Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Response document for MHRA public consultation on the proposal to make Arthriex 750mg and 1500mg Film-coated Tablets available in Pharmacies **ANNEX 1**
Ref: ARM96

Your details

Name: [redacted]

Position (if applicable): [redacted]

Organisation (if applicable): Guild of Healthcare Pharmacists

Email: [redacted]

a. Do you consider that Arthriex 750mg and 1500mg Film-coated Tablets should be available as a Pharmacy medicine?

Yes ✔ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

We are supportive of this reclassification. We believe the product is safe and effective, and the therapeutic ingredient is already widely available in pharmacies, health food stores and online.

b. Do you have any specific comments on the leaflet or the label provided in the public reclassification report? In particular:

- **If you are a potential patient, do you find the patient information leaflet (Annex 2) and the label (Annex 3) understandable?**
- **If you are a pharmacist or healthcare professional would you be confident to supply this product if suitable pharmacy training was provided?**

We believe that the information within the leaflet would be confusing to potential patients, it still reads as a leaflet relating to a medicine that is only available on prescription.

- The leaflet states that the medicine can only be used where mild to moderate osteoarthritis of the knee has been previously diagnosed by a doctor, this will not always be the case as the medicine will be promoted for sale or certainly could be, it would be better if the leaflet stated that the patient has the symptoms of osteoarthritis.
- The leaflet also stated that if you don't feel better or feel worse in 2 to 3 months you need to go back to your doctor. However it also states that it may take several weeks or longer to obtain benefit from taking the medicine. Thiss is contradictory.
- The leaflet states that it can only be used where one joint is affected, with osteoarthritis it is highly likely that both joints are affected, as such any Pharmacist would need to intervene to prevent supply where both knees are affected.
- The leaflet also states that the medicine should not be used for longer than 3 years as there is no evidence to support its use.

We would suggest that the leaflet needs a major review for it to be more suitable for patients in this new supply situation.

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

We wonder, given the wide unregulated availability of glucosamine sulphate in these strengths, why this application is for the medicine to become a Pharmacy medicine and not a General Sales List medicine (although we accept that a product cannot switch classification directly from POM to GSL). Given the medicine has a product licence we believe it will have an advantage over other non-regulated products in that the quality of the medicine is regulated. Given the current licence and PIL we believe that the ability of a Pharmacist to recommend or supervise the correct sale of this product will be very difficult in practice.

d. 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.gsi.gov.uk) to arrive by **xxxxxx 2017.** Contributions received after that date cannot be included in the exercise.