Appendix 1: Procedure for handling disclosures made under the whistleblowing scheme of the Danish Medicines Agency

Information is disclosed under the whistleblowing scheme via a link on the website of the Danish Medicines Agency The disclosure is received by the agency's whistleblowing unit The whistleblowing unit acknowledges receipt as soon as possible and no later than seven days after receipt of the disclosure The whistleblowing unit makes a preliminary assessment of the content and nature of the disclosure The disclosure falls within The disclosure falls outside the scope of the scheme the scope of the scheme The whistleblowing unit starts a detailed The whistleblowing unit informs the whistleblower investigation of the reported concern with the that the case will be closed and of any alternative involvement of internal and, as appropriate, avenues the whistleblower can pursue relevant external persons/authorities The whistleblowing unit informs the person(s) The whistleblowing unit prepares a involved in the disclosure that the case will be recommendation for a decision closed The case is reviewed and decided finally by the The case is closed Director General of the Danish Medicines Agency

The whistleblowing unit may, depending on the circumstances, inform the whistleblower of the review and outcome of the case (three/six months after submission of the disclosure)

Responsive actions, if any, are taken