Letters to the Editor

Are generic drugs the same as the originals?

¿Son los medicamentos genéricos iguales que los originales?

Dear Sir,

Due to the economic conditions of Western countries and particularly to the debt burden of Spain, physicians are being required to prescribe generics in order to diminish pharmaceutical expenditure. We can all recall patients commenting that generics “don’t have the same effect or don’t go down well”, particularly in reference to systemic antihypertensives. This raises the question of whether generics are the same as trademark medications synthesized by labs that have carried out research, efficacy and efficiency studies and bioavailability. Said labs own patents with a validity of about 20 years, which includes the time during which the drug is studied and marketed. According to Royal Decree 1345/2007, article 2.35, a generic drug is “that which has the same qualitative and quantitative composition of active principles and the same pharmaceutical form, and the bioequivalence with the reference drug has been demonstrated with adequate bioavailability studies”. There are essential differences between systemic and ophthalmological drugs. In the former, control is carried out measuring the levels of the drug in the blood (the concentration must be between 85% and 125% of the concentration obtained with the original drug). However, in the latter type of drugs this comparison is not valid and therefore the only requirement is that generic drugs for ophthalmological use must have the same concentration of active ingredients as the reference brand product and administered in the same dosage and the same pathway. These drugs are not required to demonstrate therapeutic equivalence with the reference drug. Excipients such as preservatives, antioxidants, pH regulators, thickeners, tampons and other inactive ingredients may vary. Differences in preservatives, pH and tonicity can lead to patient noncompliance. Changes in the product composition can ultimately affect the drug efficacy and this could give rise to adverse effects. The size of the drop in the amount of product in the container may vary in generics, leading the patient to self-administer inadequate treatments.

In ophthalmology the efficacy and safety of topical anti-inflammatory drugs have been studied. It has been reported that generic diclofenac is associated to a higher number of melting corneal cases than the original diclofenac (Voltaren eyedrops, Novartis). With generic diclofenac, contact dermatitis, subepithelial infiltrates and corneal sensitivity issues are more frequent. In generic prednisolone acetate, particles in suspension are of a large size and not uniform, meaning that they will remain in that state for lesser duration than the original drug (Pred-Forte, Allergan), and when the container is shaken prior to administering the drops, in 94% of cases the adequate concentration is not reached against 60% of cases with the original drug. This means that with a generic drug the treatment is more variable.

A generic formulation of latanoprost with a pH higher than the brand product was less efficient to diminish intraocular pressure than the branded version. In another study, the concentration of generic Ciprofloxacin was lower in 20% of the eyedrops.

Until the time when new studies become available, we must be aware of the unknown factors brought about by generic drugs in ophthalmology. We must take these factors into account when discussing generics with our patients. For the above reasons, patients with generic drugs or those who have been switched to generic drugs must be assessed frequently in order to ensure that the medication is working as expected without adverse side effects.

REFERENCES


Please cite this article as: Asensio-Sánchez VM. ¿Son los medicamentos genéricos iguales que los originales? Arch Soc Esp Oftalmol. 2012;87:263–4.
Dear Sir,

Regenerative medicine is a branch of this science that aims at providing strategies to restore the function of organs and/or tissues. It is a new form of therapy for patients with acute or chronic diseases in which the body is unable to restore tissue function. It is estimated that in the USA over 60 million people could benefit from this type of treatment as it covers a broad range of clinical applications in the field of medicine.1,2

Tissue regeneration mechanisms are very similar in most tissues. However, the cornea exhibits specific characteristics regarding morphology, tension, permeability and optical transparency which make it unique. It comprises a highly differentiated tissue to enable the transmission and refraction of light, which is the main optic element of the eye.3

At the level of the cornea, chemical or biological induction of regeneration by means of growth factors or other substances has brought about a significant development. Many topical agents have been utilized due to their efficient enhancement of tissue repair in wounds. Molecules such as angiotensin, retinoic acid, and amino acids such as L-arginine, soluble factors such as cytokines or interleukins, derivatives of synthetic purines, synthetic preparations of extracellular matrix and growth factors have been utilized to stimulate the operation and production of endogenous cells.

Autologous serum is also part of regenerative medicine due to its effects on the ocular surface derived from its numerous biological properties. The characteristics of serum are very similar to those of tears in what concerns pH and osmolarity and, just like tears, serum has abundant growth factors, neurotrophic factors and molecules with antibacterial action which determine that treatment will not only humidify the ocular surface but in addition will provide nutritional and growth factors which are necessary to maintain cellular feasibility as well as bactericide components that reduce the risk of contamination and infection.1–3 Tissue adhesives comprise plastic-synthetics (mostly derived from cyanoacrylates) and biological adhesives (such as those derived from fibrin). In addition, nowadays there are new adhesives derived from thrombin, hyaluronic acid, glutaraldehyde and dendritic macromers with polyethylene glycol nucleus, making them useful for various indications. Platelet derivatives must also be considered within this group.

Another type of strategies are adult stem cell therapies obtained from the limbus or the oral mucosa in patients with limbal insufficiency in which limbal stem cells are unable to maintain the integrity of the corneal epithelium. On the other hand, we must mention artificial corneas. As it occurs with other organs, the demand for corneal transplants significantly exceeds the supply.3 The first approximation to what we could consider to be an artificial cornea is keratoprosthesis. Finally, the topical application of rho-kinase inhibitor (Y-27632) has been seen in animal models to promote endothelial cellular regeneration, as well as cellular therapy applied directly to the corneal stroma from stem cells derived from human fatty tissue. The transcendence of this new form of therapy has gone beyond the limits of scientific debate to give rise to a significant ethical debate in society and the media.1,2

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Regenerative corneal medicine: Ophthalmology applications☆

Medicina regenerativa corneal: aplicaciones en oftalmología

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