medicines patent pool

PRIORITY LIST

BALOXAVIR MARBOXIL

Roche

INFLUENZA

DISEASE BURDEN

Worldwide, the annual influenza epidemic is estimated to result in about 3 to 5 million cases of severe illness, and about 300 to 600 thousand respiratory deaths.

CLINICAL RELEVANCE

Baloxavir marboxil is approved by FDA for both the treatment and the prevention of influenza. A single-dose baloxavir is safe and has superior efficacy to placebo and similar efficacy to oseltamivir (administered twice daily for 5 days) for ameliorating influenza symptoms in high-risk outpatients, with an 86% reduction in risk of developing clinical influenza.

PATENT LANDSCAPE

Primary patents on baloxavir marboxil have been filed or granted in several LMICs and they are expected to expire between 2030 and 2036. Secondary patents have an expected expiry in 2037.

SERVICE DELIVERY ENABLERS

Diagnosis is not mandatory and could be based on clinical judgment. However, testing for influenza would reduce the risk of unnecessary use of the medicine, redirect diagnosis or inform prophylactic treatment where necessary.

REGULATORY

Product approved by SRAs. Generics can adopt standard procedures like USFDA Paragraph III, Swissmedic MAGHP, EU-M4all or WHO PQ (if included in EOI). PK-based bioequivalence studies will be required. No biowaiver is possible.

MANUFACTURING

Manufacturing process is standard for tablets. No challenges foreseen in relation to excipients or final packaging. Shelf life is at least three years at room temperature.

MARKET

Baloxavir marboxil is currently not approved and not available for use in most LMICs. Based on an analysis of data of sales in HICs and UMICs where it is available, its price would be beyond the reach of most people and could potentially constitute a constrain on the ability of health systems in LMICs to respond to a possible influenza pandemic outbreak.

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***Abbreviations**: HICs= high income countries ; LMICs = low- and middle-income countries ; UMICs=upper-middle income countries ; SRAs=Stringent Regulatory Authorities ;WHO PQ EOI= WHO prequalification Expression of Interest; Swissmedic MAGHP = Marketing Authorisation for Global Health Products ; EUM4all=EU Medicines for all ; PK= pharmacokinetics*