From:	**Pharmacovigilanceservice** <Pharmacovigilanceservice@mhra.gov.uk>
To:	[redacted]
CC:	**Ord, Kathryn** <Kathryn.Ord@mhra.gov.uk>
Subject:	FW: Finasteride 1 mg
Date:	31.01.2022 10:25:33 (+01:00)

Hi [redacted]

Please can you draft a response for this query? Do let me know if it should be allocated to someone else.

Many thanks,
[redacted]

From: [redacted]
Sent: 31 January 2022 10:19
To: Pharmacovigilanceservice <Pharmacovigilanceservice@mhra.gov.uk>
Subject: Finasteride 1 mg

Madam, Sir,

We are regularly contacted by people (from many countries) suffering from physical, sexual and mental side effects related to the treatment with finasteride 1 mg for cosmetic purposes.

As you know, several associations or organisations throughout the world (PFS Foundation, PFS Network, Associazione vittime finasteride, PFS Research,...) are committed to helping the victims, alerting the Health Authorities, obtaining funds for research, collecting testimonies from patients and their families, ...

It must be noted that in the indication of androgenetic alopecia, this product is still too often distributed without a precise prior diagnosis and without a thorough analysis of the patient's situation.
Considering the duration and severity of the side effects that can occur either during the treatment or after consumption, and this for an indefinite period, it seems important that the information provided at the time of delivery of this molecule and the follow-up of the patient be subject to a reinforced framework.
We note that many dermatologists or general practitioners are not aware of the mode of action of this anti-androgenic product and its potential repercussions on the whole body. As these gaps can lead to multiple tragedies, comprehensive information for prescribers, improved as new knowledge becomes available, is urgently needed. The patient must be warned of the potentially harmful events that may occur, and of the irreversible nature of some of them, in order to make the most informed choice possible. It is also important that doctors and specialists are able to recognise symptoms quickly and report them.

Furthermore, inappropriate distribution of this drug seems to result in a distorted calculation of the benefit/risk balance.
We would therefore like to know your position on this subject as well as your intentions in order to protect consumers as much as possible and also to know what measures are envisaged to support the victims of this product. To date, as you know, there is no treatment that can cure post-Finasteride syndrome and there is no permanent solution for patients.
The Associations regularly hear that every drug has undesirable effects. This statement may be understandable in the context of the fight against a life-threatening disease, but this cannot be the case for consumers of the 1 mg dosage for cosmetic purposes who are initially in good health.

Adverse effects appear to have been minimised at the time of marketing. Admitting that a percentage of victims is "acceptable" to decision-makers, do you not think, on the other hand, that it is ethically, healthily and humanely necessary to recognise the status of these patients and to work to enable them to recover their capacities?

We note a clear under-reporting by patients and practitioners. What is your policy on reporting incentives? Is it possible to know what processes you are implementing to collect data and use them more efficiently?

Are there exchanges between regulators and clinicians? Do you have a regularly updated database that also takes into account so-called "independent" articles and studies such as those of Baylor, Melcangi, Traish, Khera, etc.? Do the reported side effects give rise to alerts, increased information, requests for additional information from the parent company and generic companies?

Thanking you in advance for your interest in the victims we are trying to help, and for our expectation of answers to their many questions.

Please accept, Madam, Sir, our sincere greetings.