM, the pharmacy is often cited as the preferred and most confidence-inspiring channel for the purchase of NMPs and that most NPMs ought to be available exclusively via the pharmacy.¹

3. Suggested measures to improve patient safety and to strengthen the role of the pharmacist in self-care

3.1 Pharmacists offer professional advice and care

Pharmacists act as the 'gate keepers' of healthcare systems. They oftentimes serve as the first point of contact for patients suffering from health problems. If the symptoms relate to a minor ailment, the pharmacist can supply a NPM, with the advice to consult a medical practitioner if the symptoms persist for more than a few days. Many pharmacies offer a board spectrum of prevention and early disease detection or screening services that help to direct patients to the appropriate healthcare professional or expert. Alternatively, the pharmacist may give advice without supplying medicine.

When dispensing NMPs to the patient, pharmacists counsel the patient on how to effectively take their medicines. Pharmacists seek to collect and integrate information about the patient's medical history and medicine record, clarify the patient's understanding of the intended dosage regimen and method of administration, and advise the patient of medicine-related precautions. In many countries, the community pharmacist is therefore in a unique position to be fully aware of the patient's past and current medical record and, consequently, can provide essential advice not only to the patient, but also to the patient's general practitioner. Such services exceed the scope of non-pharmacy outlets that offer NPMs for sale.

Through one-on-one consultations and individual patient-specific advice, pharmacists help to educate the patient and to increase his or her knowledge and awareness about the disease or ailment, the treatment plan, and how best to adhere to the treatment scheme. Pharmacists can also provide correct advice on how to administer certain NMPs to infants and pregnant women and whether these medicines are appropriate.

3.2 Treatment effectiveness and patient safety

The prime function of a pharmacist is to ensure the safety and wellbeing of the patient. In order to improve the treatment outcomes of individual patients, pharmacists not only advise and educate patients about their medicines and appropriate medicine administration, they also monitor treatment schemes and patient adherence, inform the patient about the efficiency of a given medicine and about possible adverse reactions and side effects. They also raise the patient's overall awareness of the risks of self-medication.

Monitoring patient adherence

In many countries, pharmacists support patients with chronic diseases or long-term treatment plans to stay on therapy and to gain control over their disease, oftentimes through the use of practical intervention toolkits and the use of electronic, digital or eHealth applications. As the incorrect use of medicines or the premature or sudden interruption of medicines' usage can lead to the inefficient curing of the patient's pathologies, to extended treatment periods, and therefore to increased costs to the patient and the healthcare system, such practices must be avoided. By offering reminders, toolkits, and regular consultations, pharmacists are able to improve medicine and treatment adherence, and to monitor and evaluate patients' therapeutic response. Oftentimes the pharmacist can participate in arrangements for monitoring the application of medicines, such



as practice research projects, schemes to monitor adverse medicine reactions (pharmacovigilance) and analysis of prescription-compatibility with other medicines or NPMs. Where medicine adjustments are necessary, pharmacists can contact physicians and raise awareness of possible medication-related problems.

Minimising medicine interactions

Patients may – often inadvertently – take several NPMs containing the same active ingredient or substance, thereby increasing the risk of an overdose, increased side effects and hidden pathology symptoms caused by the use of inappropriate medicines. By verifying medicine compatibility, pharmacists can analyse patients' medicine and treatment plans and advise on the range of NPMs or prescription medicines with the same or similar active ingredient. In so doing, pharmacists can help to reduce the risk of hidden pathology symptoms caused by the patient's inappropriate use of medicines. Medicine reviews can also serve as an important opportunity to inform patients about more suitable alternative medicines, about potential interactions with prescription medicines, new medication, etc.

Risks of self-medication

While patients may believe they know which pathologies they intend to cure through self-medication, they may, as stated above, be using the incorrect non-prescription product. Not only can this lead to potentially adverse drug interactions between multiple NPMs or prescription medicines if the substances are incompatible; it can also delay a correct diagnosis made by a healthcare professional and lead to adverse reactions or more severe health problems for the patient. Pharmacists, thanks to their advice and knowledge, are able to reduce or altogether prevent these risks.

In all cases, pharmacists are advantageously positioned to report medicine-related incidences to authorities and to engage in pharmacovigilance practices.

Safety, quality and access to medicines

Pharmacies play an important role in ensuring the safety and quality of medicines dispensed and contribute to patients' safe and convenient access to medicines. Not only does the pharmacist verify the legality, safety and appropriateness of the medicines prescribed or sought by the patient, the pharmacist also checks the patient medication record before recommending a given medicine (when such records are kept in the pharmacy), ensures that the quantities of medication are accurate and adequate, and decides whether the medication should be handed to the patient with appropriate counselling. Such safety considerations often surpass the capacities of non-pharmacy outlets.

Regularly inspected by the authorities, pharmacies offer clean and hygienic premises that reassure patients of the quality and safety of medicines. In addition to ensuring an accurate supply of appropriate products, pharmacists have progressively undertaken the additional task of ensuring the quality of the products they supply and are trained and highly knowledgeable on how to appropriately store NPMs in order to comply with Good Pharmacy Practice Guidelines as an extension of the Good Distribution Practice (GDP) requirements (humidity, heat, sun protection requirements, etc.). In case of safety concerns, pharmacies have firmly established recall procedures that seek to prevent the use and application of given products.

Lastly, pharmacies are essential in enabling patient access to medicines. As a one-stop healthcare destination, pharmacies are able to provide the full assortment of medicines available in a short time period thanks to the permanent support of full-line pharmaceutical wholesalers. In some countries, pharmacies are also allowed to operate delivery services that bring vital medicines to patients whenever and wherever needed.

3.3 Primary Self-Care

Pharmacists play an essential role in enabling and empowering patients to resort to self-care or selfmedication, by improving patient knowledge about NPM selection, use and the potential risks associated with a given product, but also by improving patients' overall knowledge about health and wellbeing. Patients' informed self-care is important, as it significantly reduces costs for the overall healthcare system as well as the need and length of patients' hospital stays. Routine services that can support self-care include screening services such as the measuring of blood pressure, measuring of blood sugar levels, weight management, smoke cessation, etc. Pharmacists also contribute to the prevention of illnesses by offering individualised consultations on nutrition, physical activity and overall wellbeing.

4. Conclusions

By consulting a pharmacist prior to the administration of a given NPM, patients can reduce the risks associated with incorrect medicine use and gain professional and qualified knowledge about their disease, ailment or treatment plan, how best to adhere to the treatment schemes, and gain a better understanding of medicine-related precautions (substance-interactions, side effects etc.), in a safe and clean environment that ensures the safety and quality of medicines. Pharmacists also play an important role in educating the patient about self-medication and empowering the patient to engage in safe and informed self-care practices.

Considering patients' increased recourse to self-medication and the hasards associated with the incorrect use of NPMs, GIRP, representing over 750 pharmaceutical full-line wholesalers and integrated healthcare distribution companies, feels that the pharmacy and the pharmacist provide the safest possible environment in which a patient can receive professional care and information from qualified staff about their ailments and possible treatments.

As GIRP is committed to enhancing and safeguarding patient safety and wellbeing, GIRP is equally committed to strengthening the role and perception of the pharmacist as a qualified, knowledgeable and essential source of patient care and information. NPMs should therefore be dispensed predominantly via the pharmacy where, unlike non-pharmacy outlets, there are qualified experts capable of provide patients with appropriate advice and self-care knowledge.

GIRP, European Healthcare Distribution Association, June 2016



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