

Appendix A

Fictional example to illustrate challenges and opportunities with safety information sources

A GP sends an enquiry to the MI department asking if Alopecia is a side effect of Treatment X.

A patient of his, a young lady in her mid-20s diagnosed with MS and started by Hospital Specialist on Treatment X, is anxious about possible Alopecia. The patient had quoted discussions on a patient forum that others have reported Alopecia and she has brought a screenshot from iDAP (MHRA) as below:

- Skin and subcutaneous tissue disorders	132	0
+ Angioedema and urticaria	12	0
+ Epidermal and dermal conditions	67	0
+ Pigmentation disorders	1	0
- Skin appendage conditions	50	0
- Alopecias	39	0
Alopecia	37	0
Androgenetic alopecia	2	0
+ Apocrine and eccrine gland disorders	6	0
+ Nail and nail bed conditions (excl infections and infestations)	1	0
+ Pilar disorders NEC	4	0
+ Skin vascular abnormalities	2	0
+ Social circumstances	1	0

The GP contacts the company MI department and asks for advice on how to address concerns of his patient. He mentions that he has checked BNF but did not find reference to Alopecia. He has also copied the screenshot from iDAP and admits he is not familiar with these information resources.

What response can be provided to address his enquiry?

It is assumed that alopecia is not in CDS or local label.

Response Option 1

- A relatively short response stating that Alopecia is not considered to be causally associated with Treatment X and that Alopecia can occur secondary to number of causes: increased association with Autoimmune disorders for example. A publication on non-specific background rates is provided.

Response Option 2

- As above but in addition:
- Detailed explanation of how the Company performs 'routine pharmacovigilance activities' - (likely this could be provided based on existing wording from PSMF).
- Details of comparative frequency from pivotal trials of Alopecia (may well be available in published CSRs on EMA web site)

Both responses are possible and correct. When answering questions consideration should be given as to which option will help HCPs make informed decisions. In addition, these efforts will support building trust in pharmaceutical companies.