澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
衛生局
Serviços de Saúde

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由
De/From: 部門/Dept.: 藥物事務廳 Department of Pharmaceutical Affairs
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致:
Para/To 部門/Dept.:
收件人/Att.-C/O:
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主題: 關於Rotarix的最新資訊
Ass./Subject: Latest update on Rotarix
頁數: 1/2
N° folhas/N.pages:

根據藥物生產商Glaxosmithkline Biologicals的通報，由其生產的數批輪狀病毒口服疫苗Rotarix被發現含有PCV 1病毒(porcine circovirus 1)的DNA。現有資料顯示，PCV 1病毒普遍存在於一般供食用的肉類中，但此病毒一般不會引起人體不適或導致任何疾病。就上述事件，美國食物藥物管理局(USFDA)將繼續測試有關疫苗，目前建議醫生暫停使用Rotarix，並可以另一輪狀病毒疫苗Rotateq作代替。

由於Rotarix受PCV 1病毒污染，目前並不能完全排除使用此疫苗對嬰兒造成的風險，考慮到USFDA現正繼續進行測試，而本澳亦有另一種輪狀病毒疫苗Rotateq作替代，經平衡風險效益，衛生局要求在上述由Rotarix引起風險的情況未明朗前，本澳的醫院、診所及藥房須暫時停用及供應Rotarix。此外，本廳將繼續密切監測Rotarix的安全性，並因應情況採取適當的措施。

醫生、藥劑師或其他衛生專業人士如懷疑由Rotarix或其他藥物引致的任何不良反應請以下列任一方式向本廳通報：

- 網上通報 - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- 郵寄 - 澳門士多烏拜斯大馬路 51號 華仁中心二樓
- 傳真 – 28524016

通報人士可親臨藥物事務廳索取或在http://www.ssm.gov.mo/design/services/serpt_chn.pdf網址上下載通報表格。如有任何疑問, 請於辦公時間致電85983517或85983439與藥物監測暨管理處楊燕雯藥劑師或林俊耀藥劑師聯絡, 倘遇緊急的情況, 亦可於非辦公時間傳呼85008068。

謹祝 台安!

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Glaxosmithkline Biologicals notified us of the presence of DNA originating from PCV 1 virus (porcine circovirus 1) strain in batches of its oral Rotarix vaccines. Data reviewed that PCV 1 virus exists commonly in meat for human consumption in general. This virus is not known to cause discomfort or lead to any other illnesses in humans. In respective to this incident, United States Food and Drug Administration (USFDA) will conduct further tests on the product. In the interim, the USFDA advised physicians to temporarily suspend the use of Rotarix as a precautionary measure, if required the use of Rotarix can be substituted with another rotavirus vaccine named RotaTeq.

As Rotavarix was contaminated with the PCV type 1 virus, it is impossible to completely eliminate the risk of using this vaccine onto our infant population at this present stage. Meanwhile, the USFDA is conducting further tests on the product and an alternative source of rotavirus vaccine, RotaTeq can be used as a substitute in Macao. Coupling the above issues and balancing the risk and benefit evaluation on Rotarix, before the risk of Rotarix is clarified, Health Bureau would request local hospitals, clinics and pharmacy to temporarily suspend the use and supply of Rotarix. Similarly, we will continue to closely monitor the safety concerns on Rotarix and will issue appropriate measure(s) if deemed necessary.

If physicians, pharmacists or healthcare professionals suspect any kind of adverse reaction subsequent to the use of Rotarix or other drugs, please report through any of the following methods：

- Online - http://www.ssm.gov.mo/design/webservices/c_wservices_main.htm
- Mail to - 51 Avenida do Sidonio Pais, Edificio China Plaza, 2nd Floor, Macao S.A.R., China
- Fax to - 853-28524016

The report form can be collected in person at Department of Pharmaceutical Affairs or downloaded from the website designated as http://www.ssm.gov.mo/design/services/serpt_chn.pdf.

Should you have any query, please contact Ms. Beatrice Young or Mr. Jeffrey Lam at 8598-3517 or 8598-3439 respectively from the Division of Pharmacovigilance and Pharmacoeconomics during office hours. In case of urgent situations during off hours, please page 85008068.

Thanking you in advance for your attention!

藥物事務廳廳長
Chief, Department of Pharmaceutical Affairs

蔡炳祥
Choi Peng Cheong

參考資料/References：
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