Current Status of Outcomes-Based Agreements in Selected European Countries and Canada

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BACKGROUND

- Managed Entry Agreements (MEAs) are formal arrangements designed to share the risk related to uncertain clinical benefit or economic outcomes between payer and manufacturer.[1,2]
- MEAs are classified into three major groups: financial-, outcomes-based, and value-added agreements (Table 1).[3,4,5]

Table 1. Classification of MEAs.[3,4,5]

Group	Main types
Financial-based	• Discount / portfolio discount • Price-volume agreement • Utilization cap • Capitated contract • Manufacturer-funded treatment initiation • Clinical trial enrollment agreement
Outcomes-based	• Coverage with evidence development (CED) • Pay for performance (P4P) incl. conditional treatment continuation
Value-added	• Patient support • Infrastructure improvement • Improve payer cash flow

- Two main types of outcome-based agreements (OBAs) include:
  - Pay for Performance (P4P) agreements are applied to avoid inefficient expenditure on nonresponders. Examples of possible payment mechanisms include: payment for achieved outcomes, payment for treatment continuation in responders, payback for nonperformance, and payment for management of events that the drug failed to prevent or side effects.[3,6]
  - Coverage with Evidence Development (CED) is an agreement that allows for conditional reimbursement of new potentially effective drugs while more evidence (usually RWE) is being gathered to address uncertainty.[3]

OBJECTIVES

- Identify and analyse OBAs for pharmaceuticals concluded between 2010 and September 2019 in 7 countries: Canada, France, Germany, Italy, the Netherlands, Spain and the UK.

METHODOLOGY

- Literature review was conducted in September 2019 in the following information sources: EMBASE, Medline, HTA agencies' websites, proprietary databases, grey literature.
- Information was supplemented by interviews with insiders (1-2 per country).
- Collected data included: indication, ATC code, orphan status, contract type (P4P or CED), and date.
- Statistical descriptive analysis was performed to compare the number and type of OBAs identified by country.

RESULTS

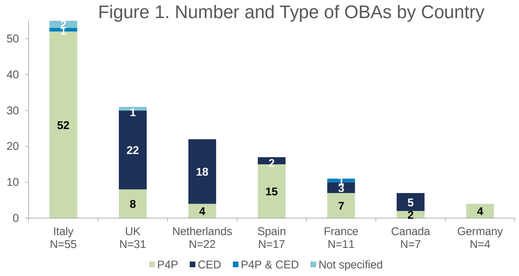
Overall Results

- In total, 147 OBAs for 93 drugs were identified.
- The majority of OBAs were P4P (N=92) followed by CED (N=50), not specified (N=3) and mixed type agreements (N=2).

Number of Agreements by Country

- Significant differences between countries in terms of number of identified OBAs were observed (Figure 1).
- The highest number of OBAs was found in Italy (N=55) and the lowest in Germany (N=4).
- The vast majority (95%; 52/55) of agreements identified in Italy were P4P deals.
- P4P agreements were also more common in Spain, France and Germany. They were used in 88% (15/17), 64% (7/11), and 100% (4/4) of the cases, respectively.
- Overall, in the Netherlands, UK and Canada a majority of CED agreements have been found. They accounted for 82% (18/22) in Netherlands, 71% (22/31) in UK, and 71% (5/7) in Canada.

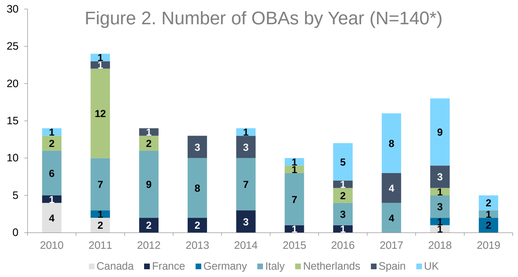
Figure 1. Number and Type of OBAs by Country



Number of Agreements per Year

- The highest number of agreements (N=24) was found in 2011, whereas the lowest in 2015 (N=10) (Figure 2).
- So far, in 2019, 5 agreements were reported.
- Since 2016, the number of OBAs increased in the UK while it decreased in Italy.
- No agreements were reported in Germany and Canada between 2012 and 2017. In 2018, for both countries single new agreements were found.
- In Spain, starting from 2011 few agreements (1-4) were identified each year apart from 2015.
- There was a significant decrease in OBAs reported in the Netherlands after 2011.
- No OBAs were reported in France after 2016.

Figure 2. Number of OBAs by Year (N=140*)

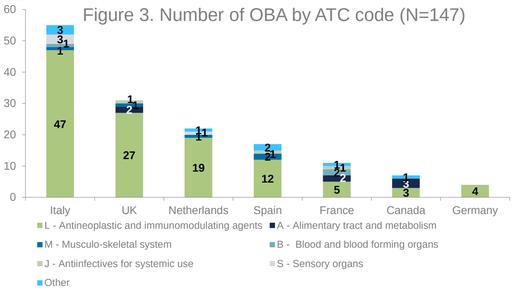


*for 7 contracts date was unknown

Total Number of Agreements by Indication

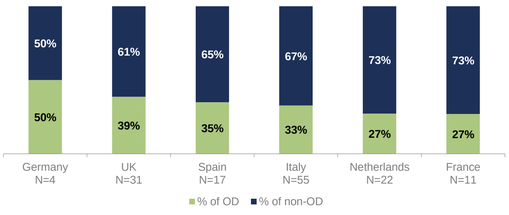
- Differences between therapeutic areas covered by OBAs were observed (Figure 3). Antineoplastic and immunomodulating indications were part of the highest number of OBAs (80%, 117/147).
- The other therapeutic areas were represented by only a few OBAs.

Figure 3. Number of OBA by ATC code (N=147)



- Among all identified OBAs, one third (34%; 47/140*) were for drugs with Orphan Designation (OD).
- The highest percentage of OBAs for ODs were observed in Germany (50%; 2/4) and the UK (39%; 19/31).

Figure 4. Percentage of OBAs with OD (N=140*)



*Canada does not assign formal OD to the drugs and was excluded from analysis

CONCLUSIONS & DISCUSSION .

- P4P contracts were more common than CED, probably because they ensure payers only pay for patients for whom therapy is successful.
- Italy lead in the number of OBAs, presumably due to well developed AIFA IT infrastructure facilitating data collection.[5,7,8]
- In Canada and Spain insufficient and fragmented infrastructure was reported as OBAs limiting factor.[1,5]
- Time trends in Germany and Canada could be explained by policy change (AMNOG law introduction in 2011; pCPA establishment in 2010), that has changed the P&R environment lowering the number of OBAs. Just recently the discussions on OBAs has returned in these countries.[1,5]
- In the UK the increase in the number of OBAs since 2016 is probably related to deals concluded within Highly Specialized Technology (HST) pathway and Cancer Drug Fund (CDF). Also in 2017, NHS took over new responsibility for negotiating OBAs directly with manufacturers.[5,9]
- Drop in the number of OBAs after 2011/2012 in the Netherlands was related to payers considering CEDs as inconclusive (efficacy difficult to prove based on observational studies). In addition at the end of 2012 the Dutch MoH announced that financially-based contracts will be favoured over OBAs[1,5]
- High number of OBAs for cancer drugs can be explained by oncology outcomes characteristics (precisely defined, short-term, easy to agree between parties).[7]
- Study limitation: this study is based on publicly available data only, therefore the actual number of OBAs may be higher.

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AMNOG – Pharmaceuticals Market Reorganisation Act
ATMP – Advanced Therapy Medicinal Products
CDF – Cacer Drug Fund
pCPA – pan-Canadian Pharmaceutical Alliance
P&R – pricing and reimbursement
RWE – real-world evidence

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