Author's response to reviews

Title: Buyer beware? Does the information provided with herbal products available over the counter enable safe use?

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Author's response to reviews:

Thank you for forwarding the comments of the two reviewers, which we found helpful. We have amended the manuscript where we felt appropriate, and have itemised each reviewer comment, and our responses are below.

Changes made to the manuscript are viewable through 'Track changes'.

We look forward to your response.

REVIEWER 1
1. Abstract: It would be useful to include one sentence in the abstract that describes how the "key safety messages" were identified from the NCCAM monographs, so that readers understand the "grading system" used for each herb.

We have revised this sentence to be more specific:
Written information provided with the products (on the pack or in a leaflet) was evaluated for inclusion of each of the key safety messages included in the monographs of the US National Center for Complementary and Alternative Medicine.

2. Abstract: In the conclusion section, I would advise using less editorial terms - for example
- in line 2 of this part "consumers need for safe use" could be re-worded as "has been recommended by regulatory agencies (or experts)."
- "The New EU legislation will ensure" should be changed to something like "strives to improve the absence of information"
- "Potential purchasers need to know" might be changed to "are likely to benefit from" and "information they need to guide safe use" might be changed to "information that has been recommended for safe use."
Our view is that the Conclusions section needs to present a view which the authors 'conclude' from the Results, based on the Discussion. On re-reading this text, we still feel it is largely appropriate. We have made one change – replacing ‘will’ with ‘should’ in the sentence beginning ‘The new EU legislation should ensure …’

3. Same concern on page 5, line 5,
- "Key pieces of information about safe use of herbal products that consumers need to know" might be changed to "that has been recommended by experts and/or regulatory agencies" or something similar.
- After the bullet points, "consumer will be unable to exercise" might be changed to something like it will be more difficult to make an informed choice.

We feel the first sentence and its associated 3 bullet points would be accepted at face value by most readers.

We accept that second sentence should be modified to become ‘Without such information it will be more difficult for the consumer to be able to make an informed choice, with possible consequent ill-health effects’.

4. Page 7, last bullet - I don't know what "high street" means.

We have changed to availability in ‘retail outlets in local shopping areas’

5. Page 8, last paragraph, "was not uncomplicated" is a double negative - I would advise saying it was complicated.

Changed to 'not straightforward'

6. Page 10, "A 10% check of products with information." I am not sure what this means. Does this mean that one person checked all information and another reviewed only 10%? Please confirm. Given the relatively small number of products and simple data abstraction, it seems reasonable to expect that two authors would do the full abstraction to confirm accuracy.

Firstly, to make this clear we have changed the wording to: ‘A check of a randomly selected 10% of the products with information on the pack only was independently conducted by DKR.

On the second point, our view is that a 10% check is acceptable and is normal practice in data abstraction of this kind.’

7. Results: "key points of safety information" and Table 2-6. I think the article would be improved if there was some brief, written summary of the information provided in the tables. I don't find much value in Tables 2-6, and Table 7 reveals most of the interesting points - perhaps Tables 2-6 could be compressed into one table or just described in broad terms.

Our experience is that editors prefer authors not to duplicate information in the text which is described in a table. Also, we do not agree that Tables 2-6 are of
little value. Without these tables, readers would not know the nature of the information provided for individual products, the legal category and whether a leaflet was supplied.

8. Table 7 - the word "information" is shown twice.
Second ‘information’ deleted

Reviewer 2

9. However, there is a formatting issue with the tables (Table 2-5) which hides some information in the first column of the tables. Could this issue be rectified so that the results could be viewed and judged, and an appropriate decision reached?

We have re-formatted the tables to resolve this problem.

10. Further detail and better explanation is required in the section on ‘Data extraction and quality assurance’ to clearly show how the data were collected and analysed, as well as how the reliability of the data collection and analysis was determined.

We have augmented this explanation as follows: ‘All of the textual information on each product (container and leaflet if present) was photocopied, creating a master copy of the information supplied with each product. This was then examined by one researcher (RD) and the presence or absence of each point of information entered onto an Excel database.’

11. Abstract, Results: The authors have stated that there were 51 of 68 products; however, the numbers given add up to 53. Could this be corrected.

We have corrected a transcription error here – it now reads 4/12 St John’s wort, rather than 6/12. (The Results section contains the correct data.)

12. Results: Regulatory category: It is not clear whether the three regulatory categories were derived from information presented on the CAM container labels or written information, or from an external source. Please clarify.

We have amended the text to clarify: ‘The rest had no classification stated - the actual product classification could only be determined on a case by case basis by the regulator.’

13. Results: Key points of safety information: This is where the results are lacking. Whilst it is important to know how many pieces of information have been included, it is even more important and essential to know what information has been included. The authors should complete the results presented in this manuscript by including information about what actual safety information (side effects, interactions and precautions) have been included and hence those that have not been included in the written information and on the labels of the CAMs studied.

We do not agree with this suggestion; the very low level of information supplied
overall is the main message of the research. We feel that including this level of
detail of information in the paper would produce unwieldy tables which most
readers would not find useful.

14. Conclusions: Perhaps the authors could also conclude by suggesting future
on-going monitoring of written information and labels for CAMs, as well as
standardisation of information provided with CAMs.

We have added to the end of the Conclusions: ‘In addition, there should be
on-going monitoring of the written information supplied with these products, to
courage improvements in this important safety issue.’

15. Could the authors check their references for completeness, for example, Ref
20, are there only three authors?

We have corrected Ref 20 to include all authors and checked the other
references which all appear correct.

16. Abstract: Results: Line 1: Remove ‘of’ after (75%).

Removed

17. Background: Paragraph 4: It should be Complementary and Alternative
Medicines. Could this be corrected throughout the text.

Corrected

18. Background: Paragraph 5: 2nd Dot Point: Is its St John’s Wort or St John’s
wort (lower case)? There is inconsistency in the text of the manuscript.

Corrected throughout the text

‘purchased’ to ‘purchaser’.

Corrected

20. Data extraction: Line 4: change ‘thorough’ to ‘through’

Corrected

21. Results: Information provided: line 4: should read: “One of the these
leaflets…”

Corrected