Objective: The objective of this study was to identify problems in the approval, pharmacovigilance, and post-approval regulatory decision-making procedures involving gefitinib and to propose countermeasures to prevent further drug-induced suffering in Japan in the future. Methods: We comprehensively reviewed reports regarding gefitinib published during the period from 2000 to 2006 by regulatory agencies, the manufacturer of the gefitinib-containing drug, cancer clinical study groups, and a scientific society. Results: We identified the following major problems in the approval, pharmacovigilance, and regulatory decision-making procedures: 1) the results of animal experiments and pre-marketing clinical trials, and reports of adverse drug reactions from other countries were not properly reflected in the label; 2) indications for the drug were expanded without strict evaluation of the external validity of pre-marketing clinical trials; and 3) despite many serious cases of interstitial lung disease (ILD) being spontaneously reported, well-designed post-marketing surveillance was not immediately performed. Conclusions: We propose a mandatory total registry of all drug users and surveillance (i.e. a prospective outcome study) as one of the rational solutions for preventing further drug-induced suffering in Japan.

Keywords

Available in: http://www.redalyc.org/articulo.oa?id=69040404