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## **How to determine whether your medical device is within scope of PAGB membership**

For a medical device product to be within scope of membership it must be;

- CE / UKCA marked under the relevant medical device legislation with the manufacturer holding registration or CE / UKCA certification as relevant and having issued a valid declaration of conformity.
- For self-care use and marketed in an existing OTC therapeutic category within the PAGB OTC directory.

Medical devices which are for diagnostic use (including diagnostic software applications) are currently out of scope.

The table below outlines the existing OTC therapeutic categories within PAGB membership and provides examples of medical device products within scope. Please note the list is not exhaustive and will be updated regulatory following review decisions for new products.

If your device is not covered in the table below but is for an OTC therapeutic condition, please submit your product for consideration to [membership@pagb.co.uk](mailto:membership@pagb.co.uk).



<b>Consumer category and description</b>	<b>Examples of medical device types in scope</b>
<p><b>Analgesics</b></p> <p>Products which provide pain relief such as for relief of back pain, muscular pain, headaches including migraine, dysmenorrhea, dental pain, and teething pain</p>	<ul style="list-style-type: none"><li>• Pain relief patches and plasters</li><li>• Cooling or warming gels, creams, ointments, and sprays</li><li>• Heat wraps for muscular pain, strains, and arthritis</li><li>• Electronic pain relief devices such as ultrasonic, muscle and neuromuscular stimulators or circulation boosters</li></ul>
<p><b>Antacids and Gastrointestinal</b></p> <p>Products which relieve the symptoms of gastrointestinal conditions such as, indigestion, bloating, flatulence, diarrhoea, constipation, worms, dyspepsia, acid reflux, colic, gripping pain, and irritable bowel syndrome</p>	<ul style="list-style-type: none"><li>• Simethicone only products</li><li>• Oral intestinal adsorbents which act in the digestive track to bind toxins, harmful substances, pathogens, and allergens and remove them from the body</li><li>• Products which balance intestinal flora to regulate bowel function and/or treat the symptoms of IBS</li><li>• Enema to relieve constipation</li></ul>
<p><b>Cough, Colds and Sore Throat</b></p> <p>Products for the treatment of cough, colds, flu, nasal congestion, and sore throats.</p>	<ul style="list-style-type: none"><li>• Preventative sprays and washes “cold and flu” defence products</li><li>• Products providing soothing relief for sore throats such as barrier and coating products</li><li>• Physical nasal aspirators e.g. aspirator tubes</li><li>• Nasal strips for nasal congestion</li><li>• Bath oils and ointments for nasal congestion</li></ul>
<p><b>Ear Care</b></p> <p>Products for the removal of wax, treatment of earache and prevention of ear infections.</p>	<ul style="list-style-type: none"><li>• Ear wax removal or softening products</li><li>• Drops to protect the ear from trapped water and to prevent ear infections</li></ul>



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<p><b>Eye Care</b></p> <p>Products to treat dry, red, or irritated eyes and minor eye infections such as conjunctivitis, blepharitis, and sties.</p>	<ul style="list-style-type: none"><li>• Eye drops, washes, mists, gels and sprays for lubricating, tear replacement or irritated eyes</li><li>• Eye patches for the prevention of infection</li></ul>
<p><b>Female Health and Genitourinary</b></p> <p>Products for emergency contraception.</p> <p>Products for the treatment of water retention including pre-menstrual water retention, vaginal infections, cystitis, vaginal dryness.</p>	<ul style="list-style-type: none"><li>• Vaginal moisturisers, lubricants and hydrating gels, creams, or ointments</li><li>• Vaginal products for the treatment and prevention of bacterial vaginosis (BV)</li><li>• Cleaning wipes for the prevention of infection and relief of irritation</li><li>• Contraceptive devices</li><li>• Spermicidal gels</li><li>• Vaginal trainers or dilators for the treatment of Vaginismus</li></ul>
<p><b>Foot Care</b></p> <p>Products for the treatment of athlete's foot, fungal nail infections, corns, calluses, warts, and verrucae.</p>	<ul style="list-style-type: none"><li>• Liquid, gel and film wart and verruca treatments containing a substance for intended action e.g. containing salicylic acid or occlusive adhesive dressings and plasters for the treatment of corns and verrucae</li><li>• Liquid fungal nail (including fingernails) treatments</li><li>• Hard skin and callus removers</li><li>• Cracked skin treatment associated with diabetic foot complications</li><li>• Pen which delivers cream to treat Athlete's Foot</li><li>• Foam cushioning products for corns, blisters, and bruises</li><li>• Insoles and gel cushions for heel pain relief</li><li>• Products for ingrown toenails</li><li>• Socks for the therapeutic relief of mild leg pain</li></ul>



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<p><b>Haemorrhoids and Circulatory</b></p> <p>Products for pain relief and treatment of haemorrhoids, pruritus' ani, proctitis and fissures. Also includes products for use post-operative ano-rectal surgery.</p> <p>Products for the treatment of cramp, bruising and haematoma.</p>	<ul style="list-style-type: none"><li>• Wipes or creams for the relief of itching and irritation or cleansing of haemorrhoids and haemorrhoid prone areas.</li><li>• Socks for the treatment and prevention of varicose veins.</li></ul>
<p><b>Hair and Scalp</b></p> <p>Products for the treatment of scalp disorders such as: fungal dandruff, seborrheic dermatitis, eczema, scaly scalp, and psoriasis.</p> <p>Head lice and head lice infections, pubic lice, and scabies.</p> <p>Alopecia and male pattern baldness.</p>	<ul style="list-style-type: none"><li>• Shampoos, sprays, and lotions which kill, eliminate, or repel head lice (e.g. those containing mineral oil).</li><li>• Nit combs</li><li>• Shampoos, sprays, oils or lotions for the treatment or prevention of scalp disorders.</li></ul>
<p><b>Hay fever and other allergies</b></p> <p>Products for the treatment of hay fever and allergies.</p>	<ul style="list-style-type: none"><li>• Allergen barrier sprays</li><li>• Sea water solutions</li></ul>



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<p><b>Heart Health</b></p> <p>Products for the prevention of thrombotic cerebrovascular or cardiovascular disease.</p>	
<p><b>Infants and Babies</b></p> <p>Products which relieve the symptoms of colic.</p>	<ul style="list-style-type: none"> <li>• Simethicone only products</li> <li>• Products for the relief of gas associated with colic</li> </ul>
<p><b>Male Health</b></p> <p>Products for the treatment of conditions such as erectile dysfunction.</p> <p>Products for contraception.</p> <p>Products for the treatment of functional symptoms of benign prostatic hyperplasia.</p>	<ul style="list-style-type: none"> <li>• Topical gel treatments for erectile dysfunction</li> <li>• Vacuum constriction devices</li> <li>• Condoms</li> </ul>
<p><b>Mouth Care</b></p> <p>Products for the treatment of conditions such as oral thrush, pain caused by mouth lesions such as mouth ulcers, aphthous stomatitis and other minor oral lesion.</p> <p>Treatment and prevention of gingivitis.</p>	<ul style="list-style-type: none"> <li>• Solutions and sprays which relieve the pain of dental lesions</li> <li>• Solutions and sprays which promote the healing of dental lesions</li> <li>• Gels that prevent and relieve mouth sores and ulcers caused by dental braces</li> <li>• Toothpastes, including those for sensitive teeth</li> <li>• Products which resist dental decay and dental caries</li> <li>• Mouth washes (other than antiseptic)</li> <li>• Devices for dry mouth conditions</li> <li>• Dental enamel strengtheners</li> <li>• Products for the removal of tonsilloliths / tonsil stones</li> </ul>



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<p><b>Skin Care and Antiseptics</b></p> <p>Treatment of skin conditions such as dermatitis, contact dermatitis, eczema, xeroderma, ichthyosis, nappy rash, insect bites, stings, allergic rashes, acne, sunburn, and rosacea.</p> <p>Viral infections such as cold sores and molluscum contagiosum.</p> <p>Products also include those for the relief of, itching as a result of the conditions above or chicken pox and localised pain.</p> <p>Products for the treatment of wounds (including antiseptics), the promotion of wound healing and burns.</p>	<ul style="list-style-type: none"> <li>• Creams, lotions, ointments for treatment of eczema and dermatitis (including contact dermatitis) and psoriasis</li> <li>• Cooling topical products which relieve reddened and irritated skin</li> <li>• Barrier ointments and creams to prevent nappy rash</li> <li>• Bath oils and treatments for dry skin conditions such as dermatitis and eczema</li> <li>• Devices for symptomatic relief of reddened, itchy, dry chapped/damaged skin</li> <li>• Barrier creams, lotions and ointments for the treatment or prevention of cold sores and molluscum contagiosum</li> <li>• Cream, lotions, ointments, spray, films, or hydrocolloid dressings for the promotion of wound healing and scar reduction or prevention e.g. treatment of keloid scars</li> <li>• General fabric and wash proof plasters</li> <li>• Bandages</li> <li>• Antiseptic wipes</li> <li>• Surgical spirit</li> <li>• Cohesive bandages</li> <li>• Slings and support bandages</li> <li>• Blister treatments</li> </ul>
<p><b>Sleep and Travel</b></p> <p>Products for travel sickness and prevention of malaria.</p> <p>Products for the treatment of temporary sleep disturbances, stress, and mild anxiety.</p>	<ul style="list-style-type: none"> <li>• Insect repellents</li> <li>• Products to prevent snoring such as, nasal strips or throat sprays</li> <li>• Nasal aspirators that help to ease children blocked and stuffy nose</li> </ul>



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<p><b>Smoking cessation</b></p> <p>Products which support the withdrawal symptoms of smoking cessation.</p>	<ul style="list-style-type: none"><li>• NRT patches or inhalers to support smoking cessation</li></ul>
<p><b>Tonics and Stimulants</b></p>	
<p><b>Vitamins, Minerals and Nutritional</b></p>	
<p><b>Weight Management</b></p> <p>Products for the treatment of excess weight.</p>	<ul style="list-style-type: none"><li>• Devices for the treatment and management of excess weight (e.g. tablets, powder sachets, drinks including tea)</li></ul>