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正本

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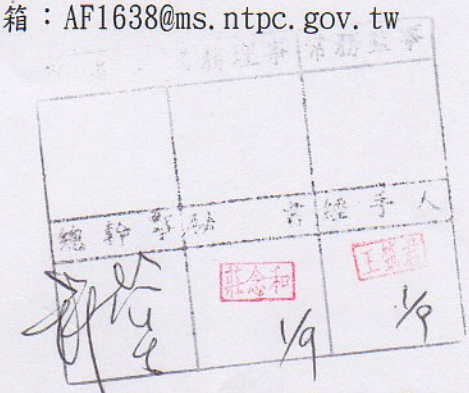
受文者：新北市藥師公會



發文日期：中華民國100年12月30日
發文字號：北衛食藥字第1001883789號
速別：普通件
密等及解密條件或保密期限：
附件：原函影本1份

主旨：檢送嬌生股份有限公司「康利斯微脂粒注射劑（衛署藥輸字第022207號）」藥品之用藥安全資訊1份，請　查照轉知。

說明：依據行政院衛生署食品藥物管理局100年12月21日FDA藥字第1005055904號函辦理。

正本：新北市藥師公會、新北市藥劑生公會、新北市醫師公會
副本：

局長林雪蓉

本案依分層負責規定授權業務主管決行

檔　　號：
保存年限：

行政院衛生署食品藥物管理局　函

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受文者：新北市政府衛生局

發文日期：中華民國100年12月21日
發文字號：FDA藥字第1005055904號
速別：普通件
密等及解密條件或保密期限：
附件：歐盟EMA藥品安全警訊（10050559040-1.pdf，共1個電子檔案）

主旨：有關嬌生股份有限公司「康利斯微脂粒注射劑CAELYX CONCENTRATE FOR INFUSION（衛署藥輸字第022207號）」藥品之用藥安全資訊如說明段，請儘速轉知所轄醫療機構或會員，以保障民眾用藥安全，請 查照。

說明：

一、歐盟EMA於11月22日發布有關美國Ben Venue Lab.,Inc.製造廠之藥品品質資訊，說明該製造廠於GMP稽查過程，被發現藥品無菌充填製程有許多品質管理缺失，可能使產品遭受污染。歐盟已針對Caelyx抗癌藥品完成評估，因無其他替代藥品，故未要求藥品回收，但僅供正在使用該藥品治療之病人，詳如附件。

二、經查，我國核准「康利斯微脂粒注射劑 Caelyx Concentrate for Infusion（衛署藥輸字第022207號）」為抗癌藥品，考量該藥品於癌症治療療程之延續性，且國內並無相同之替代藥品，故參照歐盟措施，同意該藥品僅供應正在使用該藥品治療之病人，不得使用於新病人，此外請醫師應重新審慎評估病人使用該藥品之臨床效益及風險，充分告知病患上述問題可能之風險，並嚴密監控使用該等藥品後可能之風險（如敗血症、急性發燒）。

機關收文　100/12/22
1001883789
1001034138

正本：各縣市衛生局、台灣醫院協會、中華民國醫師公會全國聯合會、中華民國藥師公會全國聯合會、中華民國藥劑生公會全國聯合會、台灣臨床腫瘤醫學會

副本：嬌生股份有限公司、行政院衛生署中央健康保險局、本局風險管理組、財團法人藥害救濟基金會全國藥物不良反應通報中心

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2011
EMA/905564/2011
Press Office

Press release

European Medicines Agency gives interim recommendations to deal with shortcomings in quality assurance at Ben Venue Laboratories

Precautionary recall for remaining batches of Busilvex, Velcade and Vidaza manufactured at Ben Venue. No new patients to be treated with Caelyx.

The European Medicines Agency (EMA) is currently reviewing shortcomings in quality assurance identified during a good manufacturing practice (GMP) inspection at Ben Venue Laboratories' manufacturing site in Ohio, USA, and their impact on centrally authorised medicines manufactured at this site.

A joint GMP inspection of the site, where a number of sterile medicines are manufactured, by the UK and French medicines regulatory agencies together with the US FDA on 7-11 November 2011 highlighted several shortcomings in the quality management system, particularly in relation to the aseptic filling process in the North Complex of the Ben Venue facility. During the inspection, Ben Venue decided to cease all manufacture and distribution of medicines from its site, which has been the object of increased GMP surveillance, and to investigate the GMP issues identified.

The Agency's Committee for Medicinal Products for Human Use (CHMP), at the request of the European Commission, is currently reviewing all centrally authorised medicines that are manufactured at the site to determine the risk to human health and to decide on appropriate regulatory action. The Agency is also in contact with the regulatory authorities of the EU Member States on the impact of this issue on non-centrally authorised products. There will be a co-ordinated national approach to these products, taking the same principles into account as for the centrally authorised medicines.

As a first step the Committee considered whether the identified GMP issues could have compromised the quality of the centrally authorised oncology medicines Busilvex, Caelyx, Velcade, Vidaza and the antiviral medicine Vistide, manufactured in the North Complex, where the quality assurance issues identified posed the greatest risk, and the potential impact of a restricted supply in the EU.

The Committee conducted a product-specific benefit/risk assessment for each medicine, covering released and quarantined batches and reviewed the need for urgent interim measures.

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As precautionary measure, the CHMP concluded that the potential risk of batch contamination due to the shortcomings in quality management at the North Complex means that only medicines which are absolutely essential to meet patients' needs can be used and which are currently not available from another source. A lower level of risk applies to products for which terminal sterilisation is in place.

For Caelyx, for which Ben Venue is the only manufacturing source, the CHMP considers the product to be essential only for patients already on treatment. It recommended that supplies should be available to maintain these patients on Caelyx but no new patients should be started on treatment with Caelyx until further notice. The CHMP advised that healthcare professionals should monitor treated patients intensively and immediately notify any relevant safety concerns that could be evidence of a quality assurance problem (particularly any cases of sepsis or suspected sepsis, such as acute pyrexia). The marketing authorisation holder, Janssen, has been asked to circulate a communication to healthcare professionals to reinforce these messages, requesting them to enhance monitoring and report any suspected adverse reaction or complaints that could be evidence of a quality assurance problem with the aseptic filling process. The CHMP will review the situation on a continuous basis.

The CHMP considers the supply of Busilvex, Velcade and Vidaza from Ben Venue no longer essential, as alternative manufacturers are currently supplying the EU market. In addition, recalling batches of these medicines supplied by Ben Venue would not lead to product shortages. Therefore, the CHMP recommends the recall from the EU market of batches manufactured at Ben Venue for Busilvex, Velcade, and Vidaza as a precautionary measure.

The CHMP concluded that remaining supplies of Vistide, from Ben Venue, can continue to be used as this product is terminally sterilised. Alternative manufacturers of Vistide are now supplying the EU.

For each product the CHMP considered whether supply from Ben Venue remained essential to meet clinical needs, whether alternative treatment options were available, the state of current EU stock levels, the possibility of sourcing the product from alternative manufacturing sites, and whether the product is aseptically produced or terminally sterilised. The Committee noted that, to date, there have been no complaints or reports of adverse reactions brought to its attention which would indicate a lack of quality assurance associated with batches manufactured at the North facility. However, the CHMP nevertheless considered that there is a potential risk of product contamination, necessitating the interim measures described above.

The inspection process and the review for all centrally authorised medicines manufactured at the Ben Venue Laboratories plant is still ongoing and the EMA will make further updates as appropriate.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The November 2011 inspection of the Ben Venue Laboratories manufacturing site was conducted by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Agence française de sécurité sanitaire des produits de santé (AFSSAPS) as a follow-up to a previous inspection conducted in March 2011 that had been triggered by the European Medicines Agency as part of a re-inspection program. This inspection had already led to the restriction in the importation of some medicines to the EU from the Ben Venue site.
3. The European review of the centrally authorised medicines Angiox, Busilvex, Caelyx, Cayston, Ceplene, Ecalta, Luminity, Mepact, Soliris, Torisel, Velcade, Vibativ, Vidaza and Vistide, manufactured at the Ben Venue site in Ohio, is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No

726/2004, on 17 November 2011. More information on these medicines can be found in the relevant European public assessment reports (EPARs).

4. The EMA is working closely with international regulatory partners and in particular the US FDA, TGA and Health Canada, in order to coordinate actions to address the GMP deficiencies at Ben Venue Laboratories manufacturing site and to share information on the impact of these quality findings for the global product supply.

5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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