

Q and A

How are acne treatment tested for efficacy?

Many of you told us that you'd bought or been prescribed treatments for spots or acne which haven't worked as well as you'd hoped and you wanted to know how they are tested for effectiveness. The answer is different depending on whether the product is a medicine or a cosmetic.

Medicines that are prescribed by a doctor and medicines you can buy without a prescription are rigorously tested for safety and effectiveness in a series of randomised controlled trials. In early phase trials, the emphasis is on proving safety, in later phase ones, it is on demonstrating efficacy. There are no exceptions to this. In late stage premarketing trials and in post-marketing trials, the products are tested in hundreds of people, often from several different countries. In the UK, the organisation responsible for overseeing the testing of medicines is called the Medicines and Healthcare Products Regulatory Agency (MHRA). All medicines must have a product license before they can be marketed. If you look at your treatment pack, you will be able to find the license number; it begins with the letters PL. If the pack doesn't have a number like this, then the treatment is not regulated within the UK as a medicine. Medicines will also always contain a pack insert with lots of information about what's in the product and what side effects might occur.

Medicines will always work better in some people than others but they should work to an extent in almost everyone. One exception is antibiotics which won't work if the target bacterium, in this case *P. acnes*, develops resistance to them. Skin colonisation with resistant *P. acnes* is now quite common in people with acne and is more common to topical than to oral antibiotics. If you are taking or using a medicinal product for acne, make sure you are following the instructions properly. If you don't, it might not work as well as it should. The instructions might be on the label; they will also be some information on the pack insert. Your doctor or pharmacist might also have given you additional advice, especially about how to use topical treatments in the first few days until your skin gets used to them.

Many products for managing skin prone to spots are regulated as cosmetics. The rules for marketing cosmetic products are different to medicines and do not include a requirement to test the product in clinical trials. Anyone can sell a cosmetic product within the EU as long as it contains permitted ingredients in permitted concentrations for permitted uses.

It is very expensive (many millions of pounds) to develop a new medicine because of all the testing that is required. It is much less expensive to market a new cosmetic remedy for spots because there is no legal requirement to test it for efficacy. All the ingredients in a cosmetic remedy will have been tested at some time for safety but not necessarily by the

company selling the product. Nowadays, some cosmetic manufacturers do test their products in clinical trials but most still don't. Many cosmetic claims are based on what individual ingredients can do in laboratory tests. As a general rule of thumb, they are less likely to be effective in more severe acne than medicines and some may only work if your acne is very mild. There is no way of knowing which products work as well as they claim other than by trying them. Cosmetic products might not be as harsh as some topical medicines and they might contain ingredients that are helpful in camouflaging spots or controlling shine.

The other category of product you might have used but didn't realise it is a medical device. Medical devices are regulated by the MHRA but the rules for testing them are less stringent than for medicines; they are typically not tested in large multicentre clinical trials but some of them might have been. Registration of a medical device with the MHRA is via self-declaration by the manufacturer and is a legal requirement. Medical devices carry the CE mark. Devices you may recognise are lights and lamps for home treatment of spots and acne. In general they are not as potent as those which are used by professionals. The emphasis for home use is on safety not efficacy. A product range called Aknicare™ is also regulated as a device because it has a physical not a pharmacological (drug-like) mode of action.

We hope this simple explanation will help you work out whether the product you're using to treat your acne is a medicine, a cosmetic or a device. With devices and cosmetic remedies, always try and find out how they were tested and what the results were before you buy them. If you can't find any information about testing in clinical trials, there might not be any! Your money might be better spent on something else. Remember, a product tested in people with mild acne might not work if you've got lots of spots. If products you can buy without a prescription aren't controlling your acne, it is wise to seek professional advice especially if you have any signs of scarring. You may need something more powerful.