

BSACI position statement on prescribing unlicensed medicines

The British Society for Allergy & Clinical Immunology (BSACI) is the national, professional, and academic society which represents the specialty of allergy at all levels. Its aim is to improve the management of allergies and related diseases of the immune system in the United Kingdom, through education, training, and research.

Our Values: Trusted, Connected, Forward Thinking.

There are times when allergists / immunologists may need to decide whether to treat a patient with unlicensed medication. This is particularly the case with specific immunotherapy. This document offers guidance on when an unlicensed medication may be used and considerations which need to be taken.

Medication licensed for specific allergen immunotherapy:

Pollen:

Grazax 75,000 SQ-T (ALK Abello) - disease-modifying treatment of grass pollen induced rhinitis and conjunctivitis in adults and children (5 years or older), with clinically relevant symptoms and diagnosed with a positive skin prick test and/or specific IgE test to grass pollen.

Itulazax 12 SQ-Bet (ALK Abello) - Indicated in adult patients (aged 18 years and over) for the treatment of moderate-severe allergic rhinitis and / or conjunctivitis induced by birch pollen, despite the use of symptomatic treatment and with a positive SPT or IgE to birch pollen.

Pollinex tree (Allergy Therapeutics Ltd) - treatment of seasonal allergic hayfever due to tree pollen in adults, adolescents and children from the age of 6 years who have failed to respond adequately to anti-allergy drugs.

Pollinex grass and rye (Allergy Therapeutics Ltd) - treatment of seasonal allergic hay fever due to grass pollen in adults, adolescents and children from the age of 6 years who have failed to respond adequately to anti-allergy drugs.

House dust mite:

Acarizax 12 SQ (ALK-Abello) - Adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation with at least one of the following conditions: (i) persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication, (ii) house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Adolescents (12-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.

Venom:

Alutard SQ bee venom (ALK Abello) - for patients aged 5 years and above with generalised and / or systemic reactions due to honey bee venom confirmed by SPT and/or intradermal test and/or specific IgE

Alutard SQ wasp venom (ALK Abello) – for patients aged 5 years and above with systemic IgE mediated allergic reactions to wasp venom, confirmed by SPT and/or intradermal test and/or specific IgE.

Food immunotherapy:

Palforzia peanut (Aimmune Therapeutics Ltd) – treatment of patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy.

The term ‘unlicensed medicine’ describes medicines, which are used outside the terms of their UK licence or that have no licence for use in the UK. There are clinical situations when the use of unlicensed medicines or use of medicines outside the terms of the licence (i.e., ‘off-label’) may be judged by the prescriber to be in the best interest of the patient based on available evidence. Such practice is particularly common in certain areas of medicine: for instance, in paediatrics where difficulties in the development of age-appropriate formulations means that many medicines used in children are used off-label or are unlicensed.

Unlicensed medicines may be prescribed if that medicine would better suit the needs of the individual patient and has been subject to peer review and with the informed consent by the patient.

Prescribing unlicensed medicines may be necessary in the following instances.

- a. There is no suitably licensed medicine that will meet the patient’s need.
- b. A suitably licensed medicine that would meet the patient’s need is not available. This may arise where, for example, there is a temporary shortage in supply.
- c. The prescribing forms part of a properly approved research project.
- d. There is a serious risk to public health and the MHRA has temporarily authorised the sale or supply of an unlicensed medicine, such as a vaccine or treatment, in response.
- e. A prescription only medicine that is unlicensed in Northern Ireland has been supplied under the Northern Ireland MHRA Authorised Route (NIMAR).

When prescribing an unlicensed medicine, you must:

- a. Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.
- b. Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or make sure that arrangements are in place for another suitable doctor to do so.
- c. Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.
- d. Give patients, or their parents or carers, sufficient information about the medicines you propose to prescribe, to allow them to make an informed decision.

The MHRA provides the following hierarchy for guidance only and each case should be considered on its individual merit.

1. An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need.
2. Although MHRA does not recommend "off label" (outside of the licensed indications) use of products, if the UK licensed product can meet the clinical need, even "off-label", it should be used instead of an unlicensed product. Licensed products available in the UK have been assessed for quality safety and efficacy. If used "off-label" some of this assessment may not apply, but much will still be valid. This is better than the use of an un-assessed, unlicensed product. The fact that the intended use is outside of the licensed indications is therefore not a reason to use an unlicensed product. It should be that the prescriber's responsibility and potential liability are increased when prescribing off-label.
3. If the UK product cannot meet the special need, then another (imported) medicinal product should be considered, which is licensed in the country of origin.
4. If none of these options will suffice, then a completely unlicensed product may have to be used, for example, UK manufactured "specials", which are made in GMP inspected facilities, but which are otherwise un-assessed (GMP inspection of "specials" manufacturers is not product specific). There may also be other products available which are unlicensed in the country of origin.
5. The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). For example, the use of products from countries where they are classed as supplements not pharmaceuticals and may not be made to expected standards of pharmaceutical GMP. These should be avoided whenever possible.

References:

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2. The supply of unlicensed medicinal products ("specials") MHRA Guidance Note 14. [The supply of unlicensed medicinal products special GN14.pdf \(publishing.service.gov.uk\)](http://www.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/281111/The_supply_of_unlicensed_medicinal_products_special_GN14.pdf)
3. Good practice in prescribing and managing medicines and devices. [Good practice in prescribing and managing medicines and devices \(gmc-uk.org\)](http://www.gmc-uk.org/guidance/Good_practice_in_prescribing_and_managing_medicines_and_devices.pdf)
4. <https://www.medicines.org.uk/emc>
5. Scadding, G. K., H. H. Kariyawasam, et al. (2017). "BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis (Revised Edition 2017; First edition 2007)." *Clinical And Experimental Allergy* **47**(7): 856-889.
6. Krishna, M. T., P. W. Ewan, et al. (2011). "Diagnosis and management of hymenoptera venom allergy: British Society for Allergy and Clinical Immunology (BSACI) guidelines." *Clinical And Experimental Allergy* **41**(9): 1201-1220.