COMPLAINT NUMBER	16/283
APPEAL NUMBER	16/020
COMPLAINANT	M. Honeychurch
APPLICANT	M. Honeychurch
ADVERTISER	Weleda New Zealand Limited
ADVERTISEMENT	Weleda Website
DATE OF MEETING	9 December 2016
OUTCOME	Not Upheld, Appeal Dismissed

SUMMARY

The Complaints Board ruled on 13 September 2016 the complaint about the Weleda Website advertisement for Cold & Flu Drops was Not Upheld. Complainant M. Honeychurch appealed the Decision.

This application was considered by the Chairperson of the Appeal Board. The Chairperson noted the Complainant's view the evidence provided to Complaints Board was misinterpreted to the extent that it affected the Decision. The Chairperson accepted the Appeal and the Advertiser was asked to respond. Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, was also given the opportunity to comment.

The Appeal Board considered all the matters afresh, including information from Medsafe, confirming the advertised product, Weleda Cold & Flu Drops, is legally entitled under the Medicines Act 1981 to make the therapeutic claims subject to complaint. The Appeal Board agreed as the claims in the advertisement complied with the applicable law, the advertisement was not in breach of the Therapeutic Products Advertising Code.

The Appeal Board ruled the complaint was Not Upheld and the Appeal was Dismissed.

Please note this headnote does not form part of the Decision.

APPEAL BOARD DECISION

The Complaints Board ruled on 13 September 2016 the complaint about the Weleda Website advertisement for Cold & Flu Drops was Not Upheld.

This application was considered by the Chairperson of the Appeal Board. The Chairperson noted the Complainant's view the evidence provided to Complaints Board was misinterpreted to the extent that it affected the Decision.

The Chairperson ruled the appeal was Accepted under ground (v), that it is in the interests of natural justice, and the matter was to be placed before the Appeal Board for determination.

The Chairperson directed the Appeal Board to consider the advertisement with reference to

Principles 2 and 3 and Part B1 Requirements 3 and 4, 4(a), of the Therapeutic Products Advertising Code. This required the Appeal Board to consider whether the advertisement was truthful and balanced and whether claims were valid and had been substantiated and whether the advertisement had observed a high standard of social responsibility. The Appeal Board was further required to consider whether the advertisement had been misleading or deceptive, or was likely to mislead or deceive, either indirectly or by implication, omission, ambiguity, exaggerated claim or comparison. The Appeal Board also needed to confirm that the advertisement was consistent with the indications included on the database of therapeutic products maintained by Medsafe.

The Appeal Board confirmed that its role was to consider the matter de novo, that is, starting from the initial complaint and reviewing all subsequent correspondence, rulings, and submissions, and considering the matter afresh.

The Appeal Board ruled the complaint was Not Upheld and the Appeal was Dismissed.

Preliminary Matter
As a preliminary matter, the Appeal Board discussed the role of the Advertising Standards Authority codes and complaints process in relation to legislation. The Appeal Board confirmed that government regulators and legislation including advertising restrictions were senior jurisdictions to the ASA.

The Complaint
The Complainant stated in their initial complaint that “This claim of relief of symptoms of colds and flu is a therapeutic claim, making this advert fall under the ASA's Therapeutic Products code. As such, the ad appears to breach Principle 2, as the claims made have not been substantiated and it seems unlikely that any homeopathic remedy has been conclusively shown to treat these symptoms.”

In their Appeal application, the Complainant challenged the efficacy of the product and said in part: “What Weleda have failed to mention to the ASA is that this registration came about due to a “grandfathering” process when the Medicines Act came into force, back in 1981. At this time, any products that had already been making therapeutic claims were able to gain registration and approval for those claims without having to provide substantiation. Medsafe said “The product was grandfathered into the current regulatory scheme following the enactment of the Medicines Act 1981. Products that were eligible for grandfathering were those that were already marketed in New Zealand and had a demonstrated history of safe use”. The grandfathering focused only on safety, and did not evaluate efficacy.

Subsequent modifications to Weleda’s Medsafe registration for their Cold and Flu Drops have had a similar lack of requirement for evidence of efficacy. Medsafe considered those changes to be within the scope of the original grandfathered set of claims - “The modified indications have been accepted as they are all encompassed by the original approval.”

As a “grandfathered” product, this Medsafe registration is not evidence of efficacy. However, Weleda have misrepresented their product registration as evidence of efficacy by claiming in their complaint response that “Given that the statement on the website is consistent with the registered indications, we consider that the claims do not contravene the Therapeutic Products Advertising Code.”

The Response from the Advertiser

The Advertiser re-iterated its position from its response to the Complaints Board. It said, in part:

> "As previously stated, Weleda Cold & Flu Drops is a registered medicine with Medsafe (TT50-8039). It is 'medicine' as defined under section 3 of the Medicines Act 1981. It is not a 'dietary supplement' as defined under reg. 2A of the Dietary Supplements Regulations 1985 or a 'natural health and supplementary product' as presently defined under the Natural Health and Supplementary Products Bill (Government Bill 324-2). Those definitions are broadly reflected in the new Therapeutic and Health Advertising Code (effective 1 September 2016).
>
> As a medicine, Weleda Cold & Flu Drops is permitted to carry, and Weleda is permitted to use, therapeutic claims to promote the product provided those claims do not breach the relevant sections of the Medicines Act. This will remain the case until such a time as either Medsafe de-classifies the product as a medicine or the product's classification is altered by legislation.
>
> Weleda accepts that Weleda Cold & Flu Drops was 'grandfathered' into the current medicines registration system following the enactment of the Medicines Act 1981 (which replaced the Food and Drug Act 1969 which in turn replaced the Food and Drugs Act 1947. Cold and Flu Drops received 'default' approval as a medicine on 31 December 1969, three months before the Food and Drug Act 1969 came into force on 1 April 1970. This 'grandfathering' process however **was applied to all relevant products at the time**, including what may be called 'conventional' medicines. There was no favouritism towards one type of medicine or another
> and **there was no requirement to (re-)submit evidence of efficacy to be registered**.
>
> In the absence of a statutory or regulatory requirement under either the Food and Drug 1969 or the Medicines Act 1981 for Weleda to freshly prove the efficacy of our Cold & Flu Drops, we do not accept that it is open to M. Honeychurch to demand we do so by way of this proceeding – particularly when they have provided no evidence to support the view that Cold and Flu Drops has no efficacy. The appropriate channel for M. Honeychurch to pursue evidence of efficacy is via a complaint to Medsafe, where they would also (we imagine) be required to provide specific clinical trial evidence on our product to support the complaint."

Comment from the Regulator, Medsafe
Medsafe confirmed that the product advertised had been 'grandfathered' from previous legislation and stated in part:

> "The 'approval date' published on the Medsafe website in relation to this product (and most Weleda products) indicates approval at 31 December 1969. This means that these products were determined to have been legally on the market prior to the commencement of the Food and Drug Act 1969 and could continue to be marketed under the current legislation, with the same indications. Proof of efficacy is not held by Medsafe.
>
> Medsafe can confirm that, under the Medicines Act 1981, Weleda is entitled to make the therapeutic claims about this product that are the subject of the complaint."

Appeal Board Discussion
The Appeal Board confirmed it was considering the matter *de novo*, taking into account all the material that had been provided to it. It confirmed the website advertisement for Weleda Cold & Flu Drops included the wording "Take at the onset of cold or flu to relieve symptoms – fever, muscle ache, headache, sore throat, sneezing and runny nose. Take with Weleda Echinacea/Thuja Comp. Active Strength Immune Support for additional effectiveness. Does not cause drowsiness."

The Appeal Board agreed this statement included therapeutic claims covered by the Therapeutic Products Advertising Code and noted the Complainant challenged the product's efficacy in relation to the claims and considered there was a lack of evidence to support them.

As in all cases, the Appeal Board said that where a claim in an advertisement was challenged by a Complainant, the onus fell on the Advertiser to provide the Complaints and Appeal Boards with substantiation of that claim. The Appeal Board also reiterated the stance that it was not an arbiter of scientific fact nor was it within its jurisdiction to verify the efficacy of a product. Instead, its focus was to consider the likely consumer take out of an advertisement rather than the absolute scientific legitimacy of a claim.

In relation to the complaint before it, the Appeal Board considered the key issue was a matter outside its jurisdiction, namely the process agreed to with the regulator during a change to legislation some decades ago. Based on the information provided to it, the Appeal Board understands that a 'grandfathering' provision is in place, allowing advertisers, and in this case Weleda, to make therapeutic claims about certain products, including the product subject to complaint, Weleda Cold and Flu Drops.

The Advertiser provided background information about the legislative grandfathering process, reference to available substantiation and confirmation the advertising was been approved by the Therapeutic Advertising Pre-vetting Service. The Appeal Board has also received information on the history relating to this matter from Medsafe, the Government regulator, and confirmation the Advertiser is entitled under the Medicines Act to make the therapeutic claims it has about Weleda Cold and Flu Drops.

The Appeal Board noted the position of the Complainant with regard to the 'grandfathering' of certain products but agreed this was a matter that should be raised directly with Medsafe.

Taking the above into account, the Appeal Board agreed that confirmation from the regulator the advertised claims were permitted under law, is sufficient support for those claims and therefore the advertisement is not in breach of Principles 2 and 3 and Part B1 Requirements 4, 4 and 4a of the Therapeutic Products Advertising Code.

Accordingly, the Appeal Board ruled the complaint was Not Upheld and the Appeal was Dismissed.

Decision: Complaint **Not Upheld, Appeal Dismissed.**

DESCRIPTION OF ADVERTISEMENT

The Weleda website advertisement for "Cold & Flu Drops, 30ml" and states: "Take at the onset of cold or flu to relieve symptoms – fever, muscle ache, headache, sore throat, sneezing and runny nose. Take with Weleda Echinacea/Thuja Comp. Active Strength Immune Support for additional effectiveness. Does not cause drowsiness." Consumers can click below this statement to see the product's ingredients and click to "add to basket" for $19.90.

COMPLAINT FROM M. HONEYCHURCH

The Weleda website advertises a product called "Cold & Flu Drops" for which a recommendation is given to "Take at the onset of cold or flu to relieve symptoms - fever,

muscle ache, headache, sore throat, sneezing and runny nose". The ingredients of this product are all at 3x (a homeopathic notation meaning 1:1000 dilution) or less.

This claim of relief of symptoms of colds and flu is a therapeutic claim, making this advert fall under the ASA's Therapeutic Products code. As such, the ad appears to breach Principle 2, as the claims made have not been substantiated and it seems unlikely that any homeopathic remedy has been conclusively shown to treat these symptoms.

The ad also breaches Principle 3, as it is socially irresponsible to make false claims about being able to treat the symptoms of these viral infections, which are very common ailments in New Zealand.

The ad also breaches Part B1 Requirement 3, as these claims are not truthful, and Requirement 4, as this advert is likely to mislead unwary members of the public who do not realise that there is no good evidence for the efficacy of homeopathy.

APPEAL APPLICATION FROM M. HONEYCHURCH

I would like to appeal ASA case 16/283, on the grounds that evidence provided to the Complaints Board has been misinterpreted to the extent that it has affected the decision.

Weleda stated in their complaint response that their Cold and Flu Drops product is registered with Medsafe, with approval to make therapeutic claims about influenza and colds. This was the basis for their defence against breach of Principle 2, Principle 3, Part B1 Requirement 3 and Part B1 Requirement 4 (a) of the ASA's Therapeutic Products code. This was the only defence of their claims that Weleda provided. No substantiation, in the form of scientific studies or other evidence, was submitted.

I have talked with Medsafe about Weleda's registration for the Cold and Flu Drops. They told me that Weleda are correct in that "this product is approved as a homoeopathic medicine for Cold and flu relief for Children to adult". This registration has been in place since 1981.

What Weleda have failed to mention to the ASA is that this registration came about due to a "grandfathering" process when the Medicines Act came into force, back in 1981. At this time, any products that had already been making therapeutic claims were able to gain registration and approval for those claims without having to provide substantiation. Medsafe said "The product was grandfathered into the current regulatory scheme following the enactment of the Medicines Act 1981. Products that were eligible for grandfathering were those that were already marketed in New Zealand and had a demonstrated history of safe use". The grandfathering focused only on safety, and did not evaluate efficacy.

Subsequent modifications to Weleda's Medsafe registration for their Cold and Flu Drops have had a similar lack of requirement for evidence of efficacy. Medsafe considered those changes to be within the scope of the original grandfathered set of claims - "The modified indications have been accepted as they are all encompassed by the original approval."

As a "grandfathered" product, this Medsafe registration is not evidence of efficacy. However, Weleda have misrepresented their product registration as evidence of efficacy by claiming in their complaint response that "Given that the statement on the website is consistent with the registered indications, we consider that the claims do not contravene the Therapeutic Products Advertising Code."

The specific parts of the code that Weleda claim their Medsafe registration covers them for are:

- Principle 2, which states that “Advertisements must be truthful” and ”Claims must be valid and have been substantiated”
- Principle 3, which states that “Advertisements must observe a high standard of social responsibility”
- Part B1 Requirement 3, which states that “advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated”
- Part B1 Requirement 4 (a), which states that “Advertisements must not directly nor by implication, omission, ambiguity, exaggerated claim or comparison mislead or deceive, or be likely to mislead or deceive”

These codes require substantiation - Principle 2 and Part B1 Requirement 3 explicitly state that adverts “must” be “truthful” and make claims that are “valid” and that have been “substantiated”. If Weleda’s claims are not backed by high quality evidence of efficacy, regardless of their “grandfathered” product registration with Medsafe, these claims are irresponsible (Principle 3) because are likely to mislead (Part B1 Requirement 4 (a)).

The Medsafe registration defence that Weleda has given would appear to be relevant to Principle 1 of the Therapeutic Products Code (“Advertisements must comply with the laws of New Zealand”). However, breach of this Principle was not part of the original complaint and so their defence is irrelevant to this complaint.

Therefore, unless Weleda are able to provide evidence that their Cold and Flu Drops are able to “relieve symptoms – fever, muscle ache, headache, sore throat, sneezing and runny nose”, I believe that this product is in breach of Principle 2, Principle 3, Part B1 Requirement 3 and Part B1 Requirement 4 (a) of the ASA’s Therapeutic Products Code.

If Weleda provide evidence in their appeal response to back up the therapeutic claims they make about their Cold and Flu Drops, I would appreciate being given the chance to submit a further document where I am able to critically evaluate their evidence. Obviously I am not able to assess Weleda’s evidence yet, as they did not provide any in their complaint response. If this is not possible, please let me know so that I can provide a summary of the scientific evidence most relevant to their claims.

Speaking in general terms about evidence, I can briefly say that I have spent time looking for evidence that homeopathic products are able to treat any medical condition better than placebo, and have so far come to the same conclusion as many major medical research organisations around the world. This is nicely summarised by Australia’s NHMRC, who said recently that “there are no health conditions for which there is reliable evidence that homeopathy is effective”.

THERAPEUTIC PRODUCTS ADVERTISING CODE

> **Principle 2 -** Advertisements must be truthful, balanced and not misleading. Claims must be valid and have been substantiated.
>
> **Principle 3 -** Advertisements must observe a high standard of social responsibility.
>
> **Part B1 Requirement 3 –** To assist consumers to make informed decisions, advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated

Part B1 Requirement 4 – Advertisements must not directly nor by implication, omission, ambiguity, exaggerated claim or comparison:

a) mislead or deceive, or be likely to mislead or deceive

RESPONSE TO APPEAL FROM THE ADVERTISER, WELEDA NEW ZEALAND LIMITED

Following is Weleda's response to the appeal from M. Honeychurch to the Advertising Standards Complaints Board Decision of Not Upheld in relation to the complaint about the recommendations for the product 'Cold & Flu Drops' on the Weleda website.

In preparing this response we have sought and obtained input and advice from our lawyers, James & Wells. This response has been prepared in conjunction with them.

SUMMARY OF RESPONSE

Given that the advertisement on the Weleda website regarding our Cold and Flu Drops product is, firstly, consistent with the listed indications for Weleda Cold and Flu Drops[1], and, secondly, is substantiated within the appropriate therapeutic systems, Weleda submits that there has been no breach of the Principles 2 or 3 or Requirements 3, 4 and 4(a) of Part B1 of the Therapeutic Products Advertising Code for this registered medicine.

More specifically, Weleda submits:

(a) In relation to Principle 2,:
- The product claims have been substantiated and are valid.
- The product is a medicine and the claims are consistent with the listed indications for the product.
- The claims are truthful, balanced and not misleading.

(b) In relation to Principle 3:
- The claims made for the product are substantiated and are fully consistent with the listed indications, and as such the advertisement is observing a high standard of social responsibility.

(c) In relation to Requirement 3:
- The advertisement contains truthful, valid, balanced claims which have been substantiated and are consistent with the listed indications.

(d) In relation to Requirements 4 and 4(a):
- The product claims are substantiated and are consistent with the listed indications. Therefore the advertisement is not likely to, nor attempts to mislead or deceive either directly, indirectly, or by implication, omission, ambiguity, exaggerated claim or comparison.

Weleda further submits that in the absence of any legislative requirement under the Food and Drugs Act 1969 and subsequently the Medicines Act 1981 to (re-)prove the efficacy of Cold and Flu Drops it is not, with respect, appropriate for M. Honeychurch to use the Code and this

[1] http://www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=13354

proceeding to 'debunk' our Cold and Flu product. The appropriate process is a complaint to Medsafe.

If the Appeal Board *was* to uphold M. Honeychurch's complaint that would, in our view, undermine Medsafe's authority as the body responsible for the regulation of therapeutic products in New Zealand.

THE ADVERTISEMENT IN ISSUE

M. Honeychurch's original complaint related to the following advertisement on the Weleda website which promotes Weleda Cold and Flu Drops:

> "Take at the onset of cold or flu to relieve symptoms – fever, muscle ache, headache, sore throat, sneezing and runny nose."

(the "advertisement")

COMPLAINANT'S/APPELLANT'S ALLEGATIONS: RE-CAP

M. Honeychurch has alleged the advertisement breached the following sections of the Therapeutic Products Advertising Code (the "Code") (in force prior to 1 September 2016):

(a) Therapeutic Products Advertising Code – Principle 2:
Advertisements must be truthful, balanced and not misleading. Claims must be valid and have been substantiated.

(b) Therapeutic Products Advertising Code – Principle 3:
Advertisements must observe a high standard of social responsibility.

(c) Therapeutic Products Advertising Code – Part B1 Requirement 3:
To assist consumers to make informed decisions, advertisements must contain truthful and balanced representations and claims that are valid and have been substantiated and
a. for medicines – must be consistent with the indications included on the database of therapeutic products maintained by the Trans Tasman Therapeutic Products Agency; and
b. for exempt therapeutic products – must be compliant with the Code.

(d) Therapeutic Products Advertising Code – Part B1 Requirement 4 and 4(a):
Advertisements must not directly nor by implication, omission, ambiguity, exaggerated claim or comparison:
(a) mislead or deceive, or be likely to mislead or deceive; or

M. Honeychurch says Weleda has breached the Code because (using the Appeal Board's summary in the Complaint Board's decision 16/283):

(a) Principle 2: as the claims made have not been substantiated and it seems unlikely that any homeopathic remedy has been conclusively shown to treat these symptoms;

(b) Principle 3: as it is socially irresponsible to make false claims about being able to treat the symptoms of these viral infections, which are very common ailments in New Zealand;

(c) B1, Requirement 3: as the claims are not truthful;

(d) B1, Requirement 4 and 4(a): as this advert is likely to mislead unwary members of the public who do not realise that there is no good evidence for the efficacy of homeopathy.

We understand from our lawyers that in normal civil court proceedings the burden of proof in a complaint for breach of a law falls on the person making the complaint with a corresponding burden on a defendant if it defends the complaint. In this proceeding M. Honeychurch has not provided any evidence to support their allegations, in either the original complaint or the appeal. The allegations are 'bare' and unsupported. In the absence of any evidence to support the complaint, then, we do not see how the Appeal Board can find the advertisement we make regarding our product breaches the Code, with or without evidence from us justifying the claim made.

Despite the absence of evidence to support M. Honeychurch's claim, we provide below what we believe to be sufficient evidence to justify our advertisement regarding Cold and Flu Drops.

WELEDA'S RESPONSE - DETAIL

For the reasons provided below, Weleda maintains its view that M. Honeychurch's complaint is unfounded and consequently the Complaint Board's original decision should be upheld.

1. Compliance with Medicines Act 1981

Part 4 of the Medicines Act 1981 relates to the advertising of medicines in New Zealand. Sections 56 and 57 in particular set out a number of restrictions applying to medical advertisements.

As previously stated, Weleda Cold & Flu Drops is a registered medicine with Medsafe (TT50-8039). It is 'medicine' as defined under section 3 of the Medicines Act 1981. It is not a 'dietary supplement' as defined under reg. 2A of the Dietary Supplements Regulations 1985 or a 'natural health and supplementary product' as presently defined under the Natural Health and Supplementary Products Bill (Government Bill 324-2). Those definitions are broadly reflected in the new Therapeutic and Health Advertising Code (effective 1 September 2016).

As a medicine, Weleda Cold & Flu Drops is permitted to carry, and Weleda is permitted to use, therapeutic claims to promote the product provided those claims do not breach the relevant sections of the Medicines Act. This will remain the case until such a time as either Medsafe de-classifies the product as a medicine or the product's classification is altered by legislation.

Weleda accepts that Weleda Cold & Flu Drops was 'grandfathered' into the current medicines registration system following the enactment of the Medicines Act 1981 (which replaced the Food and Drug Act 1969 which in turn replaced the Food and Drugs Act 1947. Cold and Flu Drops received 'default' approval as a medicine on 31 December 1969, three months before the Food and Drug Act 1969 came into force on 1 April 1970. This 'grandfathering' process however **was applied to all relevant products at the time**, including what may be called 'conventional' medicines. There was no favouritism towards one type of medicine or another and **there was no requirement to (re-)submit evidence of efficacy to be registered**.

In the absence of a statutory or regulatory requirement under either the Food and Drug 1969 or the Medicines Act 1981 for Weleda to freshly prove the efficacy of our Cold & Flu Drops, we do not accept that it is open to M. Honeychurch to demand we do so by way of this proceeding – particularly when they have provided no evidence to support the view that Cold and Flu Drops has no efficacy. The appropriate channel for M. Honeychurch to pursue

evidence of efficacy is via a complaint to Medsafe, where they would also (we imagine) be required to provide specific clinical trial evidence on our product to support the complaint.

In light of the above, we submit, with respect, that a decision of the Appeal Board to uphold M. Honeychurch's complaint would undermine Medsafe's authority as **the** body responsible for the regulation of therapeutic products in New Zealand.

Weleda thus submits that the Complaint Board was correct in its original decision not to uphold the complaint on the basis the relevant advertisement "accurately reflected what the Advertiser is able to claim in line with the product's Medsafe registration".

2. TAPS approval

The advertisement appears in a brochure for Weleda's cough and cold natural remedies products. A PDF copy of the relevant page of the brochure **accompanies** this response for the Appeal Board's viewing.

The advertisement has received TAPS approval: TAPS PP7819, based on the listed indications for the product.

Weleda submits it should – as any advertiser of therapeutic products should – be able to rely in good faith on the TAPS system to confirm that an advertisement meets the required standard and does not contravene the Code.

If following TAPS approval, an advertisement is found to breach the Code it calls into question how the TAPS system works (in particular the extent of evidence, if any, a TAPS adjudicator requires make his/her assessment) and, consequently, the very merits of the system.

3. Weleda's claims are valid and have been substantiated

Origin of substantiation evidence

The product claims and the advertisement made by Weleda were made based on the evidence held by the company and by regulators in other jurisdictions. The product is registered as a medicine in Germany, with the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte; BfArM), and is a registered medicine in other countries such as Switzerland. The medicine has been on the market internationally for over 60 years.

In Germany and in other countries, the evidence for medicinal claims is evaluated by the medicine regulator and is confidential between the company and the regulator. We understand that is also the case in New Zealand. In the present case, whilst Medsafe does not currently hold the evidence relating to Cold and Flu Drops, the therapeutic claims made for the product are based on evidence included in the relevant modules of the medicine dossier that are used for registering the product with regulators in various jurisdictions.

In Germany, the German Medicines Act and the German Federal Institute recognise and respect the traditional therapeutic systems of phytotherapy, homoeopathy and anthroposophic medicine. As stated by the German Federal Institute, "On the premise of pluralism in pharmacotherapy, the German Medicines Act explicitly postulates that the characteristics of the "particular therapeutic systems" are to be respected. For this reason, the legislator has established specific commissions (Commission C for anthroposophic medicinal products, Commission D for homeopathic medicinal products and Commission E for herbal medicinal products) to support the work of the BfArM by providing medical expertise in the respective

therapeutic fields."
(*Ref.* http://www.bfarm.de/EN/Drugs/licensing/zulassungsarten/pts/_node.html)

Members of the scientific commissions in Germany have included physicians, pharmacists, pharmacologists and toxicologists. The commissions carry out scientific evaluations of "efficacy, safety and pharmaceutical quality of medicinal products appertaining to the "particular therapeutic systems" and of traditional medicinal products".

Overview of substantiation evidence for Cold and Flu Drops

The substantiation for the Cold & Flu Drops indications are based on the product authorised in Germany and other countries, including Switzerland. There are **minor** variances in the formula of homoeopathic concentrations between countries, but the ingredients are the same and the homoeopathic variances do not have any impact on the efficacy of the product. The substantiation held for the product indications is consistent with the relevant therapeutic systems (anthroposophic/homoeopathic) and evidentiary requirements that underpin the product development.

Anthroposophic and homoeopathic substantiation includes the German Federal Institute approved and gazetted Commission C monographs (anthroposophic) and Commission D monographs (homoeopathic). Other reference sources include homoeopathic Material Medica[2] and anthroposophic and homoeopathic literature references. Approved monographs are officially published in the German Federal Gazette. These recognised monographs are similar to the better known Commission E monographs for herbal medicines.

There are two aspects to the evidence substantiation for this product:
(a) evidence for the product formulation; and
(b) evidence for the product ingredients.

(a) Product formulation**:**
The product, Infludo®**,** now named 'Cold & Flu Drops' in New Zealand, is a well-known formulation for colds and flu with well-established clinical use with the formula (including minor variants) registered in a number of countries. The Weleda German and French Infludo® has been referenced in Martindale, Part 3 Preparations[3], being the part of Martindale that contains brief details of official and proprietary preparations.

(b) Product ingredients:
The product contains homoeopathic ingredients and is used within the anthroposophic / homoeopathic modalities.

The homoeopathic preparations of Aconitum napellus, Bryonia, Eucalyptus, Eupatorium perfoliatum, Phosphorus and Sabadilla are well recognised ingredients in anthroposophic and homoeopathic medicine for various symptoms of cold and flu.

The evidence underpinning the use of the individual ingredients for the relief of the symptoms of cold and flu is justified by anthroposophic/homoeopathic substantiation.

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[2] Homeopathic Materia Medica are encyclopedia of therapeutic properties of each drug. These properties are ascertained through provings also known as Homeopathic pathogenetic trials. Further information can be located at https://en.wikipedia.org/wiki/Homeopathic_Materia_Medica; http://www.homeopathy.com.pk/boericke/

[3] Martindale: The Complete Drug Reference (38th Revised ed. Edition) is the world's most comprehensive and reliable guide to drugs and medicines. An overview of the publication can be found here: http://www.pharmpress.com/product/9780857111395/martindale38

Availability of original evidence to the Appeal Board and M. Honeychurch

It is Weleda's understanding that details of medicine dossiers and of the evidence and clinical sections for a registered medicine, typically held by the medicine regulator, are not expected to be provided to the Authority. This why we did not provide such evidence to the Complaint Board.

We have not provided any copies of dossiers or other highly commercially sensitive information with this response because the information provided in this response is sufficient. We are prepared to provide the Appeal Board with any commercially sensitive information if absolutely necessary on a restricted basis and on such terms as to be agreed with the Appeal Board.

We do not consent to providing a copy of any commercially sensitive evidence to M. Honeychurch, as requested in the appeal application, so that they may evaluate it with the intent to file further document(s) in support of the complaint. Any evidence M. Honeychurch has in their possession or control that supports their claim should have been filed when they made the initial complaint. If M. Honeychurch didn't and doesn't have any direct evidence that Weleda's Cold and Flu Drops *specifically* – not homeopathic products in general – is ineffective then not only is the complaint unfounded it is also, in our view, against the interests of natural justice that they should be now be afforded the opportunity to create evidence to suit their complaint.

PRECEDENT?

The Chairperson has acknowledged the "possible use of the decision as a precedent". With respect to the Chairperson and the Appeal Board, we do not believe it would be appropriate to use the Appeal Board's decision in this proceeding as a precedent except in so far we submit below.

Medsafe, as the government's medicine regulator, is the authority responsible for evaluating the evidence supporting classification of a purported medicine as a medicine, and, as may be required, the declassification of a medicine as a 'medicine'. As the sanctioned body, Medsafe holds the expertise, knowledge and skills to carry out this job.

What M. Honeychurch is asking the Authority to do by upholding the complaint is usurp Medsafe's authority and expressly or impliedly reject the classification of Weleda's Cold and Flu Drops as a 'medicine' and decide the product is ineffective. With respect to the Appeal Board, this is not, we think, the Authority's role. It is *Medsafe's* role to evaluate the efficacy of any medicine, including Weleda's Cold and Flu Drops (*Ref:* http://www.medsafe.govt.nz/consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp).

We submit that the Appeal Board's decision, if it upholds the decision of the Complaint Board, *could* act as a precedent to the extent it directs people with complaints about the efficacy of a medicine to lodge their complaints with Medsafe in the first instance. If, following a complaint, Medsafe declassifies a product as a medicine and reclassifies it as, for example, a natural therapy product, and an advertiser advertises that product in a manner which contravenes the Code, then we think a complaint to the Authority is appropriate.

CONCLUSION

In conclusion, we cannot see how advertising in a manner compliant with the Medicines Act AND with TAPS approval breaches the Code.

Please do not hesitate to contact me if you have any questions.

COMMENT FROM MEDSAFE

I refer to your letter of 1 November 2016 asking for Medsafe comment regarding an appeal against a decision made by the ASA Complaints Board in relation to an advertisement by Weleda New Zealand Limited on its website. You have provided a copy of the original decision by the Complaints Board, the response to this by the complainant (which was a request to appeal the decision) and a copy of the decision by the ASA to accept the appeal.
Thank you for the opportunity to comment on this.

Weleda New Zealand Limited markets a range of products which are regarded as medicines under the Medicines Act 1981. Most of these products have been 'grandfathered' from previous legislation, meaning that because they had been legally placed on the market as medicines under earlier legislation they could continue to be regarded as medicines under current legislation. This situation applies to the *Cold & Flu Drops* product which is the subject of the complaint.

Background information

The relevant legislation in force prior to the Medicines Act 1981 was the Food and Drug Act 1969. This Act came into effect in April 1970. Prior to this time the Food and Drugs Act 1947 dealt with medicines and, when first enacted, had no requirement for approval or consent before a medicine was sold or supplied. This Act was later amended by the Food and Drugs Amendment Act of 1962 which created the requirement for an approval / consent process. The Food and Drug Act 1969 further developed the requirement for approval / consent and required notification in the New Zealand Gazette before a medicine could be sold or supplied in New Zealand. The Medicines Act 1981 continued and expanded on this requirement. Both the Food and Drug Act 1969 and the current Medicines Act 1981 contain clauses effectively continuing the right to market for medicines already on the market when these Acts came into effect.

When the current legislation came into effect, companies were permitted to continue to make the claims about the indications for their products that they had made under previous legislation. In the early 1990s, when hard copy records were transferred to a database, Medsafe verified which medicines could continue to be sold or supplied based on approval and supply under previous legislation.

Weleda Cold & Flu Drops

The 'approval date' published on the Medsafe website in relation to this product (and most Weleda products) indicates approval at 31 December 1969. This means that these products were determined to have been legally on the market prior to the commencement of the Food and Drug Act 1969 and could continue to be marketed under the current legislation, with the same indications. Proof of efficacy is not held by Medsafe.

Medsafe can confirm that, under the Medicines Act 1981, Weleda is entitled to make the therapeutic claims about this product that are the subject of the complaint.

SUMMARY OF COMPLAINTS BOARD DECISION

The Weleda website advertisement promoted a Weleda homeopathic remedy, "Cold & Flu Drops," with the recommendation that they be taken at the onset of cold or flu to relieve

symptoms of fever, muscle ache, headache, sore throat, sneezing and runny nose.

The Complainant believed the therapeutic claims in the advertisement had not been substantiated. They complained that it was socially irresponsible to falsely claim to be able to treat symptoms of viral infections and to likely mislead unwary consumers who did not realise there was no good evidence for the efficacy of homeopathy.

The Complaints Board agreed that the therapeutic claims Weleda made in the website advertisement and on the packaging for its homeopathic Cold & Flu Drops accurately reflected what the Advertiser is able to claim in line with the product's Medsafe registration.

The Complaints Board ruled the complaint was Not Upheld.

SUMMARY OF CHAIRMAN'S RULING TO ACCEPT APPEAL APPLICATION

The appeal application was considered by the Chairperson of the Appeal Board. She noted the Complainant's view that the Complaints Board had misinterpreted evidence to the extent it had affected the decision regarding the Medsafe's registration process.

In determining whether the grounds had been established for an appeal, the Chairperson took into account the Complainant's view regarding the need for substantiation from the Advertiser for the claims in the advertisement, in addition to the Medsafe registration. The Chairperson said this raised an important issue and the possible use of the decision as a precedent. In light of this, the Chairperson considered it was a matter of natural justice the appeal be considered by the Appeal Board.

The Chairperson ruled the appeal was Accepted under ground (v) to be placed before the Appeal Board for determination.