RESPONSE TO RETRACTION ANNOUNCEMENT
W. Aukema, 2-july 2021, 16:23

I refer to https://www.mdpi.com/ethics:

“MDPI journals are members of the Committee on Publication Ethics (COPE). I fully adhere to its Code of Conduct and to its Best Practice Guidelines.”

I refer to https://publicationethics.org/files/cope-retraction-guidelines-v2.pdf, page 4:

Retractions are not usually appropriate if:
- The main findings of the work are still reliable and correction could sufficiently address errors or concerns
- An editor has inconclusive evidence to support retraction, or is awaiting additional information such as from an institutional investigation (for information about expressions of concern.

A. COPE
The majority of issues described in the draft retraction, criticise the choice of words and some terminology used. I feel that MDPI is not adhering to COPE retraction guidelines, for we have not been offered the opportunity to simply correct the wording in the article, to satisfy the concerns raised by Lareb.

B. REVIEW PROCESS
It is obvious that as much as three reviewers have failed to identify the points brought forward by Lareb.

As authors, we have worked hard to produce a solid article that can withstand the criticism one might expect from a peer review process that is managed by MDPI.

In hindsight, with the knowledge of today, I too understand that some of the wording in our text should and could have been chosen differently.

By retracting our article, MDPI is walking away from their responsibility to properly manage and oversee peer review. Yet I see no communication whatsoever by MDPI to that respect, despite learning in the media that multiple editors are resigning.

C. RETRACTION POINTS
The investigation by MDPI -so far- consisted of:

1. MDPI Receiving an email from Lareb (25-jun-2021)
2. MDPI Sending us the email from Lareb (28-jun-2021 08:59 morning)
3. Walach Sending MDPI confirmation of receipt (28-jun-2021 05:17 morning)
4. MDPI Posting Expression of Concern (28-jun-2021, PDF created BEFORE our response)
5. Walach Sending our response (29-jun-2021 19:11 evening)
6. MDPI Announcing their decision and draft PDF (01-jul-2021 15:35, PDF 15:33)

C.1.
MDPI has waited several days before presenting us with the concerns Lareb raised before the weekend.

C.2.
The expression of concern was produced and published before we were given a chance to send our initial response on June 29.

I feel that MDPI has not given us the opportunity -nor the time- to collect the evidence we need to counter most of the concerns raised by Lareb.

D. MY INVESTIGATION

Following our initial response, which was send to MDPI promptly, I too have performed an investigation into the concerns outlined in draft Retraction PDF you sent us. My findings are summarised below:

Issues described in the draft Retraction PDF:

1. There is no Causality
2. Cases are not certified by MDs
3. Even if so, this does not imply causation
4. Used terms ‘effects’ and ‘reactions’ when this is not established
5. Until causality is established they are ‘events’
6. Any form of statistics is incorrect and misleading

Ad 1:
Establishing causality is a complex and extreme difficult task, and I understand that for the majority of reports this has not occurred.

-> We indicated already that we are willing to reword the text to the extent where we fully comply with the lack of causality.

Ad 2:
The abbreviation used in EMA QPPV means: Qualified Person responsible for PharmacoVigilance
See 8.1 in Table VI.9. Process description - Transmission and rerouting of ICSRs to competent authorities in Member States

Also, in Table VI.12. about Nullification Requests, point 9:
On receipt of further information it is confirmed that the individual case was not medically confirmed.

-> As an individual case apparently is MEDICALLY CONFIRMED, we chose to word that as ‘certified by medical specialist’. Again, we are more than willing to change the wording in order to satisfy the concern raised.

Ad 3:
EV-M3e EV Reporting process for users - Creating and sending ICSRs part II (PDF)
Slide titled 'Creating patient death reports':

a.
In the situation where a patient has died the patient death section of the ICSR should be completed. This is for both the situations where the death is linked to a suspected drug reaction and for when the death is not associated with a suspected drug reaction

The words ‘linked’ and ‘associated’ imply a process towards causality.

b.
The reported death cause and autopsy section (if autopsy information is known) should be completed

Ad 4:
https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-good-pharmacovigilance-practices-module-vi-management-reporting-adverse-reactions_en.pdf
Figure VI.4. Business process map - Suspected adverse reaction reporting in EU - Final arrangements

Also, EMA internet access by the general public to their database of Adverse Events is through website adrreports.eu.

The abbreviation 'adr' stands for Adverse Drug Reactions. Not Events.

D. MY INVESTIGATION (cont.)

Ad 5:
This is interesting. Because EMA are using adrreport (adverse drug reactions, not ‘events’), and this particular terminology (see Ad 4.) this implies causality -at least to a certain extent- was established.

Ad 6:
Statistical analysis is an important part of disproportionality analysis in pharmacovigilance.