





Stakeholders' Perspectives on the Unmet Medical Need Concept: An EU Pharmaceutical Strategy Survey Analysis

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optimization

avenues



Methods



Pharmaceutical strategy of 2020 for Europe

Initiative from the European Commission



Descriptive statistics

Survey to elicit stakeholders' views on policy proposals

Analysis of stakeholders' responses on the policy proposals related to defining UMN and its potential R&D steering incentives

	classification	Quantitative analysis	Ihem	natic framework analysis
- 6 -	End-users HCP Industry Public body Research Other	Scoring of each		
		Answer option Heatmap Development	1-2	Not important
			2-3	Fairly important
			3-4	Important
			4-5	Very important

Defining the concept of UMN

N (%)	
90 (19%)	
82 (17%)	
172 (36%)	
36 (7,5%)	
33 (7%)	
66 (13,5%)	

Industry





478

Proposals to support innovation in UMN-areas

All other stakeholders Industry Scientific Public Scientific Public listing of support + listing of support + faster priority faster priority review MA review MA areas areas Transpare Transpare New IPR New IPR nt nt related reporting related reporting of R&D of R&D incentives incentives costs costs

All stakeholders MA that Of faster agreed not jeopardize medicines should their value and efficacy

All other stakeholders



- All stakeholder agreed that the current predefined criteria should be made quantifiable
- Industry believed that the definition for UMN should not be too strict \rightarrow hampers innovation and development
- UMN is a dynamic concept \rightarrow some stakeholders believe that criteria should be updated over time

Criteria to be added to the definition of UMN

- Industry believed that if UMN-related incentives would be dependent on cost transparency \rightarrow barrier for innovation
- All other stakeholders were not in favour of providing additional IPR incentive for industry \rightarrow overcompensation





Disease & current treatment burden

Impact on QoL ***

List of abbreviatons

UMN: unmet medical need, R&D: Research & Development, HCP: Healthcare Professional, HTA: Health technology assessment, MA: Marketing authorization, IPR: Intellectual property rights, QoL: Quality of Life

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Conclusion

<u>Absence of authorised treament and seriousness of disease</u> are important criteria for defining UMN \rightarrow made quantifiable

Industry had conflicting opinions on the proposals to steer innovation in areas with UMN and was mostly in favour of receiving scientific support, and additional IPR incentives