EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

EMA regulatory tools for early access to medicines

Conditional marketing authorisation and accelerated assessment draft revised guidelines – Description of tools and overview of changes

	Accelerated assessment	Conditional marketing authorisation
Eligibility criteria	• Medicine is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation	• Medicine fulfils unmet medical need • Medicine targets seriously debilitating or life-threatening disease, rare disease or is for use in emergency situations in response to a public health threat • Benefit-risk balance of the product is positive, and benefit to public health of its immediate availability outweigh the risk related to need for additional data • Comprehensive data expected to be provided after authorisation
Benefits	• Faster assessment of marketing authorisation application	• Authorisation can be granted early on the basis of less complete clinical data
Overview of proposed key changes	• More detailed guidance on how to justify major public health interest, i.e. fulfilment of unmet medical need • Acknowledgment that comprehensive clinical data may not be available in certain situations, allowing accelerated assessment in the context of a conditional marketing authorisation for example • Optimisation of the assessment timetable by better balancing	• Emphasis on importance of planning conditional marketing authorisation prospectively to ensure swift assessment procedure • Emphasis on advantages of engaging in early dialogue with EMA on the development programme, in particular in the context of joint scientific advice with health technology assessment bodies • Clarification of how a positive benefit-risk balance should be substantiated where

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	Accelerated assessment	Conditional marketing authorisation
	evaluation phases to reach a CHMP opinion within 150 days after the start of the marketing authorisation application procedure • Intent to request accelerated assessment to be indicated 6-7 months in advance and submission of accelerated assessment request encouraged to take place 2-3 months ahead of marketing authorisation application instead of 10-30 days ahead • Importance of early dialogue with EMA so that accelerated assessment can be planned well ahead of the submission, e.g. by detailed discussion of the data package at pre-submission meetings	there are less complete data • Examples and further guidance on the level of evidence that must be provided at the time of authorisation and data that can be provided post-authorisation • Updated guidance on extent and type of data required to be included in annual renewal submissions • Guidance on when a condition could be considered life threatening or seriously debilitating if these effects are in the long-term • Clarification on fulfilment of unmet medical needs, i.e. medicines providing major improvements in patient care over existing therapies can be eligible in certain cases