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Off the shelf:

Could CBD products disappear from UK pharmacies?

UK manufacturers of products containing cannabidiol have been given a deadline of 31 March 2021 to submit valid novel food authorisation applications, or withdraw their products from sale. Fieldfisher life sciences regulatory expert, Sarah Ellson, considers how pharmacies already stocking CBD should respond to new FSA guidance.

In February 2020, the UK's Food Standards Agency (FSA) announced it was giving manufacturers of food products or supplements containing cannabidiol (CBD), a non-psychoactive extract of cannabis plants, a deadline of 31 March 2021 to submit valid novel food authorisation applications.

After this deadline, only products which have submitted a valid application will be allowed to remain on the market in England, Wales and Northern Ireland.

In Scotland the national regulator, Food Standards Scotland (FSS), has said that products currently on the market are in contravention of the novel food regulations and businesses should take "immediate action" to obtain authorisation as a novel food

A valid application is understood to mean an application which has been checked and confirmed as containing the correct information, but not necessarily assessed for safety.

The FSA's announcement reflects an attempt to bring the UK into line with the EU's position on CBD.

In January 2019, the EU classified all synthetically obtained extracts of hemp and derived products containing cannabinoids (including CBD) as "novel foods" – i.e., food that was not widely consumed by humans in the EU before May 1997, when the first Regulation on novel food came into force.

Hemp and related products, such as cold-pressed oils, are not novel because there is evidence to show a history of consumption before May 1997.

As the UK is expected to fully leave the EU at the end of 2020, novel food applications by UK manufacturers will have to be made to a new FSA "regulated products service", rather than the European Food Standards Agency (EFSA).

In addition to requiring novel food authorisation, following a recent report by COT (an independent scientific committee that provides advice on matters concerning the toxicity of chemicals) the FSA and FSS have also advised anyone pregnant, breastfeeding or taking any medication not to consume CBD products at all.

Healthy adults should not consume more than 70mg a day (about 28 drops of 5% CBD) unless under medical direction, according to the guidelines.

What does the FSA deadline cover?

The FSA has advised that businesses in England, Wales and Northern Ireland are allowed to continue selling their existing CBD products (such as drops, powders, gummies, chocolates and drinks), up until the 2021 deadline, provided they are correctly labelled, safe to eat and do not contain illegal levels of substances that fall within the Misuse of Drugs Act 1971.

Products which are not orally consumed are not affected by the regulator's deadline.

The FSA also explicitly stated that its novel food deadline does not apply to cosmetics, vapes, products making medicinal claims or products containing controlled drugs such as Tetrahydrocannabinol (THC) the psychoactive cannabinoid in cannabis, which may be subject to separate regulation.

It further stressed that its guidance will not impact those who take medically prescribed CBD or cannabis.

How should pharmacists respond?

For pharmacies that currently stock non-medicinal CBD products, the FSA's announcement is no reason to panic, but should prompt them to think about what items they want to retail.

While there is likely to be a moratorium on any enforcement prior to the deadline, the new advice on dosage and who should avoid taking CBD altogether means pharmacists may want to consider putting all CBD products behind the counter so that advice can be given.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has also been very clear that products containing CBD, if advertised for medical purposes or making health claims, must be licensed as medicines.

It should be remembered that the FSA's guidance on CBD has been formulated in the interest of public safety.

Recently, some popular CBD products on the UK market were tested and shown to contain harmful levels of some ingredients, which is why the FSA has asked the industry to provide more information on the labels of CBD products.

Pharmacists may therefore want to consider how they can verify claims made about the active ingredients in products they are selling.

Pharmacists should always comply with the GPhC standards to provide safe and effective care and should reflect on their responsibilities when overseeing the sale of these products.

Compliance and enforcement

Obtaining novel food approval is not a quick or an easy process; the regulator's website contains detailed guidance on the type and level of information required for an application.

Once this has been submitted, applicants can expect to wait several weeks to find out whether their application is valid and can proceed to the risk assessment phase, which will take many months.

So far, no CBD products have been granted novel food status, although a decision from the EFSA on the first application it has assessed is expected in the near future.

Until the 2021 deadline it appears that enforcement will be light touch unless health claims are made which trigger MHRA involvement, or there are consumer safety concerns.

After the deadline, trading standards officers may consider taking action against manufacturers of products who have not sought novel food authorisation.

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