Access Consortium statement on COVID-19 medicines

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Vaccines have played a critical role in fighting the COVID-19 pandemic. However, medicines can still play an important role globally in treating and/or preventing COVID-19.

The medicine regulators from Australia, Canada, Singapore, Switzerland and the United Kingdom (Access Consortium) have discussed the continued need for COVID-19 medicines that are safe, effective and of high quality.

This collective statement on COVID-19 medicines builds on our May 2020 pledge to work together to counter the COVID-19 global pandemic. The statement also complements the statement on COVID-19 vaccines released in December 2020.

Our commitment

The Consortium's medicine regulators will only authorize medicines for COVID-19 if their clinical benefits outweigh their risks. Authorization is based on the required high level of evidence provided by sponsors and by evolving science.

We commit to working together wherever possible to expedite the review of applications for COVID-19 medicines, while maintaining the same scientific rigour that's expected for all applications.

To provide earlier access to COVID-19 medicines that are safe and show promising efficacy or address an unmet medical need, we may consider applying available regulatory flexibilities such as emergency, temporary or conditional authorizations. However, sponsors will have to confirm the efficacy of any promising COVID-19 drugs in a timely manner and must meet the evidential standards required for a full authorization.

Together, medicine regulators and public health agencies will continually monitor the safety, effectiveness and quality of COVID-19 medicines after their authorization.

Evidence of efficacy

Medicine regulators recognize the tremendous efforts that sponsors have made to expedite the development of promising medicines to treat or prevent COVID-19.

However, we emphasize the importance of well-designed clinical trials to evaluate the efficacy of these medicines.

Sponsors are strongly encouraged to consult relevant guidance on the required evidence of efficacy.

In general, we would like to see the efficacy of a medicine assessed against placebo or an active comparator in adequately designed randomized, double-blind clinical trials. These trials should be long enough to capture the relevant efficacy outcomes in patients infected with SARS-CoV-2.

Clinically meaningful outcomes will depend on the medicine development program. However, the need for hospitalization, intensive care unit admission, supplemental oxygen, ventilation and extracorporeal membrane oxygenation (ECMO) therapy and mortality are preferred endpoints for treatment trials over duration of hospitalization, time to clinical recovery, proportion of hospitalized patients or other endpoints. Virological endpoints are not appropriate as primary endpoints for establishing efficacy in a phase 3 trial and therefore should be assessed as secondary endpoints. Appropriate statistical considerations and analysis plans should be in place.

For prevention trials, endpoints should capture the occurrence of laboratory-confirmed SARS-CoV-2 infection, with or without symptoms, as well as emergency room visits and hospitalizations. These should be based on clear definitions and specific clinical criteria. The characteristics of exposure should be provided whenever feasible.

In addition, data to characterize the efficacy of the medicine against current variants of concern (VOC) and emerging variants of interest (VOI) should be provided.

Evidence of safety

Medicine regulators will authorize a COVID-19 medicine only if its safety profile has been established and supports a favourable benefit-risk balance. Sponsors are strongly encouraged to consult relevant guidance on the required evidence (clinical and non-clinical studies) to:

- undertake appropriate studies that follow international guidelines, including good laboratory practices (GLP) and good clinical practices (GCP)
- demonstrate the safety of COVID-19 medicines and
- ensure appropriate mitigation measures are in place to manage identified and potential risks

Regulators will monitor the continued evidence of a medicine’s safety from clinical, non-clinical and quality perspectives.

Evidence of quality

Sponsors are strongly encouraged to consult relevant guidance on the required evidence of quality.

In general, manufacturers of COVID-19 medicines must:

- follow good manufacturing practices (GMP) and
- provide sufficient data to demonstrate that the manufacturing process at each production site is well controlled and consistent

Sufficient stability data from an ongoing stability program to support the proposed expiry date must also be provided. Mitigation measures should be in place to manage outstanding identified risks in the quality information.

Monitoring safety and effectiveness (pharmacovigilance)

Sponsors are strongly encouraged to consult relevant guidance on the required evidence for monitoring safety and effectiveness. After a medicine is authorized, sponsors will be required to monitor the effectiveness and safety (pharmacovigilance) of a medicine as well as activities to minimize risk. Continued and robust monitoring ensures that a medicine's benefits continue to outweigh the risks.

Regulators will collaborate in safety monitoring, assessing new safety issues and taking quick action to mitigate risks.

Overall, health care professionals, public health authorities, sponsors and regulatory agencies are to work closely together to monitor and assess the safety of COVID-19 medicines after authorization. Just as important, patients who are taking COVID-19 medicines can also play a role in ensuring the safety of their medicines by immediately reporting any side effects to their health professionals and/or to the health authority.

Impact of initial approvals

Initial approvals are for temporary, conditional, emergency or provisional authorizations of a COVID-19 medicine. They may be based on interim analyses of ongoing randomized placebo-controlled phase 3 clinical trials. This may impact the continuation of these phase 3 clinical trials. For example, if a medicine from a particular clinical trial is approved, participants in the clinical trial may want to know whether they received the medicine or the placebo.

Initial approvals are granted for medicines only when the data from fully completed or additional ongoing clinical trials will be available within a reasonable time after the initial approval.

Similarly, initial approvals of a COVID-19 medicine may be based on interim quality information and may be subject to certain terms or conditions determined on a case-by-case basis. Sponsors are encouraged to continue their development work on the medicine in order to generate full evidence from suitable validation and stability studies.

Our statement on regulatory evidence requirements for COVID-19 medicines does not claim to be complete. Thus, sponsors seeking to obtain market authorization should consult with medicine regulators early on and throughout the development process. They should also refer to the relevant guidance for their product.

Related links

- Access Consortium statement on COVID-19 vaccines evidence (swissmedic.ch)
- Access Consortium regulators pledge support to tackle COVID-19