COMMISSION ON HUMAN MEDICINES

ISOTRETINOIN IMPLEMENTATION ADVISORY EXPERT WORKING GROUP

Minutes of the meeting held on 10th March 2023 at 14:00 via videoconference.

Members Present

[redacted]

MHRA Presenters

[redacted]

MHRA Staff

Ms C Blake
Dr A Cave
Ms L Henderson
[redacted]

Invited Expert

[redacted]

Governance

[redacted]

Apologies

[redacted]

[redacted]

1.	**Introductions and announcements**
1.1	The Chair welcomed members and outlined the confidential nature of the proceedings and that the meeting was to be recorded for the purposes of minute taking.
1.2	The Chair reminded members to provide their declarations of interest if they have not already done so, outlined the companies involved, and reminded attendees to declare any relevant interests.
2.	**Presentation on Background and recommendations (MHRA and Chair)**
2.1	Background presentations were made by the: • Chair of the Isotretinoin Implementation Advisory Expert Working Group on Isotretinoin purpose, use and current practice, and introduction to the work of the group. • Chair of the Isotretinoin Expert Working Group on the importance of listening to patients during the review. • MHRA on the recommendations contained in the CHM report on the Isotretinoin Expert Working Group.
3.	**Agree Terms of Reference**
3.1	The Terms of Terms were agreed: To inform the Commission on Human Medicines on: • Pathways and strategies for implementing the recommendations in the Isotretinoin Expert Working Group Report. • Communication and education: the development of communication and educational materials to support and record informed prescribing decisions. • Monitoring compliance: plans for measurement of compliance and impact with the recommendations • Advice and recommendations on future research and a registry

4.	**Discussions and Materials to support implementation**
4.1	**Patient involvement in implementation group, educational materials and acknowledgement form**
4.1.1	The Group discussed patient involvement in the implementation group, educational materials, and acknowledgement form. It was noted patients had been very involved in the Isotretinoin Expert Working Group and that review of any materials developed through the group by patient groups would be critical. The benefit of using both lay patients and expert patients was noted. It was considered that the materials should contain information on the benefits as well as risks of isotretinoin and should be honest about areas where there is little information. It was suggested that patient panels from BAD, BSPAD, Healthtalk and RCPCH could be used.
4.1.2	It was considered that only a single patient on the group would not be representative of the range of patients for whom isotretinoin was prescribed nor would be able to give meaningful input in such a large group.
4.1.3	It was agreed that patients would be involved in developing materials, and that this ideally should include a range of media in addition to text e.g. video. It was highlighted that an electronic resource where all information could be accessed should be developed.
4.2	**2 Prescribers implementation for under 18s**
4.2.1	The Group discussed approaches for implementing the recommendations for 2 prescribers for treatment of patients under 18s. It was noted that this was only required for the first prescription for an individual patient.
4.2.2	The group highlighted the complexity of the current prescribing environment which includes a GP then dermatologist, dermatologist and specialist nurse or pharmacist, private dermatologist. It was stated that best practice should always be mirrored in independent practice. Remote practice was mentioned but needs to be safe and consideration needs to be given on whether it is acceptable or not.
4.2.3	It was discussed whether a GP could be one of the prescribers. The discussion covered that most GPs are not experts on isotretinoin though they do some assessment based on generic knowledge of risk, signpost information and refer. The possibility that a GP proforma could be developed was discussed which could include possible treatments which would include isotretinoin, risks, and information about the patient. This would be sent by the GP and a copy could be sent to the patient.
4.2.4	The purpose of the second prescriber was discussed and whether the second prescribers should not only be making an independent decision on whether isotretinoin was suitable but there as an alternative point of contact. The shared care model of Mental Health and GPs was highlighted as was the Multi-Disciplinary Team (MDT) in tertiary care. It was discussed that any model needs flexibility otherwise access would be restricted. It was considered that there should be a range of possible options and that the second prescriber needs to have expertise with isotretinoin, which would include GPwERs. Nurse specialists would need clear guidance if they were one of the prescribers. A question was raised whether SpRs could be considered independent.

4.2.5	The problem of how to record all decisions on one system was noted. It was stated that Isotretinoin was also used for mild/moderate acne when the patient had body dysmorphia.
4.2.6	It was concluded that 2 people need to agree that isotretinoin is the most appropriate treatment with flexibility in options on who they could be. The preference would be for a MDT approach and would include a mix of dermatology consultants, dermatology SpR (with appropriate competence), GPwER. Dermatology pharmacists, Specialist Nurses, Paediatricians, associate specialist and SAS doctor, GP dermatology champions
4.3	**GPwER prescribing**
4.3.1	The item on GPwER prescribing was not covered though information on this role was shared: Become a GPwER in Dermatology - British Association of Dermatologists (bad.org.uk)
4.4	The group discussed the best way to communicate regarding side effects including sexual function and mental health. The group highlighted the importance of: • Consistency of information • Time for patient to consider • Age-appropriate patient information • Acknowledgement of risk form(s) including 'all potential risks' • Role of GP prior to referral and during treatment
4.4.1	There was a discussion on the best way to counsel patients regarding potential side effects, including sexual function and mental health, and the need for consistency. It was noted that an acknowledgement of risk form was needed and there was further discussion on what the form should contain.
4.4.2	The role of the GP prior to referral was further discussed. It was to signpost, ensuring the referral included relevant points on information sharing about the patient as consultants don't always check the electronic systems. It was thought that most GPs will mention Isotretinoin currently, but this is not always the case.
4.4.3	It was questioned what information is given and by whom should be recorded.
4.4.5	An electronic resource where all information should be developed.
4.4.6	There was a discussion on how to ensure patients understand the information, for example is giving written information sufficient? It was mentioned that when sexual function is being discussed with adolescents they should be asked if they mind discussing the topic and given the option for accompanying parents/carers to step out of the room. It needs careful discussion as members raised the concern they had over the risk of suggestibility.
4.4.7	BAD has information currently in development which could be considered by the group namely patient information, patient information on mental health, decision aid in development (as part of dose research).
4.4.8	The level of detail required in the acknowledgement of risk form was discussed and the need to ensure it did not unduly scare patients especially young patients.

4.4.9	The Group noted it was impractical for patients to sign off every risk. It was agreed that the Acknowledgement of Risk form should be shorter and supported by literature. There needs to be time to read the information and that readability should be high e.g. terms such as teratogenicity should not be used.
4.4.10	It was highlighted that information needs to be used on an ongoing basis to reinforce information on risks through treatment and that patients need to be knowledgeable about their medicine.
4.4.11	It was discussed that if patients received information around the time of referral, then they should be able to be prescribed Isotretinoin on their first consultation.
5.	**Next Steps**
5.1	The following action points were agreed. - The BAD patient information should be checked to determine if it is in line with the recommendations and circulated to the Group for comment. - MHRA to develop Acknowledgement of Risk Form in line with comments - MHRA to check whether the Isotretinoin Expert Working Group needed to be updated about the role of GPwER.
5.2	The Agenda for the next meeting was agreed and should also include an item on clarifying the definition of each of the 2 prescribers including whether SpRs could be considered independent. In addition, the following agenda items were agreed: • Follow up on action points from meeting 1 • Assessment of mental health and sexual dysfunction during treatment -Age-appropriate monitoring tools, frequency and mode of administration • Educational materials for prescribers • Overcoming resistance to change • Monitoring compliance and impact of recommendations • Future research and feasibility of registry
6.	**Any Other Business**
7.	**Date and Time of Next Meeting Friday 31st March 14:00**
	Meeting started at 14:02 ended 17:11

ANNEX 1

COMMISSION ON HUMAN MEDICINES – ISOTRETINOIN IMPLEMENTATION EXPERT WORKING GROUP

INTERESTS DECLARED 2023 – Tabled Paper I

Chairs, Members and Invited Experts adhere to the Code of Practice
Following is the list of declarations submitted by members/experts; evaluation of declared interests and decision taken for the meetings.

Key: NPNS = Non-personal non-specific, NPS = Non-personal specific, PNS= Personal specific, Other relevant interests

Products Interests taken in:	Roaccutane, Reticutan, Rizuderm, Isotretinoin
Companies Interests taken in:	Roche Products Ltd, Generics (UK) Ltd, Mylan, Alliance Pharmaceuticals Ltd, Ennogen Healthcare Ltd, Sun Pharmaceutical Industries Europe BV, Ranbaxy (UK) Limited

Chair	**Interests declared**
[redacted]	None

Members	**Interests declared**
[redacted]	**NPNS** [redacted]
[redacted]	**NPNS** [redacted]

[redacted]	None
[redacted]	None
[redacted]	**NPNS** [redacted]
[redacted]	None
[redacted]	None
[redacted]	None
[redacted]	**NPNS** [redacted]
[redacted]	None
[redacted]	**NPNS** [redacted]
[redacted]	None
[redacted]	**NPNS** [redacted]
[redacted]	**NPNS** [redacted]
[redacted]	None

[redacted] [redacted] **Attended 2nd meeting to cover** [redacted]	**NPNS** [redacted]

Invited Expert	**Interest**
[redacted]	None
[redacted]	None
[redacted]	None
[redacted]	None
[redacted]	**NPNS** [redacted]
[redacted]	**NPNS** [redacted]
[redacted]	None
[redacted]	None
[redacted]	None
[redacted]	None
[redacted]	None

[redacted]	None
[redacted]	None