



ROSEWAY — LABS —

Medicine Regulation

We are saddened by the recent attacks on compounded bio-identical hormone replacement therapy (BHRT) in favour of regulated hormone replacement therapy (HRT). As a pharmacy that offers both types of medication, we feel there should be acknowledgement that licensed offerings don't fit the needs of every patient and that patients should be empowered to choose without fear.

Compounding was the recognised process of making medication until the late 1960s, when the concept of licensing was first introduced. A pharmacist's right to compound medication is enshrined in the Human Medicines Act 2012 and the activity is regulated by the General Pharmaceutical Council (GPhC). Compounds should only be created when a prescriber has issued a valid, UK prescription to a pharmacist. They are made specifically for a named patient and are not stock items.

By its very nature, compounding is personalised. Therefore, there is mutual exclusivity between a medication that has been created for an individual and a medication that has been created for the mass market. Licensed products cost hundreds of thousands of pounds or more to bring to market. The strength, dosage form and benefit must be fixed and tested so that at the end of the trials, there is sufficient evidence to convince the MHRA that: (a) the advantages outweigh the disadvantages of taking the medicine; (b) the medicine does the most good for the least harm for most people who will be taking it; and (c) the side effects are acceptable¹. To go through this process takes years and is a significant investment for any pharmaceutical company. They must be convinced of their ability to make more money than they spend licensing the drug. Unlicensed products include any products that have not been licensed at all, have not been licensed in the UK or that have been licensed in the UK for a purpose other than which the medication is being used.

Compounded medications are unlicensed and cannot be advertised as products to prescribers or patients. We are aware of organisations – both clinical and commercial – that do this and we do not condone it.

We strongly advise any patient who is seeking BHRT to check the credentials of their prescriber. Experienced prescribers will talk patients through the safety and risks of taking licensed or unlicensed hormones in any form and will monitor their patients closely to ensure that appropriate hormones are given, in an appropriate form and strength and that patient safety is not compromised.

Compounding Safety

As a pharmacy operating in the strongly regulated UK market, we are unable to accept prescriptions for unlicensed medication from prescribers who are not registered here. However, UK prescribers are able to purchase compounded medications for their patients from outside of the UK, often from Germany or Greece. We advise all patients to check the origin of their medication, the conditions under which it is transported and the duration of time that they must wait for it, to make sure they are comfortable with the quality of the product that they receive.

It has been alleged that many BHRT prescriptions use estrone (E1, oestrone), which is seen as the least safe form of oestrogen. We do not work with this particular hormone and have never been requested to do so. Neither have we seen any prescriber marketing BHRT as a natural supplement or a 'safe' product. Credible prescribers know the risks and will explain them to their patients. Any form of HRT should only be

¹ Medicines & Medical Devices Regulation: What you need to know. MHRA 2008, 2012

prescribed if both the prescriber and the patient believe that the benefits outweigh the risks.

Another criticism of compounding is that patients are not given sufficient information about their product. We have created patient information leaflets that go out with every compound, which highlight ingredients, potential side effects and how to report any problems, including the MHRA's Yellow Card Scheme. Our end-to-end system allows the prescriber to create a prescription, then seamlessly allocates ingredients, records the formulation and method and enables dispensing. Hence all ingredients are fully traceable should any need for recall occur.

Our compounds are always made with pharmaceutical-grade raw materials, bought from reputable suppliers in the UK, USA or Europe. A certificate of analysis is always obtained so that the pharmacists can be sure of the material they are working with and we hold the relevant licenses to import. Whilst it is also possible to compound by altering the form of licensed medication (e.g. crushing a tablet), we prefer to work with powders thereby avoiding enteric coatings, fillers and preservatives, where possible.

Compounding takes place in a laboratory, inside laminar-flow cabinets to protect workers. Formulations and calculations are double checked, exact amounts of weighed ingredients are recorded to four decimal places and checks on the final product made to ensure proper distribution of active ingredients. All compounders are trained and supervised by a designated Responsible Pharmacist.

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Roseway Labs is the trading name of Galenic Laboratories Limited. We are a pharmacy dedicated to meeting the needs of private doctors and their patients. We supply licensed, unlicensed and compounded medication as well as vitamins, supplements and diagnostic testing kits. For queries please contact us on info@rosewaylabs.com or on 03330 504030.