PART VI SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for Elonva (corifollitropin alfa)

The Summary of Safety Concerns for corifollitropin alfa does not include any Important Identified Risks, Important Potential Risks or Missing Information.

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

This summary of the RMP for Elonva 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 will be included in updates of Elonva's RMP.

I. The Medicine and What it is Used for

Elonva is authorised for Controlled Ovarian Stimulation (COS) in combination with a gonadotropin releasing hormone (GnRH) antagonist for the development of multiple follicles in women participating in an Assisted Reproductive Technology (ART) program and for the treatment of adolescent males (14 years and older) with hypogonadotropic hypogonadism, in combination with human Chorionic Gonadotropin (hCG) (see SmPC for the full indication). It contains corifollitropin alfa as the active substance and it is given by solution for injection.

Further information about the evaluation of Elonva's benefits can be found in Elonva's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000743/human_med_000860.jsp&mid=WC0b01ac058001d124

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

The Summary of Safety Concerns for corifollitropin alfa does not include any Important Identified Risks, Important Potential Risks or Missing Information.

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*.

II.A List of Important Risks and Missing Information

Important risks of Elonva 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 Elonva. 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).

The Summary of Safety Concerns for corifollitropin alfa does not include any Important Identified Risks, Important Potential Risks or Missing Information.

Table II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

The Summary of Safety Concerns for corifollitropin alfa does not include any Important Identified Risks, Important Potential Risks or Missing Information as there are no important safety concerns for which prospective additional pharmacovigilance or additional risk minimization activities are warranted.

Corifollitropin alfa has been marketed since 2010 and 341,190 doses have been distributed cumulatively through 18-APR-2018. The safety profile has been well-characterised during that time and adverse events that have been reported from clinical trials, non-interventional studies and post-approval safety surveillance analysis are included in the SmPC. There are no studies planned or warranted to further characterise any identified or potential risk that would alter the established risk-benefit profile for corifollitropin alfa. There are also no additional risk minimisation activities planned or warranted beyond communication of the safety profile in the SmPC and the Patient Leaflet. The safety profile of corifollitropin alfa will continue to be monitored via routine pharmacovigilance, including utilization of the OHSS post-marketing questionnaire. Therefore, there are no longer any important identified or potential risks or missing information associated with corifollitropin alfa to be addressed in the RMP.

In conclusion, continued spontaneous safety surveillance will continue to be sufficient to monitor the safety profile and labeling will continue to provide sufficient routine risk minimisation for the post-marketing use of corifollitropin alfa.

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 Elonva.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Elonva.