

Online Supplemental Material 2

Table S1 - General characteristics of all identified procedures, as well as of the reviewed sample of procedures.

Category:		Number of occurrences:	
All Maintenance procedures 2012-2022:		297	
negative opinion:		8	
withdrawn ¹		92	
positive opinion:		197	
positive opinion without significant benefit		46	
positive opinion + significant benefit (selected sample):		151	
List of questions issued regarding significant benefit?		yes:	75
		no:	76
Grounds for positive opinion:		clinically relevant advantage:	129
		major contribution to patient care:	15
		clinically relevant advantage + major contribution to patient care:	7
Therapeutic area:		oncology:	68
		non-oncology:	83

¹There can be various reasons for withdrawals, such as if the designation holder anticipates a negative opinion from COMP, or if the designation holder received a negative opinion from CHMP, or if there are changes in the designation holder's regulatory strategy.