European Medicines Agency
Inspections

London, 9 February 2007
Doc. Ref. EMEA/INS/GMP/75464/2007

Defective Product Report Form

Suspected Defective Product Report

Shaded areas to be completed by EMEA Staff

1. Origin of Report

Information required	Information Obtained
1. Name of person	
2. Position/Status:	
3. Company	
4. Address.	
5. Telephone number.	Work: 24 hours:
6. Facsimile number.	
7. E-mail address.	
8. Time of report.	
9. Date of report.	
10. Name of EMEA recipient.	

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2. Product Details

Information required	Information Obtained
1. Name(s) of product(s) affected by the problem.	
2. Community authorisation number or other reference number.	
3. Batch(es) number	
4. Expiry date	
5. Pharmaceutical form.	
6. Strength.	
7. Pack size and type.	
8. Language on pack	
9. Site of manufacture where the defect occurred	
10. Marketing Authorisation Holders name and address.	

3. Nature of defect(s)

Information required	Information Obtained
1. Source of problem (eg. patient / hospital / pharmacy / manufacturer). (provide detailed information on complaints associated with the product/problem (i.e. date of complaint, description of complaint including details of any injury or illness, lot numbers involved))	
2. Details of defect or problem and details of any associated clinical incident (explain how the problem occurred and the date it occurred)	
3. Is consider the suspected defect to be?	☐ critical (A defect, which has the capability to adversely affect the health of the patient or animal) ☐ major (A non-critical defect, which impairs the therapeutic activity of the product) ☐ minor (A defect, which has no important effect upon the therapeutic activity of the medicinal product and does not produce a serious risk to health of the patient or animal) ☐ don't know **COMMENTS**
4. Is the problem associated with any adverse event ? (If so specify).	
5. Is there any evidence or suspicion of a risk to public/animal health (adverse effects or inefficacy)?	
6. Extent of the problem (i.e. how many batches how many patients, explain if the problem affects ALL units of the concerned batch(es)).	

7. Extent of distribution of the product / batch(es).	
8. Are the affected batches subject to Parallel Distribution? (if so, give details)	
9. Action taken so far (if any)	
10. Action planned or proposed (e.g. voluntary recall)	
11. If recall is recommended, what is the classification of the recall?	☐ Class I (The defect is a life threatening or serious risk to health) ☐ Class II (It may cause mistreatment or harm to the patient or animal, but it is not life threatening) ☐ Class III (It may not pose a significant hazard to health, but withdrawal may be initiated for other reasons) ☐ don't know
12. Indicate the level in the distribution chain to which you are extending the recall. (i.e. wholesale /retail /pharmacy /medical user) (If your recall only extends to the wholesale/distributor level, we recommend that you explain your rationale for not recalling to retail/pharmacy level.)	
13. Indicate if this recall will create a market shortage	
14. Name and address of any regulatory authority notified of the problem. (if a EEA member state is already involved in the recall, identify the country and contact)	
15. Other relevant information.	

4. Action taken by EMEA

Information required	Information Obtained
1. Referred to - name and position in EMEA and time	
2. Decision on next action (e.g. none, convene the EG or REG, refer to HoS and/or HoU) and time	

5. The following details should be confirmed with the MAH

Information required	Information Obtained
1. Site of manufacture	
2. Date of production	
3. Date of distribution	
4. Distribution (including Parallel Distributed batches)	
5. Quantity distributed	
6. Quantity on HOLD	
7. Estimate amount remaining in market place: a. Distributor level b. Retail level c. Pharmacy or veterinary level d. User level	
8. Other similar defects	
9. Potential impact on any other products manufactured by the same company	
10. Estimation of stock under the manufacturer's control.	