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Erratum

Erratum on "Traditional use and safety of herbal medicines"

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In the article, "Traditional use and safety of herbal medicines":

- On page 248, second column, where it reads:

"The extent to which the traditional use of an herb ensures that a corresponding herbal drug is safe, however, is a debachart matter."

It should read:

"The extent to which the traditional use of an herb ensures that a corresponding herbal drug is safe, however, is a debatable matter."

- On page 250, first column, third paragraph, where it reads:

"Suspicions of ineffectiveness, however, do not seem to have the same weight as safety concerns when reconsideration of a drug marketing authorization is on the chart."

It should read:

"Suspicions of ineffectiveness, however, do not seem to have the same weight as safety concerns when reconsideration of a drug marketing authorization is on the table."

- On page 250, second column, second paragraph, where it reads:

"If an herbal medicine's clinical superiority over a placebo remains unproven, however, even low risks of slight to mild adverse health effects seem unaccepchart (i.e., lack of a clinical benefit implies that risk to benefit ratios are unfavorable, even if risks are low)."

It should read:

"If an herbal medicine's clinical superiority over a placebo remains unproven, however, even low risks of slight to mild adverse health effects seem unacceptable (i.e., lack of a clinical benefit implies that risk to benefit ratios are unfavorable, even if risks are low)."

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- On page 251, first column, title “Liver toxicity associated with herbal medicines”, second paragraph, where it reads:

“Similar to conventional drugs, herbal medicines are capable of causing both predicchart and idiosyncratic DILI.”

It should read:

“Similar to conventional drugs, herbal medicines are capable of causing both predictable and idiosyncratic DILI.”

- On page 254, first column, first paragraph, where it reads:

“The scarcity of clinical trials with high methodological quality is an insurmounchart obstacle for the production of good systematic reviews of clinical data on the safety and efficacy of herbal medicines.”

It should read:

“The scarcity of clinical trials with high methodological quality is an insurmountable obstacle for the production of good systematic reviews of clinical data on the safety and efficacy of herbal medicines.”

- On page 250, before the title “Tradition and safety of herbal medicines”, insert the box below.

Box 1
Suggested requirements for pre-marketing assessment of safety of herbal medicines.

A. Demonstration of traditional use (as required by the European Medicine Agency) could be a waiver of toxicology studies for initial (phase I/II) clinical trials.
B. A complete battery of *in vitro* and *in vivo* (rodent) genotoxicity assays must be required for any herbal medicine.
C. If clinical indications of the herbal medicine result in continuous use for more than 3 months or intermittent use for more than 6 months, long-term rodent carcinogenicity assays (separate or combined to chronic toxicity studies) should be required.
D. If potentially used by women of childbearing age, reproductive and developmental toxicity studies of the herbal medicine should be required.
E. Data on the *in vitro* inhibition of a set of relevant human drug metabolizing enzymes, such as CYP3A4, 2A6, 2C9, 2C19, 2D6, should be required. Studies on the enzyme induction properties should be required as well.
F. Evidence of idiosyncratic DILI should preclude herbal drug registration or lead to drug withdrawn from the market.
G. A pharmacovigilance plan for the herbal drug should be submitted and implemented after marketing authorisation.
H. Requirements for quality control of manufactured herbal medicines should be stringent regarding botanical identification and levels of potential contaminants of toxicological relevance.