Author's response to reviews

Title: Characterization of Hypersensitivity Reactions Reported among Andrographis paniculata Users in Thailand Using Health Product Vigilance Center (HPVC) Database

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Author's response to reviews: see over
Dear Editor;

On behalf of all the authors, I would like to ask you to consider manuscript entitled “Characterization of Hypersensitivity Reactions Reported among Andrographis paniculata Users in Thailand Using Health Product Vigilance Center (HPVC) Database” for publication in BMC Complementary and Alternative Medicine journal as an original research article. This study demonstrates that Thai Vigibase can be used as a potentially effective tool for herbal adverse events monitoring particularly on hypersensitivity reaction from Andrographis paniculata (andrographis).

Andrographis is one of the herbal products that are widely used for various indications. Hypersensitivity reactions have been reported among subjects receiving andrographis in Thailand. Understanding of characteristics of patients, adverse events, and clinical outcomes is essential for ensuring population safety. Of 106 case reports, 13 case reports with hypersensitivity reaction including anaphylactic shock (n=5), anaphylactic reaction (n=4) and angioedema (n=4) were found. Causality assessment of 13 case reports were certain (n=3), probable (8) and possible (2). Our findings suggested that hypersensitivity reactions have been reported among patients receiving Andrographis paniculata. Healthcare professionals should be aware of this potential risk. Further investigation of the causal relationship is needed; meanwhile including hypersensitivity reactions for andrographis product labeling should be considered.

This manuscript has not been published and is not under consideration for publication elsewhere. All the authors have read the manuscript and have approved this submission. The authors report no conflicts of interest.

Sincerely yours,

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