RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL		
IMPORTANT - DELIVER IMMEDIATELY		Ref. IT/I/15/01
1.To: **(see list attached, if more than one)**		
2.Product Recall Class of Defect: I	**3.Counterfeit / Fraud (specify)*** Counterfeit	
4.Product: CIALIS	**5.Marketing Authorisation Number:*** **For use in Humans/ ~~animals~~** 035672031/E	
6.Brand/Trade Name: CIALIS	**7.INN or Generic Name:** TADALAFIL	
8. Dosage Form: film-coated tablets	**9. Strength:** 20 mg	
10.Batch/Lot Number: C251489	**11.Expiry Date:** 08/2016	
12. Pack size and Presentation: 4 tablets	**13. Date Manufactured:**	
14. Marketing Authorisation Holder: Eli Lilly Italia S.p.A.		
15. Manufacturer: Eli Lilly Alcobendas – Spain **Contact point:**	**16. Recalling Firm (if different):**	
17. Recall Number Assigned (if available): Ref. **IT/I/15/01**		
18. Details of Defect/Reason for Recall: The Dutch National Medicines Agency (IGZ) reported to the Italian Medicines Agency (AIFA) a case of 279 packages of CIALIS 20 mg, batch no. C251489, expiry date 08/2016, parallel imported from Italy. Dutch colleagues suspected these packages to be counterfeit due to: - the absence of the typical hologram on the secondary packaging; - the **traceability labels** (the Italian "bollino stickers") had the the same identifier on all packages, with **the serial number 009746984**; - the packaging materials do not correspond to the genuine Eli Lilly product. The batch numbers and the expiry dates correspond to a genuine batch manufactured by Eli Lilly in Spain and marketed in Italy. The counterfeit packs have been sold to a Dutch parallel trader by the wholesaler/parallel trader Pharmazena S.r.l. (IT), which purchased them from another Italian operator, which is undergoing an inspection by the Carabinieri NAS. One package has been sent to Lilly Forensic Laboratories in Indianapolis (USA) for further investigation and testing. No Adverse Events have been reported to Lilly to date with respect to the batch number involved (C251489) of CIALIS 20 mg.		
19.Information on distribution including exports (type of customer, e.g. hospitals):		
20. Action taken by Issuing Authority: Inspections to involved operators (ongoing) and follow up activities (EG trades evaluation/reconstruction, inspections to other operators, possible recall/seizure/inspection exercises also in non pharmaceutical shops); communication to the general public through a communication in the AIFA website and a press release.		
21.Proposed Action: Wholesalers, pharmacists, physicians and any other operator in possession of packs of Cialis 20mg 4 tabs, M.A. # A035672031/E, lot # C251489, expiry 08-2016, with bollino # 009746984 are requested to quarantine the product and Member States NCA is requested to report identification of such stock as soon as possible to AIFA .		
22.From (Issuing Authority): AIFA – Product Quality Office	**23.Contact Person:** Domenico Di Giorgio	
24.Signed: Domenico Di Giorgio DiGiorgio	**25.Date:** December 9, 2014	**26.Time:***