

## **ANNEX**

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

## **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE ADDRESSED TO THE MEMBER STATES**

The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The MAH shall ensure that prior to launch, all doctors who intend to prescribe Tasigna, and all pharmacists who may dispense Tasigna, are provided with a healthcare professional information pack containing the following:

- Educational brochure
- Summary of Product Characteristics (SPC) and Package Leaflet and Labelling

### **Key elements to be included in the educational brochure**

- Brief background on Tasigna, its authorised indication and posology
- Information on the cardiac risks associated with the use of Tasigna
  - That Tasigna can cause prolongation of the QT interval and that patients at risk of arrhythmia, especially torsade de pointes, should not be prescribed Tasigna.
  - The need to avoid co-prescription with any other medicines that might prolong the QT interval
  - Caution in prescribing to patients with a history of or risk factors for coronary heart disease
  - That Tasigna may cause fluid retention, cardiac failure and pulmonary oedema
- That Tasigna is metabolised by CYP3A4 and that strong inhibitors or inducers of this enzyme may significantly affect exposure to Tasigna.
  - That inhibitors may increase the potential for adverse drug reactions in particular QT interval prolongation.
  - To warn patients about OTC medicines in particular St John's Wort
- The need to inform patients about the effects of food on Tasigna
  - Not to eat within two hours before and one hour after taking Tasigna
  - The need to avoid foods such as grapefruit juice which inhibit CYP3A4 enzymes