CASE/0309/10/24 *NO BREACH OF THE CODE*

COMPLAINANT v Ethypharm UK Ltd

Allegations about an article on a third-party website

CASE SUMMARY

This case was in relation to an article that appeared on a third-party webpage, with access restricted to verified UK health professionals. The article was written by a named palliative medicine consultant, and it was clear from the outset that the article had been funded and reviewed by Ethypharm.

The complaint raised concerns with regard to the statement "Generally no absolute contraindications" and also alleged Actimorph (morphine sulfate), was promoted outside its licensed indication.

The outcome under the 2024 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Failing to maintain high standards**
No Breach of Clause 6.1	**Requirement that information must be accurate, up-to-date and not misleading**
No Breach of Clause 6.2	**Requirement that claims/information/comparisons must be capable of substantiation**
No Breach of Clause 11.2	**Requirement that a medicine must be promoted in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received about Ethypharm UK Ltd from a contactable complainant who described themselves as a concerned UK healthcare professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

"Dear PMCPA,

On the following page of a website [link provided]

The take home messages at the base of the page are: [screenshot of webpage at issue]

Note there are ‘generally no absolute contraindications’. In fact there are several specific contraindications.

The SmPC states the contraindications are:

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1,

- Children under 6 months old,

- Severe respiratory depression with hypoxia and/or hypercapnia (in absence of artificial ventilation),

- Severe bronchial asthma,

- Severe chronic obstructive pulmonary disease,

- In acute: cranial trauma and intracranial hypertension in absence of controlled ventilation,

- Uncontrolled epilepsy,

- Acute hepatic disease,

- Acute abdomen,

- Paralytic ileus,

- Delayed gastric emptying,

- Concomitant administration with opioid agonists-antagonists (e.g. buprenorphine, nalbuphine, pentazocine), opioid partial agonists (e.g. naltrexone, nalmefene), sodium oxybate,

- Concurrent administration of mono-amine oxidase inhibitors or within two weeks of discontinuation of their use.

The SmPC does not list palliative care as a different patient group with different contraindications.

There also appears to be no licenced indication of the product available on this promotional website - hence it does not explicitly state that children under 6 months old are contraindicated.

This is both selling outside of its licence as well as due to downplaying the contraindications is a patient safety issue. Please investigate."

Further information provided by the complainant

"The SmPC would be for the product that they are promoting - Actimorph. Not that the website states the name. [screenshot of webpage listing prescribing information for various strengths of Actimorph]

You raise a good point - they do not explicitly state on the website which product they are promoting and state 'content funded and prepared by Ethypharm' - they do not state that this is promotional material. They do make it is clearly prepared by themselves so they are responsible for whatever the clinician they've paid says. [screenshot of header of the webpage at issue, stating "Content funded and prepared by Ethypharm", within a slim, purple banner, adjacent to links to Prescribing information and Adverse event reporting information]

The reference is irrelevant - products have to comply to their Market Authorisation as stated in the SmPC. If there is new research that has been undertaken then the company can approach the MHRA and petition to have their SmPC updated. Until that time they cannot promote in a manner that is against the SmPC, whatever a reference might or might not state. In this particular case, the discrepancy is contradicting information in the contraindication section, which is clearly a patient safety issue. Again - palliative patients are not a recognised subgroup on the SmPC and this promotional material doesn't list anywhere the safety profile - instead stating that there aren't any. They might be from a clinical standpoint but not from a Regulatory one."

When writing to Ethypharm, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 6.1, 6.2 and 11.2 of the 2024 Code.

ETHYPHARM'S RESPONSE

The response from Ethypharm is reproduced below:

"Ethypharm acknowledges receipt of a complaint concerning a [third-party] webpage.

Ethypharm takes the ABPI Code of Practice very seriously and is always committed to maintaining high standards and ensuring compliance with the Code in all its relevant activities.

Ethypharm has conducted an investigation into this matter, and as requested, has taken into consideration the requirements of the following Clauses of the ABPI Code of Practice 2024:

- Clause 2 - Upholding Confidence in the Industry: Activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.
- Clause 5.1 – Companies must maintain high standards at all times.
- Clause 6.1 - Information, claims and comparisons must be accurate, balanced, fair, objective, and unambiguous and must be based on an up-to-date evaluation

of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration, or undue emphasis. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine.

- Clause 6.2 - Any information, claim or comparison must be capable of substantiation.
- Clause 11.2 - The promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics subject to the provisions of Clause 11.3.

Whilst investigating the matter, Ethypharm has removed the article in question from the [third-party] website.

Below we have provided a background and context for the article in question and have then addressed the points raised by the complainant with the information attained during our investigation.

Background

It is recognised that untreated or inadequately treated pain is an unmet need in palliative care patients.[1,2,3] It has also been recognised that doctors find managing the pain of such patients challenging and would welcome further training on this.[1]

The article in question, entitled 'Appropriate use of opioids for pain management in palliative care' was written by [named health professional], an established palliative care consultant, to appear on [third-party website] with access restricted to verified healthcare professionals only. The article is for educational purposes to help address the above identified issues and discusses the appropriate use of opioids in pain management, including initiation of opioid use, use of injected versus oral opioids, use of different release-rate opioids, identification and management of breakthrough pain and NICE guidelines on opioid use.

Ethypharm considered the article to be promotional in nature under the ABPI Code of Practice. It was reviewed and certified as promotional material by a Final Medical Signatory ([health professional qualification]) registered with the [name of statutory regulator], PMCPA and MHRA, ensuring that all the relevant requirements of the code for such promotional material, as detailed below, had been met. The article is well-referenced throughout and balanced between the clinical benefits and safety associated risks with the use of strong opioids in palliative care.

Point 1

Complaint

'*On the following page of a website* [link to third-party website]. *The take home messages at the base of the page are:* [screenshot of Summary section within the footer of the webpage at issue]

Note there are "generally no absolute contraindications". In fact there are several specific contraindications. The SmPC states the contraindications are: - Hypersensitivity to the active substance or to any of the excipients listed in section 6.1:

- Children under 6 months old, - Severe respiratory depression with hypoxia and/or hypercapnia (in absence of artificial ventilation),
- Severe bronchial asthma, - Severe chronic obstructive pulmonary disease,
- In acute: cranial trauma and intracranial hypertension in absence of controlled ventilation,
- Uncontrolled epilepsy,
- Acute hepatic disease,
- Acute abdomen,
- Paralytic ileus,
- Delayed gastric emptying,
- Concomitant administration with opioid agonists-antagonists (e.g. buprenorphine, nalbuphine, pentazocine), opioid partial agonists (e.g. naltrexone, nalmefene), sodium oxybate, - Concurrent administration of mono-amine oxidase inhibitors or within two weeks of discontinuation of their use.

The SmPC does not list palliative care as a different patient group with different contraindications.'

Response to Point 1

The sentence in the Summary section that the complainant is referring to has been quoted incompletely and has been taken out of context.

The complete sentence states:

'There is generally no absolute contraindication to using strong opioids in palliative care provided the dose is carefully titrated against the patient's pain.'

1. This statement is referring to **strong opioids** as a group of medicines, rather than to a particular medicinal compound, in the context of use within a specific population who often has an unmet pain management need.[1]

2. The term '**absolute contraindication**' is defined in the Rx List Drug Medical Dictionary[4] as '*a situation which makes a particular treatment or procedure absolutely inadvisable,'* and in the McGraw-Hill Concise Dictionary of Modern Medicine[5] as '*a reason for not performing a particular therapeutic intervention which is so compelling or carries such a grave risk that its performance would be reasonably regarded as constituting malpractice.'*

3. The term absolute contraindication in this sentence is referring to strong opioids as a group of medicines rather than to a particular medicinal compound, and in the context of use within a specific population who often has an unmet pain management need.

4. In the article it is made clear that specific opioids may not be appropriate for particular patients and that alternatives are to be considered.

The complete statement is making the point that there are no absolute contraindications to the use of strong opioids in general as a group of medicines in palliative patients suffering from pain, rather than to the use of specific opioids. **No reference is made in this statement to any specific generic or branded opioid medicines.**

5. The complete statement is substantiated by Pharmaceutical Press' 'Palliative Care Formulary,[6] which is clearly referenced within the article for this statement.

6. A link to a list of Prescribing Information (PI) for each opioid product marketed by Ethypharm was included in the article. When looking at the contraindications section of these PIs, taken directly from Section 4.3 of the SmPCs, there is no contraindication which appears in all of them and that would be considered to be an absolute contraindication to using any opioid product.

7. Hypersensitivity to the active or excipients appears as a contraindication in each Summary of Product Characteristics (SmPC) and PI, as it is a regulatory requirement, but this statement is specific to the active ingredient and excipients present in that particular product.

8. Regarding hypersensitivity reactions to specific opioids, cross reactivity between different opioids is rare and that alternative opioids can be considered for patients with a history of hypersensitivity to one particular opioid, provided that the patient is closely monitored.[7] Hypersensitivity to a medicinal compound therefore also does not constitute an absolute contraindication to the use of all strong opioids.

9. In the bulk of the article, examples are provided of situations where one opioid may not be suitable for a patient, with alternative opioids needing to be considered. For example, see below:

   1. **'Opioid switching**

   Some patients do not tolerate certain opioids, so convert to another opioid, e.g. from oral morphine to oxycodone.[1,6] Opioid rotation or switching may be considered if a patient obtains pain relief with one opioid and is suffering severe adverse effects.[4] Switching to specific opioids, such as fentanyl or oxycodone, has been shown to reduce constipation, nausea and clouded vision.[20]

   It is important to halve the dose of oxycodone as it is twice as strong as morphine.[6]'

   2. **'Contraindications to using opioids**

   - There are no real contraindications to prescribing opioids in palliative care,[6] however there are circumstances when it may be better to avoid the use of certain opioids, for example if a patient has renal or hepatic impairment. In renal failure, an example trial would be morphine PO 2.5 mg every 6 hours or oxycodone IR 2.5 mg every 6 hours[21]*
   - In severe liver disease, opioid doses may need to be reduced or switched.[26] **Consult specialist palliative care advice**[1]'

10. The complainant has only referred to one of the PIs linked to in the article and has listed out the contraindications for that product, Actimorph (morphine sulfate) Orodispersible tablet, but has made no reference to the rest of the PIs provided for the other Ethypharm opioid products:

    - Zomorph (morphine sulfate) Capsule,
    - Fentanyl Solution for Injection,
    - Morphine Oral Solution,
    - Morphine Solution for Injection,
    - Oxycodone Oral Solution,
    - Pethidine Solution for Injection,
    - Physeptone (methadone) Solution for Injection,
    - Maxitram SR (tramadol hydrochloride) Prolonged-Release Capsule.

In addition, the statement "Always refer to the Summary of Product Characteristics for full information before prescribing" clearly appears at the top of the article.

Point 2

Complaint

'*There also appears to be no licenced indication of the product available on this promotional website - hence it does not explicitly state that children under 6 months old are contraindicated.'*

Response to Point 2

The article is a general article discussing different generic opioids (not specific brands) some of which Ethypharm markets and others which we do not. For this reason, we did not list the licensed indications for all products in the material.

For those generic medicines mentioned in the article which Ethypharm markets, a link is provided in the article to the PI, which clearly states the approved product indication.

Furthermore, as mentioned above, it is clearly stated at the top of the article to 'Always refer to the Summary of Product Characteristics for full information before prescribing.'

Point 3

Complaint

'*This is both selling outside of its licence as well as due to downplaying the contraindications is a patient safety issue.'*

Response to Point 3

No claims have been made regarding any specific Ethypharm medicine (generic or branded) within the article that are in contravention of the information in the SmPC for the product, nor have any contraindications been downplayed. **On the contrary, Safety Information regarding the use of opioids has been highlighted throughout**

the article, as well as appearing in the linked PIs for the specific opioids. Ethypharm is dedicated to having a strong focus on patient safety. For example, see below:

1. (on the live website, these safety warnings appeared at the top of every page).

'**Opioids can cause addiction.**

Always refer to the Summary of Product Characteristics for full information before prescribing. **The major risk of opioid overdose is respiratory depression. Opioids can cause sleep related breathing disorders including central sleep apnoea (CSA) and sleep related hypoxemia.'**

2. **'Opioid switching**

Some patients do not tolerate certain opioids, so convert to another opioid, eg from oral morphine to oxycodone.[1,6] Opioid rotation or switching may be considered if a patient obtains pain relief with one opioid and is suffering severe adverse effects.[4] Switching to specific opioids, such as fentanyl or oxycodone, has been shown to reduce constipation, nausea and clouded vision.[20]

It is important to halve the dose of oxycodone as it is twice as strong as morphine.[6]'

3. **'Contraindications to using opioids**

- There are no real contraindications to prescribing opioids in palliative care,[6] however there are circumstances when it may be better to avoid the use of certain opioids, for example if a patient has renal or hepatic impairment. In renal failure, an example trial would be morphine PO 2.5 mg every 6 hours or oxycodone IR 2.5 mg every 6 hours[21]*
- In severe liver disease, opioid doses may need to be reduced or switched.[26] **Consult specialist palliative care advice**[1]
- If a patient is on methadone for drug rehabilitation and now needs opioids for cancer-related pain, **consult expert palliative care advice**. Do not stop the methadone.[26,27*] Maintenance therapy from a substance misuse service should be regarded as a separate prescription from that for analgesia.[29]'

4. **'Investigation and management of acute opioid toxicity**:[2,6*]

All patients on opioids should be monitored for side effects and signs of central nervous system toxicity. Symptoms include confusion, drowsiness, agitation, hallucinations, myoclonic jerks and respiratory depression.[3]

*Opinion based on the clinical experience and knowledge of [named health professional].'

In addition, all the PIs on the webpage contain all the safety sections from each SmPC.

Also, there is no mention of the use of any of our products outside of its marketing authorisation.

The PIs for all our opioid products are linked to in the article and it is clearly stated that the reader should always refer to a product's Summary of Product Characteristics before prescribing.

Point 4

Complaint

'*The SmPC would be for the product that they are promoting - Actimorph. Not that the website states the name.'* [screenshot of webpage listing prescribing information for various strengths of Actimorph]

Response to Point 4

The complainant has stated that the article is promoting the product Actimorph, however, this is untrue.

No reference has been made to Actimorph specifically within the article, but to the generic names of many different opioids, including but not limited to morphine, which is the active ingredient of Actimorph Orodispersible tablet.

Consequently, the PI for all of Ethypharm' s opioid products have been linked to in the article.

Point 5

Complaint

'*You raise a good point - they do not explicitly state on the website which product they are promoting and state "content funded and prepared by Ethypharm" - they do not state that this is promotional material. They do make it is clearly prepared by themselves so they are responsible for whatever the clinician they've paid says.'* [screenshot of header of the webpage at issue, stating "Content funded and prepared by Ethypharm", within a slim, purple banner, adjacent to links to Prescribing information and Adverse event reporting information]

Response to Point 5

1. As stated above, Ethypharm considered the article to be promotional in nature under the ABPI Code of Practice.

It was **reviewed and certified as promotional material**, ensuring that all requirements of the code for digital promotional material had been met, including:

- Inclusion of Job bag number and date of preparation
- Adverse Event Reporting Information statement

- Inclusion of legible Prescribing Material (PI) that is consistent with the SmPC, by means of a clear, prominent direct single link

- An accurate declaration of involvement, clearly stating that this is an "Ethypharm Funded and reviewed material "

2. There is no requirement under the ABPI Code of Practice to explicitly state on a digital webpage that the material is promotional in nature, however, as acknowledged by the complainant, it clearly states at the top of the article, as required, that the article has been funded and reviewed by Ethypharm.

It has also been ensured, as required, that access to the website in question is restricted to only verified healthcare professionals.

3. As previously mentioned, the article is a general article discussing different generic opioids, some of which Ethypharm markets and others which we do not.

For those generic names mentioned in the article where Ethypharm markets a product, the PI for the product has been linked to in the article, and the HCP is directed to it with a link at the top of the page.

4. Within the article, no favourable claims have been made about any one generic opioid over others, nor has any mention been made of any particular branded products.

Point 6

Complaint

'*The reference is irrelevant - products have to comply to their Market Authorisation as stated in the SmPC. IF there is new research that has been undertaken then the company can approach the MHRA and petition to have their SmPC updated. Until that time they cannot promote in a manner that is against the SmPC, whatever a reference might or might not state. In this particular case, the discrepancy is contradicting information in the contraindication section, which is clearly a patient safety issue. Again - palliative patients are not a recognised subgroup on the SmPC and this promotional material doesn't list anywhere the safety profile - instead stating that there aren't any. They might be from a clinical standpoint but not from a Regulatory one.'*

Response to Point 6

As stated above, no claims have been made regarding any medicines (generic or branded) within the article that are in contravention of the information in the SmPC for the product, nor have any contraindications been downplayed. There is no mention of the use of any of our products outside of its marketing authorisation.

The PI for all of our opioid products is linked to in the article and it is clearly stated that the reader should always refer to a product's Summary of Product Characteristics before prescribing.

Again, as stated above, the complete sentence 'There is generally no absolute contraindication to using strong opioids in palliative care provided the dose is carefully titrated against the patient's pain,' refers to strong opioids as a group of medicines rather than to a particular medicinal compound and this statement is substantiated by Pharmaceutical Press 'Palliative Care Formulary.[6]

The article has not stated that there are no safety considerations associated with using strong opioids in palliative care patients and as mentioned above, safety information regarding the use of opioids has been repeatedly highlighted throughout the article, for example see below:

1. (on the live website, these safety warnings appeared at the top of every page).

'**Opioids can cause addiction.**

Always refer to the Summary of Product Characteristics for full information before prescribing. **The major risk of opioid overdose is respiratory depression. Opioids can cause sleep related breathing disorders including central sleep apnoea (CSA) and sleep related hypoxemia.'**

2. **'Opioid switching**

Some patients do not tolerate certain opioids, so convert to another opioid, e.g. from oral morphine to oxycodone.[1,6] Opioid rotation or switching may be considered if a patient obtains pain relief with one opioid and is suffering severe adverse effects.[4] Switching to specific opioids, such as fentanyl or oxycodone, has been shown to reduce constipation, nausea and clouded vision.[20]

It is important to halve the dose of oxycodone as it is twice as strong as morphine.[6]'

3. '**Contraindications to using opioids**

- There are no real contraindications to prescribing opioids in palliative care,[6] however there are circumstances when it may be better to avoid the use of certain opioids, for example if a patient has renal or hepatic impairment. In renal failure, an example trial would be morphine PO 2.5 mg every 6 hours or oxycodone IR 2.5 mg every 6 hours[21]*****
- In severe liver disease, opioid doses may need to be reduced or switched.[26] **Consult specialist palliative care advice**[1]
- If a patient is on methadone for drug rehabilitation and now needs opioids for cancer-related pain, **consult expert palliative care advice**. Do not stop the methadone.[26,27*] Maintenance therapy from a substance misuse service should be regarded as a separate prescription from that for analgesia.[29]'

4. **'Investigation and management of acute opioid toxicity:[2,6*]**

All patients on opioids should be monitored for side effects and signs of central nervous system toxicity. Symptoms include confusion, drowsiness, agitation, hallucinations, myoclonic jerks and respiratory depression.[3]

*Opinion based on the clinical experience and knowledge of [named specialist health professional].'

In addition, all the PIs on the webpage contain all the safety sections from each SmPC.

Conclusion

Ethypharm has worked very hard to genuinely deliver an educational material that aims to address a very challenging unmet need in the management of pain in palliative care, the article was deemed to be promotional in nature and all necessary steps have been followed to ensure that ABPI Code of Practice requirements, ethical considerations and patient safety were at the forefront of this project.

Therefore, we believe that the article in question has not breached any of the alleged clauses (2, 5.1, 6.1, 6.2, 11.2) of the ABPI Code of Practice.

We sincerely hope that the explanation above clarifies the complainant concerns and demonstrates our commitment to follow the ABPI Code of Practice."

PANEL RULING

This case concerned an article that appeared on the website of a closed community professional network for doctors in the UK, with access restricted to verified health professionals only. The article 'Appropriate Use of Opioids for Pain Management in Palliative Care' was written by a named palliative medicine consultant. It was clear from the outset that the article had been funded and reviewed by Ethypharm.

The article discussed when to prescribe opioids, when to prescribe an alternative opioid, administration and release-rate variants, risks and considerations, and break through cancer pain. The header of the webpage included links to prescribing information, adverse event reporting information, a statement in bold, capital letters in large font, that *"Opioids can cause addiction"* followed by the statement *"always refer to the Summary of Product Characteristics for full information before prescribing.* ***The major risk of opioid overdose is respiratory depression. Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia."*** The footer of the webpage at issue, and each page in the article, included abbreviations, a list of references, adverse event reporting information and a summary section of the author's take-home messages for the use of opioids in palliative care which included the statement at issue *"There are generally no absolute contraindications to using strong opioids in palliative care provided the dose is carefully titrated against the patient's pain".*

The Panel interpreted the complaint as comprising two broad allegations, firstly, that the statement, *"generally no absolute contraindications'* was not correct as there were several specific contraindications in the summary of product characteristics (SPC) and palliative care was not listed in the SPC as a different patient group with different contraindications, and secondly, that the article promoted a medicine outside the terms of its licence as it did not state the licensed indication of the medicine or explicitly state that children under 6 months are

contraindicated, and as a whole the article downplayed contraindications which constituted a patient safety issue.

‘Generally no absolute contraindications’

The Panel considered the overall impression created by the article, the content and its intended audience. It noted the article was authored by a consultant in palliative care, and acknowledged Ethypharm’s submission that untreated or inadequately treated pain was recognised as an unmet need in the palliative care setting, and access to the material was restricted to verified health professionals only.

The Panel concluded that the material, as a whole, was educational in tone and content; it discussed opioid drugs as a therapeutic class, referring to the names of active ingredients rather than focussing on any specific medicine. The Panel noted no specific medicine was being promoted in the article and that following a request for further information the complainant had indicated that their allegations related to Actimorph, although they acknowledged that the article does not explicitly state which product is being promoted. The complainant included a list of contraindications in support of their allegation, and it appeared to the Panel that this list corresponded with the contraindications listed in the Actimorph SPC.

Ethypharm submitted that the claim ‘generally no absolute contraindications’ was part of a longer statement which provided context, and indicated the statement was made in relation to the use of strong opioids as a group of medicines specifically for pain management in palliative care where the dose has been carefully titrated against the patient’s pain.

The Panel understood the term ‘absolute contraindication’ to refer to situations when use of a medicine could cause a life-threatening situation and must be avoided. In its view it was standard clinical practice for clinicians to make an assessment of the benefits and risks associated with the use of a medicine on a case-by-case basis, bearing in mind the particular circumstances at the time.

In the Panel’s view, the statement, ‘generally no absolute contraindications’ as alleged, would need to be considered within the context of the full statement and the article as a whole, to determine whether it misled health professionals reading the article.

Having taken account of the evidence before it, in the Panel’s view, the claim in question did not relate to a particular medicine, Actimorph, as alleged by the complainant but rather that it related to the opioid class of medicines and their use in the particular circumstances of pain management in palliative care.

The Panel noted the article provided a comprehensive overview of the subject and covered a range of topics including a section on risks and considerations and was, in its view, balanced and sufficiently complete to enable recipients to form their own opinion of the therapeutic value of opioids for pain management in palliative care. The Panel concluded that, in the particular circumstances of the subject under discussion in the article, the complainant had not established that the claim at issue was inaccurate or misleading. Accordingly, the Panel ruled **no breach of Clause 6.1,** and **no breach of Clause 6.2** on the basis that within the context of the article the statement was substantiated using the references provided.

Promotion outside the licensed indication

The complainant alleged the article did not explicitly state which product was being promoted, or include a licensed indication for it, or state that children under 6 months old were contraindicated. The complainant indicated that they considered the product to be Actimorph and that these failures amounted to promotion outside of its licence which together with downplaying the contraindications was a patient safety issue.

Clause 11.2 required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics.

The Panel noted its comments above, that the article discussed opioids in general and did not place particular weight on the use of one opioid over another. Noting that the article did not mention the Actimorph brand name, and listed the generic names of various opioids available on the market, the Panel did not consider that the article promoted a specific medicine and therefore the question of whether or not a medicine was being promoted in accordance with the terms of its marketing authorisation or in a manner that was inconsistent with the particulars listed in its summary of product characteristics did not arise. For this reason, the Panel ruled **no breach of Clause 11.2**.

High Standards

The Panel noted its comments and rulings above, and that complainants bore the burden of proof to establish their case on the balance of probabilities. The Panel considered that the complainant had not established that Ethypharm had failed to maintain high standards and ruled **no breach of Clause 5.1** and accordingly **no breach of Clause 2.**

Complaint received **04 October 2024**

Case completed **16 September 2025**