Summary of risk management plan for NULOJIX (belatacept)

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

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

I. The medicine and what it is used for

NULOJIX is authorised for prophylaxis of graft rejection in adult recipients of a renal transplant(see SmPC for the full indication). It contains belatacept as the active substance and it is given by intravenous infusion.

Further information about the evaluation of NULOJIX's benefits can be found in NULOJIX'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/nulojix

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

Important risks of NULOJIX, together with measures to minimise such risks and the proposed studies for learning more about NULOJIX'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 (eg, 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, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

In the case of NULOJIX, these measures are supplemented with *additional risk minimisation measures mentioned* under relevant important risks, below.

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

II.A List of important risks and missing information

Important risks of NULOJIX 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 NULOJIX. 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 (eg, on the long-term use of the medicine).

List of important risks and missing information

Important identified risks	None
Important potential risks	Medication Errors in the Maintenance Dose when Transitioning from Drug Substance Manufacturing Process C to Process E
Missing information	Pregnancy and lactation

II.B Summary of important risks

The important risks are described in the product labeling and routine pharmacovigilance is appropriate mitigation.

Important potential risks

Medication Errors in the Maintenance Dose when Transitioning from Drug Substance Manufacturing Process C to Process E	
Evidence for linking the risk to the medicine	In theory, Process C and Process E drug products could both be in each concerned EU market for approximately 1 to 2 months, until all available Process C drug product is consumed.
Risk factors and risk groups	The risk is limited to an error by a healthcare professional, as the product is not self administered by the patient.
Risk minimization measures	Routine risk minimisation measures: A new colour will be applied to the outer package and vial label of the Process E finished product to differentiate it from the Process C finished product. Additionally, the outer package of Process E finished product will contain the warning "**IMPORTANT INFORMATION,** New maintenance dose see package leaflet" printed in red with a red frame during and after the transition (6 months) from Process C to Process E. Additional risk minimisation measures: DHPC
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None.

Missing information

Pregnancy and lactation	
Risk minimization measures	Routine risk minimization measures: SmPC Section 4.6

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 NULOJIX.

Category 1 and 2 on-going and planned additional pharmacovigilance activities

Study short name and title	**Rationale and study objectives**
None.	

Planned and on-going post-authorisation efficacy studies

Study short name and title	**Summary of objectives**
None.	

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

Category 3 on-going and planned additional pharmacovigilance activities

Study short name and title	**Rationale and study objectives**
None.	