Association of NCPE Submission Outcomes in Ireland with Added Therapeutic Value (ASMR) Rating in France

Poster · November 2022

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Association of NCPE Submission Outcomes in Ireland with Added Therapeutic Value (ASMR) Rating in France

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BACKGROUND

Health Technology Assessments (HTAs) help in prioritising access to new therapies and maintain the viability of the publicly funded health care systems (1). Prior to conducting HTAs, some countries like France and Ireland conduct a preliminary assessment. France's preliminary assessment is conducted by Transparency Commission (CT) and assesses the additional clinical benefit of a medicine and gives an Added Therapeutic Value (ASMR) rating on a scale of major improvement (ASMR I) to no improvement (ASMR V). Ireland's preliminary assessment is the Rapid Review (RR) conducted by the National Centre for Pharmacoeconomics (NCPE). The purpose of the RR is to determine whether a full HTA is required or not and to support price negotiations in cases where a HTA can be avoided. Many studies have investigated the clinical benefit ratings in France with submission outcomes in other countries, but this study is the first study to investigate the association between these preliminary assessments in France (ASMR) and in Ireland (RR).

OBJECTIVE

Given that the same clinical data is used in both preliminary assessments in France and Ireland (based on regulatory applications to the European Medicines Agency), we investigated the association between these preliminary assessments.

METHODS

All RRs (except medical devices and vaccines) submitted to the NCPE between 2015 to 2020 were extracted from the NCPE archive into a database. The year of the RR being commenced, the drug's ICD-10 category, the reimbursement scheme category, and the orphan and first-class status were recorded in the database for each RR. The outcome of each RR was recorded as HTA recommended or HTA not recommended. HTA Recommended included all such drugs with HTA recommended and HTA recommended at submitted price as RR outcome (2). HTA not recommended included all such drugs with HTA not recommended and HTA not recommended at submitted price as RR outcome (2). To populate the database for France's ASMR ratings, the publicly available source i.e., Haute Autorité de Santé (HAS) was used to create matched pairs of RR outcomes and ASMR ratings in the dataset. Care was taken to match drugs based on the same indication. To test the association between RR outcome in Ireland and ASMR rating in France Pearson's chi square test was used. A Cramer's V test was used further to establish the effect size or level of association between the two variables.

The hypothesis for the analysis was as follows: -

H_0: There is no statistically significant association between RR Outcomes in Ireland with that of ASMR Rating in France.

H_a: There is a statistically significant association between RR Outcomes in Ireland with that of ASMR Rating in France

Decision Rule: p-value less than 0.05 significance level, accept the H_a

RESULTS

There were 192 matched pairs (both RR and ASMR outcomes). Figure 1 shows that of the 192 matched pairs 53% had an ASMR rating of no improvement and 31% had a minor improvement. Of the matched pairs that received an ASMR rating of I or II (n=162), 41%, 58% and 19% were oncology, first-in-class and orphan drugs respectively (see Table 1). Corresponding figures for the matched pairs that received an ASMR Rating of III or IV (n=30) were 63%, 80% and 40% respectively (see Table 1). Overall, 81% of the matched pairs were recommended for an HTA and the remaining were not recommended for an HTA. The recommendation for a HTA varied according to the ASMR rating. Specifically, 100% of the matched pairs with an important improvement rating was recommended for a HTA, while 76%-96% of the matched pairs with other benefit ratings were recommended for a HTA (see Figure 2). RR outcome and ASMR ratings were not correlated (p=0.124, chi-square test, Cramer's *V*=0.173), showing a non-statistically significant association, p > 0.05 (Table 2). Therefore, the null hypothesis is accepted.

Discussion

Some of the explanations for not significant association could be that budget impact is very importantly factored in the RR dossier in Ireland but again not in France. Another explanation could be that the objectives of preliminary assessments are different in the two countries wherein a RR determines whether a HTA is required or not while the ASMR rating determines reimbursement level.

Conclusion

Our study showed that preliminary assessments in Ireland and France are not associated despite the fact that same clinical data is used.

Future Work

Future research will focus on generating more explanation on why there exists no association between preliminary assessments in Ireland and France. Previous research from other countries have observed strong association between assessments for cancer and orphan drugs which can be researched to supplement this study (3-5).

Figure 1: Proportion of matched pairs by ASMR rating

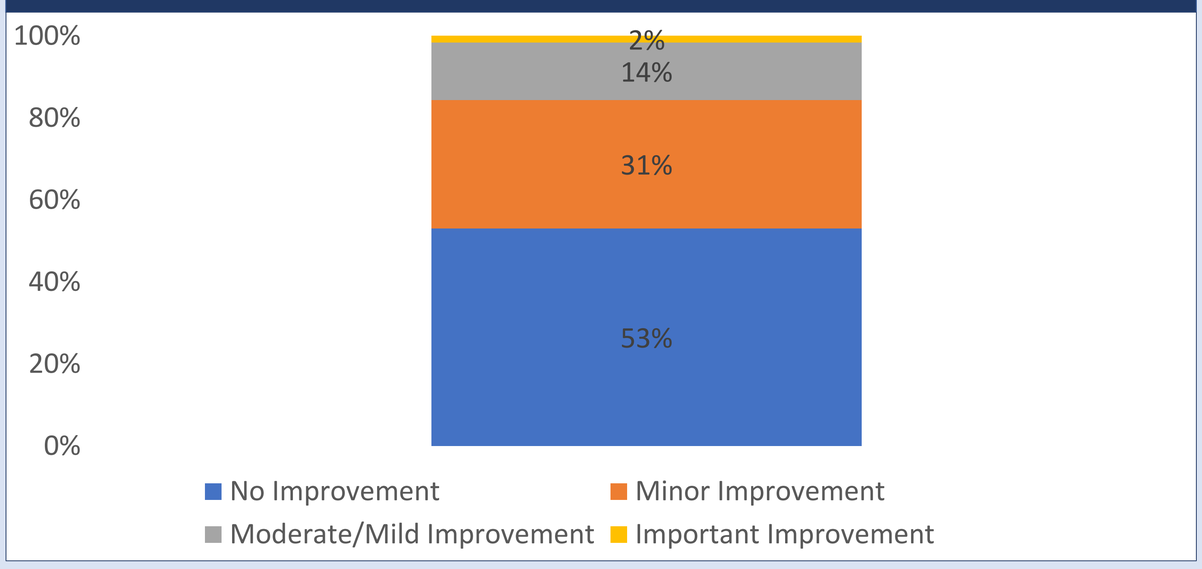

Table 1: Proportion of ASMR Ratings vs ICD-10 category, drug scheme, first-in-class, orphan status

	ASMR Rating (I and II) (n=162)	ASMR Rating (III and IV) (n=30)
Neoplasms	41%	63%
Circulatory	5%	3%
Endocrine	9%	17%
Respiratory	4%	0%
Nervous	7%	0%
Other areas	35%	17%
First in class	58%	80%
Orphan drug	19%	40%
Year 2015	15%	7%
Year 2016	19%	13%
Year 2017	20%	20%
Year 2018	17%	10%
Year 2019	17%	17%
Year 2020	12%	33%
GMS Scheme	11%	3%
Hospital Scheme	35%	57%
High-Tech Scheme	54%	40%

Figure 2: NCPE Rapid Review outcome vs HAS Added Therapeutic Value Rating

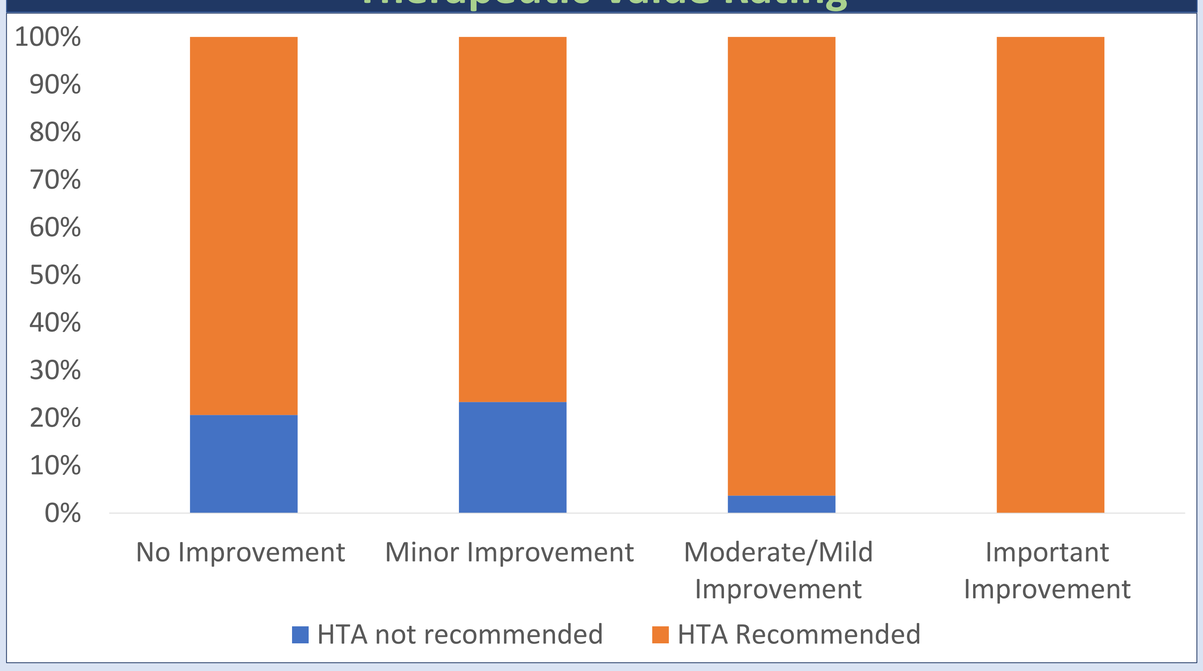

Table 2: Chi-Square Analysis of RR submission outcomes (Ireland) vs ASMR rating (France)

Chi-Square Test				Symmetric Measures			
	Value	df	Asymp. Sig. (2 Sided)			Value	Approximate Significance
Pearson's Chi Square	5.758a	3	0.124	Nominal by Nominal	Phi	0.173	0.124
Likelihood Ratio	7.839	3	0.049		Cramer's V	0.173	0.124
N of Valid Cases	192			N of Valid Cases		192	

Note: N= 192, a. 2 cells (25%) have expected count less than 5. The minimum expected count is .56

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