

Sensitivity analysis: sales in the third year on the market

Tabulation by prioritization made by the EAA System and the economic impact

		Economic Impact		
		>€4 million	≤€4 million	Total
EAA System Prioritization	Prioritized	16	39	55
	Not prioritized	8	134	142
	Total	24	173	197

EAA early awareness and alert

Measures of prioritization accuracy

Statistic		95% CIs	
Sensitivity	66.7	44.7	84.4
Specificity	77.5	70.5	83.5
PPV	29.1	17.6	42.9
NPV	94.4	89.2	97.5

CI confidence interval; PPV positive predictive value; NPV negative predictive value

Sensitivity analysis: sales threshold of €2 million

Tabulation by prioritization made by the EAA System and the economic impact

		Economic Impact		
		>€2 million	≤€2 million	Total
EAA System Prioritization	Prioritized	22	49	71
	Not prioritized	12	170	182
	Total	34	219	253

EAA early awareness and alert

Measures of prioritization accuracy

Statistic		95% CIs	
Sensitivity	64.7	46.5	80.3
Specificity	77.6	71.5	83.0
PPV	31.0	20.5	43.1
NPV	93.4	88.8	96.5

CI confidence interval; PPV positive predictive value; NPV negative predictive value

Sensitivity analysis: sales threshold of €8 million

Tabulation by prioritization made by the EAA System and the economic impact

		Economic Impact		
		>€8 million	≤€8 million	Total
EAA System Prioritization	Prioritized	9	62	71
	Not prioritized	3	179	182
	Total	12	241	253

EAA early awareness and alert

Measures of prioritization accuracy

Statistic		95% CIs	
Sensitivity	75.0	42.8	94.5
Specificity	74.3	68.3	79.7
PPV	12.1	6.0	22.7
NPV	98.4	95.3	99.7

CI confidence interval; PPV positive predictive value; NPV negative predictive value

Subgroup analysis: new active substances

Tabulation by prioritization made by the EAA System and the economic impact

		Economic Impact		
		>€4 million	≤€4 million	Total
EAA System Prioritization	Prioritized	16	50	66
	Not prioritized	5	146	151
	Total	21	196	217

EAA early awareness and alert

Measures of prioritization accuracy

Statistic		95% CIs	
		Sensitivity	76.2
Specificity	74.3	67.8	80.4
PPV	24.4	14.5	36.4
NPV	96.7	92.4	98.9

CI confidence interval; PPV positive predictive value; NPV negative predictive value

Subgroup analysis: orphan medicines

Tabulation by prioritization made by the EAA System and the economic impact

		Economic Impact		
		>€4 million	≤€4 million	Total
EAA System Prioritization	Prioritized	2	12	14
	Not prioritized	1	48	49
	Total	3	60	63

EAA early awareness and alert

Measures of prioritization accuracy

Statistic		95% CIs	
Sensitivity	66.7	9.4	99.2
Specificity	80.0	67.7	89.2
PPV	14.3	1.8	42.8
NPV	98.0	89.1	99.9

CI confidence interval; PPV positive predictive value; NPV negative predictive value

Subgroup analysis: antineoplastic and immunomodulating agents

Tabulation by prioritization made by the EAA System and the economic impact

		Economic Impact		
		>€4 million	≤€4 million	Total
EAA System Prioritization	Prioritized	12	24	36
	Not prioritized	0	38	38
	Total	12	62	74

EAA early awareness and alert

Measures of prioritization accuracy

Statistic		95% CIs	
Sensitivity	100.0	73.5	100.0
Specificity	61.3	48.1	73.4
PPV	33.3	18.6	51.0
NPV	100.0	90.7	100.0

CI confidence interval; PPV positive predictive value; NPV negative predictive value