

Questions and answers on labelling flexibilities for COVID-19 vaccines

Quality Review of Documents (QRD) group

1. Introduction

The European Medicines Agency (EMA) together with the Member States, in the context of the Quality Review of Documents (QRD) group, have developed this Questions and Answers (Q&A) document with the aim to provide operational guidance on labelling flexibilities for COVID-19 vaccines. The topics addressed in the present document are primarily based on the European Commission's [Memorandum of Understanding \(MoU\) with Member States on regulatory flexibility for COVID-19 vaccines](#); in addition, a number of these topics are stemming from numerous questions received from COVID-19 vaccine developers in the course of the last few months.

The flexibilities discussed in this document take into account the preparedness work of COVID-19 vaccine developers and the associated logistics of early printing packaging activities. The ultimate goal is to facilitate the large scale and rapid deployment of COVID-19 vaccines for EU citizens within the existing legal framework.

It is important to note that any exemption described in this document, which is in line with the current legal provisions of Directive 2001/83/EC, Title V, is of a temporary nature. Marketing Authorisation Holders (MAHs) will ultimately have to comply with the full labelling requirements. MAHs shall provide information on the length such exemptions will be needed for, including an indicative end to any derogations granted from labelling requirements. The duration of the exemptions may be limited to certain time period, number of batches in the context of the pandemic, and will be determined on a case-by-case basis.

All labelling exemptions will be reflected in the Committee for Human Medicinal Products (CHMP) assessment report and will be published on the EMA website.

Any applicant which identifies any other issue (other than those already listed in the present document) or who have difficulties in even applying the below guidance, should contact EMA (grd@ema.europa.eu) at an early stage in order to find a solution on a case-by-case basis.

¹ Changes implemented in **Rev.4**

Question 2 – Germany added to the list of Member States requiring the printed package leaflet in their national language.



As this is an evolving topic the present Q&A may be updated, as deemed appropriate.

1. Question: Is it possible to market a COVID-19 vaccine with outer and immediate packaging in English only?

Answer: Yes. All EU Member States, as well as Norway and Iceland, have agreed to grant a temporary exemption (article 63(3) of Directive 2001/83/EC) from the obligation to provide the printed packaging components in their national language(s). Outer and immediate labelling can be printed in English only.

Applicants do not need to contact separately the respective National Competent Authorities (NCAs) to request such an exemption. Applicants will have to inform directly EMA at grd@ema.europa.eu on the above plans.

Applicants are also reminded that the obligation to provide translations of the product information electronic annexes in all EEA languages, as per standard post-opinion procedure, is not waived.

2. Question: Is it possible to market a COVID-19 vaccine with the printed package leaflet only in English?

Answer: The MoU includes the provision that package leaflets may not be included inside the medicinal product cartons, but will have to be provided separately by the MAH, who will be responsible for the distribution of the printed package leaflet locally in the national language(s). However, the majority of EU Member States, as well as Norway and Iceland, have agreed to grant a temporary exemption (article 63(3) of Directive 2001/83/EC) from the obligation to provide the printed package leaflet in their national language(s). Except for the countries listed further below, package leaflets can be printed in English only. However, in such case alternative ways of providing access to the package leaflet in the national language(s) must be ensured (see questions 4 and 6).

Applicants do not need to contact separately the respective NCAs to request such an exemption. Applicants will have to inform directly EMA at grd@ema.europa.eu on the above plans.

Applicants are also reminded that the obligation to provide translations of the product information electronic annexes in all EEA languages, as per standard post-opinion procedure, is not waived.

The following Member States **will still require the printed package leaflet in their national language(s)**: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Germany and Greece.

3. Question: Is it possible to omit the inclusion of the package leaflet in the outer carton?

Answer: Yes. The difficulties of including the printed package leaflet in the pack of a COVID-19 vaccine are acknowledged due to the logistical challenges associated with initiating printing activities at an early stage in order to facilitate the large scale and rapid deployment of the vaccine.

Applicants, who are not able to comply with the requirement of including the package leaflet in the carton of the vaccine, must distribute the printed package leaflet containing the full authorised information alongside the supplies of the vaccine.

4. Question: Can I provide national translations of the package leaflet via a Quick Response (QR) code?

Answer: Yes. All EU Member States, as well as Norway and Iceland, have agreed to allow the provision of translations of the package leaflet in their national language(s) via a QR code, as an additional means to access statutory information. To ensure that all vaccinees have access to the QR code providing the national translations of the package leaflet, the QR code needs to be included also in the printed package leaflet and NOT only on the outer packaging as these medicinal products will be handled by healthcare professionals. Alternatively, it may be accepted, for instance, to have a separate

card with the QR code that can be given to the vaccinees. In case more than one QR code is intended to be included in the printed package leaflet (e.g. separate QR codes for HCPs and for vaccinees) an explanatory statement shall be included next to the QR code explaining its purpose.

In cases, where in line with the answer to question 2, certain Member States have accepted an English only printed package leaflet, applicants shall use QR codes or similar means to provide access to the corresponding national translations (see question 6).

5. Question: Can an abbreviated package leaflet or other format of shortened information be included in the outer carton?

Answer: No. An abbreviated package leaflet or other format of shortened information will not provide all the essential information for the safe and effective use of the vaccine. Moreover, missing information may be alarming and create confusion to the vaccinees.

6. Question: Is it acceptable that the number of printed package leaflets does not correspond to the number of doses?

Answer: The MoU allows the possibility of separate distribution of printed package leaflets to accommodate for one patient leaflet per dose (also in line with the decision taken for H1N1 vaccines) and for the accelerated availability of the vaccine respectively. However, considering environmental aspects and potential limited storage capacity of vaccination centres, the majority of the EU Member States, as well as Norway and Iceland, agreed to accept a reduced number of distributed printed package leaflets either in English or in their national language(s) (see question 2).

The following Member State **will still require equal number of printed package leaflets, corresponding to the number of doses**: Greece. For the language to use on the printed package leaflet see question 2.

Nevertheless, MAHs shall put in place mechanisms to ensure that each vaccinee can receive the package leaflet in his/her language upon request without burdening healthcare professionals administering the vaccine. Some Member States could potentially accept that vaccinees are offered the choice to either receive a printed leaflet or be referred to an electronic version of the latter (e.g. QR code). Applicants are strongly advised to contact NCAs to discuss and plan accordingly.

7. Question: Is the use of one Global Trade Item Number (GTIN) within the unique identifier acceptable by all Member States?

Answer: Yes. All EU Member States, as well as Norway and Iceland, have agreed to the use of one GTIN within the unique identifier in order to facilitate supplies of COVID-19 vaccines.

8. Question: Can the printed Blue Box information be omitted?

Answer: Yes. All EU Member States, as well as Norway and Iceland, have agreed to temporarily accept the omission of the printed Blue Box information (for alternatives ways to provide Blue Box information see questions 9 & 10).

9. Question: Is it acceptable to provide the Blue Box information via a QR code?

Answer: Yes.

10. Question: Is it acceptable to use stickers to provide Blue Box?

Answer: In case the Blue Box is included, the majority of EU Member States, as well as Norway and Iceland, will accept the use of stickers (GMP compliant) to provide the Blue Box, except for Romania, Spain and The Netherlands.

11. Question: Can I omit the EU number?

Answer: Applicants can request early provision of the EU number, e.g. at the start of the Rolling Review process, to ensure that the EU number can be printed on the packaging.

12. Question: Can I omit certain particulars from the outer carton?

Answer: Yes. Due to the expedited development, it is understandable that some particulars (e.g. product specifications) may not be final at the early stage of printing packaging materials. In such a case, it might, in principle, be acceptable to omit some particulars (e.g. the statement of active substance in line with SmPC section 2 "Qualitative and Quantitative composition" from the outer carton (section 2 of Annex IIIA)). Applicants will need to inform in advance EMA by sending a justification request to grd@ema.europa.eu. The QRD group will confirm the acceptability of such request on a case-by-case basis.

13. Question: Can the obligation to perform a user testing on the package leaflet be waived for all COVID-19 vaccines?

Answer: No. Despite the difficulties in recruiting respondents due to isolation measures in different countries and short timelines, applicants should make every effort using alternative methods and technologies to ensure the readability of the proposed package leaflet.

In case of difficulties, the approach to be applied should be discussed with EMA on a case by case basis.

14. Question: Can the expiry date be made available via a QR code instead of being printed on the packaging components?

Answer: The expiry date is an important element that ought to be printed on the labelling components in order to ensure the correct use of the vaccine. A QR code alone cannot replace statutory information, such as the expiry date.

15. Question: Are there any specificities related to the naming review process for COVID-19 vaccines?

Answer: As per standard process (invented) names for COVID-19 vaccines must be submitted to the Name Review (NRG) group for review/approval. It is not mandatory to have an agreed (invented) name at the start of the procedure, however there must be an agreed one by the time of concluding the assessment.

NRG is committed to review the (invented) names for COVID-19 vaccines as a matter of priority. In order to facilitate identification of COVID-19 related applications to the NRG, it is strongly advised to ensure that the submission is sent to the correct inbox (NRG@ema.europa.eu) and that the title of the submission e-mail contains the key word "COVID".

If an applicant chooses the format 'Common name + MAH/trademark', NRG review and approval are still required. It is important to note that the order as displayed above should be strictly followed, i.e. the name of the MAH/trademark cannot be placed at the beginning of such a naming proposal.

It should be noted that for the common name, a preliminary Biological Working Party (BWP) agreement is strongly recommended; this is particularly important in the context of early printing activities. The assessment of the acceptance of the common name would, however, still be a matter of assessment and subject to final approval by the CHMP.

16. Question: Can I distribute the vaccine components separately (antigen vial/adjuvant vial or diluent)?

Answer: No. It is expected that different components of the finished product should be packaged together, i.e. as a single product, when covered under the same marketing authorisation. Separate distribution of different components increases the risk of handling errors and could impact traceability and reporting of Adverse Drug Reactions.

In cases where it is not possible to package the vaccine components together for objective reasons, that cannot be addressed by existing technical solutions (e.g. due to incompatible storage conditions), an exception may be considered only on a case by case basis. In such a case the applicant should provide to EMA (grd@ema.europa.eu), as early as possible, their justification, including proposals to minimise the improper transfer and/or use of any of the separate components.

17. Question: Can I submit mock-ups of proposed labelling at an early stage (before formal submission) for review by EMA?

Answer: Yes. Applicants are encouraged to submit as early as possible their proposed mock-ups for outer and immediate labelling to allow sufficient time for review and interaction with EMA reviewers.

18. Question: Can peel-off labels or any other tool (e.g. 2D barcode) be used on the immediate packaging for traceability purposes?

Answer: MAHs may consider the use of peel-off labels on the immediate packaging in the context of improving traceability. However, for multidose vials it may not be feasible to provide peel-off labels as part of the affixed vial label. The use of a 2D barcode is encouraged, where appropriate (see [Lessons learned from the review of the labelling of centrally authorised pandemic vaccines](#)).

Traceability tools should be described in the Risk Management Plan. The implementation of such traceability tools should be agreed at national level (see GVP P.II: Biological medicinal products).