EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Labelling flexibilities for COVID-19 therapeutics

Quality Review of Documents (QRD) group

1. Regulatory considerations

The Q&A on labelling flexibilities for COVID-19 vaccines provides various exemptions to vaccine developers in order to facilitate their rapid deployment at large scale during the pandemic. These flexibilities are exceptional and may not be appropriate or necessary for all other products with a COVID-19 claim. To avoid any misuse, the full application of these flexibilities will not be automatic.

On the other hand, it is necessary to adopt a pragmatic and balanced approach for future requests from therapeutics' developers with similar arguments (as for COVID-19 vaccines), i.e. the need for immediate availability; to this end it is also important to consider and manage in the most efficient way the administrative and logistical impact of such requests to National Competent Authorities (NCAs) and EMA, but also to Health Care Professionals (HCPs) and patients.

Therefore, a series of qualification criteria have been set up to filter requests for labelling flexibility for COVID-19 therapeutics with the aim to determine the applicability of already established exemptions for COVID-19 vaccines.

2. Criteria

The following criteria are cumulative:

A. The proposed (and eventually approved) indication should be for the treatment of coronavirus disease 2019 (COVID-19) or for COVID-19 complications.

B. The candidate medicinal product should be subject to medical prescription and handled and administered by a HCP ONLY. Any medicine for self-administration should not benefit from these additional flexibilities, particularly the language exemptions.

C. The candidate medicinal product should be a new Marketing Authorisation Application (MAA). Any extension of indication of an already existing MA should, in principle, be excluded, unless fully justified. It is indeed expected that Marketing Authorisation Holders (MAHs) of Centrally Authorised Products (CAPs) have already in place systems and facilities to address the logistical challenges arising from printing, including language requirements, also in case of a need to increase production capacity. An

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extension of indication of an already authorised COVID-19 medicine aiming at introducing an indication not related to COVID-19, will not benefit from such exemptions.

D. These labelling and packaging flexibilities are reserved for medicines with important role in tackling the pandemic taking into account the overriding public health need for a quick and steady supply and the associated time constraints. Candidate medicinal products accepted for Rolling Review (RR) are considered to qualify as such medicines.

Medicinal products for treatment of COVID-19 that fulfil all of the above criteria can, in principle, benefit from the flexibilities currently foreseen for vaccines in the Memorandum of Understanding. However, final verification of the appropriateness will be considered in the context of the individual submissions of the company and may be adapted as appropriate.

It is important to note that any exemption eventually granted, which will be in line with the current legal provisions of Directive 2001/83/EC, Title V, will be of a temporary nature. MAHs will ultimately have to comply with the full labelling and packaging requirements. Applicants shall provide information on the length such exemptions will be needed for, including an indicative end to any derogation 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. Applicants will have to provide a motivated estimate of the expected delay in case no derogation would be allowed.

All requests should be addressed directly to EMA at qrd@ema.europa.eu and applicants should not contact separately the respective NCAs. Member States will be informed about the flexibilities being applied for in a particular case, in advance of the authorisation, through the QRD group. The duration of flexibilities granted will be agreed at this group. All labelling exemptions will be reflected in the Committee for Human Medicinal Products (CHMP) assessment report and will be published on the EMA website.