

Bioidentical Hormone Therapy is a medicine that is unlicensed.

Bioidentical Hormones prescribed in our clinic come from a regulated Pharmacy, although the medicine is unlicensed. It means that the pharmacy falls under all quality inspections, ensuring the safety of the created product but it cannot licence the product itself, as its variation is too high. The treatment is bespoke to every patient, although following similar evaluation.

In the UK there are two accredited regulated pharmacies that prescribe Bioidentical Hormones. To ensure all the safest options, we have decided to work with both of them:

The first is a compounding Pharmacy ¹'[The London Specialist Pharmacy](https://specialist-pharmacy.com/)' regulated, complies with the standards of the General Pharmaceutical Council (GPhC)

The second is a manufacturing Pharmacy '[Customised 4U Pharmacy](http://www.customised4upharmacy.co.uk/)'² It is licenced under Medicine and Healthcare Products Regulatory Agency (MHRA GMP approved)

Therefore, Bioidentical Hormone Replacement Therapy is a regulated service but due to its individualised approach to patients, it cannot be licensed.³

Your Prescriber requires to adhere to legal regulations. They need to abide by when prescribing an unlicensed medication for you, they have chosen a product that is safe but may not be classified as a medicine and so has not been through the medicine licensing process.

Some of the reason your prescriber would prescribe an unlicensed product for you include:

- They believe that this medicine would work well for your condition, even though it is not licenced, for a different condition not stated in its licence, it is said to be 'unlicensed'.
- The medicine is not available in the UK and we have to get it from another country which has similar high standards of the licencing as the UK.
- The medicine is normally available in one form, such as a tablet, but the liquid form may be argued to be more efficient therefore its special form has not been licensed yet.
- They are using a different strength of a medicine, not commonly used by GP's. But required for a specific purpose or individual e.g. bioidentical hormone replacement therapy.
- The numbers of Patients could be so small for a full clinical trial to be conducted - it is also possible that a licencing process is underway but this may take time to complete.

¹ "Specialist Pharmacy." <https://specialist-pharmacy.com/>. Accessed 13 Jan. 2019.

² "CUSTOMISED 4U PHARMACY – YOUR BIO IDENTICAL HORMONE" <http://www.customised4upharmacy.co.uk/>. Accessed 13 Jan. 2019.

³ "Medicines information - NHS." <https://www.nhs.uk/conditions/medicines-information/>. Accessed 7 Jan. 2019.