

Safeguarding public health

Defective Medicines Report Centre & Unlicensed Imports
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DRUG SAFETY INFORMATION

For immediate dissemination during working hours

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EL(07)A15

Our Ref: MDR 10-10/07

Dear Healthcare Professional,

MHRA statement on talc preparations for Pleurodesis

MHRA is of the opinion that talc preparations for pleurodesis are medicinal products. They promote an inflammatory reaction in the local tissues through a metabolic / immunological response after exposure to the talc. MHRA therefore considers that these are not medical devices and intends to treat these products as medicines with effect from 01 January 2008

Consequently, talc preparations for pleurodesis should be licensed as medicinal products for use in the UK and manufacturers of these preparations are invited to submit appropriate manufacturing authorisation applications. Further information concerning the regulatory requirements for licence applications is available from the MHRA website (1).

Given the current absence of licensed talc preparations for pleurodesis these products will be required to be prescribed by healthcare professionals as unlicensed medicines for the special clinical needs of individual patients on the direct personal responsibility of the prescriber.

Further information concerning the regulatory requirements for unlicensed medicines are provided in the MHRA Guidance Note No 14, "The Supply of Unlicensed Relevant Medicinal Products for Individual Patients", which is available from the MHRA website (2).

Importers of any medicine that is unlicensed in the UK must notify the MHRA in accordance with The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005/2789. For further information, please see also Guidance Note 14.

Notifications for importation of unlicensed medicines received by the MHRA will be assessed in the normal manner and objections may be raised where there are prohibitive safety or quality concerns, or in the case of non-objections to import, advice issued where users need to be aware of safety or quality issues.

Users should consult their suppliers to ensure continuity of supply following these changes.

Users should be aware that published literature (3) indicates that there may be an increased incidence of adverse reactions, including delayed adult respiratory distress syndrome, linked with the use of small particle size talc preparations. It is therefore important that all adverse events,

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units

Chief Pharmacists: England, Scotland, Wales, Northern Ireland

Prison Health Policy Unit (DH)

Medical Supplies Agency (MOD)

Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar

Special Hospitals

Healthcare Commission for distribution to Independent Health Care Establishments

Medicines and Healthcare products Regulatory Agency

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An executive agency of the Department of Health

whether real or suspected, associated with the use of these products are reported to MHRA in order to help build up a safety profile.

Adverse reactions should be reported to MHRA via the following link:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=288

Recipients are asked to bring this information to the attention of professionals with an interest in respiratory medicine by copy of this letter.

Yours faithfully,

Graham Matthews

Senior Pharmaceutical Assessor
Defective Medicines Report Centre & Unlicensed Imports

REFERENCES

MHRA Web Pages

1. Requirements for Marketing Authorisations

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=102

2. MHRA Guidance Note No 14

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=579

3. Recent Published Literature

3.1. J P Collier et al, "Safety of pleurodesis with talc poudrage in malignant pleural effusion: a prospective cohort study", *The Lancet*, 369, pg 1535 – 1539, (2007).

3.2. M Noppen, "Who's (still) afraid of talc?", *European Respiratory Journal*, 29, pg 619 – 621, (2007).