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BRAND NAME VERSUS GENERIC DRUGS: A POINT OF VIEW ON THE SAFETY AND EFFICACY

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ABSTRACT

A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights. One mechanism to reduce pharmaceutical spending is to increase utilization of generic medications in daily practice, but there are many ethical issues inherent in utilizing brand name versus generic medications. In fact some points, such as bioequivalence and the role of excipients, may be clarified regarding the clinical efficacy and safety during the switch from brand to generic formulations. The use of generic drugs could be related with an increased days of disease or might lead to a therapeutic failure.

INTRODUCTION

One mechanism to reduce pharmaceutical spending is to increase utilization of generic medications in daily practice, but there are many ethical issues inherent in utilizing brand name versus generic medications. Time and again the importance of generic prescribing has been emphasized, primarily to reduce the cost of drugs. In fact, following the entry of a generic drug, a branded drug loses about 50% of its market share after 3 months and 80% after 1 year (Zore *et al*., 2013). As legally defined in Italy, generic drugs are equivalent to the brand formulation if they have the same active substance (with a difference of ±5%), the same pharmaceutical form, the same therapeutic indications and a similar bioequivalence (±20%) relatively to the reference medicinal product (Law n. 425/1996 in G.U. n. 208 of 05.09.1996. Legislative Decree no. 219/06) (Kefalas and Ciociola 2011). Many people become concerned because generic drugs are often substantially cheaper than the brand-name versions. They wonder if the quality and effectiveness have been compromised to make the less expensive products. The FDA (U.S. Food and Drug Administration) requires that generic drugs be as safe and effective as brand-name drugs. Davit B.M. *et al*., in an interesting study, comparing 2070 single-dose clinical bioequivalence studies of orally administered generic medicine products approved by the Food and Drug Administration (FDA), from 1996 to 2007, demonstrated that the products did not significantly differ (Davit *et al*., 2009). However, while generic drugs are tested for bioequivalence within a certain range compared to innovator drugs, safety and efficacy testing is not required; therefore, generic drugs are not necessarily therapeutically equivalent to branded drugs (Zore *et al*., 2013). In fact, other authors documented the development of side-effects or clinical failure after the switch from brand to generic formulation (Kanis *et al*., 2012; De Vuono *et al*., 2013; Diez-Perez *et al*., 2012; Privitera, 2008; Hendeles *et al*., 1990).

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MATERIALS AND METHODS

In the last years, several generic drugs have been introduced in Italy. In the pharmaceutical service of the sanitary district of Herculaneum (Naples, Campania Region), some cases of therapy failure with generic drugs have been documented. An example: a 64-year-old male has been brought to her general practitioner's attention for the development of an acute

bacterial bronchitis. Body temperature was 39.6°C with a coughing with green mucus and shortness of breath. Therefore, paracetamol (1000 mg as need) and levofloxacin (as generic drug, in agreement with Italian law) 500 mg tablet once daily for 10 days were prescribed, but 5 days later the patient returned to the general practitioner for the persistence of symptoms. A this point, generic levofloxacin was changed to Tavanic® (brand formulation of levofloxacin) with a complete improvement of symptoms in 3 days.

RESULTS AND DISCUSSION

In our experience, we found a reduced efficacy of many other generic drugs (antibiotics, analgesics, anti-inflammatory and antispasmodic drugs) indicated in some acute conditions. One cause can be the difference in excipients. In fact, many of the doubts concerning the effectiveness of different generic drugs compared with the original are assigned to the excipients. In Italy, the actual law (Legislative Decree 219/2006) does not consider as relevant for drug response the differences in excipients. But, several studies documented that a difference in excipients is related with the loss of response during treatment with the generic formulations (Blencowe *et al*., 2010; Collier *et al*., 2010; Paveliu *et al*., 2011). Another important aspect to consider are the amount of impurities. Several studies are shown that generics formulations had a total impurity rate superior to the maximum permissible in comparison to brand formulation. This factor has been previously reported to affect the bioavailability of the drug and therefore, its therapeutic efficacy (Gasser *et al*., 2013; Tange *et al*., 2012; Taylor *et al*., 2010). In this light, the switch from brand to generic formulation might not always be considered favorable according to cost-effectiveness. In conclusion, in our experience, the use of generic drugs could be related with an increased days of disease or might lead to a therapeutic failure. Further clinical studies with clear end-points and more rigorous analyses of tolerability and efficacy in patients as well as in healthy subjects are urgently needed to reassure health professionals about the interchangeability of a generic drug and the corresponding brand-name drug.

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Conflicts of Interest

The authors declare that they have no conflict of interest.

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