

PRIMARY CARE TRUST SENIOR PHARMACIST v FLYNN PHARMA

Distaclor MR email

The senior pharmacist at a primary care trust (PCT) complained about the promotion of the antibiotic Distaclor MR (extended release cefaclor) by Flynn Pharma in an unsolicited email which had been sent to a local named GP. In particular the local medicines management team was concerned that prescribers were offered six free starter packs of Distaclor. The Department of Health (DoH) guidance on the supply of medicines out-of-hours services stated that a full course of medicines should be supplied as appropriate to the presenting condition; the supply of starter packs was not appropriate.

The detailed response from Flynn is given below.

Flynn did not know the identity of the GP but submitted that the email was sent via a third party provider which made it clear at the outset to those NHS employees that agreed to go on the database that they would be sent promotional material from pharmaceutical companies. In the absence of any detailed information from the complainant and in the light of Flynn's submission the Panel ruled no breach of the Code.

The Code allowed starter packs for a primary care prescriber to initiate treatment when there might be an undesirable or unavoidable delay in having a prescription dispensed. The amount should be sufficient to tide a patient over until their prescription could be dispensed. Antibiotics were listed as an example of a medicine that might be provided as a starter pack.

The Panel noted the DoH's advice that the supply of starter packs was not appropriate. There might be occasions where the prescriber could not dispense a full course and in the limited circumstances outlined in the Code the supply of a starter pack was helpful when it was in the patient's best interest to start treatment as soon as possible.

Although not supported by the DoH advice, the Panel did not consider that the principle of offering starter packs of an antibiotic breached the Code as alleged. It might be argued that the offer of a starter pack was presented in the email at issue as the main reason for using Distaclor. However the Panel did not consider that in this regard the email failed to promote the rational use of Distaclor and no breach of the Code was ruled. The company had not failed to maintain high standards.

The senior pharmacist at a primary care trust (PCT), complained about the promotion of the antibiotic Distaclor MR (extended release cefaclor) by Flynn Pharma Ltd in an unsolicited email which had been sent to a local GP.

COMPLAINT

The complainant stated that the local medicines management team was concerned about the email which appeared to breach the Code. In particular the team was concerned that prescribers were offered six free starter packs of Distaclor. The Department of Health (DoH) guidance on out-of-hours services, 'Securing proper access to medicines in the out-of-hours period' stated in section 2.8 that:

'Where medicines are supplied out-of-hours it should be a full course as appropriate to the presenting condition, i.e. the amount that would otherwise have been prescribed. The supply of starter packs is not appropriate.'

When writing to Flynn, the Authority asked it to respond in relation to Clauses 7.10, 9.1 and 9.9 of the Code.

RESPONSE

Flynn stated that in common with many other companies, it retained the services of a third party provider to contact relevant NHS recipients, the records for which were maintained on a database of NHS employees. All such NHS employees had been previously contacted by the provider as part of a validation process.

During the first contact the provider identified itself and outlined what it was, what it did, and the need for an email address in order to allocate an access code to its NHS online directory service. The NHS employee was informed that they might from time to time receive communications from one of the provider's associated/affiliated companies which would be relevant to their medical or non medical specialisation or administrative responsibilities. The communication was along the lines of '[the provider] will from time to time send information by email about our associated/affiliated companies and their clients' product and services, which may include updates on specialist services, conferences and seminars, diagnostic, medical and pharmaceutical promotional materials as well as official information'.

A follow-up email to the NHS employee confirmed the points raised and the access code. This email also invited comment from the recipient and asked them to make contact if they needed to amend any of the information held. It also reiterated that they would be sent information about products and services along with other medical and non-medical information.

In order to ensure that only those recipients who wished to receive such material did so there was an opt-out facility on all the provider's emails (the footnote on the promotional item in question referred).

The provider regularly re-evaluated its opt-in procedures.

Finally, Flynn noted that Cases AUTH/2111/3/08 and AUTH/2112/3/08 dealt with the same issue (alleged unsolicited email) and in both no breach was ruled. The point at issue in the present case was fundamentally the same. The Distaclor MR email had not been unsolicited and recipients had given prior, fully informed consent to receive promotional emails on behalf of pharmaceutical companies. Thus, Flynn respectfully submitted that there was no breach of Clause 9.9.

In regard to the second matter, the complainant had noted advice contained in a 'practical guide' previously issued by the DoH for PCTs and organised providers entitled 'Delivering the Out-of-Hours Review. Securing Proper Access to Medicines in the Out-of-Hours Period' (Gateway Number 4107). Specifically the complainant cited Section 2.8 which advised that 'where medicines are supplied out-of-hours, it should be a full course as appropriate to the presenting condition The supply of starter packs is not appropriate'. Flynn was not previously aware of this guidance which it understood was issued in 2005.

The DoH advice was just that – advice – and health professionals and other interested stakeholders (where they were aware) should and would, generally take it into account and apply it wherever possible and practicable. It did not, however, carry the force of regulation or statutory authority and allowed proper authority for prescribers to not follow such advice where they considered circumstances dictated. Flynn submitted that there were circumstances in which a prescriber might wish or need to issue a starter pack to initiate treatment pending the dispensing of a complete prescription by a pharmacy. Notwithstanding the sound intent and principles of the DoH advice, Flynn considered that there were situations in which it was not possible for the prescriber to both prescribe and dispense a full course of treatment. The promotional email at issue specifically referred to service provision 'out-of-hours or when the local pharmacy is closed'. Issues of prescription payment, processing and reimbursement came to mind, amongst others which, in Flynn's view, had not

been considered in the DoH advice.

The DoH advice had not been widely promulgated and indeed the Code itself, in both the 2006 and 2008 editions, referred to starter packs in the supplementary information to Clause 17, which was at variance with the DoH advice. Specifically, the Code advised that:

'Starter packs are small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night or in other instances where there might be some undesirable delay in having a prescription dispensed. It follows from this that the types of medicines for which starter packs are appropriate are limited to those where immediate commencement of treatment is necessary or desirable, such as analgesics or antibiotics.'

Thus in two successive versions of the Code which had been issued after the DoH had published its advice, explicit reference was made to antibiotic starter packs and it was entirely reasonable that a supplier might be influenced and directed by information set out in the Code. Whilst there were relevant arguments, on both sides, as to the extent to which the supply of antibiotic starter packs constituted 'best practice', it was not a prohibited activity and nor did it breach the Code's 'high standards' test (Clause 9.1), the prime intent of which in any event was concerned with matters of suitability and taste, which did not appear to be at issue here.

Flynn assumed that the Authority's reference to Clause 7.10 was in the context of the importance of taking and completing a full prescribed course of antibiotics. Clearly this objective was not achieved by taking only the two doses available in the Distaclor MR starter pack. A directive to take a complete course of treatment was however clearly included in the patient leaflet accompanying the starter pack and in the prescribing information which was electronically linked to the promotional email. Thus, Flynn respectfully maintained that it had taken proper account of the product's risk/benefit profile in terms of prescriber and patient directions as to the importance of taking a full course of treatment as prescribed. Although not subject to or referenced in this complaint, the claims made in the email were consistent with the licensed indications and known evidence as to both the safety and efficacy of Distaclor MR.

In response to a request for further information, Flynn provided a copy of the mailing sent to NHS employees and issued by the provider. This was underpinned by the provider's internal opt-in policy which was regularly reviewed. Although this was not issued to health professionals, it provided relevant guidance as to the standards and controls applied. Relevant abstracts from the policy statement were provided.

PANEL RULING

The complainant had complained that the email was sent unsolicited to a named GP. Flynn did not know the identity of that GP. Flynn submitted that the email was sent via a provider which maintained a database of NHS employees and made it clear at the outset to those that agreed to go on the database that they would be sent promotional material from pharmaceutical companies. In the absence of any detailed information from the complainant and in the light of Flynn’s submission the Panel ruled no breach of Clause 9.9.

With regard to the supply of starter packs the Panel noted that Clause 17 allowed starter packs for a primary care prescriber to initiate treatment when there might be an undesirable or unavoidable delay in having a prescription dispensed. The amount should be sufficient to tide a patient over until their prescription could be dispensed. The supplementary information to the Code specifically cited antibiotics as an example of a medicine that might be provided as a starter pack.

The Panel noted the DoH document and its advice that the supply of starter packs was not appropriate. There might be occasions where the prescriber could not dispense a full course and in the limited circumstances outlined in the Code the supply of a starter pack was helpful when it was in the patient’s best interest to start treatment as soon as possible.

Although not supported by the DoH advice, the Panel did not consider that the principle of offering starter packs of an antibiotic was in breach of the Code as alleged. It might be argued that the offer of a starter pack was presented in the email at issue as the main reason for using Distaclor. However the Panel did not consider that in this regard the email failed to promote the rational use of Distaclor and no breach of Clause 7.10 was ruled. The company had not failed to maintain high standards and no breach of Clause 9.1 was ruled.

Complaint received	3 December 2009
Case completed	19 February 2010
