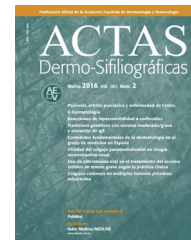




ACTAS Derma-Sifiliográficas

Full English text available at
www.actasdermo.org



OPINION ARTICLE

What Lies Behind Drug Shortages, the Consequences—and a Good Alternative[☆]



El desabastecimiento de los medicamentos: ¿qué hay detrás? Causas, consecuencias y una buena alternativa

E. Abarca Lachén,^{a,*} D. Marro Ramón^b

^a Farmacéutico comunitario. Profesor de Formulación de Medicamentos Individualizados. Facultad de Ciencias de la Salud, Universidad San Jorge, Villanueva de Gállego, Spain

^b Farmacéutico comunitario, Director del Máster Universitario en Atención Farmacéutica y Farmacoterapia, Facultad de Ciencias de la Salud, Universidad San Jorge, Villanueva de Gállego, Spain

Received 4 September 2015; accepted 29 November 2015

“The pharmacies are experiencing shortages of over 30 medicines” reported the *Heraldo de Aragón* on May 15 2014. “Warning of shortages for 170 unprofitable drugs by pharmacists” ran the headline in *JANO* on December 22 2014. “Andalusian Pharmacists denounce shortages of drugs due to drug auction” said the Andalusian edition of the *ABC* on April 9 2015. “Price war encourages drug shortages” claimed the *Voz de Galicia* on July 19 2015. And so on.

For some time now, a range of media outlets have been reporting stock-outs of some drugs. Perhaps you have been one of the physicians affected and this situation has puzzled you, alarmed you, or even caused a major setback in your daily practice. Or perhaps, without having been directly affected, these headlines have caused you a mild, though unpleasant sense of uncertainty.

One of the problems that general and hospital pharmacies face increasingly frequently is stock-outs of pharmaceutical products, including those with dermatological indications.

The problem not only affects pharmacists, who cannot dispense the prescribed medication (unless it can be replaced by another product), but also impacts the work of physicians who prescribed these medications. The main losers are, however, the patients who take them.

Unfortunately, as affirmed by Sánchez Brunete, “the word patient is being used increasingly as an adjective rather than a noun.”¹ In the present article, we propose a reflection on the causes and consequences of problems with drug supply. Also, with an eye on the future, we will analyze whether the suggested solutions are appropriate and then make our own specific proposal.

As the reader knows well, the *Agencia Española de Medicamentos y Productos Sanitarios* (AEMPS, the Spanish drug approval body), a state organization that operates under the auspices of the Spanish Ministry of Health, Social Policy, and Equality, is responsible for guaranteeing that the drugs marketed in Spain meet the criteria for quality, safety, effectiveness, and continuity of supply. Their website informs the public of drugs with supply problems. Currently, according to the AEMPS, 176 drugs approved in Spain have problems with supply.² In 59 of these cases (33.5%), there are no other approved drugs with the same active ingredient and the same route of administration, and of these a total of 26 drugs (15%) cannot even be acquired as foreign drugs.

In addition, the problem has worsened in the last 6 years (Fig. 1), as noted by the AEMPS in their 2014 annual report³:

[☆] Please cite this article as: Abarca Lachén E, Marro Ramón D. El desabastecimiento de los medicamentos: ¿qué hay detrás? Causas, consecuencias y una buena alternativa. *Actas Dermosifiliogr.* 2016;107:178–182.

* Corresponding author.

E-mail addresses: edgarabarcalachen@hotmail.com, eabarca@usj.es (E. Abarca Lachén).

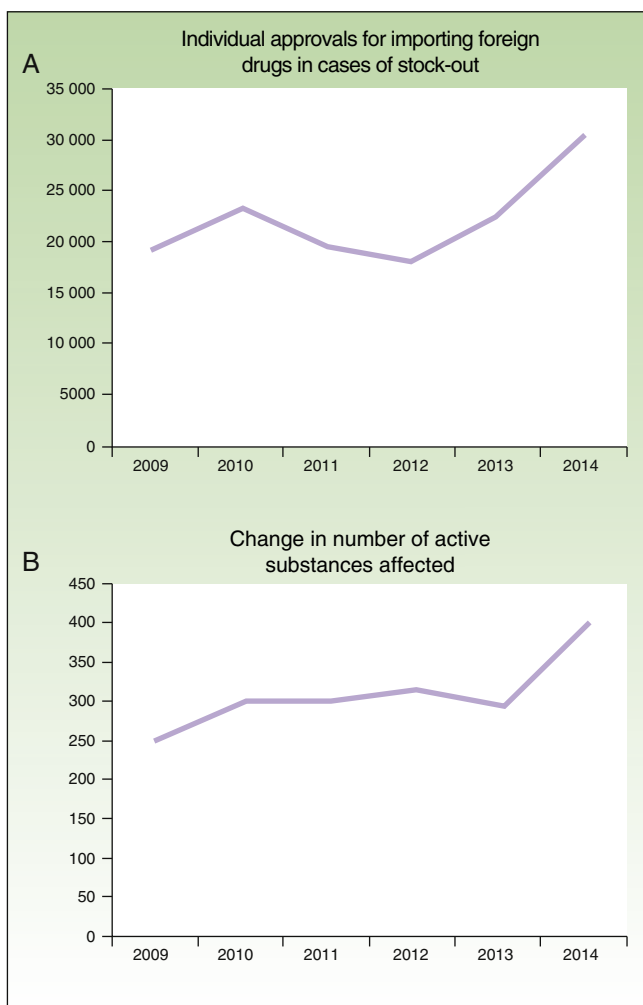


Figure 1 Number of individual approvals for importing foreign medicines in case of stock-outs (A) and number of active ingredients involved (B) between 2009 and 2014, according to the annual reports of the AEMPS for 2012, 2013, and 2014.³

“The figure is considerably higher than the previous year, in both the number of active drug substances that are imported as a foreign drug and the number of individual requests, with this increase attributable to a greater number of stock-outs.”

In most cases, the problem can be attributed to 1 of 4 major causes:

- Problems with suppliers: surprisingly drug manufacturers increasingly depend on a single supplier of starting materials (active ingredients, excipients, packaging material) in a limited number of countries such as India, China, or Brazil.
- Outsourcing of production: several nations use a small percentage of world drug production, in an increasingly demanding regulatory framework, and more stringent quality metrics, and so greater investment is required. From the profitability point of view, it is therefore not viable for drug companies to manufacture their own drugs.

- Growing demand for some drugs: this increase in drug demand is due, above all, to the progressive aging of the population and also to the appearance of increasingly effective treatments.
- Stockpiling policies of some buyers.

One of the most recent examples on a long list of stock-outs was that of Fortecortin (Merck) in April 2014, which caused a lot of comment although the stock-out itself was not entirely novel. In fact, many of the situations described as stock-out, which is understood to mean “a problem with the supply of a drug that requires a change that has an impact on patient care and requires the use of an alternative therapeutic agent” and that therefore can lead to certain alarm within society should not actually be considered as such.

Spanish pharmacists have a very efficient tool for resolving specific problems in supply of an irreplaceable drug: pharmaceutical compounding of the drug under medical prescription (traditionally known as *magistral formula*). The elaboration is fully guaranteed, the product fully complies with the regulations, and the active ingredients and excipients are obtained from a supply industry bound by tight international legislation that fully guarantees the quality of the production process.

Such compounding is in fact the origin of the pharmacy profession, and one of the tasks of highest prestige associated with the job. Currently, these drugs are of unquestionable clinical importance and help provide a health service of the highest technological and professional degree.

Compounding pharmacists have been mitigating the effects of stock-outs for a long time, adapting the drugs to the specific characteristics of patients with special needs. In short, such professionals have been providing a service that, as far as possible, guarantees that each patient receives at a given time, and accurately, the treatment that he or she needs. Paradoxically, when the AEMPS reports an episode of stock-out, it almost never suggests customized drug formulation as a means to solve the problem. The AEMPS statements suggest resorting to foreign medicine services, changing treatment, restricting the indications for use, and forbidding exportations, but they rarely propose pharmaceutical compounding.²

However, it would be of great benefit for everybody to know the causes and, from the standpoint of our profession, we will attempt to clarify them. Such knowledge would be of widespread benefit: first, our patients would have an easier solution, the physicians would see their therapeutic arsenal extended, the compounding pharmacists would see an increased value placed on the tasks for which they have been trained and for which there is an established legal framework, and finally the Spanish authorities would be able to offer quality alternatives to their citizens while saving on costs.

Possible Causes and Impact

What options are available at present for patients who need one of these drugs? The information on the AEMPS website offers only one solution: obtain the drugs from outside Spain,

Download English Version:

<https://daneshyari.com/en/article/3182173>

Download Persian Version:

<https://daneshyari.com/article/3182173>

[Daneshyari.com](https://daneshyari.com)