

Review of: "mRNA: vaccine or gene therapy? Regulatory issues."

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Potential competing interests: No potential competing interests to declare.

1. The abbreviation "EMA" is not defined in the Abstract.
2. The Aim of the manuscript is not clearly stated in the Abstract nor in the Introduction.
3. Wrong punctuations exist in the article on many occasions. For example:
"... influenza vaccines: ..."
4. Access Date for Reference 3 is not mentioned.
5. Space required: "... Moderna &Merck ..."
6. In the sentence: "According to the FDA^[4], ..."

Reference 4 is not direct source of the claim.

7. Please double-check: "... typeI of pro-drug ...".
8. Please re-phrase the following sentence and use appropriate punctuations:

The FDA points out the particular problems of pro-drugs concerning the complete or incomplete conversion into an active substance and the question of toxicity: how the pro-drug contributes significantly to the toxicity profile of the active drug and in particular according to the site of transformation and action.

9. There are long sentences on several occasions, which can easily be split into two.

For instance:

In general, the regulation of a drug concerns the good manufacturing practices (GMP), these GMP are detailed in an EMA document of 2001 updated in 2012 which applies to all human drugs including vaccines ...