Summary of risk management plan for Tandemact (Pioglitazone/glimepiride FDC)

This is a summary of the risk management plan (RMP) for Tandemact. The RMP details important risks of Tandemact, how these risks can be minimised, and how more information will be obtained about Tandemact's risks and uncertainties (missing information).

Tandemact's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tandemact should be used.

This summary of the RMP for Tandemact should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Tandemact's RMP.

I. The medicine and what it is used for

Tandemact is authorised for second-line treatment of adult patients with type II diabetes mellitus who show intolerance to metformin or for whom metformin is contraindicated and who are already treated with a combination of pioglitazone and glimepiride (see SmPC for the full indication). It contains pioglitazone and glimepiride as the active substances and it is given by mouth as a tablet.

Further information about the evaluation of Tandemact's benefits can be found in Tandemact's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/medicines/human/EPAR/tandemact

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

Important risks of Tandemact, together with measures to minimise such risks and the proposed studies for learning more about Tandemact's 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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Tandemact is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tandemact are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Tandemact. 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	Pioglitazone None Glimepiride Blood dyscrasias
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Blood dyscrasias	
Evidence for linking the risk to the medicine	There have been reports of low blood cell counts (red blood cells, white blood cells and platelets, or sometimes all 3 types at the same time) in patients taking glimepiride. Although rare, they can be life threatening.
Risk factors and risk groups	Elderly patients appear overrepresented. A particular risk group for hemolytic anemia appears to be G6PD deficient patients, this is considered a class effect.
Risk minimisation measures	**Routine risk minimisation measures** SmPC 4.4 and PL sections 2 and 4 providing special warning on the possible risk of blood dyscrasias and advising that treatment with Tandemact requires regular haematological monitoring; cautioning use in patients with G6PD-deficiceny and to consider treatment with non-sulfonylurea alternative. **Additional risk minimisation measures** None

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 Tandemact.

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

There are no studies required for Tandemact.