Presidenza del Consiglio dei Ministri

MOTION

ON NON-OPTIMAL PHARMACEUTICAL PACKAGING

23 June 2017

A number of regulations[1] have given rise to a path for the production of optimal pharmaceutical packs, even in single-dose form, proportional to the requirements imposed by the course of therapy. Despite this, no systematic intervention has been carried out yet and there are still many packs in which there is no correspondence between the days of treatment and the number of therapeutic units (pills, tablets, capsules or the like) according to medical prescriptions. In fact, most of the medications in a blister pack often contain a number of tablets that is, on average, 30% above or below the normal course of therapy for which it is used. This forces doctors to prescribe and consumers to buy a second pack of the drug or to keep the pack in storage, often until the product expires. The same applies for medicines in drop form since frequently a fraction of the substance remains unused in its container.[2]

The Italian Drug Agency notes that what ends up in the "bin" are mainly antibiotics followed by analgesics, syrups, drugs for hypertension and heart failure, antiplatelet agents and anticoagulants[3]. This results in a waste of public resources, which could otherwise be used, and/or an unnecessary burden on citizens' spending[4].

Persisting with inappropriate drug packaging is therefore particularly deplorable, given that it is not particularly difficult to reduce this waste and the healthcare industry is already allowed to prepare single doses of drugs in accordance with proper conservation and preparation. Since the consumer has been directed by the Institutions to use generic medicines in order to contain household expenditure and that of the State itself, it is, therefore, particularly incomprehensible to find an indifferent attitude with regard to waste on this scale.

These inappropriate drug packs create additional problems that can be summarized as follows:

---

[1] With reference to some regulatory interventions in the hospital setting, please note paragraph 5 of art. 11 of Decree-Law no. 158/2012 "Urgent provisions to promote the country's development through a higher level of health protection" (converted into law no. 189 of 8 November 2012) where it states: "The Regions and autonomous Provinces of Trento and Bolzano are authorized to test, within the limits of their budget availability, repackaging, including customization and distribution of medicines to patients being treated in hospitals and residential facilities in order to eliminate product waste and the risks of errors and misuse. The unpacking operations and repackaging of medicines are carried out in compliance with Good Manufacturing Practices".
The law of 23 December 2014, no. 190 "Provisions for the preparation of the annual and multiannual state budget" (Stability Law 2015) at paragraph 591: "For the purpose of rationalizing and containment of pharmaceutical expenditure, by decree of the Minister of Health in agreement with the Minister of Economy and Finance, after consulting the Higher Health Council, and the competent parliamentary committees, on the basis of a proposal drawn up in agreement with the AIFA and the National Federation of Associations of Physicians-Surgeons, the methods have been defined for production and distribution in hospitals, on an experimental basis for a two year period, of medicines in single-dose form. By the same decree, the period during which the continuation of the production and marketing of multi-packs is permitted and the procedures for the monitoring of financial targets reached are laid down."

[2] This problem also exists for veterinary drugs. The Hygiene and Health Commission of the Senate adopted a single text that brings together two bills concerning the marketing of veterinary medicines, including the anticipation of the rationalization of drug packaging. "Measures concerning the marketing of veterinary medicinal products, unified text no. 499, 540). Article 3 regulates the phased transfer of veterinary medicines for pet animals by pharmacists authorized for direct and retail sales.

[3] For example, for antibiotic treatments, only part of the packs are used, or for chronic treatments the number of tablets in the pack is too low, or in the case of analgesics or non-steroidal anti-inflammatory drugs the compositions available contain a high number of tablets when only a few units are needed.

[4] Il Sole 24 Ore Sanità, 2016, n. 35.

- The patient is likely to use the product for longer periods than those needed for treatment.
- Having available partially used packs is an incentive for do-it-yourself treatment with inappropriate doses and schedules of administration, this is not recommended for the health of the individual patient, or for public health in light of the antibiotic resistance issue.
- Having at home partially used packs is a danger to children who may accidentally take the medicine.
- Unused products are rarely returned to pharmacies; they are often released into the environment, increasing the rate of soil and water pollution.

For these reasons, the NBC recommends that Institutions should continue to provide timely information to doctors and consumers for the responsible and conscious use of pharmaceuticals, precisely in defence of the consumers themselves. It also recommends implementing measures designed to reduce the unjustified waste of medicines from maxi or mini packaging marketed by the pharmaceutical industry.

Among the possible solutions, the NBC specifically recommends - similar to practices in other countries, such as the United Kingdom and the United States - that for some prescription medicines, in particular antibiotics, a pharmacist should prepare customized packages containing the precise number of tablets or single-dose vials required to complete the cycle, without manipulation of the product.

In addition, the NBC recommends extending throughout the territory the measures already foreseen at the experimental stage for hospital facilities.

** ** **

The text was drafted by Profs. Lorenzo d'Avack, Silvio Garattini, Carlo Petrini.

The motion was discussed and voted in plenary session on 23 June 2017 by Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Francesco D'Agostino, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Mario de Curtis, Carlo Flamigni, Silvio Garattini, Anna Gensabella, Assuntina Morresi, Andrea Nicolussi, Laura Palazzani, Massimo Sargiacomo, Lucetta Scaraffia, Monica Toraldo di Francia, Grazia Zuffa.

The advisory members Drs. Maurizio Benato (FNOMCeO), Carlo Petrini (ISS) also gave their adhesion to it.

Prof. Carlo Caltagirone and the consultant Prof. Anna Teresa Palamara both absent from the plenary session subsequently adhered to the motion.