



**ANNEX 1**

**Response document for MHRA public consultation on the proposal to make Colourstart Test Patch available from general sales outlets without prescription**

Ref: ARM 97

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**Your details**

Name: [REDACTED]

Position (if applicable): Professional Support Pharmacist

Organisation (if applicable): Royal Pharmaceutical Society

Email:

**1. Do you consider that Colourstart Test Patch should be available as a General Sale List (GSL) medicine?**

Yes                       No                       Not sure

Please provide any comments or evidence to support your response:

Hair colourants are widely available, as such a test to check for a potential allergy to a common ingredient in hair colourants would be welcomed.

Pharmacies should be included in the list of retailers to supply Colourstart, as they also sell hair colourants, and pharmacists are well placed to provide additional advice to a person with any questions about the product or if a reaction occurs.

**2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Colourstart Test Patch?**

Leaflet appears comprehensive. However, it is difficult to judge as print looks small so may not be easy to read in which case instructions will not be easy to follow. In the warning and precautions section of the leaflet it mentions: "Talk to your doctor or pharmacist before using Colourstart if any of these factors apply to you. Your doctor or pharmacist will decide what to do" – It is not clear which factors this is referring to?

In the section on taking other medicines, you have included some oral or topical steroids and immunosuppressant medicines, however there are more that can be included, for example for oral steroids – fludrocortisone or dexamethasone.

**3. Do you have any other comments on the reclassification?**

Pharmacists should be made aware when the product is launched, as they are mentioned in the patient information leaflet as a person to go to for queries prior to product usage and how to deal with non-serious reactions.

**4. The MHRA may publish consultation responses. Do you want your response to remain confidential?**

Yes                       Partially\*                       No

\*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email ([reclassification@mhra.gov.uk](mailto:reclassification@mhra.gov.uk)) to arrive by **7 November 2018**. Contributions received after that date cannot be included in the exercise.