Janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

6 June 2015

**CONCERTA® (METHYLPHENIDATE HYDROCHLORIDE)Prolonged and painful erections (Priapism) have been reported with stimulants used in the treatment of ADHD including Concerta.**

**Dear Healthcare Professional,**

**Janssen-Cilag scientific office in agreement with the SAUDI FDA would like to inform you of the following important changes in the prescribing information for CONCERTA® (methylphenidate hydrochloride):**

**Summary**

- **Prolonged and painful erections (priapism) requiring immediate medical attention (sometimes requiring surgical intervention), have been reported in people taking methylphenidate-containing medicines, including CONCERTA®. Priapism has been observed in both paediatric and adult patients.**
- **Priapism may not occur immediately and can develop after some time on methylphenidate, often following an increase in dose.**
- **Priapism has also occurred during periods of methylphenidate withdrawal (e.g. during drug holidays or during discontinuation).**
- **Patients should be instructed to seek immediate medical attention if they develop abnormally sustained erections or frequent and painful erections to prevent potential long-term effects on the penis.**

**Further information**

**CONCERTA® is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).**

**In October 2013, the United States (US) Food and Drug Administration (FDA), requested class labeling changes to be implemented following evidence of an association between the use of stimulants used in the treatment of ADHD and priapism .**

**Based on this safety signal, the company conducted an analysis of available information. A cumulative review identified some cases of priapism reported worldwide with the use of methylphenidate, of which 2 cases reported a positive dechallenge and rechallenge providing sufficient evidence to consider priapism related to the use of CONCERTA®. The estimated reporting frequency of priapism and CONCERTA® is as following : a-EU: "rare" between 1 in 1000 and 1 in 10,000 based on post-marketing reports b-Global: "very rare" approximately 25 per 12,371,561 person-years based on spontaneous reporting rate .**

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**The information in this letter has been approved by the Saudi Food and Drug Authority.**

**Call for reporting**

**Any suspected adverse events should be reported to the national spontaneous reporting system according to the national regulations.**

**SFDA (National pharmacovigilance and drug safety department)**
**Email to: npc.drug@sfda.sa**
**Fax: +966-11-2057662**
**Online: http://ade.sfda.gov.sa/**

**Or**
**You can contact company scientific office at:**
**Email to: GCC-PV2@its.jnj.com**
**Fax: +966-11-2153190**

**Yours faithfully,** 7/10/11

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