INTRODUCTION

An adverse drug reaction is a harmful or unwanted or unexpected effect directly related to the use of a drug. A drug could be prescribed for diagnosis, prevention or therapeutic purposes. All adverse drug reactions should be reported. Specially those which are life threatening, force to hospitalization, or are unexpected and not previously described in the literature or in the SPC.

The link between dermatologists and/or allergologists looking for substances responsible of possible cutaneous adverse reactions induced by drugs, and the pharmaceutical companies responsible of production and marketing of these drugs, consists mainly in two aspects:

- shared responsibility in the reporting to the local Health Authorities of all adverse events notified, ensuring the mandatory requirements about notification Drug side-effects in the countries specified in the SPC.
- collaboration to identify the active ingredients and vehicles responsible of the event.

RESULTS

The chart II and the figures 2, 3, 4, 5, show the results of the study by means of the cutaneous provocation tests with the complete products, the active principles and the contributed vehicles.

MATERIAL AND METHODS

The study was carried out in the Immunoallergic Section at the Department of Dermatology (Hospital del Mar, IMAS). Patients suffering for a possible cutaneous adverse drug reaction were included in 2003-04. Each patient gave the respective informed consent and followed the protocol specified in the Figure 1. Upon our request the Medical Departments of Bayer, Recordati, Farma Lepori and Sanofi-Aventis provided us with the forms to report the cutaneous adverse reaction. These companies as well as, Villas and Vecctem, provided also the active substances and vehicles necessary to perform the study. For the Remicade (rifaximin) case, we were specifically asked to report the adverse drug reaction to Centocor, when the case was published at the European Society for Contact Dermatitis meeting (Copenhagen 2003) Even we had a very good response from the major part of the companies asked, this was not always the same in the past. Chart I picks up the active ingredients and the vehicles studied looking for the responsible for the cutaneous adverse reaction. Each test included a control group.

CONCLUSIONS

The collaboration of the pharmaceutical industry to identify the responsible of certain adverse drug reactions shows to be extremely useful. It allows to work with the components that directly have been used in the formulation. Many of these components are difficult to be obtained in the series of marketed patch test. It is necessary to study the active principle and the vehicles to get a complete diagnostic that would allow the patient to avoid the allergen or allergens in other formulations. This excellent collaboration with the pharmaceutical companies has taken us to drive a more active and accurate drug surveillance strategy. Close relationship between dermatologists and allergologists dedicated to the study of the cutaneous drug adverse reactions, and the pharmaceutical companies shows to be effective and good for best patient care.

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