1. Introduction: Irish Law and the Threshold

The principle that the opportunity cost of providing new interventions in terms of other services foregone be considered when adopting novel treatments is recognised in Irish law as part of the 2013 Pricing and Supply of Goods Act [1]. While the Act does not detail how the opportunity cost should be considered common practice in cost-effectiveness analysis (CEA) is to use a cost-effectiveness threshold as a proxy for the opportunity cost of reimbursement.

Ireland has suffered a profound fiscal crisis since 2008. Years of rapid health expenditure growth came to an abrupt end. Figure 1 shows the profound reduction in overall health and pharmaceutical spending since 2008.

Prior to 2012 Ireland did not have an explicit cost-effectiveness threshold. Instead, a “notional” threshold was used by Irish cost-effectiveness advisory bodies. Initially this threshold was €45,000/QALY, but was revised down to €20,000 in 2009, apparently due to concerns of budget sustainability.

In October 2012 a pricing and supply agreement between the Irish Pharmaceuticals Healthcare Association, a pharmaceutical industry representative body, the Irish Department of Health and the Health Service Executive, the body responsible for delivering public healthcare in Ireland, made the threshold explicit for the first time[2]. The agreement revised the threshold back up to €45,000/QALY.

This poster examines the current Irish threshold and details four reasons why it might not support the rational allocation of health resources.

2. Four Reasons for Concern:

2.1 The Threshold as a Price Floor not Ceiling

The 2012 agreement states that all interventions reaching the threshold will be adopted. It also states that those exceeding the threshold will not necessarily be rejected, but referred on for further negotiations, presumably to be adopted with incremental cost-effectiveness ratios (ICERs) above the threshold. As such, there is no explicit upper reimbursement limit and the Irish threshold operates in principle not as a price ceiling, but rather as a price floor.

In practice some reimbursement applications are made below the threshold, possibly reflecting a need to achieve a rapid reimbursement decision or pricing constraints from other markets. Conversely, many applications are made at ICERs above the threshold and have subsequently been adopted. The extent of agreed reductions on the initial application price are not disclosed. Table 1. reports the ICERs on application of a number of recently accepted intervention in Ireland. Note both the high ICERs and that some interventions have been adopted without assessment. The function of the threshold as a price floor and the lack of a binding ceiling means it may only be a weak control on the adoption of cost-ineffective interventions.

2.2 The Threshold only Applies to Drugs

The 2012 threshold only applies to drugs. It is therefore unclear if the previous €20,000 threshold applies to non-drug interventions or if the €45,000 threshold applies to all interventions. The application of different thresholds would clearly result in inefficiencies and inequities in the allocation of healthcare resources between drug and non-drug uses.

2.3 The Threshold has no Empirical Basis

None of the thresholds applied in Ireland to date have been supported by empirical evidence. The current Irish threshold was revised back up to €45,000/QALY, but was revised down to €20,000 in 2009, apparently due to concerns of budget sustainability.

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Figure 1 Real GDP and Health Expenditure Index, 1990 = 100


2.4 A €45,000 Threshold is Probably too High

While the current Irish threshold is not supported by any empirical evidence, recent work to estimate an appropriate threshold for the UK based on actual services displaced found a threshold of £13,000/QALY [3]. Assuming that Ireland’s threshold should be broadly comparable, this suggests that the current threshold is too high. Further evidence regarding the appropriateness of the current Irish threshold could be found by investigating the cost-effectiveness of services in that are either subject to long waiting lists or being curtailed due to current spending cuts. While such work is yet to be done, it seems likely that at least some of the currently curtailed services are more cost-effective than the current threshold.

Table 1. Recently approved interventions in Ireland with ICERs at initial appraisal

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Initial ICER at Review</th>
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<tbody>
<tr>
<td>Bevacizumab</td>
<td>€47,900/QALY</td>
</tr>
<tr>
<td>Sunetinib</td>
<td>€57,380/QALY</td>
</tr>
<tr>
<td>Afinitor</td>
<td>€113,000/QALY</td>
</tr>
<tr>
<td>Ezcaridine</td>
<td>€26,136/100</td>
</tr>
<tr>
<td>Evolocumab</td>
<td>€649,015/QALY</td>
</tr>
<tr>
<td>Cabozantinib</td>
<td>€120,084/QALY</td>
</tr>
<tr>
<td>Venetoclax</td>
<td>€131,883/QALY</td>
</tr>
<tr>
<td>Azololbcept</td>
<td>Not reviewed</td>
</tr>
<tr>
<td>Apremilast</td>
<td>Not reviewed</td>
</tr>
<tr>
<td>Milnacipran</td>
<td>Not reviewed</td>
</tr>
</tbody>
</table>

3. Conclusions

Although thresholds have recognised flaws as decision rules [4], they offer a simple and transparent means of prioritising care. If the threshold is too high then newly adopted interventions may displace more care than they provide, thereby reducing the overall effectiveness of the health system. While the most obvious and commonly voiced moral concern with the application of cost-effectiveness is a worry that care is denied on the basis of cost, the concern of an excessive threshold is that insufficient rationing is taking place.

The drug-only scope of the current threshold, its function as a price floor and its more than doubling at a time of ongoing profound fiscal difficulty all contribute to a sense that it may put the interests of manufacturers ahead of patients. Therefore, it is important that Irish cost-effectiveness experts reconsider the current threshold and work to establish a new threshold that more accurately reflects the opportunity cost of interventions displaced or under-provided.

Restoring the balance between existing services and new candidate interventions is essential for the efficient and equitable function of the Irish health system.

References