

# PHARMACIST v SANOFI PASTEUR MSD

## Promotion of Zostavax

A senior primary care pharmacist, complained about an email from a Sanofi Pasteur MSD representative to a general practice which referred to supplies of Zostavax (varicella-zoster virus (live)). Zostavax was indicated for the prevention of herpes zoster (shingles) and herpes zoster-related post-herpetic neuralgia (PHN).

The email referred to Zostavax, the national programme for immunising certain patients and the opportunity to maximise on profit for the surgery (£26 per dose profit now compared to enhanced payment of around £7 from September). A letter template to invite patients for the shingles vaccine was provided. The email stated that this invitation had been very well received and had allowed surgeries to set up dedicated clinics.

The complainant stated that he/she and his/her colleagues considered that encouraging GPs to prescribe for profit was inappropriate and queried whether such was in breach of the Code with regard to inducement.

The detailed response from Sanofi Pasteur MSD is given below.

The Panel noted that the definition of promotion excluded measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Further the supplementary information to the Code Terms of Trade stated that such measures or trade practices were excluded from the provisions of that clause. The terms prices, margins and discounts were primarily financial terms. The Panel noted that other trade practices were subject to the Code and had to comply with it.

The Panel noted that the email in question had been sent by one representative to practice managers. It encouraged practice managers to maximize profit by ordering Zostavax for patients 50-69 and 80 years old ahead of the introduction of the national programme for patients 70 to 79 years of age. The email also referred to the vaccine's protection. The email did not quantify the discount but made it clear that practices would, in effect, earn £26 per dose profit for each patient vaccinated now compared to around £7 from September when the national programme started. Any unused vaccine could be returned at no cost. The email included a template letter for the practice to send to patients and referred to the establishment of vaccine clinics.

Whilst the Panel had some concerns about the email, taking all the circumstances into account and on balance the Panel decided that as the arrangement related to the cost of the vaccine ie financial terms it could take the benefit of the

exemption for terms of trade and no breach was ruled.

The Panel was, nonetheless, concerned about the impression given by the letter. It appeared to advocate vaccinating certain groups of patients primarily on the basis of profit to the surgery. The Panel noted the complainant's view that the impression of encouraging GPs to prescribe for profit was inappropriate. The email and template letter had been sent to practice managers without the company's knowledge or approval. The Panel considered that high standards had not been maintained and a breach was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such circumstances.

A senior primary care pharmacist, complained about the promotion of Zostavax (varicella-zoster virus (live)) by a representative from Sanofi Pasteur MSD. Zostavax was indicated for the prevention of herpes zoster (shingles) and herpes zoster-related post-herpetic neuralgia (PHN).

### COMPLAINT

The complainant referred to an email from a Sanofi Pasteur MSD representative to a general practice which read:

'I just wanted to give you an update on Zostavax, any quantity of Zostavax purchased has 100% sale or return on it. 40 doses would get you the maximum discount and current stock has an expiry of 28th Feb 2013. The National programme will start in September 2013 for patients 70-79 years of age. Now is the opportunity to catch your 50-69 and 80 year old's (and those turning 80 before September) to give patients protection and to maximise on profit for the surgery (£26 per dose profit now compared to enhanced payment of around £7 from September). Many of our surgeries are doing this now and have been able to vaccinate 20 patients plus a day and it is proving to be very successful. Please find attached the letter template to get your patients in for the shingles vaccine. This invitation has been very well received which has allowed surgeries to set up dedicated clinics to have patients vaccinated.'

The complainant stated that he/she and his/her colleagues considered that encouraging GPs to prescribe for profit was inappropriate and queried whether such was in breach of the Code with regard to inducement.

When writing to Sanofi Pasteur MSD the Authority asked it to consider the requirements of Clauses 2, 9.1 and 18.1 of the Code.

## RESPONSE

Sanofi Pasteur MSD stated that it was committed to maintaining high standards in promoting its vaccines and always strove to comply with the Code. The company was thus very concerned about the complainant's allegations and had endeavoured to investigate the matter thoroughly.

In summary, Sanofi Pasteur MSD considered that the UK Human Medicines Regulations 2012 and Clause 1.2 (and accordingly the supplementary information for Clause 18.1) permitted trade practices relating to discounts. Accordingly, the company's discount arrangement was consistent with relevant UK regulations, did not constitute an inducement to prescribe and was not in breach of Clause 18.1.

Sanofi Pasteur MSD submitted that it had processes and policies in place with regard to the use of emails and promotional materials in order to maintain high standards in the promotion of its vaccines, consistent with the underlying principles set out in Clause 9.1. The representative's conduct was an isolated act. The company took this matter very seriously and upon learning of the complaint, immediately reminded employees of its established processes and policies.

As the email had not prejudiced patient safety or public health, nor served as an inappropriate inducement to prescribe as set out in the supplementary information for Clause 2, the activities or materials associated with the promotion of Zostavax could not be properly considered as falling within the scope of a censured act contemplated by Clause 2.

With regard to Clause 18.1, Sanofi Pasteur MSD noted that the provision of discounts was allowed under the Code. The Human Medicines Regulations 2012, Regulation 300(6) and specifically Clause 1.2 of the Code allowed promotional activity in relation to 'trade practices relating to prices, margins or discounts which were in existence on 1st January 1993'. These were primarily financial terms and normally covered cash discounts or equivalent business discount schemes on purchases of medicines, including volume discounts provided they were clearly identifiable and invoiced.

Past cases had consistently confirmed this position, specifically in relation to volume based discounts:

- Case AUTH/2371/11/10 - the Panel considered that discussions on discounts could be made together with promotion of medicines.
- Case AUTH/2230/5/09 - the Panel ruled that a complainant had the burden of proving their complaint on the balance of probabilities. Although it noted the serious allegation, the Panel did not consider that the complainant had provided evidence to show that, on the balance of probabilities, the representative had offered discounts during the course of promotion such that the arrangements amounted to an inducement to prescribe the company's products.

The Panel thus ruled no breach of the Code.

- Case AUTH/2272/10/09 - the Appeal Board considered that discount schemes would result in more prescriptions of a company's product and clarified that the schemes were not necessarily unacceptable as long as the arrangements complied with the Code. In that case, a primary care organisation would potentially qualify for a larger rebate if its prescribers increased the number of packs of the company's products they prescribed.

Therefore, Sanofi Pasteur MSD believed that its volume-based discount structure was permissible under the Code and the UK Human Medicines Regulations. Such discount structures were, and had been for many years (and certainly before 1993), a standard trade practice and were used widely in the vaccine industry. Sanofi Pasteur MSD provided examples of discount schemes offered by other vaccine manufacturers taken from publicly available sources and submitted that the NHS understood discounts to be part of normal trade practices.

Vaccines such as Zostavax, which were not part of a national vaccination programme, could be purchased and, in certain circumstances dispensed by GP practices. After these GP practices had purchased the vaccine, almost always at a volume based discount, the surgery would seek reimbursement for the list or NHS price of the medicine, as laid out in 'GMS statement of financial entitlements'.

However, the NHS reserved the right to impose a clawback (refund) of some of these discounts from the GP practice and had established a clawback rate of £11.18 per dose for Zostavax. The existence of this clawback demonstrated that the NHS expressly recognised that discounting was expected when surgeries bought Zostavax. Indeed, the receipt of a discount would be necessary if a GP practice was to be able to offer this vaccination service to patients as they would have to acquire the vaccine at £88.78 (list price £99.96) to just break even. There would of course be additional costs to the practice incurred in prescribing and then administering the vaccine (usually at a separate clinic run by the practice nurse) so the additional discount would justifiably reflect the cost associated with providing the service.

The email must, therefore, be considered in this context. It was sent to practice managers whose role involved the financial management of the practice which might include the purchase of medicines for personal administration. As the email was commercial in nature and did not refer to the clinical benefits of Zostavax, it would only be relevant to individuals who had a commercial role and were empowered to make purchasing decisions that were financially viable. Such individuals would naturally be interested in receiving information about discounts available from vaccine manufacturers.

In view of the above, Sanofi Pasteur MSD considered that the discount offered by the representative was an acceptable trade practice as contemplated by the Code and was not an inducement to prescribe. The company thus denied a breach of Clause 18.1.

With regard to Clause 9.1, Sanofi Pasteur MSD submitted that it had provided comprehensive training for its staff with regard to adherence to the Code and had strict policies in place in relation to the approval of promotional materials and the use of emails. Training on the Code was compulsory for all members of staff, with specific training programmes for representatives. Knowledge of field-based staff was assessed via an accreditation process on completion of the training. The representative who sent the email at issue had fully completed his/her training on the Code and had received updates on the changes to the Code in 2012.

Sanofi Pasteur MSD stated that its policy on communication with customers prohibited employees from using these forms of communication promotionally; any deviation from this policy was considered a serious matter.

Sanofi Pasteur MSD stated that it had determined that the email in question and the letter template were prepared and sent by one representative. The representative had acknowledged in his/her disciplinary meeting that his/her actions violated company policies and procedures and that he/she had acted alone.

Neither the email nor the letter template was reviewed or sanctioned by the company. Indeed, Sanofi Pasteur MSD had not prepared any letter template inviting patients for shingles vaccination. The independent drafting and sending of this email was completely contrary to how the company expected and trained its representatives to act. Company procedures strictly prohibited representatives from preparing their own promotional materials. The company took this deviation very seriously and had carried out the following actions:

- Using key search words and phrases, a search of all emails sent from staff was conducted to confirm whether the email sent to the complainant was an isolated incident. Based on this search and the representative's own admission, Sanofi Pasteur MSD believed that this representative was the only staff member to send such an email communication.
- A communication had been sent to all representatives to re-emphasise company policy on the prohibition of the use of emails for promotional purposes. The company had also taken the opportunity to reconfirm the adequacy of its procedures.

The company considered it unacceptable for any member of staff to deviate from its policies.

Sanofi Pasteur MSD submitted that its established process and policy on promotion of vaccines was consistent with the underlying principles set out in Clause 9.1.

With regard to Clause 2, Sanofi Pasteur MSD submitted that this incident had not prejudiced patient safety and/or public health. The Human

Medicines Regulations 2012, Regulation 300(6) and Clause 1.2 of the Code allowed volume based discounts and the offer of a discount that by its terms constituted an acceptable trade practice could not amount to an inducement to prescribe.

Sanofi Pasteur MSD was committed to maintaining high standards in promoting its vaccines and had appropriate policies and procedures in place to help ensure this. Consequently, the company did not consider that its actions had brought discredit upon or reduced confidence in the industry and therefore it denied a breach of Clause 2.

## PANEL RULING

The Panel noted that Clause 1.2 excluded from the definition of promotion measures or trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993. Further the supplementary information to Clause 18.1 Terms of Trade stated that such measures or trade practices were excluded from the provisions of that clause. The terms prices, margins and discounts were primarily financial terms. The Panel noted that other trade practices were subject to the Code and had to comply with it.

The Panel noted that trade practices may have evolved since 1 January 1993. Companies should take particular care to ensure that any trade practice which could not take the benefit of the relevant exemption complied with all the requirements of the Code and in particular Clause 18.1 which included a prohibition on inducement to prescribe, supply, administer, recommend, buy or sell any medicine. In this regard the Panel considered that particular care should be taken in relation to such trade practices and general practice where it might be argued that a personal financial benefit might accrue to the partnership contrary to Clause 18.1. Companies would be well-advised to ensure such trade practices offered to general practice met the requirements of the relevant exemption.

Turning to the case at issue the Panel noted that the email in question had been sent by one representative to practice managers. It encouraged practice managers to maximize profit by ordering Zostavax for patients 50-69 and 80 years old ahead of the introduction of the national programme for patients 70 to 79 years of age. The email also referred to the vaccine's protection for patients. The Panel noted that the email did not quantify the discount but made it clear that practices would, in effect, earn £26 per dose profit for each patient vaccinated now compared to around £7 from September when the national programme came into effect. Any unused vaccine could be returned at no cost. The email included a template letter for the practice to send to patients and referred to the establishment of vaccine clinics.

Whilst the Panel had some concerns about the email, taking all the circumstances into account and on balance the Panel decided that as the arrangement related to the cost of the vaccine ie financial terms it could take the benefit of the exemption to Clause 18.1,

Terms of Trade. Thus the Panel ruled no breach of Clause 18.1.

The Panel was nonetheless concerned about the impression given by the letter. It appeared to advocate vaccinating certain groups of patients primarily on the basis of profit to the surgery. The Panel noted the complainant's view that the impression of encouraging GPs to prescribe for profit was inappropriate. The email and template letter had been sent to practice managers without the company's knowledge or approval. The Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such circumstances.

**Complaint received**      **1 February 2013**

**Case completed**        **26 April 2013**

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