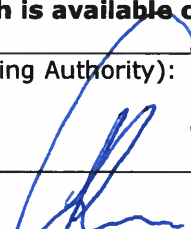


Reference Number **MTII/03/01**

1. To: (see list attached, if more than one)		
2. Product Recall Class of Defect: <b>II</b>	3. Falsification / Fraud: <b>No</b>	
4. Product: <b>Irinotecan Hydrochloride 20mg/ml Concentrate for solution for infusion</b>	5. Marketing Authorisation Number: <b>MA054/10502</b> <b>MA1269/05102 (Post MA transfer to Accord Healthcare Ireland Limited)</b> <b>For use in humans</b>	
6. Brand/Trade Name: <b>Irinotecan Hydrochloride 20mg/ml Concentrate for solution for infusion</b>	7. INN or Generic Name: <b>Irinotecan Hydrochloride</b>	
8. Dosage Form: <b>Concentrate for solution for Infusion</b>	9. Strength: <b>20mg/ml</b>	
10. Batch number: <b>X21343</b>	11. Expiry Date: <b>10/2021</b>	
12. Pack size and Presentation: <b>01 x 5ml</b>	13. Date Manufactured: <b>03/2019</b>	
14. Marketing Authorisation Holder: <b>Accord Healthcare Ltd., UK</b>		
15. Manufacturer: <b>Intas Pharmaceuticals Limited, Factory: Plot 457/458 &amp; 1911218P Matoda, Sarkhej -Bavla Highway, Taluka -Sanand, Ahmedabad - 382 210, Gujarat, India</b>  Contact Person: <b>Prashant Jagad</b>  Telephone: <b>+919033575058</b>	16. Recalling Firm: <b>Accord Healthcare Ltd.</b>  Contact Person: <b>Shishir Bahad</b>  Telephone: <b>+44 1912 133 920</b>	
17. Recall Number Assigned (if available): <b>MDR 02-03/20</b>		
18. Details of Defect/Reason for Recall: <b>Recall due to the presence of particles observed in some product vials of batch X21343</b>		
19. Information on distribution including exports (type of customer, e.g. hospitals):  <b>The batch being recalled in Malta (batch X21343) has been manufactured from mother batch X19532. Other batches have been manufactured from the same mother batch X19532 and distributed in various Member States. Kindly contact the MAH for more information.</b>		
20. Action taken by Issuing Authority: <b>Class II Recall of batch X21343 up to pharmacy level</b>		
21. Proposed Action: <b>All competent authorities should evaluate required action if the affected batch is available on their market</b>		
22. From (Issuing Authority): <b>Medicines Authority 203, Level 3, Rue d'Argens Gzira GZR1368 Malta</b>	23. Contact Person: <b>Kevin Gauci</b>  Telephone: <b>00356 23439118</b>	
24. Signed: 	25. Date: <b>20<sup>th</sup> July 2020</b>	26. Time: <b>09:30</b>