CONFIDENTIAL

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Dear Carole

Revised Patient Access Scheme – erlotinib – first line treatment in EGFR-TK mutation positive non-small cell lung cancer (NSCLC)

I am writing to confirm the Department of Health's position on the revised Patient Access Scheme (PAS) arrangements that have been proposed by Roche for Tarceva (erlotinib) in the first line treatment of EGFR-TK mutation positive non-small cell lung cancer. The proposal is for a simple discount scheme, with the discount applied to original invoices for NHS purchases of erlotinib.

I understand that Roche have proposed the simple discount PAS on the condition that the level of discount offered through the scheme should remain confidential and should not be published in final NICE guidance.

The Department is content in this case for the PAS proposal to be considered in the relevant appraisal, with the level of discount remaining confidential.

NICE must of course be satisfied that sufficient information can be communicated to stakeholders to explain an appraisal recommendation. In this regard, what constitutes a sufficient level of transparency is a matter for the Institute to determine in developing its guidance. In addition, the NHS must have access to the discount price when final NICE guidance is made available, so Trusts and commissioners are able to properly account for the PAS.

I note that there is an existing PAS for erlotinib, which was recommended as part of guidance on the use of erlotinib in 2nd line treatment of NSCLC (TA162). This PAS originally made the price of erlotinib equivalent to that of a comparator treatment, docetaxel. It is equivalent to a simple discount of 14.5% and is currently offered across all orders of erlotinib.

If erlotinib is recommended with the revised PAS by the Institute in the ongoing technology appraisal, the PAS included in that appraisal will supersede the existing PAS for erlotinib included in TA162. It is, of course, a

matter for the Institute to determine what revisions or updates would be required to TA162 to reflect this change.

Yours sincerely

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Pharmacy and Industry Group