

24th June 2021

FOI 21/618

Dear

Thank you for your email dated 27 May 2021, where you have requested, in the interest of transparency, details of which of your emails (article, research, social media etc) have been seen by the Isotretinoin Expert Working Group (IEWG) and which ones have been withheld.

We have reviewed our email records and identified 131 emails received since August 2019 when a review of isotretinoin was first agreed. These emails include a range of topics associated with isotretinoin and are presented in date order in table 1.

All of the emails have been shared with the MHRA assessment team. Information provided in the emails has largely been incorporated into the assessment reports which have already been considered by the IEWG.

Generally the Commission of Human Medicines' (CHM) Expert Working Groups do not receive direct correspondence in order to maintain their independent status. However, the MHRA has committed to providing the IEWG with all of the information received from patients and stakeholders and this includes correspondence. Therefore, the emails which were either marked for the attention of the IEWG or included a statement requesting or giving permission to share the information with the IEWG are being shared with the IEWG.

Table 1. Breakdown of correspondence received

| Shared | Date sent | Sent to | Subject |
|---------------|------------------|----------------|---|
| No | 06/08/2019 | | FW: Isotretinoin chemically castrating young males leading to suicide |
| No | 21/08/2019 | | RE: Isotretinoin chemically castrating young males leading to suicide |
| no | 06/09/2019 | | Re: Isotretinoin chemically castrating young males leading to suicide |
| no | 09/09/2019 | | FW: Isotretinoin chemically castrating young males leading to suicide |
| Yes | 09/09/2019 | | FW: Isotretinoin chemically castrating young males leading to suicide (link to Ido's YouTube video) |
| No | 21/09/2019 | | FW: EWG Isotretinoin |
| No | 31/10/2019 | | RE: EWG Isotretinoin |
| No | 21/11/2019 | | FW: FW: Family victim impact statement |

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|-----|------------|---|---|
| No | 10/12/2019 | Customer services MHRA complaints | Re: EWG Isotretinoin |
| Yes | 19/12/2019 | | RE: roaccutane |
| No | 23/12/2019 | | Dates and international |
| No | 06/01/2020 | plus 1 external | RE: About Isotretinoin |
| Yes | 08/01/2020 | | FW: My recording 1.m4a |
| No | 08/01/2020 | | FW: Please copy, paste and share on Facebook and any other forums |
| Yes | 09/01/2020 | | Stefan |
| Yes | 09/01/2020 | | FW: EWG Isotretinoin |
| No | 10/01/2020 | | RE: Dates and international |
| No | 24/01/2020 | plus 1 external | Yellow card query reminder |
| No | 30/01/2020 | | Re: No response |
| No | 08/02/2020 | customer services plus 1 external to MHRA | RE: ROACCUTANE SIDE EFFECTS FOR FRENCHPATIENT Gilbert COHETTE |
| Yes | 12/02/2020 | Yellow card mailbox plus 1 external to MHRA | RE: GCEP-00140961 Isotretinoin and its effects on me. |
| Yes | 14/02/2020 | | FW: Témoignage de traitement au Roaccutane |
| No | 02/03/2020 | plus 1 external to the MHRA | FW: No response or info yet |
| No | 05/03/2020 | Yellow card mailbox Customer services | Fw: Yellow card query reminder |
| Yes | 12/03/2020 | | Fw: FW: DOCUMENTS for the attention ofthe EWG |
| Yes | 12/03/2020 | | Fw: video + read the comments. Attention of the EWG |

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|-----|------------|--|---|
| No | 13/03/2020 | MHRA complaints | Fw: No response or info yet |
| No | 01/04/2020 | | Another suicide |
| Yes | 02/04/2020 | | RE: Another suicide |
| No | 01/05/2020 | isotretinoin mailbox plus 1 external to the MHRA | FW: Témoignage de traitement au Roaccutane |
| No | 01/05/2020 | isotretinoin mailbox plus 1 external to the MHRA | RE: Testimony for Isotretinoin |
| Yes | 04/05/2020 | isotretinoin = MHRA customer services | Fw: ACCUTANE and erectile dysfunction |
| No | 13/05/2020 | | Fw: NICE review date. |
| No | 13/05/2020 | isotretinoin mailbox plus 1 external to the MHRA | - lack of response. |
| Yes | 28/05/2020 | | Fw: Brouillard mental Noé |
| No | 29/05/2020 | customer services isotretinoin mailbox | FW: Témoignage de traitement au Roaccutane |
| No | 12/06/2020 | | RE: CSC 7300 FW: update, Audio, tapering, monitoring |
| Yes | 02/07/2020 | pharmacovigilance service isotretinoin mailbox | Fw: Before you take that pill aggression, suicide and murder |
| Yes | 02/07/2020 | pharmacovigilance service isotretinoin mailbox | RE: Another suicide |
| Yes | 02/07/2020 | isotretinoin mailbox | Another suicide |
| Yes | 02/08/2020 | pharmacovigilance service isotretinoin mailbox plus 1 external to the MHRA | Fw: For the attention of the EWG (2) Congress bill - receipt needed |

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| Yes | 02/08/2020 | pharmacovigilance service isotretinoin mailbox | Fw: For the attention of the IEWG (1) Congress safety meetings 2000 and 2002 A receipt is needed |
| Yes | 03/08/2020 | pharmacovigilance service isotretinoin mailbox plus 1 external to the MHRA | EWG 3 monitoring and suspension |
| No | 05/08/2020 | MHRA customer services | isotretinoin at home treatment during Covid |
| Yes | 07/08/2020 | customer services isotretinoin mailbox plus multiple external to the MHRA | CSC 12583 EWG 3 Health Canada,Pregnancy, SD, suicide |
| Yes | 07/08/2020 | MHRA customer services others external to MHRA | EWG 3 Health Canada,Pregnancy, SD, suicide |
| No | 07/08/2020 | MHRA customer services | Re: isotretinoin at home treatment during Covid |
| Yes | 16/08/2020 | cc'ed to others outside the MHRA | IEWG 4 Is the risk of this worth it? |
| No | 26/10/2020 | | IEWG |
| No | 03/11/2020 | | Re: IEWG |
| Yes | 18/11/2020 | | Immediate action |
| No | 23/11/2020 | | Fw: Audio ref Our Reference: CSC 21091 |
| No | 30/11/2020 | | FW: Our Reference: CSC 21091 dermatology myth |
| Yes | 04/12/2020 | isotretinoin = customer services | FW: Témoignage de traitement au Roaccutane |

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|-----|------------|---|---|
| yes | 09/12/2020 | isotretinoin = customer services | CSC 24075 - AAD's official new statement on isotretinoin: "The truth about isotretinoin side effects" |
| Yes | 11/12/2020 | isotretinoin = customer services plus external emails | Fw: submission CMDh and congress s |
| Yes | 04/01/2021 | isotretinoin = customer services | CSC 27270 Fw: [External] FW: Before you takethat pill aggression, suicide and murder |
| Yes | 11/01/2021 | isotretinoin = customer services | CSC 28062 FW: questions not answered |
| Yes | 11/01/2021 | | questions not answered |
| Yes | 13/01/2021 | isotretinoin = customer services | FW: Understanding isotretinoin damage. 3 |
| Yes | 13/01/2021 | isotretinoin = customer services | Fw: Before you take that pill aggression, suicide and murder 5 |
| Yes | 13/01/2021 | isotretinoin = customer services | The Atlantic 7 |
| Yes | 13/01/2021 | isotretinoin = customer services | Harvard 6 |
| Yes | 13/01/2021 | isotretinoin = customer services | Fw: Life destroyed 6 |
| Yes | 14/01/2021 | isotretinoin = customer services | The deadly truth about "Accutane 'ring of fire 12 |
| Yes | 14/01/2021 | isotretinoin = customer services | - uninformed dermatologists and patients 13 |
| Yes | 14/01/2021 | isotretinoin = customer services | Fw: Nathan Accutane/ THE COVER UP |
| Yes | 14/01/2021 | isotretinoin = customer services | B12, Vit's A,D,E testosterone, DHT, estrogen, cortisol and homocysteine deficiency. |
| Yes | 14/01/2021 | isotretinoin = customer services | Distinguish between suicide risks and thoughts on suicide |
| Yes | 15/01/2021 | isotretinoin = customer services | important document with Isotretinoinhistory 14 |
| No | 15/01/2021 | isotretinoin mailbox | Re: Audio ref Our Reference: CSC 21091 |
| Yes | 16/01/2021 | isotretinoin = customer services | Life destroyed personal account. 15 |
| Yes | 16/01/2021 | isotretinoin = customer services | Fw: Isotretinoin Victim impact statement 16 |
| Yes | 21/01/2021 | isotretinoin = customer services | CSC 28062 isotretinoin suicides 17 |
| Yes | 25/01/2021 | isotretinoin = customer services | CSC 28062 Isotretinoin does cause suicides. 18 |
| No | 29/01/2021 | | Call for information request |
| Yes | 29/01/2021 | | Roche duplicity |
| Yes | 30/01/2021 | isotretinoin = customer services | for the attention of the EWG 19 |
| | 30/01/2021 | isotretinoin = customer services | CSC 28062 Fw: Another paper |
| Yes | 31/01/2021 | isotretinoin = customer services | Must watch EWG 17 |
| Yes | 01/02/2021 | isotretinoin = customer services | attention of the EWG |

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|-----|------------|--|---|
| Yes | 01/02/2021 | isotretinoin = customer services | attention IEWG Understanding isotretinoin damage. |
| Yes | 02/02/2021 | isotretinoin = customer services | case histories provided by charity For the attention of the EWG |
| Yes | 02/02/2021 | isotretinoin = customer services | Follow up to Isotretinoin damage sent 1/2/2021 For the attention of the EWG |
| Yes | 02/02/2021 | isotretinoin = customer services | Fw: Isotretinoin chemically castrating young males EWG |
| Yes | 02/02/2021 | isotretinoin = customer services | Fw: Drug disaster as heinous as thalidomide. |
| Yes | 02/02/2021 | isotretinoin = customer services | Fw: Isotretinoin - Part 1 Baroness |
| Yes | 02/02/2021 | isotretinoin = customer services | Fw: Isotretinoin Part 2 Baroness |
| Yes | 02/02/2021 | isotretinoin = customer services | FW: Life destroyed |
| Yes | 02/02/2021 | isotretinoin = customer services | CSC 28062 submission for the attention of the EWG |
| Yes | 05/02/2021 | isotretinoin = customer services | Fw: Isotretinoin |
| Yes | 05/02/2021 | isotretinoin = customer services Plus 1 external | CSC 28062 Ban Isotretinoin |
| Yes | 07/02/2021 | isotretinoin = customer services | CSC 28062 cocktail of drugs |
| Yes | 08/02/2021 | isotretinoin = customer services | iso treatment questionnaire |
| Yes | 08/02/2021 | isotretinoin = customer services | Petition FDA |
| Yes | 08/02/2021 | isotretinoin = customer services | attention of the EWG |
| Yes | 08/02/2021 | isotretinoin = customer services | for the attention of the EWG |
| Yes | 10/02/2021 | Pharmacovigilance service isotretinoin = customer services | Pharmacovigilance FOI |
| Yes | 15/02/2021 | MHRA customer services | CSC 36012 Isotretinoin |
| No | 15/02/2021 | MHRA customer services | Isotretinoin |
| Yes | 16/02/2021 | isotretinoin = customer services | Isotretinoin/Thalidomide |
| Yes | 16/02/2021 | isotretinoin = customer services | Arrogant doctor |
| No | 16/02/2021 | MHRA customer services | CSC 26012 - Isotretinoin call for information. |
| Yes | 23/02/2021 | | FW: Spontaneous |
| No | 01/03/2021 | | Re: questions not answered |
| No | 28/03/2021 | MHRACustomerServices@mhra.gov.uk | OFFICIAL SENSITIVE - Re: CSC 37083 - RE: Audio response needed |
| Yes | 28/03/2021 | plus many external to the MHRA | Re: Patient Safety Isotretinoin a drug to rival Thalidomide. |
| No | 30/03/2021 | MHRACustomerServices@mhra.gov.uk | Fw: Fw: CSC 37083 - RE: Audio response needed |
| No | 07/04/2021 | MHRACustomerServices@mhra.gov.uk | Fw: Audio from meeting with |
| No | 07/04/2021 | | Re: ISOTRETINOIN |
| No | 19/04/2021 | MHRA complaints | Fw: questions not answered |
| No | 23/04/2021 | Pharmacovigilance service | FOI 21/440 - Freedom of Information request Roche adverse reporting |

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| No | 04/05/2021 | isotretinoin = customer services | Fw: ACCUTANE and erectile dysfunction |
| No | 04/05/2021 | isotretinoin = customer services | CSC 48740 - Fw: ACCUTANE and erectile dysfunction |
| No | 10/05/2021 | MHRA customer services | Re: Our Reference: 202122/Q1/01 |
| no | 23/05/2021 | 1 external | Re: EWG meeting , testimony and suggestions |
| No | 27/05/2021 | MHRA customer services | Re: CSC 48683: ACCUTANE and erectile dysfunction |
| No | 27/05/2021 | MHRA customer services | Re: Audio from meeting with June Raine |
| No | 27/05/2021 | MHRA customer services MHRA Complaints | FOI 21/618 - CSC 52420 - Re: complaint isotretinoin |
| No | 04/06/2021 | MHRA customer services | Re: CSC 52837 - Audio |
| * | 05/06/2021 | customer services | Fw: My son's death [GENQ-00136517] |
| * | 07/06/2021 | MHRA customer services | Fw: Isotretinoin |
| * | 07/06/2021 | MHRA customer services | Fw: EWG meeting , testimony and suggestions |
| No | 07/06/2021 | | Isotretinoin |
| * | 07/06/2021 | MHRA customer services | Isotretinoin |
| * | 09/06/2021 | MHRA customer services | Isotretinoin |
| * | 09/06/2021 | MHRA customer services | Request to have Isotretinoin banned for under 18's and greatly restricted for all other patients |
| * | 10/06/2021 | MHRA customer services | British Association of Dermatologists not wishing to engage |
| * | 12/06/2021 | MHRA customer services | CSC 54229 - Isotretinoin, another death, Australia |
| * | 14/06/2021 | MHRA customer services | Isotretinoin |
| * | 15/06/2021 | MHRA customer services | Re: CSC 37083 - RE: Audio from meeting with |

*The status of the latest emails is still to be determined and as requested will be confirmed in those.

However, it is important to note that individual names and the senders details have been redacted for Data Protection when emails and documents have been shared with the IEWG. The links to publicly available information have been provided and are not subject to additional redaction by the MHRA.

The reasons why some your emails have not been shared with the IEWG include:

- Email only included questions directed to the MHRA.
- Email did not include a request or permission for the information to be shared with the IEWG.
- Duplicate emails received by different members of MHRA staff. In these cases, only one version of the email is shared with IEWG.

- Duplicate emails received on different dates. In these cases, only one version of the email is shared with IEWG.
- Email checking on the status of an earlier email submitted by yourself or a third party. In these cases only the original will be shared with the IEWG.
- Email chains which include information from a third party that do not include specific permission for their information to be shared

A separate response regarding the audio recording of the MHRA meeting held on 31 July 2019 and the emails relating to your request to share the audio recording will be sent to you as soon as we have received final advice and clearance from senior management. This has been rather more complex than we first imagined which has caused the delay.

We hope that this answers your request for details of which of your emails have been seen by the Isotretinoin Expert Working Group and which ones have been withheld, with reasons for why these have been withheld.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division