



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 February 2016  
EMA/CHMP/100611/2016  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Giotrif afatinib

On 25 February 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Giotrif. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a new indication as follows:

Giotrif as monotherapy is indicated for the treatment of locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.

For information, the full indications for Giotrif will be as follows:

“Giotrif as monotherapy is indicated for the treatment of

- Epidermal Growth Factor Receptor (EGFR) TKI-naïve adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutation(s);
- locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy (see section 5.1).”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

