Regulatory Approaches of EMA and FDA for accelerated approval of marketing-authorisation application

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INTRODUCTION

The regulatory authorities in the European Union (EU) and the United States of America (USA) have developed different mechanisms to accelerate the development of medicines and the process of approval of medicines, intended for the treatment of serious diseases, medicines with unmet medical needs as well as medicines that represent innovation medicines (obtained with the most current technology based on molecular genetics and immunology) and are of major interest to public health.

The aim of this study was to conduct comparative analysis of the regulatory approaches applied for the accelerated procedures for marketing authorization, implemented by European Medicines Agency (EMA) and Food and drug administration (FDA).

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

	PRIME	Accelerated assessment	Conditional marketing authorisation	Compassionate use
Type of mechanism	**Support scheme for medicine development**	**Regulatory tool for early access**		
Medicines eligibility criteria	**Major interest for public health** and in particular from the viewpoint of **therapeutic innovation** (unmet medical need)		For **seriously debilitating or life-threatening diseases**, **orphan medicines** and **medicines for emergency situations**	For **chronically, seriously debilitating or life threatening diseases**, with no satisfactory treatment authorised in the EU;
Submission of application	**During the development**, based on preliminary clinical evidence (proof of concept)	**6-7 months before submission** of marketing-authorisation application: notify EMA of intention to request accelerated assessment	Scientific advice/protocol assistance Request **when submitting marketing-authorisation application**	CHMP opinion on compassionate use cannot be requested by applicants, they should be **submitted through national competent authorities**

FDA U.S. FOOD & DRUG ADMINISTRATION

	Priority Review	Breakthrough Therapy	Fast Track	Accelerated approval
Type of mechanism	**Designation**	**Designation**	**Designation**	**Approval Pathway**
Eligibility criteria	Medicines for **seriously debilitating or life-threatening conditions**			
Submission of application	With **IND or after**, but no later than the pre-BLA or pre-NDA meeting	With **IND or after** but no later than the end-of-phase 2 meeting	With **original BLA, NDA, or efficacy supplement**	**During development**

COMPARATIVE ANALYSIS OF THE ACCELERATED PROCEDURES IN EU AND USA	
EMA	
Accelerated assessment	**The timeframe for review and evaluation of the submitted documentation is shorter (150 days) compared to standard review (210 days).**
Conditional marketing authorisation	**Marketing authorisation granted before completed data are available.**
Compassionate use	**Benefit for the seriously ill patients which cannon be treated/ included in the ongoing clinical trials**
PRIME	**Early identification of the candidates for accelerated approval**
FDA	
Fast Track	**Accelerated development and approval. Rolling review**
Accelerated approval	**Shorter time for development and approval; approval based on a surrogate or intermediate endpoint**
Priority Review	**Shorter time for review (6 months) compared to standard review (10 months).**
Breakthrough Therapy	**Intensive guidance on efficient drug development, Organizational commitment, Rolling review**

CONCLUSION

The various tools for accelerated marketing authorization of a medicine support the process of evaluation of the documentation submitted in the marketing authorization process and reduce the approval time. Enhanced regulatory support provides higher degree of success of applications for marketing authorization.

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