ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

The Marketing Authorisation Holder shall ensure that all physicians who are expected to prescribe Vectibix are provided with educational materials informing them of the importance of KRAS ascertainment before treatment with panitumumab. The key elements of these educational materials will be the following:

- Brief introduction to the Vectibix indication and the purpose of this tool
- Brief introduction to KRAS and its role in the panitumumab mechanism of action
- Information that in patients with mutant KRAS tumours panitumumab has shown a detrimental effect in combination with FOLFOX and no effect as monotherapy and in combination with FOLFIRI
- Recommendation that Vectibix:
    - should only be used in patients whose tumours are wild-type KRAS
    - should not be used as monotherapy or in combination with FOLFIRI in patients whose tumours are mutant KRAS or patients whose tumours have not been tested for KRAS status
    - is contraindicated in combination with FOLFOX in patients with mutant KRAS tumours or in patients with unknown KRAS tumour status
- Information on how the KRAS testing should be appropriately conducted

The Marketing Authorisation Holder shall agree the format and content of the above materials with the National Competent Authority of each Member State.