PRIMARY CARE TRUST CHIEF PHARMACIST/ ASSOCIATE DIRECTOR OF PUBLIC HEALTH v GLAXOSMITHKLINE

'Dear Practice Nurse' letter about Rotarix

The chief pharmacist and associate director of public health at a primary care trust complained that a 'Dear Practice Nurse' letter about Rotarix (rotavirus vaccine) was sent by GlaxoSmithKline to non-prescribers.

The Panel noted that the letter introduced Rotarix as the first gastroenteritis vaccine in Europe for infants from six weeks of age. Clinical data and details of the dose schedule within the context of UK routine childhood vaccinations were provided together with information about how to order the vaccine.

The Panel noted that the letter was one part of a co-ordinated mailing that targeted prescribers and administrators of paediatric vaccines. GlaxoSmithKline submitted that in all cases, as a minimum, the lead prescriber within each practice would have received information on Rotarix prior to the practice nurse letter in question being received.

The Panel noted GlaxoSmithKline's submission that within the UK approximately 800 nurse prescribers could prescribe from a full formulary. The majority of nurses could not prescribe particular medicines or vaccines unless a patient group direction had been authorized. The Panel considered that it was reasonable to provide the letter to practice nurses irrespective of whether they could prescribe the product given their role in the administration and ordering of vaccines. No breaches of the Code were ruled.

The chief pharmacist and associate director of Public Health at a primary care trust complained about a 'Dear Practice Nurse' letter (ref ROT/LTR/06/26848/1c) concerning Rotarix (rotavirus vaccine) sent by GlaxoSmithKline UK Ltd.

COMPLAINT

The complainant was extremely concerned that this letter was sent to non-prescribers; this issue had been raised by the practices the complainant worked with as none of the information seemed to have been sent to the prescribers themselves. The complainant asked if it was ABPI policy for companies to target non-prescibers without any information being provided to prescribers.

When writing to GlaxoSmithKline, the Authority asked it to respond in relation to Clauses 9.1 and 12.1 of the Code.

RESPONSE

GlaxoSmithKline stated that the mailing was part of a co-ordinated communication that targeted both prescribers and administrators of paediatric vaccines. As such, GlaxoSmithKline denied breaches of Clauses 12.1 and 9.1.

GlaxoSmithKline explained that when Rotarix was launched at the end of May 2006 a letter, which included a parent's information leaflet, was sent to a wide range of interested and relevant health professionals including the lead paediatric vaccine GP in every practice, lead paediatric practice nurses, health visitors, paediatricians and consultants in communicable disease control. The same mailing was sent at the end of July to private GPs and in August to all UK paediatric nurses and paediatric gastroenterologists. A copy of the letter and the leaflet was provided.

A follow-up letter, the subject of this complaint, was sent on 27 September 2006 as a reminder that the vaccine was now available and could be ordered, if required, from the GlaxoSmithKline Customer Contact Centre. In order to audit follow-up responses, this mailing was targeted to UK primary care practices in three ways: in the first group of practices, all GPs and all practice nurses were sent the letter; in the second group the letter was sent to the lead paediatric GP and the lead paediatric vaccine nurse whilst in a third group of practices, no mailing was sent at all. There were approximately a third of UK primary care practices within each group. As such there would be variability in the extent of the mailing between practices, but GlaxoSmithKline stated that in all cases, at a minimum, the lead prescriber within each practice would have received information on Rotarix before the practice nurse received a letter.

Given the mailing strategy described above, there were 52 practices where the practice nurse mailing would have been sent to a branch surgery which fell into group two but where the main practice surgery would have fallen into group three. In that case a practice nurse might have received the follow-up mailing but not the lead paediatric vaccine prescriber. In all cases, however, the lead paediatric vaccine prescriber would have received the original launch mailing.

GlaxoSmithKline knew that practice nurses appreciated receiving information about new vaccines that they were likely to be involved with administering or discussing with parents. Given that Rotarix was the first rotavirus gastroenteritis vaccine in Europe for infants, and also given the potential public health benefits GlaxoSmithKline considered it important that prescribers and potential administrators of this vaccine should be made aware of it. There was no doubt that practice nurses were a relevant audience in both the letter and spirit of the Code.

With regard to prescribing there were currently about 800 accredited nurse prescribers in the UK who could

prescribe from a full formulary. In the majority of cases, however, practice nurses could not prescribe particular medicines or vaccines unless a patient group direction had been authorised within that practice or area population. A large majority of practice nurses were however involved with the administration and ordering of vaccines. As such, the purpose of the letter was to build on the initial launch mailing to lead paediatric vaccine prescribers in all practices to make nurses aware of the availability of Rotarix.

Given the complaint, GlaxoSmithKline assumed that the time lag between the launch mailings (which clearly covered the lead paediatric vaccine GP prescribers in all practices), and the practice nurse mailing in question, together with the strategy to variably target different practices meant that the complainant did not know about the launch mailings. This might have appeared to be the case to a greater extent if the practice fell within the 'second group' as described earlier.

Nevertheless, despite the extensive launch mailing it was clear that a practice nurse mailing was a legitimate exercise that complied with the Code. Nurses were professionals in their own right and promotion to them was a legitimate activity. GlaxoSmithKline had taken steps to ensure that a prescriber in every practice had received a mailing prior to the practice nurse mailing. Thus GlaxoSmithKline strongly refuted any breach of Clause 12.1 and thus Clause 9.1.

PANEL RULING

The Panel noted that the letter at issue introduced Rotarix as the first gastroenteritis vaccine in Europe for infants from six weeks of age. Clinical data was discussed and details of the dose schedule within the context of UK routine childhood vaccinations was provided. Information about how to order the vaccine was also provided.

The Panel noted that the letter was one part of a co-ordinated mailing that targeted prescribers and administrators of paediatric vaccines. GlaxoSmithKline had submitted that in all cases, as a minimum, the lead prescriber within each practice would have received information on Rotarix prior to the practice nurse letter in question being received.

The Panel noted GlaxoSmithKline's submission that within the UK approximately 800 nurse prescribers could prescribe from a full formulary. The majority of nurses could not prescribe particular medicines or vaccines unless a patient group direction had been authorized. The Panel considered that it was reasonable to provide the letter to practice nurses irrespective of whether they could prescribe the product given their role in the administration and ordering of vaccines. No breach of Clause 12.1 was ruled. High standards had been maintained; no breach of Clause 9.1 was ruled.

Complaint received **16 October 2006**

Case completed **15 December 2006**