MEDICINES CONTROL AGENCY

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Recommended Effectiveness Data

In general, for approved medicines (medicinal products) with unapproved use as well as unapproved medicinal products MCA recognises that comprehensive effectiveness data are unlikely to be available for every EUA medicine, and the information necessary to authorise emergency use of a product will depend on the circumstances of the declared emergency, as well as available knowledge about the product's safety profile. MCA plans to assess the sufficiency of the effectiveness data and the risk-benefit profile of each candidate product on a case-by-case basis.

MCA recommends that requests for consideration for EUA includes any available relevant scientific evidence regarding the following:

1. The mechanism(s) of the product's action to diagnose, treat, or prevent the disease or condition underlying the request.
2. Preclinical testing data, such as in vitro evidence of effect of the product in preventing or reducing the toxicity of the specified agent.
3. Data to demonstrate effectiveness in diagnosing, treating, or preventing the subject disease or condition in at least one animal species expected to react with a response predictive for humans, where the animal study endpoint is clearly related to the desired benefit in humans (e.g. enhancement of survival or prevention of major morbidity).
4. Evidence of effectiveness in humans (e.g. in published case reports, uncontrolled trials, controlled trials, if available, and any other relevant human use experience).
5. Data to support the proposed dosage (including pharmacokinetics and pharmacodynamic data) for the intended use.