PART VI: SUMMARY OF THE RMP

VI.1 The Medicine and What it is Used for

Iron supplements intended for oral administration remain the most common treatment option for ID. They contain bivalent (iron(II); e.g., ferrous sulphate, ferrous fumarate, ferrous gluconate) or trivalent (iron(III); e.g., iron polymaltose complex) iron forms. Iron needs to be reduced in order to be absorbed from the GI tract. However, more than 80-90% of ingested iron remains unabsorbed [6]. Oral iron therapy is the treatment of choice for the majority of patients because of the ease of administration and the perceived effectiveness, safety and economy. Although appropriate for many patients, oral iron (in particular in the bivalent form) can cause dose-dependent, undesirable effects in up to 40% of patients [5].

The active ingredient of Maltofer is a water-soluble complex of a polynuclear iron(III)-hydroxide core with a polymaltose shell.

The polymaltose shell accounts for the stability and solubility of the complex thus avoiding exposure of the gastric epithelium to the free iron. The controlled uptake of iron from the stable iron(III)-hydroxide core assures a very low toxicity and good tolerance. In contrast, ferrous salts have been proposed to be taken up by both an active mechanism and also by a passive pathway, i.e., paracellular diffusion [28].

The benefit of Maltofer in the treatment of ID is widely supported from the clinical evidence, thus demonstrating the efficacy and good tolerability of Maltofer at treating or preventing ID in patient populations of all ages.

Also, a quantitative statistical analysis of several studies comparing IPC versus ferrous sulphate efficacy (as assessed by Hb levels after approximately 2 months of treatment) and safety (as assessed by incidence of side effects), demonstrated similar efficacy. Side effects were reported less frequently with IPC (14.9%) than with ferrous sulphate (34.1%; $p<0.001$), particularly upper digestive troubles, diarrhoea and constipation. The tolerance of IPC in adults was clearly better than that of ferrous sulphate, which may result in better acceptability and treatment adherence [29].

Maltofer is indicated for treatment and prevention of ID (oral drops) and treatment and prevention of ID in adults and adolescents above the age of 12 (chewable tablets).

VI.2 Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

VI.2.1 List of Important Risks and Missing Information

Table 20 List of Important Risks and Missing Information

Important identified risks	None
Important potential risks	None
Missing information	None

VI.2.2 Summary of Important Risks

Not applicable. There are no important identified or potential risks.

Table 21 Important Identified Risk

Risk	What Is Known (Including Reason Why it is Considered as Potential Risk)
Not applicable	Not applicable

Table 22 Important Potential Risk

Risk	What Is Known (Including Reason Why it is Considered as Potential Risk)
Not applicable	Not applicable

Table 23 Missing Information

Missing Information	What Is Known
Not applicable	Not applicable

VI.2.3 Post-authorisation Development Plan

Not applicable.

VI.2.3.1 Studies Which Are Conditions of the Marketing Authorisation

Not applicable. During the reporting period there are no studies which are conditions of the Marketing Authorisation.

VI.2.3.2 Other Studies in Post-authorisation Development Plan

Not applicable. There are no other studies in post-authorisation development plan.