

MEDICINES MANAGEMENT PHARMACIST v LEO

Template letter to request GP initiation of Picato

A medicines management pharmacist complained about pre-printed forms for Picato gel (ingenol mebutate) issued by Leo Pharma that could be used by dermatologists to communicate their prescribing recommendations to GPs. The complainant was concerned that the forms were being used locally to get around the fact that Picato was not on the formulary.

The detailed response from Leo is given below.

The Panel noted that the material in question was a preprinted letter addressed 'Dear Dr' which recommended that a patient be prescribed Picato. There was space for the doctor to include patient and clinical details. This was followed by details of Picato's indication and some clinical trial outcomes and provision for the clinician's signature. Prescribing information was included on the reverse.

The Panel noted that the Code did not necessarily prohibit the promotion of non-formulary medicines, but such promotion had to comply with the Code. In this regard, the Panel noted that in relation to representatives the Code stated, *inter alia*, that the arrangements in force at any particular establishment must be observed.

The Panel noted that according to Leo, Picato was on a local clinical commissioning group and trust formulary and that a review of a formulary submission to a local medicines management group had been deferred. The Panel noted Leo's submission that there were no published restrictions preventing the promotion of medicines prior to formulary inclusion in the five hospitals where the material was distributed. The relevant local medicines management group policy on certain meetings stated that ideally the medicines management group would prefer that companies promoted mainly products included in the local formulary or those that had been approved for use within the local health economy. It did not otherwise restrict or comment on the promotion of non-formulary medicines. In addition, the Panel noted Leo's submission that the referral footprint of dermatologists at the hospitals where the item was distributed included practices not covered by the guidance.

The Panel noted that the complainant was concerned that the promotional material was being distributed despite Picato's non-formulary status. The Panel noted that the material in question did not comment on or raise any inferences about Picato's formulary status. The Panel did not consider that the material gave a misleading impression about Picato's formulary status and in that regard ruled no breach of the Code.

The Panel noted its comments above on the relevant requirements of the Code and local guidelines. The Panel did not consider that the company had failed to maintain high standards in this regard. No breach of the Code was ruled.

A medicines management pharmacist at a clinical commissioning group (CCG), complained about a piece of promotional material for Picato gel (ingenol mebutate) issued by Leo Pharma which was in the form of a pad of 30 pre-printed A4 forms (ref 4340a/000526).

The form could be used as a template for dermatologists to communicate their prescribing recommendations to GPs. It was distributed to dermatologists, specialist registrars and a few GPs with a special interest in dermatology.

Picato was indicated for the cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.

COMPLAINT

The complainant stated that as a result of one of the forms (with prescribing information on the reverse) making its way to a surgery where she worked as a pharmacist (it was not clear whether this was via a patient), one of the GPs there asked her whether he should prescribe Picato. The complainant had looked into this matter on his behalf and was advised by the local commissioning support unit (CSU) that Picato was not presently on the formulary as the request was initiated by Leo rather than via a dermatologist as was customary. The complainant had therefore advised the GP that he should instead prescribe solaraze as this was recommended first line for actinic keratosis. The medicines management team was concerned, however, that the forms were being used across the local health economy to get around the fact that Picato was not on the formulary.

When writing to Leo Pharma, the Authority asked it to respond in relation to Clauses 7.2 and 9.1 of the Code.

RESPONSE

Leo stated that the forms, which had been certified for promotional use, were offered in face-to-face meetings to dermatologists and specialists throughout the UK and not only in those areas where Picato was not on the local formulary. Leo explained that in the area in question, the forms were distributed by two representatives to specialist secondary care dermatologists, specialist registrars and to four GPs with a special interest (GPSIs) in dermatology, from the end of February 2013 to date.

Although most of the forms were distributed in five hospitals, one in particular received more than the others. Where accepted, each dermatologist or specialist recipient received one book containing a pad of 30 forms. Leo submitted that the local representatives advised dermatologists that Picato was on a local CCG and trust formulary (from 13 April) and that a submission to the local medicines management group was due for review on 13 July (which had subsequently been deferred). The health professionals that they were distributed to had the expertise and authority to both prescribe, and recommend the prescription of, Picato according to their clinical judgement in individual patients. Leo representatives were briefed on the appropriate use of the forms before they were distributed.

Leo submitted that although the Code did not specifically preclude promotional activities prior to formulary inclusion, before distributing the forms, the local representatives took due care to find out about, and act in accordance with, local NHS restrictions on the promotion of products. There were no published restrictions preventing the promotion of medicines prior to formulary inclusion in the five hospitals where the forms were distributed including the hospital which received the majority of forms due to its status as a national tertiary referral centre and because it was the primary base for most local dermatologists.

Leo representatives were briefed that they should distribute the forms to dermatologists and GPSIs so that, if they wished, they could use it as a detailed template for communicating their prescribing recommendations clearly to the patients' GPs, some of whom would not be in the local area.

The decision to recommend Picato in a particular patient (based on their clinical need and any applicable formulary restrictions in the locality of the patient) was entirely the responsibility of the dermatologist, specialist registrar or GPSI. The representatives did not request any dermatologist to recommend Picato for patients that they knew were resident where Picato was not on the local formulary. At no point did Leo representatives ask them to prescribe Picato for any specific patient or to direct their prescribing recommendations towards patients from any particular locality. The further distribution of the template letter was at all times, in the control of the recipient specialist.

With regard to primary care (which covered GPs & GPSIs), local medicines management group in conjunction with the local CSU provided guidance to GPs on medicines use and a list of recommended (formulary) products. Until recently, the local medicines management group did not have any published local restrictions on the promotion of products prior to their inclusion on its formulary. The local medicines management group published a guidance document on its website towards the end of July and a copy was provided. Leo submitted that this guidance only restricted the promotion of non-formulary medicines at company sponsored educational meetings and not their promotion in other contexts.

Leo noted that the local medicines management group guidance allowed for the recommendation by specialists of medicines which were not on its formulary in restricted instances. The group's website page headed 'Formulary Subgroup' stated that: 'The formulary is applicable to new initiations and treatments in approximately 80% of patients'. Leo submitted that it would be the responsibility of the specialist to be aware of, and act within these restrictions when recommending a medicine to their primary care colleagues. It was also important to note that the referral 'footprint' of dermatologists at the hospitals where this item was distributed, included GP practices outside the local area which were not covered by local guidance.

Leo stated that, in summary:

- this was a promotional item which contained accurate information appropriate to the recipients;
- the representatives were briefed on the use of the forms prior to their distribution;
- the representatives made themselves aware of locally published restrictions on the promotion of medicines;
- there were no published, blanket local restrictions which prevented the promotion of non-formulary medicines;
- recipients were not requested to prescribe Picato in any specific patients nor direct their prescribing recommendations to patients from any particular locality;
- recipients were, at all times, in full control of the further distribution of the forms.

With regard to Clause 7.2, Leo submitted that the forms contained no claims or information in relation to the local or regional formulary review or inclusion status of Picato, nor was there any recommendation to prescribe Picato before inclusion in any formulary or guidelines. All the information contained in the form related purely to providing clarity to the recipient GP on what the specialist had recommended, how that clinical recommendation could be implemented and key summary information on Picato. All of this information was accurate, balanced and capable of substantiation.

Leo reiterated that the decision to recommend Picato in a particular patient (based on their clinical need and any applicable local formulary restrictions) was entirely the responsibility of the dermatologist. Leo representatives did not ask dermatologists to prescribe Picato for any specific patient or direct their prescribing recommendations towards patients from any particular locality, nor were specialists asked to distribute the forms to localities where Picato was not on formulary.

Leo stated that it was common practice for many hospital consultants to advise and recommend prescription of medicines by GPs for their referred patients rather than provide a hospital prescription. This was dependent on local hospital policy and the forms contained information that accurately assisted the consultant to do that, and only that, where they had made an independent decision to do so.

Leo considered that all of the information in the forms was accurate, balanced, complete and fully appropriate for its intended purpose and audience. Leo did not consider that dermatologists or general practitioners had been misled by the form and therefore denied a breach of Clause 7.2.

Leo submitted that high standards had been maintained at all times. As set out above, the forms were certified for a legitimate purpose; they were distributed to appropriate recipients and did not contain any misleading information. Nor were recipients requested to further distribute them in a manner that could breach local NHS restrictions or exceed their authority. Recipients were, at all times, in full control of the further distribution of this item.

Representatives were briefed as to the intended purpose, recipients and manner of use of the forms prior to their distribution; the forms were distributed in compliance with the Code. Leo submitted that the details indicated that high standards had been maintained, that there had been no breach of Clause 7.2 and, in overall conclusion, that there had been no breach of Clause 9.1.

PANEL RULING

The Panel noted that the material in question was a preprinted letter addressed 'Dear Dr' which recommended that a patient be prescribed Picato. The form had spaces for the doctor to fill in, including the patient's name, date of consultation and a tick box indicating the area requiring treatment and dosage. This was followed by details of Picato's indication and information about the phase III clinical trial data. The hospital name and department had to be provided in the top right hand corner and there was provision for the clinician's signature at the end of the letter. Prescribing information was included on the reverse.

The Panel noted that the Code did not necessarily prohibit the promotion of non-formulary medicines, but such promotion had to comply with the Code. In this regard, the Panel noted that in relation to representatives the Code stated, *inter alia*, that the arrangements in force at any particular establishment must be observed, (Clause 15.4).

The Panel noted that according to Leo, Picato was on a local CCG and trust formulary (from mid April) and that a review of a formulary submission to the local medicines management group had been deferred. The Panel noted Leo's submission that there were no published restrictions preventing the promotion of medicines prior to formulary inclusion in the five hospitals where the material was distributed. Section 4 of the local medicines management group policy: engagement with the pharmaceutical industry, in relation to sponsorship of educational meetings or the local medicines management group conference, stated that ideally the local medicines management group would prefer companies to promote mainly products included in the local formulary or those that had been approved for use within the local health economy'. The policy also set out a process for appointments with pharmaceutical company representatives and the provision of information about medicines. It did not otherwise restrict or comment on the promotion of non-formulary medicines. The local medicines management group formulary subgroup stated that the formulary was applicable to new initiations and treatments in approximately 80% of patients. In addition, the Panel noted Leo's submission that the referral footprint of dermatologists at the hospitals where the item was distributed included practices not covered by the local guidance.

The Panel noted that the complainant was concerned that the promotional material was being distributed despite Picato's non-formulary status. The Panel noted that the material in question did not comment on or raise any inferences about Picato's formulary status. The Panel did not consider that the material gave a misleading impression about Picato's formulary status and in that regard ruled no breach of Clause 7.2.

The Panel noted its comments above on the relevant requirements of the Code and local guidelines. The Panel did not consider that the company had failed to maintain high standards in this regard. No breach of Clause 9.1 was ruled.

Complaint received 13 August 2013

Case completed 27 September 2013