

Ainsworths homeopathic kits

From: [REDACTED]
Sent: 26 January 2012 16:18
To: [REDACTED]
Subject: RE: Ainsworths homeopathic kits
Dear [REDACTED]

Thank you for your consideration of our proposals regarding the website. We accept your suggestion and have already made the necessary changes to ensure that the web pages concerned are clearly annotated with a note that the unlicensed kits are not for sale to UK customers.

I appreciate your agreement that retail outlets may sell through their existing stocks of unlicensed kits and confirm that we will, with immediate effect, discontinue further supply of unlicensed kits to all UK retail outlets.

Thank you for your commitment to prioritize the HR applications for pending new licenses. In respect of this we seek your assistance with the CTD submission as this is far more complicated than the format employed in previous applications. I understand that the BAHM received assurances from your department only recently that all its members would be offered a dedicated seminar, in February, on how to adapt the CTD to homeopathic applications. We are obviously keen to pursue this matter and time is of the essence in order to perform in accordance with our schedule agreed with yourselves. To that effect can you assist my Regulatory Affairs colleague with specific answers and guidance if the seminar is not imminent? My colleague is willing to meet you for a short briefing on how to make these CTD applications if you are willing to assist.

Regards

[REDACTED]

From: [REDACTED]
Sent: 26 January 2012 10:52
To: [REDACTED]
Subject: FW: Ainsworths homeopathic kits

Dear [REDACTED]

Thank you for your email.

I have discussed your proposal to change the wording on the advertisement for unregistered kits on the Ainsworths website with my colleagues in the Advertising Unit. They have advised that the Agency is unable to monitor advertisements to the non UK public and therefore if you wish to advertise the unregistered kit to non UK consumers, the wording must clearly indicate that the kit is not for sale to UK consumers.

Ainsworths homeopathic kits

We are unable to approve your request for a time frame of 6 months to inform UK retail outlets of the change and you should discontinue supply of the unregistered kits to them with immediate effect. As you have mentioned, we have agreed that outlets that you have already supplied the kits to may sell through the stock but must not be supplied with further kits.

We understand that you wish to reassure customers that there will be a smooth transition to the registered kits and that is why we have given you our commitment to prioritise HR applications, thus ensuring that the registered kits are on the market as soon as possible.

On receipt of this email, please confirm in writing that you will cease supply of the unregistered kits within the UK with immediate effect.

Regards

From: [REDACTED]
Sent: 13 January 2012 15:05
To: [REDACTED]
Subject: RE: Ainsworths homeopathic kits

Thank you for your confirmation of the new application schedule for our Essential kit, we will do our best to adhere to this timescale.

I appreciate your comments regarding withdrawing UK advertising and I am sure you will appreciate our concern that these products are freely available for sale outside the UK. As you are aware, we have already discontinued all advertising in the UK and would be grateful if you can consider allowing us to change the wording on our website making it clear that the kits will only be available for sale outside of the UK.

The reason for this request is that over half of these kit sales are to overseas clients, mostly to Japan. These clients do not speak English although they are highly computer literate and purchase exclusively from our website. We have no other reliable means of reaching this market or crossing the language barrier. The sensitivity of this market to changes in availability is very great, as we have discovered in the recent past and the Japanese public use the web and blogs more than UK. Therefore business can be lost very quickly to an overseas competitor.

As you may appreciate we have spent a great deal of time and effort building these overseas markets, the loss of which would affect us greatly. Most especially, the larger Japanese market which suffered a dramatic setback and was almost destroyed two years ago.

With regard to your query regarding the requested six month period, this is requested for several reasons. Firstly we need time to wind down the operation and inform the retail outlets that we are replacing at least one kit as seamlessly as possible without destabilizing our market. In this respect I am grateful that you will allow the retail outlets to sell through stock and we anticipate that it will take six months to make the changecover to the newly licensed kit whilst at the same time reassuring our customers that there will be a smooth transition. Secondly we have a very varied client base for these kits beyond retail outlets and it will take some time to contact these clients and explain the situation. Meanwhile I give you my assurance that we will cease the retail sale and supply of kits outside of our licensing permissions immediately.

Warm regards

[REDACTED]

From: [REDACTED]
Sent: 13 January 2012 10:09
To: [REDACTED]
Subject: FW: Ainsworths homeopathic kits

Dear [REDACTED]

I refer to my email below and would be grateful if you could confirm today that the points regarding advertising, sale and supply will be implemented.

Many thanks

Regards

[REDACTED]

From:
Sent: 10 January 2012 16:16
To:
Subject: RE: Ainsworths homeopathic kits

Dear [REDACTED]

Thank you for your email. Your time table to submit the HR applications is acceptable.

The MHRA enforces the advertising for UK based websites and therefore the advertisement for the non registered kits must be removed from the Ainsworth website as soon as possible.

Regarding your last point - We do require a timeframe of six months to discontinue sales and supply of the kits within the UK- can you provide a reason for requiring 6 months as this seems rather excessive. It is requested that Ainsworths cease sale and supply of the non registered kits immediately. Outlets that you have already supplied the kits to may sell through the stock but must not be supplied with further kits.

Please can you confirm that the points stated above regarding advertising, sale and supply will be implemented.

Many thanks

Regards

From: [REDACTED]
Sent: 10 January 2012 12:14
To: [REDACTED]
Subject: RE: Ainsworths homeopathic kits

Dear [REDACTED]

May I wish you a Happy New Year.

We are complying with the terms of your letter and are in the process of making new applications for the unregistered remedies in our kits. Thank you for your suggestion about utilizing the existing kit name and content for the purposes and also for the advice about the discount structure.

In order to facilitate the process, and in particular your work flow, I have below a proposal for a timeframe of new applications for our Essential Kit.

1. First remedy submission for change of existing stock to new pill HR within one month
2. 32 submissions for change of existing stocks to pill formulation within six weeks of satisfactory response to (1) above
3. 9 new submissions for new stocks in existing pill formulation within 3 months of satisfactory response to (1) and (2) above

I am sure the above will be useful information in relation to planning departmental time in order to give these priority as we discussed.

You should confirm in writing within seven days of the date of this letter that you have received it and

Ainsworths homeopathic kits

understood the contents and provide a timeframe for discontinuing the sale, supply or advertising of the remedy kits listed above until such time the remedies are registered for use in the UK by this Agency

I confirm we have received and understood your letter and that we have already discontinued the UK advertising of the kits until we have received new marketing authorisations. We do require a timeframe of six months to discontinue sales and supply of the kits within the UK.

Thank you for your very able assistance and cooperation in this matter.

Warm Regards

[REDACTED]

From: [REDACTED]
Sent: 03 January 2012 10:24
To: [REDACTED]
Subject: Ainsworths homeopathic kits

Dear

Please find attached a letter regarding the above matter.

<<Ainsworths remedy kits 3-1-12.pdf>>

Regards

[REDACTED]

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