Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

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

Your details

Name: [redacted]

Position (if applicable): Policy Manager

Organisation (if applicable): National Pharmacy Association

Email:

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

Yes ☐ No x☐ Not sure ☐

Please provide any comments or evidence to support your response:

The provision of Colourstart test patch ought to be through the pharmacy as a P medicine. Community pharmacists are well positioned to provide the advice and support to the customer, including side effects, and potential interactions with medicines such as corticosteroids or immunosuppressants. The community pharmacist would also be able to advice in the case of a false positive result as well as in instances when the positive reaction may persist for weeks or months.

The provision of this patch through the pharmacy, may also lead to an "increase and/ or earlier diagnosis" of potential undiagnosed skin conditions, which in turn would lead to immediate advise and treatment.

Most community pharmacies are open on weekends and late evenings, and therefore, the provision of the Colourstart Test Patch through the Pharmacy would aid in the accessibility of this medication.

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

Patient information leaflet (Annex 2)

The Patient information leaflet appears to be comprehensive as to the uses and contraindications of the colourstart test patch.

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

The NPA as a national body for independent community pharmacy will support its members with various education and training tools, when the change from POM to P is approved.

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

Yes ☐ Partially* ☐ No x☐

*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) to arrive by **7 November 2018.** Contributions received after that date cannot be included in the exercise.