Summary of the Risk Management Plan (RMP)

Name of the medicinal product:	Alluzience
Active substance:	Complexus toxini botulinici A et haemagglutinini
Version number of the current RMP:	7.3
Name of the marketing authorisation holder:	Future Health Pharma GmbH
Date of RMP:	13. Juli 2020

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 risks as well as to prevent or minimise them. The RMP summary of “Alluzience” 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 “Alluzience” in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. “Future Health Pharma GmbH” is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Alluzience”.

1 PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

1.1 Summary of the Risk Management Plan for Dysport (BTX-A-HAC powder) and Alluzience (BTX-A-HAC solution)

This is a summary of the Risk Management Plan (RMP) for Dysport (BTX-A-HAC powder) and Alluzience (BTX-A-HAC solution).

The RMP details important risks of Dysport (powder) and Alluzience (solution), how these risks can be minimised and how more information will be obtained about the risks and uncertainties (missing information).

Dysport's and Alluzience's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dysport and Alluzience should be used.

1.1.1 The Medicine and What it is Used for

Alluzience is authorised for the treatment of moderate to severe glabellar lines.

Dysport is authorised for:

- Symptomatic treatment of focal spasticity affecting the upper limbs (arm spasticity) in adults;
- Symptomatic treatment of focal spasticity affecting the lower limbs (leg spasticity) in adults;
- Symptomatic treatment of focal spasticity affecting the upper and lower limbs (arm and leg spasticity) in adults;
- Symptomatic treatment of lower limb focal spasticity (leg spasticity) in children aged 2 years or older;
- Symptomatic treatment of upper limb focal spasticity in children aged 2 years or older
- Spasticity affecting the upper and lower limbs in children aged 2 years or older
- Spasmodic torticollis (also known as cervical dystonia; a painful condition involving involuntary neck movement) in adults;
- Blepharospasm (involuntary contraction of the eye muscles) in adults;
- Hemifacial spasm (repetitive, irregular twitching of facial muscles on one side of the face) in adults;
- Axillary hyperhidrosis (excessive sweating of the underarms);
- Moderate to severe glabellar (frown) lines;
- Moderate to severe lateral canthal lines (crow's feet).

See the SmPC for full indications. It contains botulinum toxin type A-haemagglutinin complex (BTX-A-HAC; a form of botulinum toxin) as the active substance and it is given by injection, with the dose and location of injection dependent on what Dysport (powder) or Alluzience (solution) is being used to treat.

1.1.2 Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risk

Important risks of Dysport (powder) and Alluzience (solution), together with measures to minimise such risks and the proposed studies for learning more about these risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- 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 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.

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) and signal detection assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

1.1.3 List of Important Risks and Missing Information

Important risks of Dysport (powder) or Alluzience (solution) 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 Dysport (powder) or Alluzience (solution). 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).

Important identified and potential risks, together with missing information, are summarised in Table 1.

Table 1 Summary of Safety Concerns

Important identified risks	• Distribution of the effects of the toxin to sites remote from the site of administration
Important potential risks	• None
Missing information	• None

1.1.4 Summary of Important Risks

The important identified risks of distribution of the effects of the toxin to sites remote from the site of administration are summarised in Table 2.

Table 2 Important Identified Risks - Distribution of the Effects of the Toxin to Sites Remote from the Site of Administration

Important identified risk - distribution of the effects of the toxin to sites remote from the site of administration	
Evidence for linking the risk to the medicine	The risk of the toxin spreading to sites other than where administered was initially identified during postmarketing surveillance (i.e. real world use). The risk is considered important because spread of the toxin can produce unwanted weakness of other muscles or more generalised systemic effects (effects throughout the body) such as dysphagia (difficulty swallowing), dyspnoea (difficulty breathing) and respiratory failure (not breathing in sufficient oxygen).
Risk factors and risk groups	Patients who have other conditions that would make them susceptible to these symptoms e.g. neuromuscular transmission disorders (disorders that impair muscle function) such as myasthenia gravis and patients with pre-existing swallowing and breathing difficulties.
Risk minimisation measures	**Routine risk minimisation measures:** • Warnings and advice regarding adverse effects from remote spread of the toxin are included in Section 4.4 of the PI. • Section 4.8 of the PI. • Prescription only medicine. **Additional risk minimisation measures:** There are no additional risk minimisation measures.

PI=product information.

1.1.5 Postauthorisation Development Plan

1.1.5.1 Studies which are Conditions of the Marketing Authorisation

There are no studies required for BTX-A-HAC products as a condition for marketing authorisation.

1.1.5.2 Other Studies in the Postauthorisation Development Plan

There are no other studies required for Dysport.