

DO HTA PROCESSES CORRELATE WITH REIMBURSEMENT RECOMMENDATIONS FOLLOWING EMA APPROVALS?



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Background

Health technology Assessment (HTA) has gained importance as health policy decision-makers increasingly recognise its ability to guide more efficient use of resources (1). However, HTA processes and recommendations can vary greatly between European agencies leading to patient access inequalities and delayed access to medicines. The need for a more consistent approach to HTA is well recognised and initiatives are already in progress for greater European collaboration (2).

This research seeks to expand on a previous study that categorised the diversity of regulatory and reimbursement system processes across Europe (3). This was achieved by the development of two taxonomies that enabled the creation of archetypes to group agencies with similar processes (3). This research compares the two taxonomies (System and HTA process) with HTA outcomes from a selection of European countries to identify correlation.

Methodology

•HTA recommendations or listing outcomes were collected for NAS's granted approval by EMA from 2008 to 2012 from the official national agency websites for 9 European jurisdictions: Belgium; England; France; Germany; Ireland; Italy; Netherlands; Scotland and Sweden. Vaccines, generics, line extensions and NAS's previously approved in Europe are excluded.

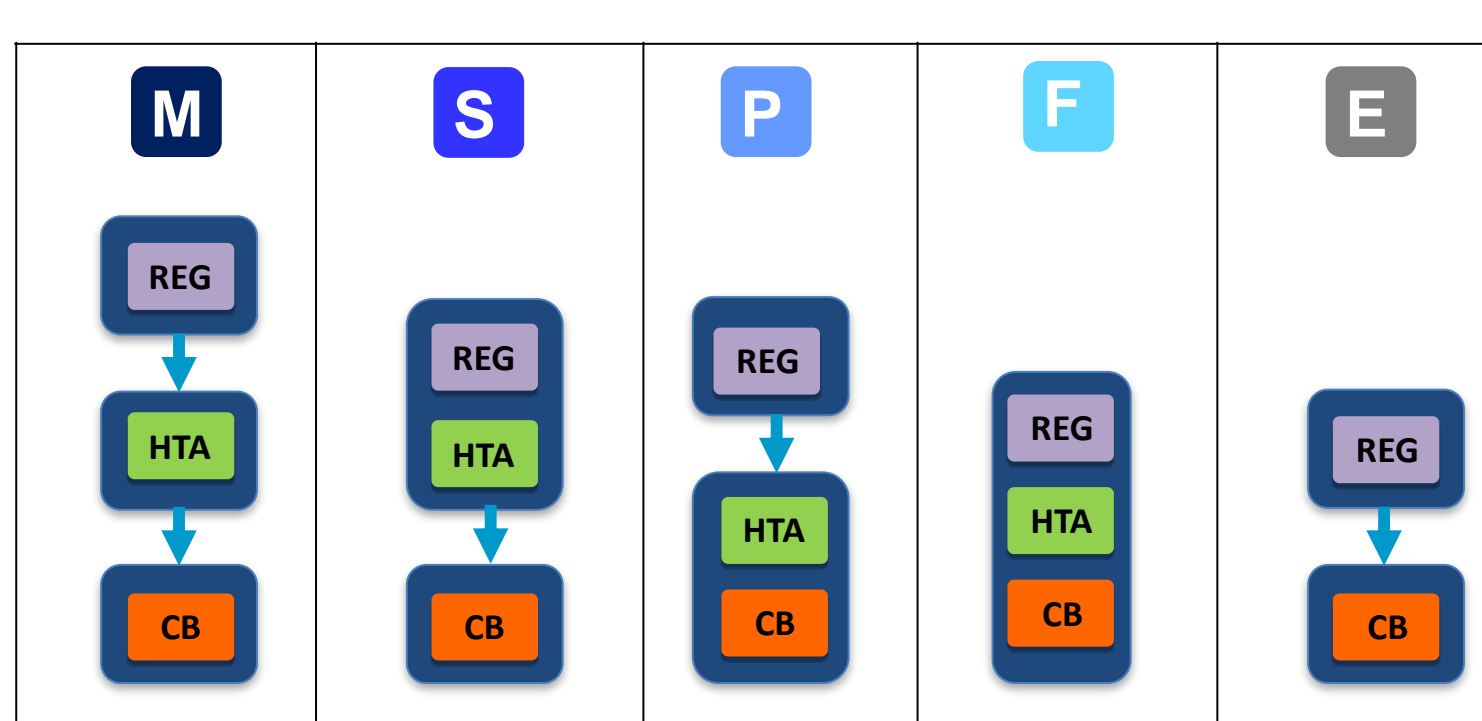
•An online translation tool was used to aid data collection when an English version of the website was not available. When more than one review was published, the first HTA recommendation or listing was recorded. Each HTA recommendation or listing was then allocated into one of three categories : recommended; recommended with restrictions or not recommended. The recommended and restricted categories were combined for the two category classification.

•The HTA recommendations and listing categories were coded for direct comparison between agencies to identify: total number of NAS's reviewed; congruence of outcomes for the two category classifications and congruence of outcomes for the three category classification. The 9 European jurisdictions were subsequently grouped by their System taxonomy and HTA process taxonomy to facilitate the identification of congruent outcomes by taxonomy (Figure 1 and 2).

Objectives

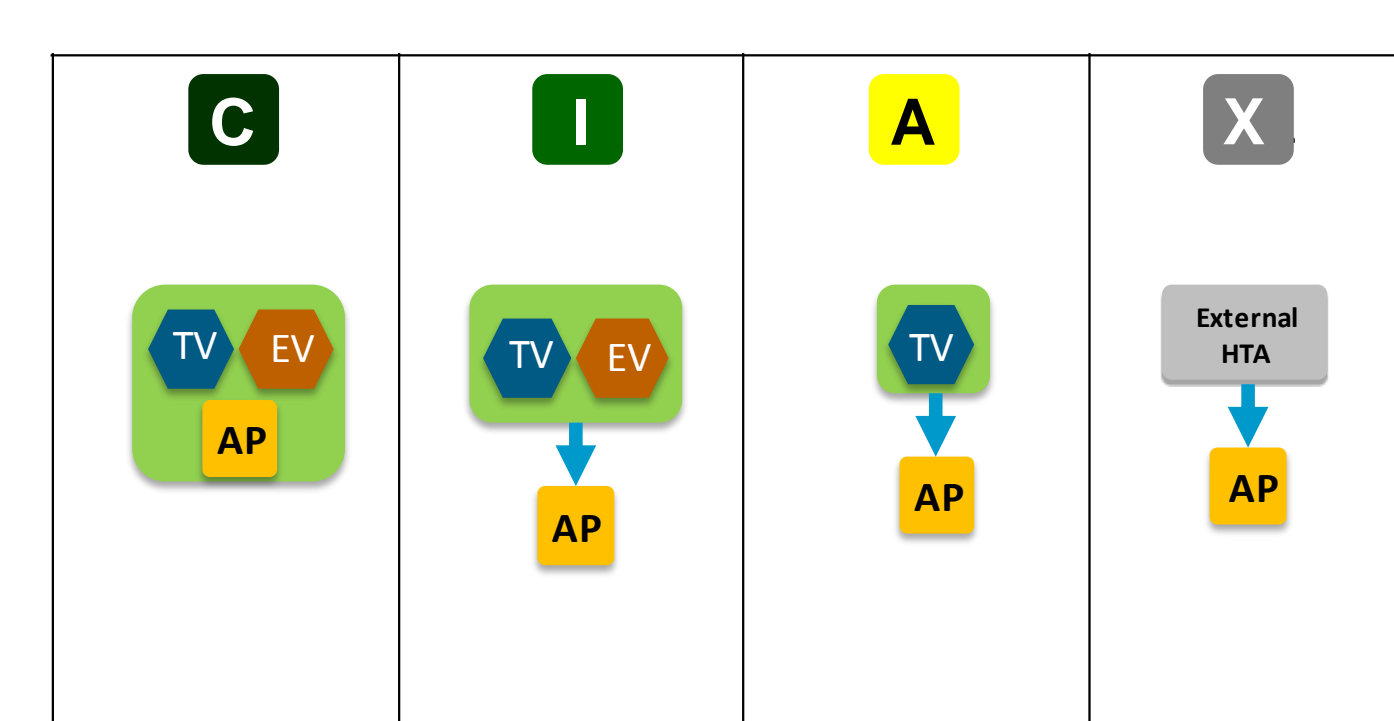
- 1) Compare positive and negative HTA recommendations for New Active substances (NAS's) granted EMA approval from 2008 to 2012
- 2) Compare positive, restricted and negative HTA recommendations for NAS's granted EMA approval from 2008 to 2012
- 3) Assess the relationship between System taxonomy with HTA recommendations for NAS's granted EMA approval from 2008 to 2012
- 4) Assess the relationship between HTA process taxonomy with HTA recommendations for NAS's granted EMA approval from 2008 to 2012

Figure 1: System taxonomy adapted from Allen et al. (2013)



Key: Regulatory agency (REG); HTA agency (HTA); Decision-making Coverage Body (CB)

Figure 2: HTA process taxonomy groups adapted from Allen et al. (2013)



Key: Therapeutic Value (TV); Economic Value (EV); Appraisal (AP)

Results

This research identified 102 NAS's granted EMA approval from 2008 to 2012. HTA recommendations or listings were sourced from the public domain for 9 European jurisdictions and categorised into three and two categories for comparison and directly compared between agencies for both the two and three category classifications. The percentage of congruent recommendations for the three category comparisons are provided in tables 1 and 2 accompanied by the total number of NAS's reviewed by both agencies. Similar tables have also been developed for the two category comparison but are not presented in this poster. The agencies listed in table 1 have been colour-coded and grouped according to their System taxonomic group (Figure 1). France and Germany display the greatest congruence and Scotland and England demonstrate the lowest congruence for jurisdictions allocated to the same System taxonomic group for both two and three categories classifications with 93% and 45% respectively (Table 1).

The congruence of HTA recommendations and listings have also been compared for the HTA process taxonomic groups (Figure 2) (Table 2). France and Netherlands display the highest percentage of congruent recommendations for the largest total of NAS's reviewed (n=72) for both the two and three category classifications (Table 2).

Table 1: Total congruence of HTA recommendations or listings allocated to 3 categories with System taxonomy

Congruent outcomes by 3 categories (n= total number of products reviewed)	Germany	Ireland	France	Netherlands	Belgium	England	Scotland	Sweden	Italy
Germany	N/A	54% (24)	93% (30)	68% (25)	79% (24)	60% (15)	33% (21)	31% (16)	100% (17)
Ireland	54% (24)	N/A	54% (50)	51% (47)	64% (42)	55% (29)	51% (49)	33% (42)	70% (40)
France	93% (30)	54% (50)	N/A	71% (72)	68% (68)	58% (38)	26% (74)	46% (57)	88% (66)
Netherlands	68% (25)	51% (47)	71% (72)	N/A	60% (57)	60% (35)	44% (63)	52% (54)	67% (58)
Belgium	79% (24)	64% (42)	68% (68)	60% (57)	N/A	65% (31)	27% (60)	54% (46)	83% (58)
England	60% (15)	55% (29)	58% (38)	60% (35)	65% (31)	N/A	45% (38)	53% (30)	64% (33)
Scotland	33% (21)	51% (49)	26% (74)	44% (63)	27% (60)	45% (38)	N/A	50% (56)	22% (60)
Sweden	31% (16)	33% (42)	46% (57)	52% (54)	54% (46)	53% (30)	50% (56)	N/A	56% (45)
Italy	100% (17)	70% (40)	88% (66)	67% (58)	83% (58)	64% (33)	22% (60)	56% (45)	N/A

Key: ≥70%- high congruence; ≥50%- medium congruence; <50%- low congruence

Table 2: Total congruence of HTA recommendations or listings allocated to 3 categories with HTA process taxonomy

Congruent outcomes by 3 categories (total number of products reviewed)	Germany	England	Belgium	Scotland	Ireland	Sweden	Italy	France	Netherlands
Germany	N/A	60% (15)	79% (24)	33% (21)	54% (24)	31% (16)	100% (17)	93% (30)	68% (25)
England	60% (15)	N/A	65% (31)	45% (38)	55% (29)	53% (30)	64% (33)	58% (38)	60% (35)
Belgium	79% (24)	65% (31)	N/A	27% (60)	64% (42)	54% (46)	83% (58)	68% (68)	60% (57)
Scotland	33% (21)	45% (38)	27% (60)	N/A	51% (49)	50% (56)	22% (60)	26% (74)	44% (63)
Ireland	54% (24)	55% (29)	64% (42)	51% (49)	N/A	33% (42)	70% (40)	54% (50)	51% (47)
Sweden	31% (16)	53% (30)	54% (46)	50% (56)	33% (42)	N/A	56% (45)	46% (57)	52% (54)
Italy	100% (17)	64% (33)	83% (58)	22% (60)	70% (40)	56% (45)	N/A	88% (66)	67% (58)
France	93% (30)	58% (38)	68% (68)	26% (74)	54% (50)	46% (57)	88% (66)	N/A	71% (72)
Netherlands	68% (25)	60% (35)	60% (57)	44% (63)	51% (47)	52% (54)	67% (58)	71% (72)	N/A

Key: ≥70%- high congruence; ≥50%- medium congruence; <50%- low congruence

Conclusions

•This research has met all four objectives by categorising the HTA recommendations and listings by two and three categories for comparison and by comparing the congruence of HTA recommendations and listings with the System taxonomy and HTA process taxonomy. The jurisdictions included in this study can be allocated to the two most popular groups of the System process taxonomy and three HTA containing groups of the HTA process taxonomy to produce pairs for comparison (Figures 1 and 2)(3).

•This research has identified pairs of agencies within the same taxonomy that demonstrate high congruence for both the two and three category comparisons (e.g. France and Netherlands). However, there are also pairs of agencies within the same taxonomy group that have produced low congruence: Ireland and Sweden (Table 2). This could suggest that there are other factors that influence the outcome of HTA recommendations and listings and these will be investigated in future studies.

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