

Reference number	Product name	Dosage Form	Active ingredient/s	Product Indications or Claims	Reason/Remarks	Date of decision letter
CC003/11a	Easylax Glycerol Suppositories (Adults)	Suppositories	Glycerol	Loosens and lubricates the stools, facilitating their evacuation	Easylax products have a metabolic action, causing an alteration in the speed of a normal chemical process participating in, and available for, normal body function, in this case, bowel evacuation.	11-Oct-11
CC003/11b	Easylax Glycerol Suppositories (Children)	Suppositories	Glycerol	Loosens and lubricates the stools, facilitating their evacuation	Easylax products have a metabolic action, causing an alteration in the speed of a normal chemical process participating in, and available for, normal body function, in this case, bowel evacuation.	11-Oct-11
CC003/11c	Easylax Chamomile and Mallow Glycerol Micro-enema 9g (Adults)	Micro-enema	Glycerol, wheat starch, liquid mallow extract, liquid chamomile extract, purified water	Loosens and lubricates the stools, facilitating their evacuation through a softening action	Easylax products have a metabolic action, causing an alteration in the speed of a normal chemical process participating in, and available for, normal body function, in this case, bowel evacuation.	11-Oct-11
CC003/11d	Easylax Chamomile and Mallow Glycerol Micro-enema 3g (Children)	Micro-enema	Glycerol, wheat starch, liquid mallow extract, liquid chamomile extract, purified water	Loosens and lubricates the stools, facilitating their evacuation through a softening action	Easylax products have a metabolic action, that is, they cause an alteration in the speed of a normal chemical process participating in, and available for, normal body function, in this case, bowel evacuation.	11-Oct-11

Reference number	Product name	Dosage Form	Active ingredient/s	Product Indications or Claims	Reason/Remarks	Date of decision letter
CC003/11e	Easylax Sodium Acid Phosphate Enema	Enema	Sodium acid phosphate	Loosens the stools and facilitates their evacuation	Easylax products have a metabolic action, that is, they cause an alteration in the speed of a normal chemical process participating in, and available for, normal body function, in this case, bowel evacuation.	11-Oct-11
CC005/11	Total Parenteral Nutrition (TPN)	Intravenous (IV)	Various	Intravenous feeding that provides a patient with all of the fluid and the essential nutrients they need when they are unable to feed themselves by mouth.	TPN products with a special manufacturing licence (manufactured under special licences for hospitals, for example) are 'Specials' and as a consequence do not have (or need) a Marketing Authorisation.	25-May-11
CC010/11	Helium Oxygen 25:75	Gas	Helium and Oxygen	To assist the flow of oxygen into the alveoli and to reduce the work of breathing in patients with severe airway obstruction (upper or lower). Rapidly reduces the respiratory effort associated with airway obstruction and therefore can reduce the work of breathing, which will improve patient comfort.	This product is being used to treat a medical indication; its uses are medicinal	26-Sep-11
CC012/11	Dr. Numb	Cream	Lidocaine and Prilocaine	Numbing of pain - Needle Pain, Tattooing, Body Piercing, Waxing etc	The product contains prilocaine and lidocaine, which are local anaesthetics	20-Jul-11

Reference number	Product name	Dosage Form	Active ingredient/s	Product Indications or Claims	Reason/Remarks	Date of decision letter
CC015/11a	Savoy Burn Relief Spray	Spray	Benzocaine, Chlorhexidine (as diacetate) and Denatured Ethanol, Isopropyl Myristate, Butane.	Savoy Burn Relief Spray is formulated to bring fast relief from minor burns and scalds. It cools the area and relieves the pain and hence reduces swelling. It also contains a powerful antiseptic.	Presence of the anaesthetic benzocaine	27-Dec-11
CC015/11b	Savoy Antiseptic First Aid Spray	Spray	Resin, Benzocaine, Chlorhexidine (as diacetate). Denatured, Ethanol, Isopropyl Myristate, Butane.	Savoy First Aid Spray provides an antiseptic protective covering for cuts, scratches, abrasions, minor burns and scalds.	Presence of the anaesthetic benzocaine	27-Dec-11
CC027/11	Laennec	Ampoules	Water soluble substance of a product of enzymatic human placenta (This product is human placental extract, and contains various biological active substances. However, the active ingredients cannot be specified as a single substance or several sorts of substances	Unique immunomodulator and hepatoprotector. Improves hepatic function in chronic hepatic diseases, for example in all types of hepatitis, cirrhosis, cholangitis. In dermatology - psoriasis, atopic dermatitis (as moderate, as severe degree), chronic herpes, acne, hyperpigmentation diseases, hair loss. in cosmetology - reducing of skin elasticity, pH normalisation, lipid balance normalisation, wrinkles smoothing and normalisation	The product is claiming to treat various medical indications: "Improves hepatic function in chronic hepatic diseases, for example in all types of hepatitis, cirrhosis, cholangitis. In dermatology - psoriasis, atopic dermatitis (as moderate, as severe degree), chronic herpes, acne, hyperpigmentation diseases."	24-Oct-11

Reference number	Product name	Dosage Form	Active ingredient/s	Product Indications or Claims	Reason/Remarks	Date of decision letter
CC028/11b	Weleda Massage Balm with Arnica	Cutaneous oil	Dried flowers of Arnica montana, dried leaves of Betula pendula, Lavender, Lavandin oil, Rosemary oil, Sunflower seed oil	Relieves the symptoms of rheumatic pain, muscular pain and stiffness, backache, fibrositis, bruising, cramps and sprains	Amount of Arnica montana - 3.23% w/w. The product has medicinal properties as well as medicinal claims	12-Oct-11
CC003/12	Annique Rooibos Pamperlang - Resque Mist	External Application	Denat, Alcohol, Aspalathus Linearis, Menthol, Camphor Eucalyptus, Globulus Oil, Methyl Salicylate, Mentha Piperita Oil, Polysorbate-20, Parfum, Citric Acid, Rooibos	A little miracle-worker for neck and muscle pain, headaches, sinus and hay fever. It is also a great mood-lifter during stressful moments when you need to be calm. Brings instant relief from insect bites and skin irritation or rashes. Improves circulation, reduces the symptoms of cold, flu, sinusitis and bronchitis	The text on the outer packaging of the product contains medicinal claims because it is being stated that Annique Rooibos Pamperlang can be used to improve certain diseases, including, headache, hayfever, cold, flu, sinusitis and bronchitis. In addition, it is being stated that the product is a mood lifter. The product contains camphor and methyl salicylate.	28-Mar-12

Reference number	Product name	Dosage Form	Active ingredient/s	Product Indications or Claims	Reason/Remarks	Date of decision letter
CC012/12	Slendaliss	Patches	Acrylates Copolymer, Glycerin, Polysorbate 20, Propylene glycol, cyclodextrin, Fucus Vesiculosus Extract, Hedera Helix Extract, Aesculus hippocastanum Extract, Camellia Sinensis Extract, Carnitine Caffene phenoxyethanol, methyl paraben, ethyl paraben, propyl paraben, Cinnamomum Cassia Oil, Eugenia caryophyllus oil, Zingiber Officinale Oil, Alcohol Amylclinnamyl, Cinnamal, eugenol, isoeugenol	<p>For transdermal Slendaliss high-tech is used with the active ingredients are released gradually and directly through the deepest layers of skin in the areas where they are needed. According to the manufacturer, you can achieve a weight loss of 1.5 kg to 2 per week with a balanced diet. Since Slendaliss is not taken, the drug neither liver, stomach or intestines and are therefore through better absorbed by the body, providing maximum efficiency is achieved. The Slendaliss agents form a safe, healthy and fat-reducing appetite and so can reduce the feeling of hunger.</p> <p>Slendaliss patch:</p> <ul style="list-style-type: none"> • are easy to handle and reliable in its effect • are transparent and nearly invisible • give the drugs specifically used to gradually • can reduce cellulite and localized fat deposits 	<p>It is being claimed that the use of Slendaliss patches results in weight loss and elimination of cellulite but also that it causes appetite suppression, with a direct pharmacological effect on the brain</p>	06-Jun-12