Precision versus non-precision oncology drug submissions to the National Centre for Pharmacoeconomics in Ireland

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BACKGROUND

Contemporary development of oncology drug treatments are quickly moving towards precision medicine where a companion diagnostic (CDx) is required to identify tumour signatures in patients who will respond to therapy. Precision oncology drugs represent a paradigm shift compared to non-precision oncology drugs in the treatment of patients, delivering more clinical benefit, and lowering healthcare costs.(1, 2)

The National Centre for Pharmacoeconomics (NCPE) assesses all new drugs approved by the European Medicines Agency (EMA). The Corporate Pharmaceutical Unit of the Health Service Executive (HSE) notifies the pharmaceutical applicant to prepare a Rapid Review (RR) which is then submitted to the NCPE for assessment. The NCPE will then recommend or not recommend a Health Technology Assessment (HTA). The HTA submission to the NCPE will then be appraised and its recommendation will be sent to the HSE drugs committee in Ireland for the final decision on reimbursement.

OBJECTIVE

We investigated the characteristics of all oncology drugs RR and HTA assessments submitted to the NCPE since 2010 with a focus on precision oncology drugs, which benefit a subset of patients whose tumours display specific molecular signatures.

METHODS

We developed a database derived from all oncology RR and HTA assessments conducted by the NCPE from 2010 until October 2022.(3) The database excluded CAR T-Cell, chemo-, hormonal, mixed precision and non-precision, modified virus, and radiopharmaceutical therapies. Based on indication, oncology drugs were labelled precision or non-precision. If the indication was inconclusive the EMA's summary of product characteristics was crossed checked to determine whether the oncology drug was accompanied by a CDx for that oncological condition.(4) The dataset of biologic and small molecule oncology drugs were extracted from 30 pharmaceutical companies that had made RR submissions to the NCPE. Additional information was added to the database regarding reimbursement scheme (Hospital or High-Tech), whether the drug had a new and unique mechanism of action ('first-in-class'), and orphan status. The descriptive statistics and reimbursement timelines from this database were then compared for precision and non-precision oncology drugs.

RESULTS

Since 2010 there have been 84 RR submissions for precision oncology drugs and 87 submissions for non-precision oncology drugs to the NCPE. Precision oncology drugs represented 35% of all biologic and small molecule oncology submissions from 2010 to 2016 which increased to 54% from 2017 to October 2022 (see figure 1), with the tipping point in 2019. Differences between precision and non-precision drugs were statistically significant for both first-in-class (83% vs 67%; p-value = 0.012) and orphan status (12% vs 34%; p-value < 0.001) (see figure 2). Further analysis showed that precision oncology drugs were less likely to be hospital drugs (38% vs 62%) and more likely to be High-Tech drugs (56% vs 36%) (see figure 2). Following a RR, a HTA was slightly less likely to be recommended for precision than non-precision oncology drugs (64% vs 76%) (see figure 3) and a positive reimbursement recommendation following a HTA was slightly more likely for precision vs non-precision oncology drugs, although not statistically significant (69% vs 67%; p = 0.823) (see figure 3). Finally, the average number of days to a reimbursement decision was slightly longer for a precision oncology drug compared to non-precision oncology drug (600 versus 585 days) although this difference was not statistically significant (p = 0.427). Figure 4 shows average timelines have varied over time with precision oncology drugs initially taking longer than non-precision oncology drugs to achieving reimbursement to very little difference in 2021.

Figure 1: Precision versus non-precision oncology drug Rapid Review submissions to NCPE

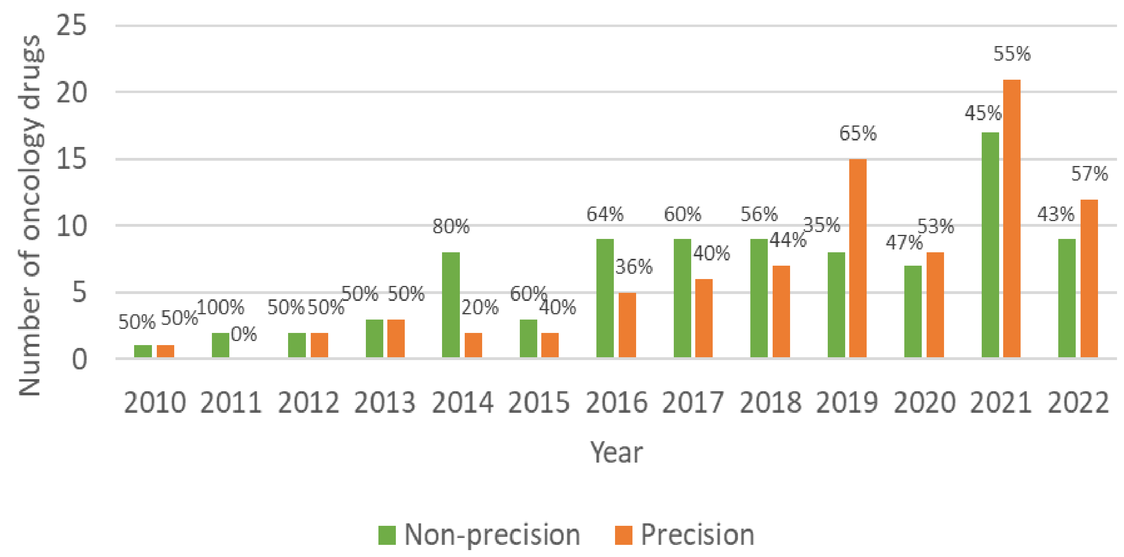

Figure 2: Proportion of precision and non-precision oncology drugs amongst first-in-class, orphan drug status, and hospital and high-tech drug scheme

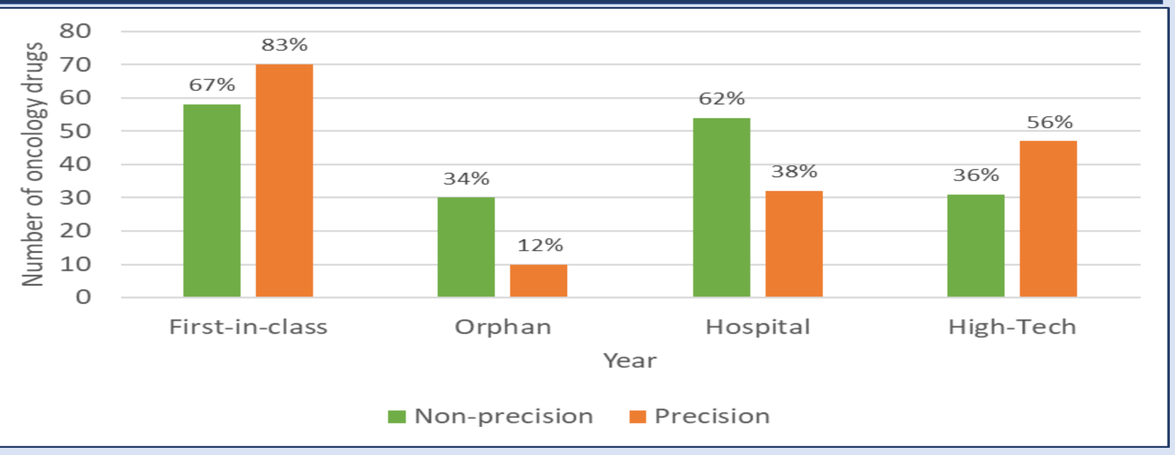

Figure 3: Proportion of precision and non-precision oncology drugs with HTA recommendation and a reimbursement

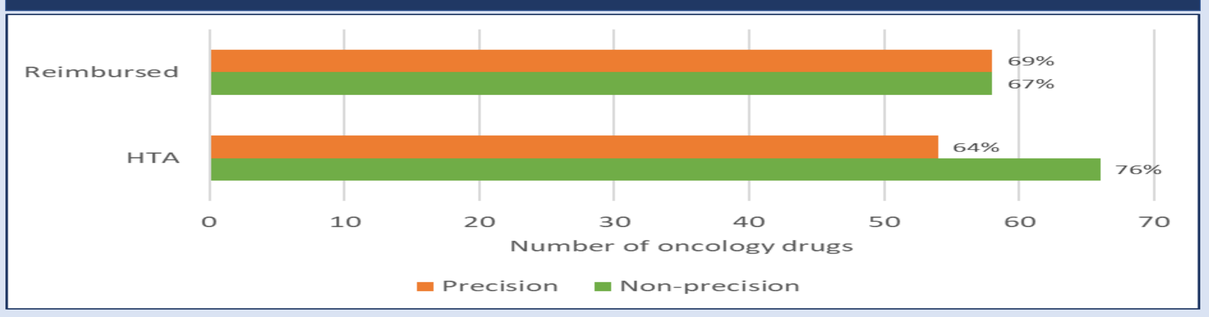

Figure 4: Average number of days to reimbursement decision for precision versus non-precision oncology drugs*

*This represents a sample of oncology drugs submitted to the NCPE for assessment as not all drugs were reimbursed or had a reimbursement date

CONCLUSION

There has been an increase in precision oncology drugs evaluated by the NCPE in recent years as their inherent value is realised by manufacturers, payers, and patients alike. RRs of precision and non-precision oncology drugs were equally as likely to be recommended for a HTA despite statistically significant differences in first-in-class and orphan status. While the number of precision versus non-precision oncology drugs submissions are lower for Hospital drugs there are more submissions for High Tech oncology drugs which are precision. Precision oncology drugs overall had a slightly slower (which improved over time) but more favourable reimbursement outcome than non-precision oncology drugs, but this difference was not statistically significant.

REFERENCES

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