



**FINAL DETERMINATIONS MADE IN ACCORDANCE WITH REGULATION
3A OF THE MEDICINES FOR HUMAN USE (MARKETING
AUTHORISATIONS ETC.) REGULATIONS 1994 AS AMENDED.**

VOLUME 4

(October 2010 – July 2014)

This document provides a list of Final Determinations issued by the Borderline Section on behalf of the Licensing Authority of the United Kingdom. Details of the product names, the names of the companies to whom the determination notices were issued and brief details of the reasons for the determination are provided.

A number of the determinations have been made after taking into account advice by the Independent Review Panel for Borderline Products and where applicable their advice is shown in the individual entry.

It should be noted that determinations are made on the basis of a product status at the time it was investigated. In some cases products will continue to be marketed in the UK having made appropriate modifications to ingredients and/or product presentation, to bring them into line with the Regulations, or because they were determined not be medicines.

A list of the determinations is given on the next page, ahead of individual entries for each product. Products are shown in the order that the determinations notices were issued.

All new entries to this document are shown in Red.

(Last amended/edited July 2014)

PRODUCT	COMPANY
1. Neem Psoriasis Skin Cream	Natures Natural Products
2. Manflu Soothing Hot or Shot Drink	Manflu Ltd
3. Covonia Cough Lozenges	Thornton & Ross Ltd
4. Bright Eyes Drops	Ethos Products Ltd
5. Bio Quinone Q10 Gold	Pharma Nord (UK) Ltd
6. Mole & Wart EZ Clear	The Mole & Wart Remover Company
7. Magnesium Oil Joint Spray	Better You Ltd
8. Phytaligic	Natural Health Products
9. FSC Milk Thistle	Bee Health Ltd
10. FSC Black Cohosh Root 600mg	“ “ “
11. FSC Prune & Senna	“ “ “
12. Viridian Black Cohosh Root	Viridian Nutrion
13. Jack3D	Cheap UK Supplements
14. Nitebalm	Phytoscience Ltd
15. Senna Tablets BP 7.5 MG	M & A Pharmachem
16. Black cohosh 500mg	Badham Pharmacy
17. St John's wort 100mg	“ “
18. Milk thistle Standardised Extract 100mg	“ “
19. Devil's Claw 450 mg capsules	Bee Health Ltd
20. Senna Extract Tablets	Natures Remedy Ltd
21. Senna 7.5MG Sennosides Tablets	Power Health Products Ltd
22. Flash Fighters	Holland and Barrett.
23. Ecz-Tend Soothing Cream	Gentle Green
24. St John's wort Vegetarian Caps	Viridian Nutrition
25. Jointment Balm	“ “
26. Viridian Milk Thistle	“ “
27. FCS Saw Palmetto	Bee Health Ltd
28. Hypericim St John's Wort Drops	Bioforce (UK) Ltd
29. Valeriana Valerian Drops	“ “ “
30. Black Cohosh Support	The Natural Health Practice Ltd
31. HealthAid Diaglucoforte	Health Aid
32. Nature's Best Prostex Saw Palmetto caps	Lamberts Healthcare Ltd
33. Agnus Castus Chaste Tree Drops	A Vogel (Bioforce UK Ltd)
34. St John's wort 500mg	Power Health Products Ltd
35. St John's wort Hyperpower HPX 4000	“ “ “
36. Echinacea 300 Standardised 4% Extract	“ “ “

1	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Neem Psoriasis Skin Cream</p> <p>Natures Natural Products</p> <p>N/A</p> <p>The product was medicinal because it was presented by both brand name and description as a product for the treatment of psoriasis. Additionally the website on which it was promoted extended the claims to treatment of eczema and chronic skin conditions. Claims also included "cools the skin relieving inflamed areas caused by certain skin conditions". As inflammation is related to adverse symptoms and conditions this claim was also medicinal.</p>
2	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Manflu Soothing Hot or Shot Drink</p> <p>Manflu Ltd</p> <p>The product is a medicine by presentation.</p> <p>Man Flu is a popular and well recognised colloquial term used to refer to a man with a cold who is exaggerating his symptoms. The product was promoted with graphics showing a man in bed with what would be associated with a first aid symbol. Additionally the product contained Echinacea, Vitamin C and Zinc, all which are commonly associated with the relief and prevention of colds and flu symptoms.</p>
3	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Covonia Cough Lozenges.</p> <p>Thornton & Ross Ltd</p> <p>The product is a medicine by presentation.</p> <p>The product was marketed with an implied medicinal claim in its brand name, and in common with the successful promotional material used to sell the company's licensed products with similar brand names. In addition the product was promoted with claims such as "...to help people tackle their cough and cold symptoms while on the move"; "rapidly relieve uncomfortable symptoms of the common cold"; "soothes the throat" and "...hassle free alternative to carrying around a medicine bottle". In consequence the averagely well informed consumer would have made an association between use of the product and the treatment of the symptoms of adverse medical conditions.</p>

4	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Bright Eyes Drops</p> <p>Ethos Products Ltd</p> <p>N/A</p> <p>The product was presented with claims as a treatment for cataracts and AMD. These were made on various websites, in major daily newspaper articles and via the use of published testimonials. Additionally the product contained N-Acetyl-Carnosine (NAC), which is regarded as a medicinal substance when used topically in eye products.</p>
5	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>BIO-QUINONE Q10 GOLD</p> <p>Pharma Nord (UK) Ltd</p> <p>N/A</p> <p>The product was presented with claims as a treatment for pain, particularly in patients taking statins. The claims were enhanced by use of an endorsement of a well known "TV" doctor, implying approval by the medical profession.</p>
6	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Mole & Wort EZ Clear</p> <p>The Wart & Mole Remover Company</p> <p>N/A</p> <p>The product is presented as a treatment for warts which are caused by the HPV virus. Because the HPV virus is an adverse medical condition the product for treatment should be licensed for sale in the UK. The product contains the herbs Ancardium Occidentale and Chellidonium Majus both of which have a long history of traditional use in herbal medicine and therefore should be licensed in the UK. Chellidonium is also restricted by The Medicines (Retail Supply of Herbal Remedies) Order 1977 (SI 1977/2130)</p>

7	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Magnesium Oil Joint Spray</p> <p>Better You Ltd</p> <p>N/A</p> <p>The product was presented with claims to treat muscle and joint pain. These were made on the company's website and in an edition of "Your Healthy Living" magazine.</p>
8	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Phytalgic</p> <p>Natural Health Products</p> <p>N/A</p> <p>The product was presented with claims to treat unspecified joint pains and osteoarthritis of the knees. These were made partly through the choice of brand name, the graphics on the product packaging showing a man and woman in clear states of discomfort, on the company's website and in various forms of advertising including a press release, articles in Your Healthy Living and Natural Product News. They were additionally repeated through the use of published testimonials.</p>
9	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>FSC Milk Thistle</p> <p>Bee Health Ltd</p> <p>N/A</p> <p>The product fell within the second limb of the definition of a medicinal product. The herb Milk thistle has long history of use in medicine and its pharmacological effects are well documented. It has no valid or wide ranging use in food or food supplements and products containing this herb require authorisation before being placed on the UK market.</p>

<p>10</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>FSC Black Cohosh Root 600mg</p> <p>Bee Health Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the herb Black cohosh in medicine, and the extensive published information on the herbs uses. Arguments for use of products containing this herb for another purpose would not be tenable. The second limb was satisfied due to the well known and documented pharmacological properties of the herb which has been used to treat a variety of adverse medical conditions such as menopausal complaints. It has also been used for its analgesic properties. A number of serious adverse effects have been connected with use of the herb and products should display suitable warnings to consumers. Products containing this herb require authorisation before being placed on the UK market.</p> <p>The MHRA takes the view that the erroneous labelling of a herbal medicinal product as a food or dietary supplement is unacceptable and may mislead consumers. Such mislabelling does not alter the correct legal classification.</p>
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<p>11</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>FSC Prune & Senna</p> <p>Bee Health Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the individual and combined uses of Prunes (in capsule/tablet form) and Senna in medicine, and the extensive published information on their uses. Arguments for use of products containing this combination for another purpose would not be tenable. The second limb was satisfied due to the well known and documented pharmacological properties of the fruit and herb which have been used most commonly as laxatives and for the treatment of constipation. Continuous use without medical supervision could lead to bowel damage and dependence. Products containing this herb require authorisation before being placed on the UK market.</p> <p>The MHRA takes the view that the erroneous labelling of a herbal medicinal product as a food or dietary supplement is unacceptable and may mislead consumers. Such mislabelling does not alter the correct legal classification.</p>
<p>12</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Viridian Black Cohosh Root (30 and 90 capsules)</p> <p>Viridian Nutrition</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the herb in medicine, and the extensive published information on its uses. The second limb was satisfied due to the well known and documented pharmacological properties of the herb which has been used most commonly as a treatment for rheumatism and adverse menopausal symptoms. Products containing this herb require authorisation before being placed on the UK market.</p> <p>The MHRA takes the view that the erroneous labelling of a herbal medicinal product as a food or dietary supplement is unacceptable and may mislead consumers. Such mislabelling does not alter the correct legal classification.</p>

<p>13</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Jack3D</p> <p>Cheap UK Supplements</p> <p>The product is a medicine</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied because the presentation of the product drew links to substances that are themselves presented as having properties for treating or preventing disease in human beings.</p> <p>The second limb was satisfied due to the inclusion of DMAA (<i>also known as Methylhexanamine, methylhexanamine, dimethylamylamine, 4-methyl-2-hexanamine, 4-methyl-2-hexylamine, 2-amino-4-methylhexane, 1,3-dimethylamylamine, 1,3-dimethylpentylamine, Geranmin, Geranium oil and Cranesbill</i>), which has been associated with significant effects on human physiology resulting in regulatory action being taken to remove it from sale in a number of countries around the world. Additionally the product contained Schizandrol A, which is an extract of the Schisandra chinensis herb. The herb has well known and documented uses in herbal medicine and has the potential to exert significant effects on human physiology.</p>
<p>14</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Nitebalm</p> <p>Phytoscience Ltd</p> <p>The product is a medicine</p> <p>The product fell within the first limb of the definition of a medicinal product. It was presented with implied claims to induce sleep, including a claim to be an alternative to prescribed medicines and publication of testimonials relating to treatment of sleep disturbance.</p>

<p>15</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Senna Tablets BP 7.5 MG</p> <p>M & A Pharmachem</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The herb Senna has well established and documented use in medicine, in particular for its laxative effects. It is available in a number of authorised medicinal products and is recognised for its medicinal uses by both the scientific community and by consumers.</p>
<p>16</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Black Cohosh 500mg</p> <p>Badham Pharmacy</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the herb Black cohosh in medicine, and the extensive published information on the herb's uses. Arguments for use of products containing this herb for another purpose would not be tenable. The second limb was satisfied due to the well known and documented pharmacological properties of the herb which has been used to treat a variety of adverse medical conditions such as menopausal complaints. It has also been used for its analgesic properties. A number of serious adverse effects have been connected with use of the herb and products should display suitable warnings to consumers. Products containing this herb require authorisation before being placed on the UK market.</p> <p>The MHRA takes the view that the erroneous labelling of a herbal medicinal product as a food or dietary supplement is unacceptable and may mislead consumers. Such mislabelling does not alter the correct legal classification.</p>

17	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>St John's Wort 100mg</p> <p>Badham Pharmacy</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the herb St John's wort in medicine, and the extensive published information on the herb's uses. Arguments for use of products containing this herb for another purpose would not be tenable. The second limb was satisfied due to the well known and documented pharmacological properties of the herb which has been used to treat a variety of adverse medical conditions such as depression. Products containing this herb require authorisation before being placed on the UK market.</p> <p>The MHRA takes the view that the erroneous labelling of a herbal medicinal product as a food or dietary supplement is unacceptable and may mislead consumers. Such mislabelling does not alter the correct legal classification.</p>
18	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Milk Thistle Standardised Extract 100mg</p> <p>Badham Pharmacy</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the herb Milk thistle in medicine, and the extensive published information on the herb's uses. Arguments for use of products containing this herb for another purpose would not be tenable. The second limb was satisfied due to the well known and documented pharmacological properties of the herb which has been used to treat a variety of adverse medical conditions, in particular hepatic complaints. Products containing this herb require authorisation before being placed on the UK market.</p> <p>The MHRA takes the view that the erroneous labelling of a herbal medicinal product as a food or dietary supplement is unacceptable and may mislead consumers. Such mislabelling does not alter the correct legal classification.</p>

<p>19</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Devil's Claw 450 mg capsules</p> <p>Bee Health Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the herb Devil's claw in medicine, and the extensive published information on the herb's uses. Arguments for use of products containing this herb for another purpose would not be tenable. The second limb was satisfied due to the well known and documented pharmacological properties of the herb which has been used for its analgesic properties. Products containing this herb require authorisation before being placed on the UK market.</p> <p>The MHRA takes the view that the erroneous labelling of a herbal medicinal product as a food or dietary supplement is unacceptable and may mislead consumers. Such mislabelling does not alter the correct legal classification.</p>
<p>20</p>	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Senna Extract Tablets</p> <p>Natures Remedy Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to the familiarity of the averagely well informed consumer with the current day and long traditional uses of the herb Senna in medicine, and the extensive published information on the herb's uses. Arguments for use of products containing this herb for another purpose would not be tenable. The second limb was satisfied due to the well known and documented pharmacological properties of the herb which has been used most commonly for its laxative effects. Products containing this herb require authorisation before being placed on the UK market.</p>

21	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Senna 7.5MG Sennosides Tablets</p> <p>Power Health Products Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product because it was presented on the company website as a laxative and because the product contains an extract of Senna, which is a well known herbal medicinal substance with well established medicinal use, and which contains active constituents with the capacity to modify physiological function.</p>
22	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Flash Fighters</p> <p>Holland & Barrett</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product because it was presented with a brand name that implied it could be used to treat Hot Flashes (also known as hot flushes and night sweats) and because the product contains the herbs Black cohosh and Agnus castus, both of which have well known, established and traditional uses in the treatment of adverse menopausal symptoms.</p>
23	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Ecz-Tend Soothing Cream</p> <p>Gentle Green</p> <p>N/A</p> <p>The product satisfied the first limb of the definition of a medicinal product due to its brand name and the content of the company's website, which was mainly dedicated to the treatment of adverse skin conditions, in particular eczema.</p>

24	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>St John's Wort Vegetarian Capsules</p> <p>Viridian Nutrition</p> <p>N/A</p> <p>The product satisfied the first limb of the definition of a medicinal product due to the well known and established uses of St John's wort in herbal medicine and the averagely well informed consumer's familiarity with it.</p> <p>The product also satisfied the second limb of the definition due to the well documented evidence relating to the use of St John's wort in herbal medicine for the treatment of a variety of adverse medical conditions.</p>
25	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Jointment Balm</p> <p>Viridian Nutrition</p> <p>N/A</p> <p>The product satisfied the first limb of the definition of a medicinal product due to a combination of its brand name, together with the well known and established uses of a number of its active ingredients in herbal medicine and the averagely well informed consumer's familiarity with them.</p> <p>The product also satisfied the second limb of the definition due to the inclusion of extracts of Comfrey root, St John's wort, Rosemary, Eucalyptus and Chili pepper in its formulation, all of which have well documented evidence of use in herbal medicine for the treatment of a variety of adverse medical conditions.</p>

26	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Viridian Milk Thistle</p> <p>Viridian Nutrition</p> <p>The product is a medicine under the second limb of the definition.</p> <p>The product satisfied the second limb of the definition due to the well documented evidence relating to the use of Milk thistle in herbal medicine for the treatment of a variety of adverse medical conditions. On the basis of current scientific data, the dosage of active herb used in the product was considered to be capable of restoring, correcting or modifying physiological function in humans.</p>
27	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>FSC Saw palmetto 320mg</p> <p>Bee Health Ltd</p> <p>N/A</p> <p>The product fell within the second limb of the definition of a medicinal product. Currently available and published scientific data has demonstrated the herb's ability to modify physiology through pharmacological means. The herb is well known for its medicinal use in the treatment of benign prostatic hyperplasia, for which is it most commonly administered and recommended by health advisers.</p>
28	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Hypericim St John's Wort Drops</p> <p>Bioforce (UK) Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied by the presentation of a product containing a commonly used herbal remedy which is well known for its medicinal uses. The second limb of the definition was satisfied due to currently available and published scientific data has demonstrated the herb's ability to modify physiology through pharmacological means. The herb is well known for its medicinal uses especially in the treatment of conditions such as mild depression.</p>

29	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Valeriana Valerian Drops</p> <p>Bioforce (UK) Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied by the presentation of a product containing a commonly used herbal remedy which is well known for its medicinal uses. The second limb of the definition was satisfied due to currently available and published scientific data has demonstrated the herb's ability to modify physiology through pharmacological means. The herb is well known for its medicinal uses especially as a sedative and treatment for disorders such as sleep disorders, anxiety and stress.</p>
30	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Black Cohosh Support</p> <p>The Natural Health Practice Ltd</p> <p>The product was a medicine under both limbs of the definition.</p> <p>The product fell within the first limb of the definition due to the implied medicinal claims made for its use. These provided strong evidence that the product was not a food supplement intended for the whole community in order to supplement a healthy diet. It was instead targeted at a specific consumer group by age and gender, seeking treatment and management of adverse effects of the menopause.</p> <p>The product fell within the second limb of the definition of a medicinal product due to the inclusion in its formulation of Black cohosh. Currently available and published scientific data has demonstrated this herb's ability to modify physiology through pharmacological means. The herb is well known for its use in the treatment of a variety of medical conditions including adverse symptoms of the menopause and rheumatism. Additionally its known association with adverse liver symptoms further supported its pharmacological effects.</p>

31	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>HealthAid Diaglucoforte – 60 Tablets</p> <p>Health Aid</p> <p>The product was a medicine under both limbs of the definition.</p> <p>The product fell within the first limb of the definition due to its brand name and the claims made for its use. These factors provided strong evidence that the product was not a food supplement intended for general supplementation of a healthy diet. It was instead targeted at a specific consumer group seeking treatment and management of diabetes. The presentation included claims to balance and modify blood sugar levels and help prevent diabetic attacks.</p> <p>The product fell within the second limb of the definition of a medicinal product due to the inclusion in its formulation of Karela fruit (Bitter melon) extract, Fenugreek powder extract and Gymnema silvestre extract. Currently available and published scientific data has demonstrated these herbs' ability to modify physiology through pharmacological means. The herbs are well known for their use in the treatment of a variety of medical conditions including diabetes.</p>
32	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>Nature's Best Prostex Saw Palmetto capsules 160mg</p> <p>Lambert's Healthcare Ltd</p> <p>The product was a medicine under both limbs of the definition.</p> <p>The product fell within the first limb of the definition due to its brand name and the public familiarity with the use of saw palmetto. These factors provided a strong implication that the product was not a food supplement intended for general supplementation of a healthy diet. It was instead targeted at a specific consumer group seeking to treat adverse conditions of the prostate gland.</p> <p>The product fell within the second limb of the definition of a medicinal product. Currently available and published scientific data has demonstrated the herb's ability to modify physiology through pharmacological means. The herb is well known for its medicinal use in the treatment of benign prostatic hyperplasia, for which is it most commonly administered and recommended by health advisers.</p>

33	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>A Vogel Agnus Castus Chaste Tree Drops</p> <p>A Vogel (Bioforce (UK) Ltd)</p> <p>N/A</p> <p>The product fell within the second limb of the definition due to the herb's ability to modify physiology through pharmacological means. This is supported by currently available and published scientific data. The herb is well known for its medicinal uses especially in the treatment of symptoms of premenstrual syndrome.</p>
34	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>St John's Wort 500 mg</p> <p>Power Health Products Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to wide public familiarity of the herb and its associated uses in medicine and lack of uses in food. The second limb of the definition of a medicinal product was satisfied due to extensively available and published scientific data which has demonstrated this herb's ability to modify physiology through pharmacological means. The herb is well known for its use as an anti-depressant medicine.</p>
35	<p>Product Name:-</p> <p>Company to whom notice was issued:-</p> <p>Panel Advice</p> <p>Licensing Authority's Determination and reasons</p>	<p>St John's Wort Hyperpower HPX 4000</p> <p>Power Health Products Ltd</p> <p>N/A</p> <p>The product fell within both limbs of the definition of a medicinal product. The first limb was satisfied due to wide public familiarity of the herb and its associated uses in medicine and lack of uses in food. The second limb of the definition of a medicinal product was satisfied due to extensively available and published scientific data which has demonstrated this herb's ability to modify physiology through pharmacological means. The herb is well known for its use as an anti-depressant medicine.</p>

36	Product Name:- Company to whom notice was issued:- Panel Advice Licensing Authority's Determination and reasons	Echinacea 300 Standardised 4% Extract Power Health Products Ltd N/A The product fell within the second limb of the definition of a medicinal product due to the inclusion in its formulation of Echinacea (extract). Currently available and published scientific data has demonstrated this herb's ability to modify physiology through pharmacological means. The herb is well known for its use in the treatment of a variety of medical conditions.
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