Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 19th February 2014 Our Ref: MDR 6-2/14

Dear Healthcare Professional,

GlaxoSmithKline (Malta) Ltd

Product	**Batch**
NiQuitin 2 mg Lozenges	**1376925**
	1307115
NiQuitin 4 mg Lozenges	**1386276**

The above batches of medicinal are being recalled up to wholesale dealer level on a voluntary basis by GlaxoSmithKline (Malta) Ltd through Alfred Gera & Sons Ltd (local distributor) under the supervision of the Medicines Authority.

The recall is being carried out due to deviations related to in-process compression specifications. All batches identified conformed to the registered product specifications at release and a medical assessment by GlaxoSmithKline concluded that oral exposure to nicotine does not have a significant impact on clinical efficacy or pose a significant toxicological risk.

Nevertheless the Medicines Authority is in agreement with the voluntary recall due to the above-mentioned deviations in in-process specifications.

Wholesale dealers are asked to quarantine all stock of the affected batches and await instructions by Alfred Gera & Sons Ltd which is responsible to recall the affected stock.

Yours faithfully

Karl De Marco
Medicines Inspector

Medicines Authority Distribution (if applicable): Not Applicable