Additional Information provided by the External Assessment Centre

Impact of a potential royalty payment from Vibratip to the NHS.

Background

NICE became aware from the sponsor of an issue relating to royalties. The NICE Technical Analyst therefore asked Newcastle and York EAC to obtain further information from the sponsor and provide opinion on any impact this claim may have on the economic evaluation presented to MTAC at the Committee Meeting to be held on 12th June 2014.

The EAC emailed the sponsor about this issue and received a response which is Commercial in Confidence (Appendix 1).

EAC opinion:

The sponsor appears confident from sales projections that royalties will begin to be generated from Vibratip in late 2014 and may accumulate to appreciable sums in future. The recipient of these royalties from McCallan Medical is the single NHS Foundation Trust which holds the intellectual property (IP) rights to Vibratip. The sponsor did not provide any information regarding the subsequent division of royalties from the NHS Foundation Trust to any other parties, but did concede that 'the royalty obviously cannot be shared out to offset any direct Vibratip costs around the country'.

Therefore, for UK sales, the NHS benefits overall only by a reduced cost [redacted] on those devices sold to the single NHS Foundation Trust which holds the IP rights to Vibratip. This is more or less negligible.

The sponsor appears to imply that favourable UK guidance will also lead to increased overseas sales and therefore increased revenues to the NHS from non-exchequer sources. However, since NHS Trusts are separate legal entities, revenue would not flow to the wider NHS, but rather stay within the single NHS Foundation Trust which holds the IP rights to Vibratip. The likes of the National Institute for Health Research (NIHR) accept this position, and argue that the public benefit arises from making innovative technologies available more widely. So, pragmatically, requiring individual NHS organisations to share their revenue across the whole NHS would more or less stop innovation in its tracks. In this case, the single NHS Foundation Trust which holds the IP rights to Vibratip would likely argue (rightly) that they took the risk in supporting the product and therefore should retain the revenues, such as they are.

We would therefore advise that, whilst the single NHS Foundation Trust holding Vibratip IP rights may benefit from royalty payments in the future, there is no national requirement for this local income stream to be diverted to patient care. Even if some

of the royalties are apportioned to patient care in this single NHS Foundation Trust, the impact upon all other NHS providers is negligible.

This new information on future royalties therefore does not have any impact upon the economic evidence assessment conducted by the EAC and does not change any of the results or conclusions presented in the EAC assessment report.

Appendix 1.

Question posed by Newcastle and York EAC to the sponsor, 04/06/2014:

Subject: Query on Vibratip royalties information

The External Assessment Centre (EAC) has been asked by NICE to contact you to request clarification on the [redacted] royalty to the NHS from Vibratip, which you mentioned in a recent telephone call.

Any information you provide to the EAC can be treated as commercial-in-confidence if required.

NICE would like you to clarify if there is a royalty payment from Vibratip to the NHS in current operation, or planned for the future. If there is, can you please provide further details on which organisation(s) receive the money and how it is calculated?

For your information, we have experience of similar royalty mechanisms from medical devices developed within Newcastle upon Tyne Hospitals NHS Trust (NUTH) over the years. In our case, any royalties arising from sales would return to the licensor (NUTH) in accordance with a licence agreement between the Trust and the licensee. Usually, revenues would be shared between various parties who had contributed to the development of a product, after deduction of direct exploitation costs (e.g. patent protection etc). Other parties in our case might include Newcastle University, funding bodies (e.g. Wellcome Trust, NIHR) who may take ~25% and collaborating or private funding partners. Some organisations share revenue with the inventors themselves. The details depend on local agreements and are not normally made public.

There is no requirement, as far as we are aware, for NHS Trusts who receive royalty payments to use the money to reduce their costs of patient care. So, although some of the royalty may be used for public benefit in the broadest sense, it would not appear reasonable to claim that royalties from Vibratip offset some of the cost to the NHS. To a first approximation, we would advise NICE that they don't. However, I appreciate that our experience in NUTH may not be comparable to the licensing and royalties arrangements for Vibratip, so I would of course very much welcome your views in response, and any further information you can share on royalty payments and benefactors, specific to Vibratip.

An email response was received from the sponsor on the 5th June. It was marked as commercial-in-confidence and cannot be reported here.