## Part VI: Summary of the risk management plan

### Summary of risk management plan for Pirfenidone 267 mg and 801 mg Film-coated Tablets

This is a summary of the risk management plan (RMP) for Pirfenidone 267 mg and 801 mg Film-coated tablets. This RMP details important risks of Pirfenidone 267 mg and 801 mg Film-coated Tablets, how these risks can be minimised, and how more information will be obtained about Pirfenidone 267 mg and 801 mg Film-coated tablets risks and uncertainties (missing information).

Pirfenidone 267 mg and 801 mg Film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pirfenidone 267 mg and 801 mg Film-coated tablets should be used.

### I. The medicine and what it is used for

Pirfenidone 267 mg and 801 mg Film-coated tablets are authorised for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).

It contains Pirfenidone as the active substance and it is given as tablets by oral route. The tablets are to be swallowed whole with water and taken with food.

### II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Pirfenidone 267 mg and 801 mg Film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Pirfenidone 267 mg and 801 mg Film-coated tablets risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Pirfenidone 267 mg and 801 mg Film-coated tablet, these measures are supplemented with additional risk minimisation measures mentioned under ´summary of important risks´, below.

If important information that may affect the safe use of Pirfenidone 267 mg and 801 mg Film-coated Tablet is not yet available, it is listed under 'missing information' below.

#### *II.A List of important risks and missing information*

Important risks of Pirfenidone are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Pirfenidone. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further

evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | • Photosensitivity reaction and rash<br>• Drug-Induced Liver Injury (DILI)<br>• GI symptoms |
| Important potential risks | • Severe skin reactions |
| Missing information | • QT Prolongation<br>• Underlying specific cardiac events |

### *II.B Summary of important risks*

| **Photosensitivity reaction and rash** | |
|---|---|
| Photosensitivity reaction and rash | *Routine risk minimisation measures:*<br>Listed in SmPC section 4.2,4.4 and 4.8.<br>Listed in PL section 2 and 3.<br>*Additional risk minimisation measures:*<br>A Safety Checklist about monitoring and management of photo-sensitivity reaction and rash will be made available at the time of launch to all local medical staff involved in managing patients with IPF. It requests reporting of serious adverse reactions and clinically significant ADRs of special interest including photosensitivity reactions and skin rashes to the MAH, where an association is suspected. Any other clinically significant ADRs based on the judgment of the prescriber are also to be reported. |

| **Abnormal liver function tests, increased ALT and AST levels, total serum bilirubin increased in combination with increases in ALT and AST** | |
|---|---|
| Drug-Induced Liver Injury (DILI) | *Routine risk minimisation measures:*<br>Listed in SmPC section 4.2, 4.4 and 4.8.<br>Listed in PL section 2, 3 and 4.<br>*Additional risk minimisation measures:*<br>A Safety Checklist about monitoring and management of DILI is to be distributed to all local medical staff involved in managing patients with IPF, and may be redistributed in case of further updates or launch of new formulations. It requests HCPs to report serious adverse reactions and all clinically-significant ADRs of liver-related abnormalities to the MAH. Any other clinically significant ADRs based on the judgment of the prescriber are also to be reported. |

## *II.C Post-authorisation development plan*

### II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Pirfenidone 267 mg and 801 mg Film-coated tablets.

### II.C.2 Other studies in post-authorisation development plan

There are no studies required for Pirfenidone 267 mg and 801 mg Film-coated tablets.