Swiss Summary of the Risk Management Plan (RMP) for Vedolizumab (ENTYVIO)

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Marketing Authorization Holder: Takeda Pharma AG

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risk as well as to prevent or minimise them.

The RMP summary of ENTYVIO is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of ENTYVIO in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Takeda Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of ENTYVIO.

Summary of risk management plan for ENTYVIO (vedolizumab)

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

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

This summary of the RMP for Entyvio 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 Entyvio's RMP.

I. The medicine and what it is used for

Entyvio is authorised for ulcerative colitis, Crohn's disease and chronic pouchitis (see SmPC for the full indications). It contains vedolizumab as the active substance and it is available as powder for concentrate for solution for infusion and as solution for injection, to be administered by intravenous infusion or by subcutaneous injection (ulcerative colitis and Crohn's disease only) respectively.

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

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

Important risks of Entyvio, together with measures to minimise such risks and the proposed studies for learning more about Entyvio'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 periodic safety update report (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 Entyvio is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Entyvio 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 Entyvio. 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	• None
Important potential risks	• None
Missing information	• Long-term safety

II.B Summary of important risks and missing information

Missing Information: Long-term Safety	
Risk minimization measures	**Routine risk minimisation measures:** None **Additional risk minimisation measures:** No risk minimisation measures
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** MLN0002SC-3030 See Section II.C of this summary for an overview of the post-authorisation development plan.

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 Entyvio.

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

MLN0002SC-3030: A Phase 3b Open-label Study to Determine the Long-Term Safety and Efficacy of Vedolizumab Subcutaneous in Subjects with Ulcerative Colitis and Crohn's Disease.

Purpose of the study: To obtain data on long-term safety and tolerability of vedolizumab SC in subjects with UC or CD.