

Mr Nicholas Brox
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USA

Date 5th March 2013

MHRA Ref: E/2013/0215

Dear Mr Brox,

Reference your letter of 22nd January, received by myself on 12th February regarding the regulatory status of the iGrow Hair growth System.

You have advised that the product sold in the USA and Canada as a medical device with the claim that it is intended to promote hair growth in males with androgenetic alopecia and that they system is a helmet which incorporates lasers and LED's and is intended to treat impaired hair follicles for individuals suffering from androgenetic alopecia.

As previously explained to your consultant, 'Androgenetic alopecia' is the medical terminology for baldness or going bald (sometimes referred to as 'pattern baldness'). This wording is used interchangeable with 'baldness': Baldness or going bald in general terms is not considered to be a medical condition, but rather a genetic predisposition, therefore a product intended to 'treat' Androgenetic alopecia alone (with no claims to treat any other type of alopecia) would be unlikely to be considered to be a medical device under 93/42/EEC.

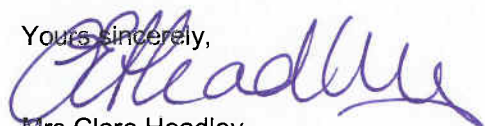
Thus with the current claims as stated in your letter, MHRA would not regard the iGrow system to be a medical device under directive 93/42/EEC.

There are, however, other types of alopecia (totalis, areata, traction etc) which are regarded as medical conditions as they happen suddenly (often for no apparent reason) and some forms result additionally in eyelash and eyebrow loss. Products which are intended to treat such conditions would be likely to be regarded as medical devices or medicinal products depending upon their mode of action.

MHRA is not able to comment on the views of other EU Member States with respect to the applicability of the medical device directives to individual products; however can comment that divergent opinions are not unknown.

Please note that whilst we are willing to give any help and advice we can, any views given by us on the interpretation of the Regulations represent our best judgement at the time, based on the information available. Such views are not meant to be a definitive statement of law, which may only be given by the Courts. Accordingly we would always advise you to seek the views of your own professional advisors.

Yours sincerely,



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