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Current Situation of the Additional Severe Adverse Effects of Marketed Medicine

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When a novel additional adverse effect is reported for a marketed medicine, the medical information leaflet has to be revised to inform physicians and pharmacists of this. Pharmacists are responsible for informing patients of early warning symptoms to avoid the subsequent appearance of severe adverse effects. However, at present, patients may suffer from severe adverse events because such symptoms may remain unrecognized until the medicine is on the market. As a result, investigations to predict and prevent novel additional adverse effects of medicines are required. In this study, we investigated a novel additional adverse effect classified as a pharmacological effect based on the drug safety update (DSU). As a result, skin disorders including toxic epidermal necrolysis and Stevens Johnson syndrome, and pseudomembranous colitis have become evident as additional adverse effects of antibiotics, with a high incidence. In addition, neuroleptic malignant syndrome and aplastic anemia have also been reported as adverse effects of central nervous system agents.
Therefore, it is important to provide patients with information about the early warning symptoms related to such adverse effects, even though such adverse effects are not contained in the patient information leaflet.