Decision of the ADVERTISING REGULATORY BOARD

Complainant	Health Products Association of Southern Africa
Advertiser	Austell Laboratories (Pty) Ltd
Consumer/Competitor	Competitor - Industry body
File reference	Piascledine- HPA
Outcome	Partially upheld
Date	22 July 2019

The Directorate of the Advertising Regulatory Board has been called upon to consider a complaint lodged by the Health Products Association of South Africa ("the HPA") against a television commercial for the Piascledine complementary medicine product sold and marketed by Austell Laboratories (Pty) Ltd.

Description of the advertising

The television commercial includes the following voice over:

> *"The millions suffering from stiff and painful joints, should not be taking glucosamine and chondroitin.*
>
> *People with high blood pressure, diabetes, asthma, a shellfish allergy or those using blood thinners are at risk. Check the package insert before taking*

glucosamine and chondroitin, they can affect your blood pressure and diabetes and trigger asthmatic or allergic reactions.

Fortunately, there is PIASCLEDINE. It does not contain Glucosamine and Chondroitin and is the only clinically proven osteoarthritis treatment that reduces pain, improves movement, slows disease progression, lessens your need for harmful anti-inflammatories, and is safe to use with other medicines.

PIASCLEDINE, no glucosamine, no chondroitin. The number one osteoarthritis treatment worldwide including South Africa"

Complaint

The complaint is, in parts, technical in nature, and is summarised as follows.

The active ingredients of the Piascledine product are avocado oil and soybean oil, making it a Complementary Medicine, in terms of Medicines and Related Substances Act 101 of 1965. The Complainant recognises that the product has not been called up for registration, but submits that it should nevertheless comply with current legislation, specifically as some of the claims are so-called "high-risk".

The Complainant makes the point that avocado oil and soybean oil, found in Piascledine, could cause allergic reactions and other side-effects and consumers should be warned of this.

The Complainant discusses, in some detail, the science behind both glucosamine and chondroitin, as well as avocado oil and soybean oil. The Complainant mentions that there are certain interactions between both chondroitin and glucosamine, with Warfarin, and advises that these interactions are published on the packaging of these products. The Complainant avers that similar interactions exist between Warfarin and avocado oil and soybean oil and these should be mentioned by the Advertiser.

The Complainant submits that the manner in which the commercial is executed, and in particular the manner in which the alleged "*Glucosamine Chondroitin Health Risk"* is

communicated, is likely to create the impression that products containing glucosamine and chondroitin are likely to cause severe damage to users, and as, such is unjustifiably playing on fear as to the effects of using products containing glucosamine and/or chondroitin.

The Complainant submits, not only is the commercial likely to mislead consumers in over-claiming the drug-interaction of chondroitin but it is at the same time omitting the material fact that avocado oil has the same moderate Warfarin drug-interaction as chondroitin. It is thus misleading consumers as to the Warfarin drug-interaction of chondroitin and avocado oil, the one over-claimed and the other omitted. It is further submitted that this exacerbates the fact that the commercial unjustifiably plays on fear as to the effects of using products containing glucosamine and/or chondroitin.

Furthermore, the Complainant submits that the commercial is discrediting products containing glucosamine and/or chondroitin in order to promote Piascledine. Piascledine is not promoted on its own merits, but (falsely and fearfully) on the alleged demerits of competing products. As such, the commercial is disparaging of products containing glucosamine and/or chondroitin and also constitutes comparative advertising.

The Complainant requests the Advertiser to prove certain claims made and also demonstrate that the publication of such claims are in the public interest.

Lastly, the Complainant requests substantiation of the claims that Piascledine product is the "*... only clinically proven osteoarthritis treatment that reduces pain, improves movement, slows disease progression, lessens your need for harmful anti-inflammatories, and is safe to use with other medicines"* and its claim that its Piascledine product is "*..The number one osteoarthritis treatment worldwide including South Africa*".

Response

Werksmans responded on behalf of Austell by contesting the ARB's authority to hear the matter and apply the Code of Advertising Practice ("the Code"). They aver that the Code was published by the Advertising Standards Authority of South Africa ("the ASA") and that

this body is currently in liquidation. They request clarity on the basis on which the ARB is entitled to make use of the Code published by and belonging to the ASA.

They go on to state that their client, the Advertiser, is not a member of the ARB.

Response on the merits

The Advertiser addresses the merits as follows.

As a matter of record and fact, the Piascledine product is a complementary medicine that has yet to be called up for registration and it need not therefore comply with any of the legislation concerned.

Dealing with the allegations of fear and misleading claims, the Advertiser states that the television commercial seeks to highlight to consumers suffering from stiff, painful joints and osteoarthritis, the possible harmful effects of glucosamine and chondroitin. In this regard, the potential harmful effects of these ingredients constitute true scientific information that is already in the public domain (including the package insert of various joint supplement products on the South African market).

The potential harmful effects of glucosamine and chondroitin have also been well documented in scientific studies. The Advertiser referred the Directorate to an independent expert report from Dr van Heerden, which speaks to the potentially harmful effects of glucosamine and chondroitin - such report being based on numerous scientific sources. The conclusion is that the television commercial cannot be considered to instil fear– but instead seeks to promote transparency in the interests of consumers.

In so far as the possible side-effects or contraindications of the Piasceldine product are concerned, the Advertiser states that the aforementioned information need not be listed or dealt with in an advertisement. They state that there is nothing misrepresented about the Piascledine product in the television commercial and a misrepresentation cannot exist due to the fact that the possible side-effects or contraindications are not referred to in the advertisement. The possible side-effects and contraindications of Piascledine are reflected in the package insert for the product.

Regarding the complaint about disparagement and comparative advertising, the Advertiser states that the television commercial does not make any direct or indirect references to any products containing glucosamine and chondroitin. Instead, the commercial only makes statements regarding the possible effects of glucosamine and chondroitin. Accordingly, they aver, no disparaging statements are made in the advertisement about any other product on the market and no product, on the market, is compared with the Piascledine product.

The Advertiser reiterates that the remarks made in the commercial regarding the effects of glucosamine and chondroitin are neither disparaging nor defamatory. The potentially harmful effect of these ingredients is true information that is already in the public domain. The report by Dr Van Heerden was again referred to.

The Advertiser states that it is in the interests of the public to be made aware of potentially harmful effects associated with glucosamine and chondroitin – particularly in so far as the information is directed at patients, many of whom are suffering from an array of ailments and may be at risk if they are exposed to glucosamine and chondroitin. The statements, accordingly, also promote public health and public health awareness and are, therefore, in the public interest.

Dealing with substantiation of the claims made, the Advertiser states that the claims made in the commercial are clinically supported. In this regard, in relation to the statement that Piascledine *is "[t]he only clinically proven osteoarthritis treatment that reduces pain, improves movement, slows disease progression, lessens the need for harmful anti-inflammatories and is safe to use with other medicines",* the Advertiser referred the Directorate to a bibliographic review of the available information relating to treatment options. This bibliographic review is intended to prove that only Piascledine was demonstrated to reduce the concomitant intake of Nonsteroidal Anti-Inflammatory Drugs ("NSAIDs") in osteoarthritis patients in controlled or comparative studies, with NSAIDs sparing effect being assessed as the primary outcome, and by extension affirms

that Piascledine is the only product clinically proven to provide all of the benefits mentioned in the commercial.

Additionally, with reference to the statement that Piascledine is the *"number one osteoarthritis treatment worldwide including South Africa",* the Advertiser referred the Directorate to reports prepared by IQVIA Proprietary Limited. According to the Advertiser, the first report indicates that Piascledine is the 1st brand of the class ATC M5X – Musculo-Skeletal product in the world while the second report contains details that Piascledine holds the number one spot in the Total Private Market ("TPM") data set in both value and volume in the past two Moving Annual Total or MAT periods. The TPM data set provides insight into the total private market in the pharmaceutical industry.

The Advertiser makes the statement that appropriate consideration of the documents it submitted in support of its response is necessary for the proper adjudication of the complaint.

Application of the Code of Advertising Practice

The following clauses were considered in this matter:

Fear- Clause 3.1 of Section II

Substantiation- Clause 4.1 of Section II

Misleading claims – Clause 4.2.1 of Section II

Disparagement- Clause 6 of Section II

Comparative Advertising- Clause 7 of Section II.

Decision

Having considered in detail all the material before it, the Directorate of the ARB issues the following findings.

Jurisdiction

The Advertiser has indicated that it is not a member of the ARB and is not bound by the decisions thereof.

The Memorandum of Incorporation of the ARB states:

"3.3 The Company has no jurisdiction over any person or entity who is not a member and may not, in the absence of a submission to its jurisdiction, require non-members to participate in its processes, issue any instruction, order or ruling against the non-member or sanction it. However, the Company may consider and issue a ruling to its members (which is not binding on non-members) regarding any advertisement regardless of by whom it is published to determine, on behalf of its members, whether its members should accept any advertisement before it is published or should withdraw any advertisement if it has been published."

In other words, if you are not a member and do not submit to the jurisdiction of the ARB, the ARB will consider and rule on your advertising for the guidance of our members.

The ARB will, however, rule on whatever is before it when making a decision for the guidance of its members. This ruling will be binding only on ARB members, and on broadcasters in terms of the Electronic Communications Act.

The ARB will therefore proceed to consider this matter for the guidance of its members.

Code Ownership

The Advertiser contends that the ARB has no basis on which to administer the Code of Advertising Practice, which it contends is the property of the Advertising Standards Authority, which is currently in liquidation.

The ARB has considered this contention but considers it to be without merit. It is beyond the scope of this decision to canvas each and every aspect of this issue, but the ARB has concluded that it is not precluded from applying the Code of Advertising Practice in these proceedings for the following main reasons. It must be noted that these reasons are independent and self-standing and that each of them separately lead to the conclusion that the Advertiser's contention is without merit:

- First, the MOI of the ARB makes clear that the ARB is to enforce the Code of Advertising Practice. It provides inter alia
  ". . . 3.1.3 address and fill the lacuna left by the liquidation of the Advertising Standards Authority of South Africa (1995/000784/08), which lacuna creates a risk that consumers will be exploited, and the advertising and marketing industry will be brought into disrepute;
  3.1.4 adopt and enforce, as far as reasonably possible, the existing and established Code of Advertising practice in the Republic (as administered until now by the Advertising Standards Authority of South Africa (1995/000784/08)). . ."
  On this basis, the ARB has the jurisdiction to apply the Code in this complaint.

- Second, the core of the Advertiser's complaint is that the ARB is violating the property rights of the ASA. But if there were any merit in that complaint, that is not an issue that the Advertiser has standing to raise in these proceedings.

- Third, the contention that the Code forms part of the property of the ASA such that the ARB is precluded from applying it is without merit in view of the fact the Code of Advertising Practice is based on the international ICC Code that all Self Regulatory Organisations use as their starting point. A line by line comparison with this document will reveal that the core of the Code of Advertising Practice is a

direct reflection of this document. The ICC have confirmed, in writing, that, "The ARB is recognised by the International Council for Advertising Self-Regulation (ICAS) as the official body responsible for implementation of advertising standards in South Africa. Accordingly, the ARB has justifiable remit to apply and enforce a national code of advertising practice".

- Fourth, the contention that the Code forms part of the property of the ASA such that the ARB is precluded from applying it is without merit in view of the fact the creation of the Code of Advertising Practice occurred on an ongoing basis through consultation with the industry. The industry makes submissions to the SRO which the SRO then either accepts or rejects. Sometimes the SRO may fine-tune the drafting of the submission, but any property rights such as existed in the Code (if there were any) lay with the advertising and marketing industry, rather than the ASA. The advertising and marketing industry has now mandated the ARB to enforce the Code, as appears from the MoI of the ARB.

- Fifth, the contention that the Code forms part of the property of the ASA such that the ARB is precluded from applying it is without merit in view of the fact that section 55 of the Electronic Communications Act must be read with the definition in section 1 which defines Advertising Standards Authority as "*the entity which regulates the content of advertising, or any entity that replaces it but has the same functions*". The ARB has replaced the ASA and has the same functions as it had. It is thus entitled to enforce the Code.

Compliance with legislation

The product has not been called up for registration by the Medicines Control Council.

In any event, the mandate of the ARB is restricted to the application of the Code of Advertising practice, and the Directorate will therefore not consider the aspect of the complaint that relates to compliance with the relevant legislation.

Merits

The Directorate notes that in considering most aspects of this complaint, the question has come down to the same central theme, perhaps best embodied in Clause 6 of Section II which essentially states that advertisements should not attack, discredit or disparage other products, but that comparisons highlighting a weakness in an industry or product will not necessarily be regarded as disparaging when the information is factual and in the public interest.

The Directorate notes that the following appears to be the factual situation, as supported by Dr van Heerden's opinion and *ex facie* accepted as common cause:

- Many osteoarthritis treatments include the ingredients glucosamine and chondroitin;
- These ingredients have known contra-indications for some people who have high blood pressure, diabetes, asthma, a shellfish allergy or are taking blood thinners;
- These contra-indications are not inevitable if you have these conditions, but caution should be exercised;
- Piascledine is a possible option for people for whom glucosamine and chondroitin are contra-indicated, with the possible exception of those on blood thinners.

The Directorate notes, with reference to Clause 6 of Section II as cited above, that as an over-arching finding, Piascledine should be able to communicate the information that it is a viable alternative for those for whom glucosamine and chondroitin are contra-indicated, with the possible exception of those on blood thinners (this will be discussed more fully below.) This is a factual advantage of Piascledine, and in so far as it arguably disparages products with those ingredients, it is a factual weakness that is highlighted.

The Directorate also notes that there is no duty on Piascledine to highlight its own weaknesses, as long as the failure to do so does not mislead consumers. Put clearly, Piascledine need not disclose its possible inter-action with blood thinners if it does not put itself forward as an alternative for those on blood thinners. But if it puts itself forward

as an alternative for those on blood thinners, then it must clarify that there may be certain exceptions.

As the final over-arching finding, the Directorate notes that there is a difference between communicating this information factually, and communicating this information incorrectly and hysterically. There is "highlighting a weakness" and there is causing a panic. The Directorate kept coming back to the idea of "what you say versus how you say it".

It is with this over-arching framework in mind that the Directorate proceeds.

Fear- Clause 3.1 of Section II

Clause 3.1 of Section II states that "Advertisements should not without justifiable reason play on fear."

As stated above, the Directorate accepts that it appears that there are potential risks associated with Glucosamine and Chondroitin. Indeed, parts of the wording of the commercial sum up the factual situation, as set out in Dr van Heerden's report, in a rational manner:

> *"People with high blood pressure, diabetes, asthma, a shellfish allergy or those using blood thinners are at risk. Check the package insert before taking glucosamine and chondroitin, they can affect your blood pressure and diabetes and trigger asthmatic or allergic reactions. . .".*

However, the commercial does not stop here. The commercial starts with the words: "*The millions suffering from stiff and painful joints, should not be taking glucosamine and chondroitin*" while the words "HIGH RISK" appear on the screen. This statement is not supported by the opinion from Dr van Heerden, whose opinion shows that at best there MIGHT be a risk for some people who have the listed conditions. This is not a definite outcome ("should not be taking") for "all the millions who suffer from stiff and painful

joints", as implied by the commercial. It is interesting that Dr van Heerden incorrectly believes that this sentence says, "*The millions suffering from stiff and painful joints, **who** should not be taking glucosamine and chondroitin".*

In addition to the words in the voice-over mentioned above, the commercial portrays a large red "danger" sign, with the words "HEALTH RISK!" This, together with the wording "should not be taking glucosamine and chondroitin" and "are at risk" creates the impression that the products are inherently dangerous to everyone with these conditions, and that the health risks are unavoidable.

As stated before, the Directorate does not have a problem with the Advertiser communicating that *some* patients have contra-indications for glucosamine and chondroitin, and that *if* you are indeed one of these patients and *your doctor has contra-indicated using these ingredients*, Piascledine is an option (athough, it would appear, as discussed below, that it is in fact not always an option for patients taking blood thinners).

What the Directorate takes issue with is the way that this is communicated, in that:

- The language, as indicated above, goes beyond the factual situation;
- The blood thinners risk in fact, *ex facie*, also exists for Piascledine;
- The on-screen warnings and tone of communication create a general communication of hysteria around the risks of these drugs.

It is therefore not so much *what* is said – although, as indicated, there are inaccuracies – but *how* it is said. The *overall* communication triggers fear in all consumers taking osteoarthritis remedies that are not Piascledine, and a sense that they have been putting their health at terrible risk.

The Directorate therefore finds that the television commercial is in breach of Clause 3.1 of Section II.

Misleading claims – Clause 4.2.1 of Section II

The complaint links the allegation of a breach of Clause 4.2.1 of Section II to its arguments in respect of the above. Given the above findings, the Directorate is in agreement that the commercial is misleading in so far as the commercial:

- Implies that everyone taking glucosamine and chondroitin is at risk;
- Implies that such risk is unavoidable and inevitable for people with the highlighted conditions;
- Implies that Piascledine is an alternative for everyone on blood thinners.

Given the findings above, the Directorate has no option but to rule that the commercial in its current format is misleading and in breach of Clause 4.2.1 of Section II.

Substantiation- Clause 4.1 of Section II

The Complainant calls for substantiation of the following claims:

1. *"…the only clinically proven osteoarthritis treatment that reduces pain, improves movement, slows disease progression, lessens your need for harmful anti-inflammatories, and is safe to use with other medicines"*
2. *"The number one osteoarthritis treatment worldwide including South Africa."*

Clause 4.1 of Section II specifies that "Documentary evidence, other than survey data, must emanate from or be evaluated by a person/entity, which is independent, credible and an expert in the field to which the claims relate and be acceptable to the [ARB]."

The reasons for this are self-evident. The Directorate cannot be an expert on every field in which it is called to resolve advertising disputes. This is particularly true in complex medical matters such as the one at hand.

The Advertiser argues that the statements regarding the Piascledine product are clinically supported. Regarding the first claim, they referred the Directorate to a bibliographic review of the available information relating to treatment options. They advise that the bibliographic review shows that "only PIASCLEDINE was demonstrated to

reduce the concomitant intake of Nonsteroidal Anti-Inflammatory Drugs ("NSAIDs") in osteoarthritis patients in controlled or comparative studies, with NSAIDs sparing effect being assessed as primary outcome and by extension affirms that PIASCLEDINE is the only product clinically proven to provide all the benefits mentioned in the advertisement."

The conclusion of the bibliographic review states as follows: *"This bibliographic review shows that only PIASCLEDINE ® was demonstrated to reduce the concomitant NSAIDs intake in OA [osteoarthritis] patients in controlled or comparative studies, with NSAIDs sparing affect being assessed as primary outcome."*

The Advertiser has not, in the first place, provided any information about the independence, credibility and expertise of the entity that conducted the bibliographic review. The letterhead states "Laboratoires Expanscience". The Directorate conducted its own research and found that this entity in fact sells Piascledine (ref https://www.expanscience.com/en/products/rheumatology-osteoarthritis).

It is therefore not independent in this matter, and on that measure alone, does not meet the requirements of Clause 4.1 of Section II.

In any event, and simply for the guidance of the Advertiser, the Directorate also notes that it would appear that the only part of the claim that is supported by the bibliographic review is the portion that relates to lessening the need for anti-inflammatories.

It may be, by extension of reasoning, that less NSAIDs are used because some of the other symptoms or issues are addressed, but the review is not clear on this point and does not address the claims made relating to reducing pain, improving movement, slowing disease possession and being safe to use with other medicines.

Furthermore, the science placed before the Directorate by the Complainant, which the Advertiser appears to accept, is that both avocado oil and soybean oil have some sort of interaction with certain drugs, like Warfarin. The statement that Piascledine is safe to use with other drugs therefore appears to be unsubstantiated.

The Directorate therefore finds that the claim *"…the only clinically proven osteoarthritis treatment that reduces pain, improves movement, slows disease progression, lessens your need for harmful anti-inflammatories, and is safe to use with other medicines"* has not been substantiated in terms of Clause 4.1 of Section II of the Code.

Turning then to the claim that the product is the number one osteoarthritis treatment worldwide and in South Africa, this claim can be broken down into two claims, one relating to being number one worldwide, and the other being number one in South Africa.

The Directorate has perused the IQVIA website and is satisfied that IQVIA appears to be an independent expert in the field of medical and health claims research.

The Directorate accepts the IQVIA research survey and is satisfied that, because Piascledine is the number one product sold into pharmacies in both value and volume, the claim that it is the number one osteoarthritis treatment *in South Africa* is adequately substantiated.

However, the claim that the product is number one **worldwide** is not substantiated. In the first place, the evidence provided by the Advertiser in the "South Africa" report specifically states that "The top products internationally are Synvisc (in value) and Turkadon (in volume)". If the Directorate is to accept this report as credible with respect to the South Africa claim, it cannot disregard the findings on the international situation.

Secondly, in the report submitted in support of the world-wide claim, retail sales in China are excluded. Given that China's consumer market is the second largest, after the USA, excluding China from the sales skews the numbers. The Advertiser has provided no explanation as to why the China figures should be disregarded.

Given this, the claim "No. 1 osteo-arthritis treatment worldwide" is unsubstantiated and therefore in breach of Clause 4.1 of Section II of the Code.

Disparagement- Clause 6 of Section II

The Advertiser is correct in saying that its television commercial does not attack, discredit or disparage other *products*, but rather makes statements regarding the possible effects of glucosamine and chondroitin, which are found in a number of different products.

The commercial does, however, appear to highlight a weakness in an industry, as envisioned by Clause 6.2 of Section II. In this case, the industry would be complementary medicines for osteoarthritis, containing glucosamine and chondroitin. The question, then, is whether such information is factual and in the public interest. It may well be in the public interest to be aware of some of the shortcomings of glucosamine and chondroitin.

However, as the commercial is in breach of Clause 4.1 and Clause 4.2.1 of Section II and not adequately substantiated, it is not entirely factual.

In addition, taking into consideration Clause 6.3 of Section II, which guides the Directorate to take cognisance of the intention of the Advertiser, the way in which the claims are made and the take-out of the television commercial as a whole, it certainly appears to be the intention of the Advertiser to steer consumers away from products containing glucosamine and chondroitin. Although these ingredients sometimes have negative contra-indications or drug interactions, they may be the correct medication for a large number of users.

The Directorate concludes that the television commercial is in breach of Clause 6 of Section II of the Code.

Comparative Advertising- Clause 7 of Section II

Comparative advertising is acceptable in terms of the Code subject to certain strict requirements which are set out in Clause 7 of Section II. As should be clear at this point, the Directorate takes no issue with the mere comparison of the two products.

However, the commercial is in breach of both Clause 4.1 and 4.2.1 of Section II. Clause 7.1.2 calls for compliance with Clause 4.1, and Clause 7.1.4 calls for compliance with

Clause 4.2.1. In addition, Clause 7.1.9 states that, “The contextual implication is strictly limited to the facts”. As the Directorate has repeatedly stated, this commercial goes out of the arena of the facts and into the arena of fear-mongering.

Given this, the Directorate finds that the commercial is in breach of Clause 7 of Section II of the Code.

Sanction

Members of the ARB are advised not to accept the aforementioned television commercial in its current format.