Revatio (sildenafil): Drug Safety Communication - FDA Clarifies Warning About Pediatric Use for Pulmonary Arterial Hypertension

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FDA於2012年08月建議：美國FDA提醒，1至17歲兒童不應使用Revatio (sildenafil)治療肺動脈高壓。FDA目前澄清：Revatio (sildenafil)只核准用於成人肺動脈高壓，不被核准用於兒童，然而醫療人員必須考慮藥物治療議處是否可能超過潛在風險。

FDA於2012年8月修訂Revatio藥品仿單，仿單標示：「使用Revatio，尤其是長期使用，不建議在兒童身上。」此建議是根據一項長期臨床試驗研究，研究結果：兒童使用高劑量sildenafil之組別較使用低劑量的sildenafil者，有較高的死亡風險。FDA目前澄清：個別兒童仍可做利益風險評估，例如，當其他治療選擇受限且Revatio使用情形可被密切監測時。

建議：

FDA最初建議的證據沒有改變。這次發布訊息，是為了傳達Revatio仿單標籤的效力。

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AUDIENCE: Cardiology, Pediatrics, Pharmacy

ISSUE: FDA is clarifying its previous recommendation related to prescribing Revatio (sildenafil) for children with pulmonary arterial hypertension (PAH). Revatio is FDA-approved only to treat PAH in adults, not in children; however, health care professionals must consider whether the benefits of treatment with the drug are likely to outweigh its potential risks for each patient.

FDA revised the Revatio drug label in August 2012, adding a warning stating that “use of Revatio, particularly chronic use, is not recommended in children.” This recommendation was based on an observation of increasing mortality with increasing Revatio doses in a long-term clinical trial in pediatric patients with PAH. FDA issued a Drug Safety Communication at that time. There may be situations in which the benefit-risk profile of Revatio may be acceptable in individual children, for example, when other treatment options are limited and Revatio can be used with close monitoring.

BACKGROUND: The purpose of the August 2012 recommendation was to raise awareness of clinical trial results showing a higher risk of mortality in pediatric patients taking a high dose of Revatio when compared to pediatric patients taking a low dose. This recommendation was not intended to suggest that Revatio should never be used in children; however, some health care professionals have interpreted this information as a contraindication, and have refused to prescribe or administer the drug.

RECOMMENDATION: The evidence behind FDAs initial recommendation has not changed; this communication is clarifying the strength of the warning communicated in the Revatio drug label.