European Medicines Agency
Inspections

London, 9 February 2007
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Decision Checklist

Reports of Defective Centrally Authorised Products

Decision Checklist

	Information required	STATUS[1]	INFORMATION OBTAINED / COMMENTS / DECISIONS
	1. Name of person / organisation reporting problem.		
	2. Name of IS Co-ordinator		
	3. Name of product affected by the problem.		
	4. Community authorisation number or other reference number.		
	5. Pharmaceutical form.		
	6. Strength.		
	7. Pack size and type.		
	8. Language on pack		
	9. Marketing Authorisation Holders name, address and contact person for quality defects		
	10. Supervisory Authority (including contact point)		
	11. Issuing authority (country where the defect was found)		
	12. Rapporteur		
	13. EMEA Project Manager		

[1] Insert ☑ when finalised; N/A when the point is not applicable and leave blank in all other cases

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	14. Is product authorised under centralised system		Yes	
			No	Report sent to .....… Date.....
	15. Physical and electronic file created		Name Location on the LAN	
	16. Finalise Defective product report			
	17. Nature of the defect			
	18. Preliminary recall classification together with SA including a rationale for the decision		(Tick as appropriate) ☐ Class I: is a recall situation in which there is a reasonable probability that the use of, or exposure to, a defective product is life threatening or could cause serious risk to health or death. ☐ Class II: is a recall situation in which the use of, or exposure to, a defective product could cause illness or mistreatment but is not Class I. ☐ Class III: is a recall situation in which the use of, or exposure to, a defective product is not Class I or II and may not pose a significant hazard to health, but withdrawal may have been initiated for other reasons.	
	19. Agree a timeframe for the investigation with the SA		*(Thick as appropriate)* ☐ *Class I: immediate action with minimum delay (within 1 hour of completion of Defective Product Report)* ☐ *Class II: within 4 hours* ☐ *Class III: within 24 hours*	
	20. If more than one SA. Decide who will manage the investigation			
	21. Final evaluation of the seriousness of the defect using the recall classification and evaluation if the suspected product defect may have safety implications.		(Tick as appropriate) ☐ Class I ☐ Class II ☐ Class III	
	22. Decision taken to initiate the ECG / RECG / classify as a safety problem and hand over to PhV / not continue the investigation		Decision: Time:	Date: By whom:
	23. Need to take extraordinary meassures		Decision: Time:	Date: By whom:

	24. Require(with deadline) and receive further information from the MAH-QD		(Thick as appropriate) ☐ History of the incident. ☐ Any other reports which may be related. ☐ The distribution pattern of the batch (e.g. restricted to known hospitals, widespread through wholesalers, parallel distribution). ☐ Volume of product in the market (e.g. total volume of product distributed with expiry dates, countries involved in the EU/EEA, MRA, CADREAC, PIC and third countries). ☐ Probability that other batches are affected in the same way, and their distribution. ☐ Any remaining stock with the manufacturer. ☐ Effectiveness of the recall (if a voluntary recall has been planned or carried out). ☐ Details of the investigation(s) carried into the cause of the defect by the MAH. ☐ Corrective/preventative/follow-up action taken/proposed by the MAH. ☐ Overall conclusions.
	25. Decision on appropriate action., If it is considered necessary because of the potential risk to public/animal health this decision should be taken without waiting for full information or participants of the European Crisis Group to be available		The actions may be one or more of the following *(tick as appropriate)*: ☐ Filing without follow-up (no further action) ☐ Further investigation. ☐ Quarantine of remaining stock at manufacturer. ☐ GMP inspection and measures to avoid recurrence. ☐ Sampling & Testing by an Official Medicines Laboratory. ☐ Distribution of a “caution in use” notice to concerned health professionals. ☐ Recall of the batches and depth of recall. ☐ Notification of the batch recall to selected health professionals. ☐ Notification of the batch recall to all health professionals. ☐ Notification of the batch recall through the media. ☐ Publication on the EMEA web site. ☐ Press release Decision: Date: Time: By whom:
	26. Decide whether the EMEA certificate team should be notified		
	27. Preparation of Rapid Alert by ISC or SA		
	28. Decide on follow-up actions to be included in the RA		
	29. Prepare send list		
	30. Send Rapid alert		
	31. Monitor follow-up actions		
	32. Conclusion of follow-up actions		
	33. Monitor if variations are necessary to be implemented		

	34. If so, contact the EMEA PM and MAH		
	35. Write a summary of the whole procedure and distribute to the ECG participants as the procedure has been closed out		
	36. Make sure that the filing is complete		
	37. Notify all parties that the crisis is terminated		
	38. Verify if variations are implemented		