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PHARMACOVIGILANCE

Pharmacovigilance, risks and adverse effects of self-medication

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Summary Self-medication means resorting to one or more drugs in order to treat oneself without the help of a doctor. This phenomenon is developing fast. In this review, we will discuss the main definitions of self-medication; we will then present a few important characteristics of this therapeutic practice: prevalence, reasons, populations involved and drugs used. Whilst the theoretical risks of self-medication have been abundantly discussed in the literature (adverse effects, interactions, product, dosage or treatment duration errors, difficulty in self-diagnosis, risk of addiction or abuse...), there is in fact very little detailed pharmacovigilance data concerning the characteristics and the consequences of this usage in real life. This study therefore

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Non-steroid
anti-inflammatory
drugs;
Benzodiazepines

describes the all too rare data that is available: patients, clinical characteristics, "seriousness" and drugs involved in the adverse effects of self-medication. It also discusses leads to be followed in order to minimize medication risks, which are obviously not well known and clearly not sufficiently notified.

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Abbreviations

ANSM	French Drug Agency (<i>Agence nationale de sécurité du médicament et des produits de santé</i>)
ENT	ear, nose and throat
GP	general practitioners
HIV	human immunodeficiency virus
NSAIDs	non-steroidal anti-inflammatory drugs
WHO	World Health Organization

Introduction

The self-medication market, which amounted to 7.6% of the global pharmaceutical market in France in 2012 (11.2% in Germany, 12.3% in the United Kingdom and 14% in Belgium) is now on the rise (+ 3.2% in 2012) [1].

Self-medication can first of all be envisaged as resorting one or more drugs without the help of a doctor [2,3].

Beyond this simple definition, several others have been suggested. For Giroud [4], it is "the act of treating oneself with over-the-counter drugs without resorting to a doctor". It is a "practice that reduces the number of visits to the general practitioners (GP), sometimes unnecessary (and costly), but it is by no means without limits or danger" [4]. For Fainzang [5,6], self-medication can be seen as "the act, for an individual, of consuming a drug, on his/her own initiative, without consulting a doctor for the case in hand, whether the drug is already in his/her possession or whether he/she has obtained it for that purpose (at a pharmacist's or from another person)". This definition, with a wider scope than the previous one, therefore includes the use of drugs that have already been prescribed for another pathology or for another person. It is in this case a re-use of drugs that are often found in the family's medicine cabinet or today frequently purchased on the Internet.

Venulet and Schulz [7] talk about "the treatment of a real or imaginary pathology using drugs that have been chosen without any medical advice". The main advantage of this definition is that it excludes drug dependence and drug abuse.

The Health Authorities (Drugs Agency, *Agence nationale de sécurité du médicament et des produits de santé* [ANSM]) talk of "officinal medication drugs". A drug is said to be officinal medication when it is intended for the treatment of common symptoms over a short period, does not require a visit to a doctor, but is to be accompanied by advice from a pharmacist. This type of drug is also subjected to appropriate packaging (dosage, treatment duration) and an

information leaflet. The 2008 Decree authorized certain drugs to be displayed on the counter, readily accessible, in an area dedicated to that effect. The 2008 list comprised 217 pharmaceutical products, covering 71 therapeutic domains, 12 plant-based drugs and 19 homeopathic drugs [8]. This number increased to 390 in 2010 [3].

For the French Medical Association Board (*Conseil de l'ordre des médecins*), "self-medication is the use – with no medical prescription, and by people on their own initiative for themselves or their relatives – of medications considered as such and having been granted their marketing authorization, with the possibility for the patient of getting help and advice from pharmacists... It can only be for the treatment of a symptom, the nature of which is at least ambiguous and which presupposes that the duration of the treatment is short and mono-symptomatic" [9].

According to the World Health Organization (WHO), self-medication drugs are "medications requiring no medical prescription. They are manufactured, distributed and sold in priority to consumers for use on their own initiative and under their own responsibility whenever they consider it appropriate" [10].

Generally speaking, all these self-medication definitions also involve the notion of "self-medicalization", with all its corollaries of "self-information", "self-diagnosis", "self-examination" and the difficulties inherent in these practices [6].

In fact, the term self-medication does not exist in French Law: The Public Health Code only recognizes, on the one hand, medications that have a marketing authorization and on the other hand, medications that are not listed. However, for the Health Authorities, it is important to distinguish those with compulsory medical prescription and those with optional medical prescription. This definition however does not include practices that can be the most frequent in self-medication, namely the re-use, without any medical advice, of medication already used by the patient or by his relatives after medical prescription.

After having discussed the main characteristics of self-medication in this review, we will now turn to recent notions of pharmacovigilance concerning self-medication substances.

The principal characteristics of self-medication

It is not our intention to review all the legal, regulatory, medical or educational aspects linked to self-medication,

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