正本

檔　　號：
保存年限：

新北市政府衛生局　函

地址：22006新北市板橋區英士路192-1號
承辦人：姜俞臣
電話：(02)22577155 分機1310
傳真：(02)22572761
電子信箱：ak9458@ntpc.gov.tw

24158
新北市三重區重新路5段646號8樓
受文者：新北市藥師公會

發文日期：中華民國104年7月21日
發文字號：新北衛食字第1041306770號
速別：普通件
密等及解密條件或保密期限：
附件：原函及相關資料影本各1份

主旨：檢送有關「Zyvoxid 600mg」（批號H94148）」警訊相關資料，該產品在境外發現偽品流通，為維護國民之健康與安全，惠請轉知所屬會員，如有案內違規產品應立即下架勿販售，請查照。

說明：依據衛生福利部食品藥物管理署104年7月14日FDA企字第1041203115號函辦理。

正本：新北市藥師公會
副本：

局長 林奇宏

本案依分層負責規定授權業務主管決行

檔　　號：
保存年限：

衛生福利部食品藥物管理署 函

地址：11561 臺北市南港區昆陽街161-2號
聯絡人：莊秉慷
聯絡電話：02-27877243
傳真：02-26532055
電子信箱：dpqbdpqb@fda.gov.tw

受文者：新北市政府衛生局
發文日期：中華民國104年7月14日
發文字號：FDA企字第1041203115號
速別：普通件
密等及解密條件或保密期限：
附件：資料2份(A21020000I104120311500-1.PDF)

主旨：檢送案內所陳藥品「Zyvoxid 600mg」（批號H94148）」警訊相關資料2份，該產品在境外發現偽品流通，為維護國民之健康與安全，請將該產品於市面可能販售及網路刊售之情事列入稽查工作重點，查明依法處辦，請 查照。

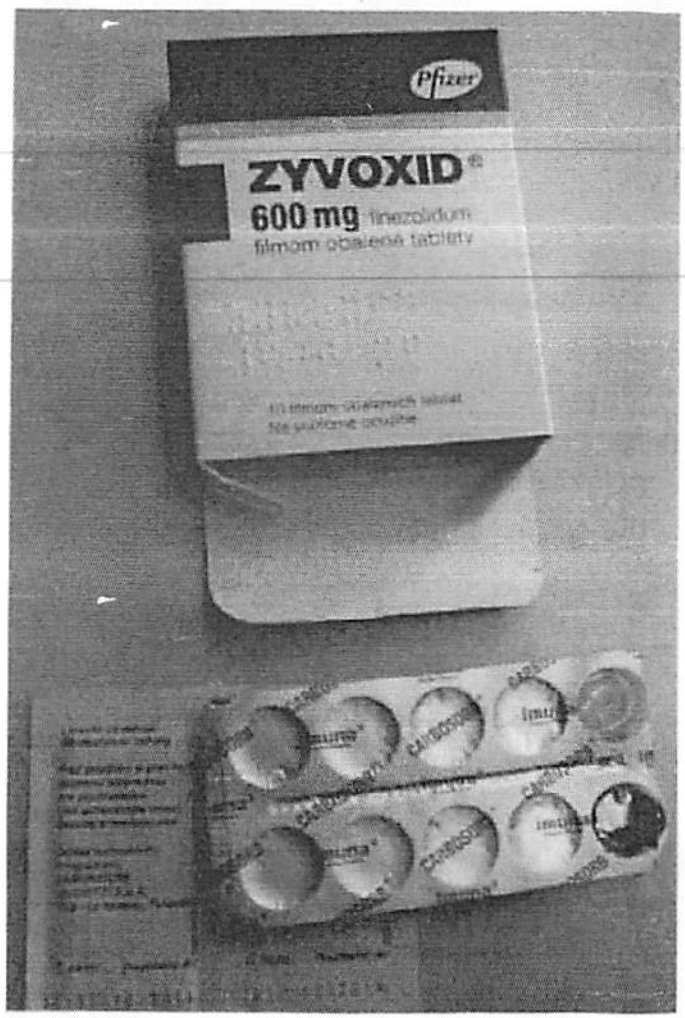
說明：依據本署104年7月8日接獲德國Landesamt fur soziales jugend und versorgung經PIC/S Rapid Alert System通報藥品警訊相關資料辦理。

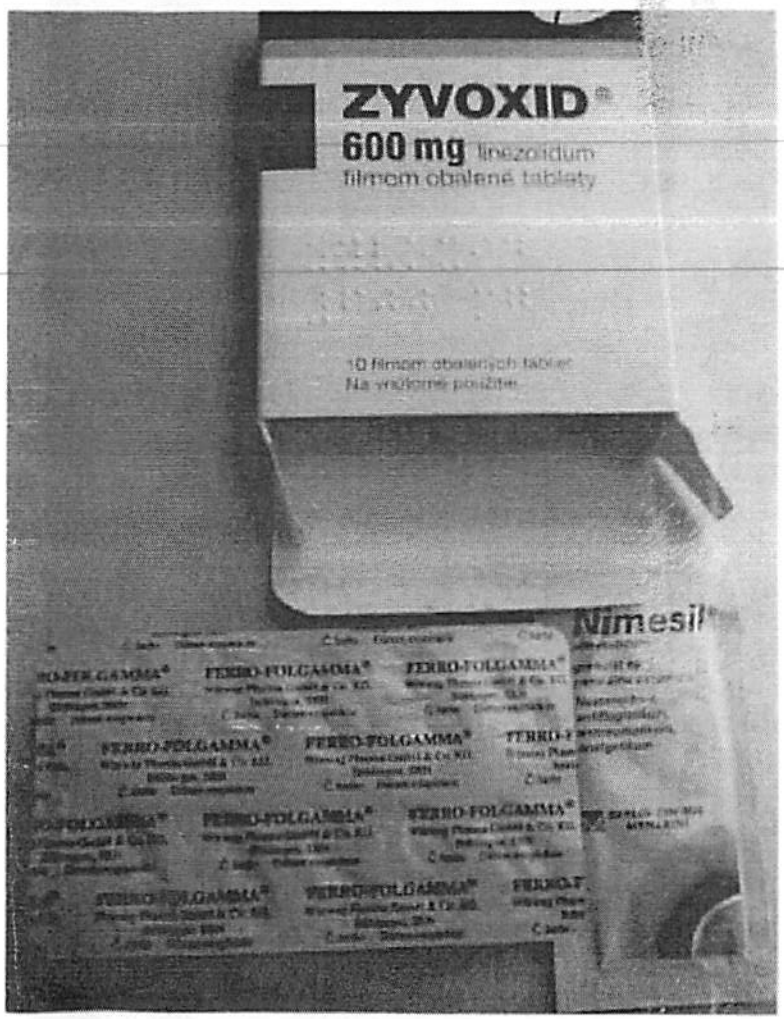
正本：各縣市衛生局
副本：

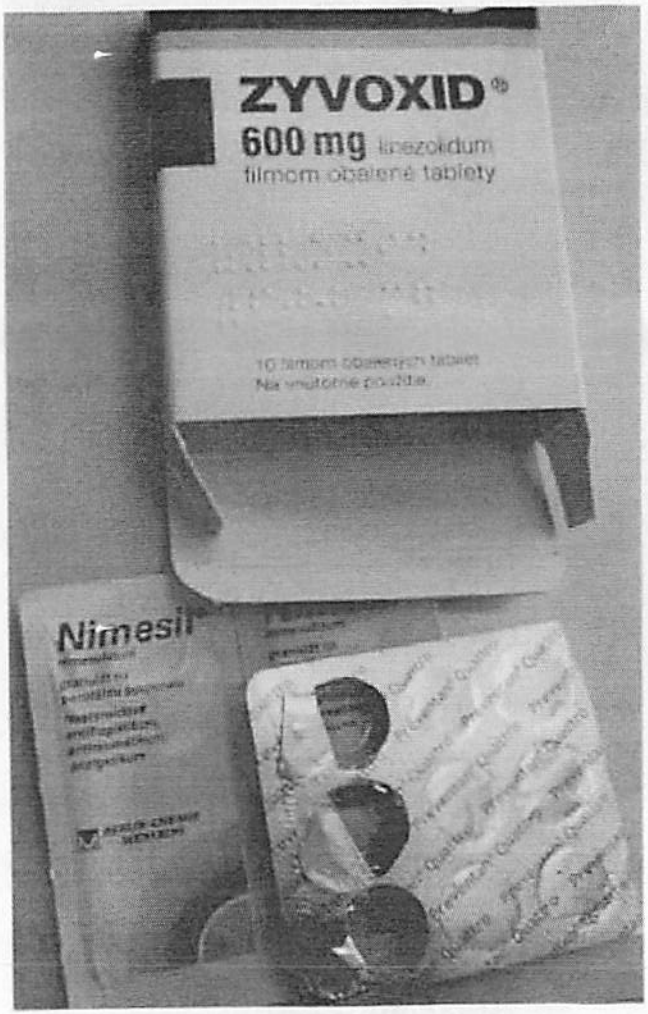
姜俞臣　　衛生局

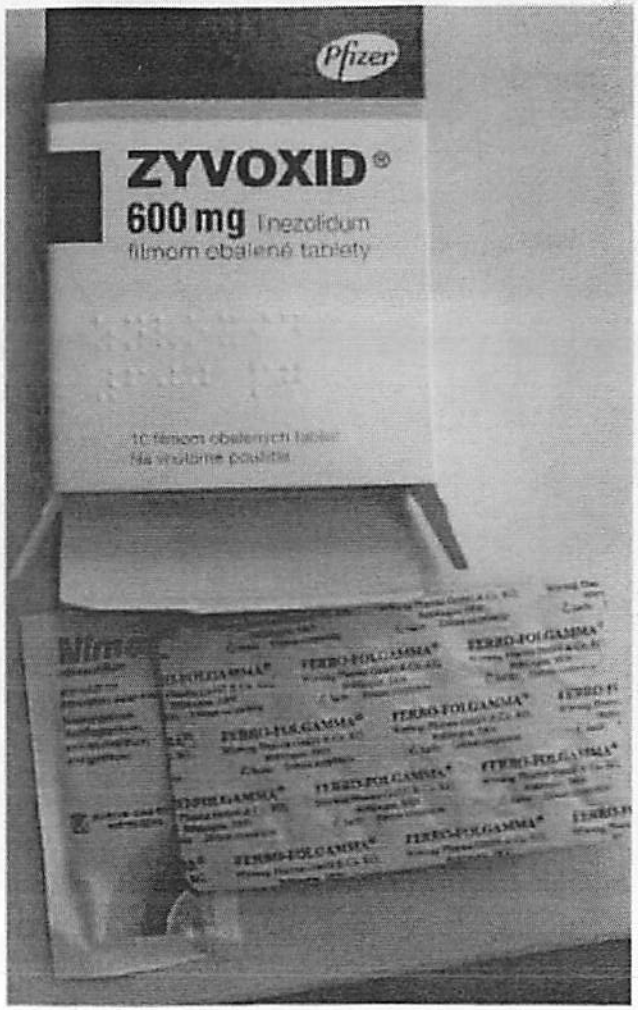
1041306770(2015/07/14)

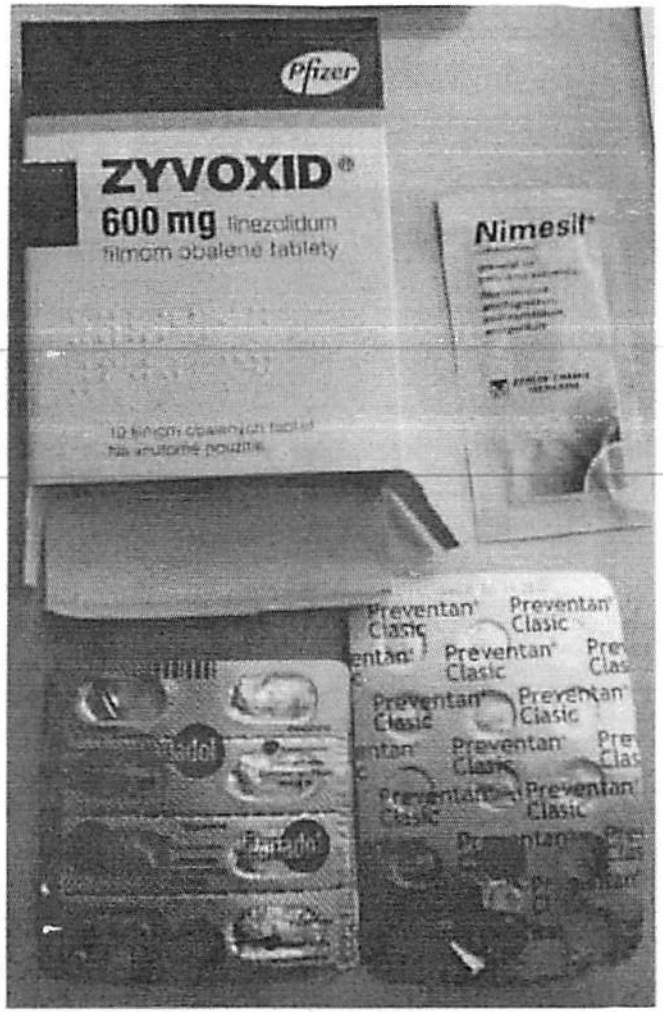
Zyvoxid 600 mg: Inhalt der gefälschten Ware der Charge H94148 mit Verfall 10/2016 (Importware aus der Slowakei).

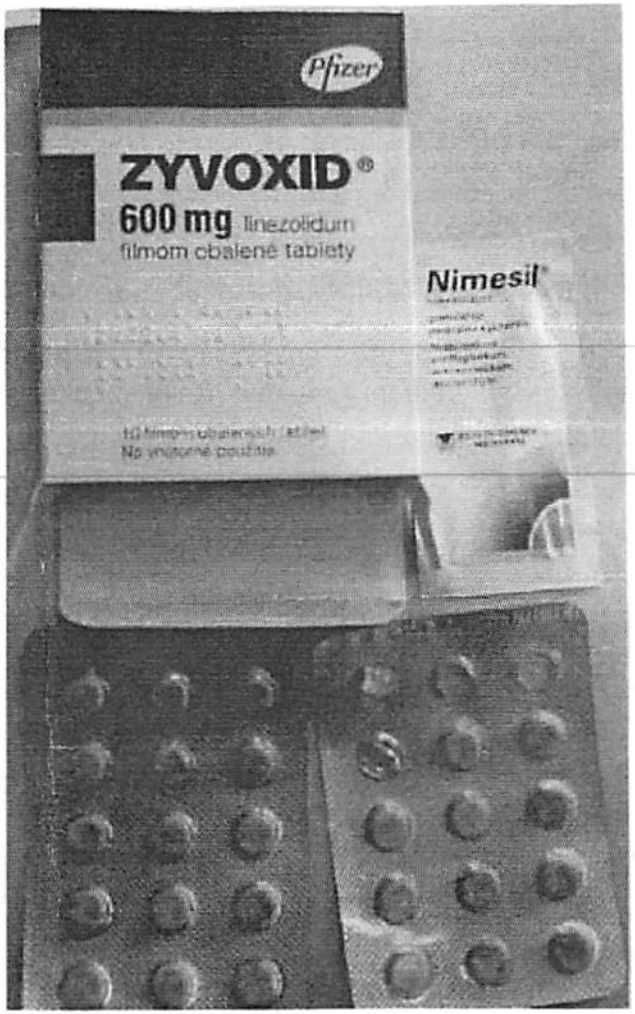


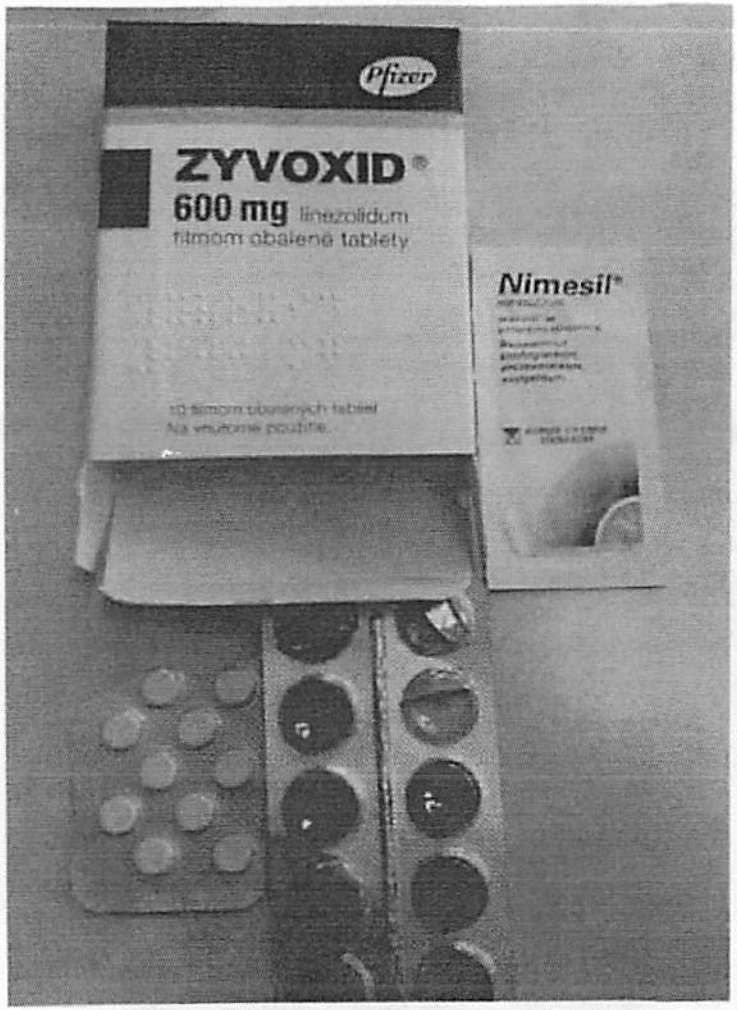



ZYVOXID®
600 mg linezolidum
filmom obalené tablety
Nimesil


Pfizer
ZYVOXID®
600 mg linezolidum
filmom obalené tablety


Pfizer
ZYVOXID®
600 mg linezolidum
filmom obalené tablety
Nimesil
Preventan Classic


Pfizer
ZYVOXID®
600 mg linezolidum
filmom obalené tablety
Nimesil



Exemplarisch ist die Lasche einer Schachtel mit den Angaben zu Charge und Verfall abgebildet:

Ergebnis:

Alle sieben Packungen enthalten einen fremden Inhalt (z. T. angebrochene oder zerschnittene Blister anderer Präparate). Zyvoxid ist in keiner Packung vorhanden.

Densborn, 07-Juli-2015/P. Koch/Stufenplanbeauftragter der CC Pharma GmbH

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

Meldende Stelle

Landesamt für Soziales, Jugend und Versorgung

Moltkestr. 19

54292 Trier

1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636
☒	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
☒	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1263
☒	Oberste Landesgesundheitsbehörde	

2. Product ~~Recall~~ Class of Defect: (1) (circle one)	3. Counterfeit / ~~Fraud~~ (specify)* Report of suspected counterfeit product
4. Product: **Zyvoxid 600mg**	5. Marketing Authorisation Number: * For use in humans/~~animals~~ (delete as required)
6. Brand/Trade Name: Zyvoxid 600mg	7. INN or Generic Name: Linezolid
8. Dosage Form: film-coated tablets	9. Strength: 600mg
10. Batch/Lot Number: H94148	11. Expiry Date: 10 2016
12. Pack size and Presentation: 10 film coated tablets	13. Date Manufactured: not known

14. Marketing Authorisation Holder: *

Pfizer Europe MA EEIG, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

15. Manufacturer†:	16. Recalling Firm (if different): Not applicable!
Contact Person:	**The suspected counterfeited packages were detected by parallel importer CC-Pharma, D-54570 Densborn during the check of incoming goods. No packages of the concerned Zyvoxid shipment from Czechia were released by CC-Pharma!**

17. Recall Number Assigned (if available)

18. Details of Defect/Reason for Recall: On July 7th, 2015 CC-Pharma GmbH, Densborn checked a delivery of 7 packages Zyvoxid 600mg Tablets (10 film-coated tablets)(Slovakian product) from the wholesaler Evopharm (Brünn, Czechia). The secondary packaging showed some slight differences, which might attract attention only on a second look (Attachment 1). But the content of the packages was completely different to the original: (even opened) blisters from other medicinal drugs (with its name on the blister foil) were inside (Attachment 2). None of the packages contained Zyvoxid tablets. The different content is easy to detect, while the counterfeit secondary packaging seems to be only less noticeable. According to an additional information by CC Pharma GmbH the batch H94148 was received several times before from wholesalers with correct packaging and content.
19. Information on distribution including exports (type of customer, e.g. hospitals): * CC-Pharma did not sell the packages to any customer, the packages are now in quarantine
20. Action taken by Issuing Authority: Information of the Competent Authorities in Germany by RAS
21. Proposed Action: Warning information to parallel importers in other federal states by their competent authority. Inspection of the delivering wholesaler by competent authority in Czechia to check supply chain.

22. From (Issuing Authority):	23. Contact Person:
Landesamt für Soziales, Jugend und Versorgung Moltkestraße 19 54292 Trier	Markus Walther walther.markus@lsjv.rlp.de Telephone: 0651 / 1447 208

24. Signed:	25. Date: 08.07.2015	26. Time: *10:45

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has released the batch in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.