Editors’ Opinion

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Vasoconstrictive decongestants: the authorities’ dithering leaves patients in danger

The cardiovascular and neurological adverse effects of vasoconstrictive decongestants (ephedrine, naphazoline, oxymetazoline, phenylephrine, pseudoephedrine and tama
ingheptane) used to relieve symptoms of the common cold are well known (1,2). In France, nasal preparations have been placed on List II of moderately dangerous substances and are therefore available by prescription only, while oral forms are available without a prescription.

Since the 1990s, several pharmaceutical reports on these drugs have been published in France, and all have given similar results regarding serious and even fatal adverse effects such as myocardial infarction and stroke, sometimes in young patients. In addition, these reports show that adverse effects are more frequent with oral forms than with nasal forms; that the recommended treatment periods and maximum doses are not respected; and that several medications containing vasoconstrictive decongestants are often taken concomitantly (2-4). Until early 2013, the main measures taken by the French health products agency (ANSM, formerly Afssaps) consisted of modifying the SPCs and patient leaflets to limit the duration of treatment and to add contraindications and warnings (a)(4,5).

In late 2012, after reviewing the results of the latest pharmacovigilance update, which yet again confirmed these dangers, the ANSM National Pharmacovigilance Committee recommended that oral vasoconstrictive decongestants become subject to compulsory medical prescription. On 7 January 2013, this recommendation, that only sought to limit the use of these drugs, had not resulted in any effective action. Furthermore, ANSM “has no plans at this time to apply this measure broadly and indis-