Membership of the Scottish Government Sodium Valproate Advisory Group as at 11/03/2021

Alison Strath	Interim Chief Pharmaceutical Officer, Scottish Government
John Paul Leach	Consultant Neurologist
Laura McIver	Chief Pharmacist, Healthcare Improvement Scotland
Roch Cantwell	Consultant Perinatal Psychiatrist
Daniel Smith	Professor of Psychiatrist
Alastair Cook	Principal Medical Officer, Scottish Government
Marion Bennie	Chief Pharmacist, Public Health Scotland
Corrine Love	Senior Medical Officer, Scottish Government
Andrew Walker	Lead Clinical Pharmacist Adult Mental Health, NHS GGC
Euan Reid	Lead Pharmacist, NHS Fife
Scott Hill	National Clinical Lead, ADTCC
Scott Mitchell	Director of Pharmacy, NHS Forth Valley
Bruce Guthrie	Professor of General Practice
Richard Davenport	Consultant Neurologist
Juliet Brock	Medical Officer, Mental Health Commission for Scotland

Scottish Government Sodium Valproate Advisory Group
1st July 2019 14.00 – 16.00
Jury's Inn 43 Jeffrey Street Edinburgh EH1 1DH

Minutes

Present
Rose Marie Parr Chair
[redacted]
John Paul Leach
Bruce Guthrie
Daniel Smith
Richard Davenport
Marion Bennie
[redacted]
Juliet Brock
Laura McIver
Scott Hill
Scott Mitchell
Euan Reid
[redacted
Corrine Love
[redacted]

Apologies
Catherine Calderwood
Roch Cantwell
John Mitchell

Item	Description	Responsible and due by
1	**Welcome and Introductions** The Chair welcomed everyone to the first meeting of the Sodium Valproate Advisory Group. Apologies were given by Catherine Calderwood; Roch Cantwell; John Mitchell. She confirmed that the Chief Medical Officer (CMO) was fully committed to the group and will attend a future meeting.	
2	**Introduction from the CMO** The chair provided an overview of the purpose of the group and highlighted that as well as the questions included within the Terms of Reference, the CMO was keen for the group to consider some key questions. These were: • To consider what advice is currently being given to women of child bearing potential receiving Sodium Valproate and how well that advice is being given; • To cover advice for all groups of clinicians prescribing Sodium Valproate; • Ensuring advice is given to all ages of women aged 12 to 50 with support and information being provided to their families where they consent to this; • To consider the possible introduction of shared decision making for some difficult choices regarding a very effective	

	drug for epilepsy but with the known side effects and teratogenicity and fetotoxicity.	
3	**Overview of the Policy Framework and update on the UK position from MHRA** **[redacted]** the Medicines and Healthcare products Regulatory Agency (MHRA) gave an update on the work which is being done at UK level, focusing on the following points: • The effects of the Pregnancy Prevention Plan for Sodium Valproate • The impact current measures are having on prescribing and the decrease which has been seen in Sodium Valproate prescribing trends. • Future MHRA plans in this area, including the proposal for a 'Sodium Valproate Register' and the review of all women on Sodium Valproate. Scott Mitchell provided an update on the work which had been taken forward by NHS Forth Valley to monitor and measure the safety of Sodium Valproate and to invite women of childbearing age taking the medicine for a review which would consider whether to provide counsel or change their medicine. Scott highlighted some of the difficulties which were being faced in their efforts. These included patients being difficult to identify and find, identifying an appropriate age range and also that if patients thought there medicines were going to be changed they would not turn up at the appointment. **Action: [redacted]** to share slides with Scottish Government, for further dissemination within group	**[redacted]**
4	**Contributions and Objectives** Members of the group were invited to give their thoughts on what they thought the drive and purpose of the group should be. Key issues raised were: • the lack of sanction if someone does not engage with reviews. • the group should consider why some patients don't engage with clinicians and review of their medication e.g. the real life outcomes that patients would be concerned with, such as loss of driving licence. • the difficulties for patients with incapacity and the legal framework for such patients. • the use of Sodium Valproate in bi-polar disorder and whether there is an opportunity for the group to explore the potential to phase out usage in this indication as the evidence of effectiveness is not that good.	
5	**Drug Utilisation Study Report – Part A – Update from Information Services Division** **[redacted]** presented an overview of Part A of the Drug Utilisation Study Report.	

	Action: ISD to de-anonymise slides and share with group	ISD
6	**Drug Utilisation Study Report – Part B – Proposal from Information Services Division** **[redacted]**provided the group with ISD's proposals for Part B of the Drug Utilisation Study Report, which will look at co-prescribing of contraception with Sodium Valproate. Comments from the group: • there may be very valid reasons why some Sodium Valproate patients are not on contraception, and that it would be worth investigating these further by looking at a group of patients and why they are not on contraception. • the group should perhaps have a wider remit to look at the risks of all anti-epileptic drugs in pregnancy. **[redacted]** confirmed that the MHRA are looking at this and agreed to circulate a paper which had gone to the Commission on Human Medicines. • there is a need to look at how Scotland as a whole responds to regulatory warnings, and that this shouldn't be left to individual NHS Boards. • specialist nurses have been conducting treatment reviews in NHS Forth Valley, and Scott Hill queried what the current guidance said about this. **[redacted]** agreed to share the guidance with the group. • Whether the remit of the group could be extended to include the consideration of the effects of paternal exposure to Sodium Valproate for offspring. **Action**: ISD to present on Part B of Drug Utilisation Study Report at next meeting **Action: [redacted]** to share paper which had gone to Commission on Human Medicines covering risk across all Anti-Epileptic Drugs **Action: [redacted]** to share guidance on specialist nurses with group	ISD **[redacted]** **[redacted]**
7	**Terms of Reference** Comments were invited on the content: • it was proposed that some charities should be invited to be members of the group, specifically Epilepsy Scotland and Epilepsy Connections, Bi-Polar Scotland. It was agreed to consider this. • Important to align the National Therapeutic Indicators and the work of the group, as well as linking with the development and roll out of SPIRE. The chair asked Bruce Guthrie to prepare a paper for the next meeting of the group covering this point	

	• Consideration should be given to sub-groups to take forward specific areas of work. • Consideration should be given to the possibility of a separate Scottish version of the 'annual risk acknowledgement form', in electronic format. Scottish Government agreed to look at this. **Action:** Bruce Guthrie to draft a paper for consideration at next meeting regarding the group's ability to use NTI and SPIRE **Action:** Scottish Government to look into possibility of creating Scottish version of 'annual risk acknowledgement form' in electronic format. **Action:** Scottish Government to consider whether patient representative groups (e.g. Epilepsy Scotland, Epilepsy Connections and Bi Polar Scotland) should be included in the group	Bruce Guthrie Scottish Government Scottish Government
8	**Date of Next Meeting** The next meeting of the group would be on 10th December 2019 between 2pm and 4pm at St. Andrew House, Edinburgh.	
9	**AOB** John Paul Leach highlighted a study which has been conducted in Scandinavia looking at the usage of all anti-epileptic drugs during pregnancy, and suggested that this would be of interest to the group. **Action:** John Paul Leach to share paper with group for interest.	John Paul Leach

Scottish Government Sodium Valproate Advisory Group
27th January 2020 14.00 – 16.00
Community Pharmacy Scotland, 43 Queen Street, Edinburgh, EH2 3NH

Minutes

Present
Rose Marie Parr Chair
[redacted]
John Paul Leach
Bruce Guthrie
Daniel Smith
Marion Bennie
[redacted]
[redacted]
[redacted]
Juliet Brock
Laura McIver
Scott Mitchell
[redacted]
[redacted]

Apologies
Catherine Calderwood
Roch Cantwell
John Mitchell
Scott Hill
Richard Davenport
Euan Reid
Corrine Love
[redacted]

Item	Description	Responsible and due by
1	**Welcome and Introductions** The Chair welcomed everyone to the second meeting of the Scottish Government Sodium Valproate Advisory Group. Apologies were given by Catherine Calderwood; Roch Cantwell; John Mitchell; Scott Hill; Richard Davenport; Euan Reid; Corrine Love **[redacted]**	
2	**Measuring and monitoring of safety: Review of Sodium Valproate Prescribing (Presentation)** **[redacted]** gave an overview of the work that has been done in NHS Forth Valley to ensure that care was taken when prescribing Sodium Valproate. It was noted the data did not include patients on contraception. Laura agreed to get the figures of those who are on contraception. ***Action:*** **[redacted]** to provide figures on patients who are on contraception.	
3	**Update on Area Drugs and Therapeutics Committee Collaborative (ADTCC)/HIS work on the risk of taking Sodium Valproate during pregnancy** Laura McIver provided an update on the work which HIS, through the ADTCC, have been doing on the risk of taking Sodium Valproate during pregnancy. In particular, it was noted that there was a proposal to Scottish Patient Safety Programme (SPSP) to	

	ensure compliance with MHRA guidelines, but that there had been no response yet. It was agreed that this paper would be circulated within the group. Laura agreed to act as confidante between the Sodium Valproate Advisory Group and ADTCC. Daniel Smith noted that there is not much data on the prescribing of Sodium Valproate in bipolar disorder, and queried whether HIS could do some work around this. It was agreed that Daniel Smith would meet with Laura McIver to discuss this further, and that Daniel Smith would share a CSO grant application on this with the group for information. ***Action:*** *Laura McIver to share SPSP proposal with group.* ***Action****: Daniel Smith and Laura McIver to meet to discuss possible HIS work relating to bipolar disorder and Sodium Valproate.* ***Action:*** *Daniel Smith to share CSO grant application with group.*	Laura McIver Daniel Smith & Laura McIver Daniel Smith
4	**Drug Utilisation Study Report – update from Information Services Division** ISD presented on the paper tabled for discussion. It was confirmed ISD will soon receive termination data, which will allow a fuller picture to be given. It was highlighted ISD will be sensitive to what data is collected and how this data was used. It was clarified that methodological differences account for the differences which exist between the Scottish data and the UK data. It was agreed that ISD would discuss these differences with the MHRA. ***Action****: ISD to discuss methodology with MHRA*	ISD
5	**The ability to align work with National Therapeutic Indicator, and the possible usage of SPIRE (paper 02/04)** Bruce Guthrie presented on the paper tabled for discussion, in particular that: • The National Therapeutic Indicator (NTI) for Sodium Valproate isn't a reliable measurement and is poorly designed. It was agreed that ISD and Bruce Guthrie would work with the NTI team to redesign and refresh the data. ***Action:*** *Bruce Guthrie and ISD to work with the NTI team on the Sodium Valproate NTI.*	Bruce Guthrie & ISD
6	**Work plan (paper 02/02 & paper 02/03 for decision)**	

	[redacted] gave an overview of the proposed work plan (paper 02/02). Members agreed the work plan subject to the amendment to make it action focused. ***Action:*** SG agreed to update the work plan and re circulate to the group.	Scottish Government
7	**Terms of Reference** The terms of reference were agreed, subject to the removal of the words “very effective” in the first sentence. ***Action****: SG to update terms of reference.*	Scottish Government
8	**Date of Next Meeting** It was confirmed the next meeting will be held in July 2020 following the Independent Medicines and Medical Devices Safety Review.	
9	**AOB** It was agreed ISD would stratify the data presented by age of the pregnancy. Marion Bennie confirmed that ISD had been invited to observe a meeting around the creation of a “Sodium Valproate registry” in England and Wales, and that she would report back to the group. ***Action:*** *ISD to stratify data by age and update the group on the Sodium Valproate registry.*	ISD

Scottish Government Sodium Valproate Advisory Group
17th August 2020 14.00 – 16.00
Virtual via Microsoft Teams

Minutes

Present

Rose Marie Parr Chair
[redacted]
[redacted]
[redacted]
Juliet Brock
Daniel Smith
John Paul Leach
Euan Reid
[redacted]
[redacted]
Marion Bennie
[redacted]
Andrew Walker
[redacted]
Roch Cantwell
Bruce Guthrie
[redacted]
[redacted]

Apologies

Scott Hill
Laura McIver
[redacted]
Richard Davenport
Scott Mitchell
Corinne Love
Alasdair Cook

Item	Description	Responsible and due by
1	**Welcome and Introductions** The Chair welcomed everyone to the third meeting of the Scottish Government Sodium Valproate Advisory Group. Apologies were given for: Scott Hill; Laura McIver; **[redacted]**; Richard Davenport; Scott Mitchell; Corinne Love; Alasdair Cook	
2	**Recap of Position** **[redacted]**gave an update of figures from NHS Forth Valley and agreed to send these on to the group. Daniel Smith gave an update and confirmed that work had not progressed due to Covid-19. Marion Bennie suggested that it may be beneficial to look at Congenital Anomalies and Rare Diseases Registration and Information Service for Scotland (CARDRISS) for collaboration ***Action***: **[redacted]** *to share figures from NHS Forth Valley with wider group*	**[redacted]**
3	**Update from Public Health Scotland**	

	[redacted] and Marion Bennie gave an update on the Valproate use data which showed that: • Valproate use is going down across all age groups • Pregnancy exposure to valproate is also going down John Paul Leach added some valproate exposed pregnancies will be informed and intentional, and this is out with the scope of the group. Bruce Guthrie noted there could be potential harm to older patients if they are taken off Sodium Valproate when they are not of child bearing potential.	
4	**Review of the IMMDS Review's 9 recommendations on Scottish specific level – for discussion** The CPO gave an overview of the 9 recommendations of the Cumberlege Review. The CPO confirmed that there would be a debate in the Scottish Parliament on the Review in Autumn. It was agreed that there was a lack of Scottish engagement with the MHRA, and that it was important that Scottish clinicians are involved in any regulatory work of the MHRA. Bruce Guthrie noted the actions for improvement within the report are as important as the overarching recommendations. It was also agreed the issue was wider than simply sodium valproate or anti-epileptic drugs, and there is a need to look at prescribing for pregnant people generally. Concerns were also raised on the usage of Sodium Valproate out with epilepsy. Daniel Smith confirmed that the psychiatry community were clear Sodium Valproate should not be prescribed for people of childbearing potential for bi-polar disorder. It was suggested data from one quarter of initiations on sodium valproate is needed in order to work out where prescriptions are coming from and why. PHS agreed to look into this. ***Action**: Scottish Government to engage with MHRA on the issue of Scottish involvement* ***Action**: PHS to look into one quarter of prescribing data*	Scottish Government Public Health Scotland
5	**Next Steps** The CPO confirmed that the group would continue, and the Scottish Government would think about who should potentially be added to the group going forward.	

	Action: *Scottish Government to consider membership of group*	Scottish Government
6	**AOB** The CPO confirmed there would be another meeting of the group towards December, avoiding Monday's as this day was problematic for some members. It was confirmed PHS will complete the work commissioned by Scottish Government by the end of 2020. It was agreed the Scottish Government and Public Health Scotland would work together to bring forward a proposal for the next meeting. ***Action:*** *Scottish Government to arrange future meeting* ***Action:*** *Scottish Government to work with PHS on proposal for next meeting.*	 Scottish Government Scottish Government & Public Health Scotland

Scottish Government Sodium Valproate Advisory Group
10th December 2020, 11.00-13.00
Virtual via Microsoft Teams

Minutes

Present: Alison Strath **(**Chair)**, [redacted]** John Paul Leach, **[redacted]**Laura McIver, Roch Cantwell, Daniel Smith, Alastair Cook, **[redacted]**, Marion Bennie, **[redacted]** Corrine Love, Andrew Walker, Euan Reid

Apologies: Scott Hill, Scott Mitchell, **[redacted]** Bruce Guthrie, Richard Davenport

Item	Description	Responsible and due by
1	**Welcome and Introduction** The Chair welcomed everyone to the fourth meeting of the Scottish Government Sodium Valproate Advisory Group. Apologies were given for: Scott Hill; Richard Davenport; Scott Mitchell; **[redacted]**; Bruce Guthrie *Action: Scottish Government to update minute of third meeting in relation to the action for PHS on prescribing data*	Scottish Government
2	**IMMDSR recommendations – update from SG** Alison Strath, Interim Chief Pharmaceutical Officer (CPO), gave an update on the work of the Scottish Government in relation to the Independent Medicines and Medical Devices Safety Review (IMMDSR), in particular around meetings with patient groups and specialist centres. It was agreed that there needs to be pace and traction around this work.	
3	**Drug Utilisation Study Report (Data)** Marion Bennie gave a presentation to the group based on the report she had produced. The executive summary in the report shows the trend for sodium valproate exposure over time and that the overall trends are moving in the right direction with exposure rates falling. **[redacted]** It was noted that access to datasets for teratogenic medicines are limited. There was some discussion about inviting a GP colleague onto the group.	
4	**Epilepsy Register** **[redacted]** gave a presentation on the development of the epilepsy register.	

	Andrew Walker confirmed that there had been an audit of mental health services in NHS Greater Glasgow and Clyde, and that they were looking to create something similar to the epilepsy register. It was agreed that Andrew Walker and **[redacted]** would pick this up off-line to discuss further. It was agreed that there was a need to be more ambitious by broadening the focus from sodium valproate to include other anti-epileptic medicines and other teratogenic medicines. The work of this group will be key to meeting our commitments to the IMMDSR. It was discussed how it would be helpful to know the diagnosis associated with people being prescribed Sodium Valproate, and that we need to establish a wider 'surveillance' system for medicine safety.	
5	**Next Steps** It was agreed that the: a) Scottish Government would develop a work plan around teratogenic medicines b) terms of reference for the Sodium Valproate Advisory group would be revised and that a revised draft would be shared with the group prior to the next meeting. *Action: Scottish Government to share work plan around teratogenic medicines and revised terms of reference with the group*	Scottish Government
6	**Date of next meeting, frequency and future membership** It was agreed that Scottish Government would explore whether other policy areas and further general practice representation should be incorporated into the group. The group also agreed the need to ensure that the work of the group is transparent for patient groups to access. It was also agreed that there would be another meeting of the group in early 2021. *Action: Scottish Government consider broadening membership of group* *Action: Scottish Government to set up a fifth meeting of group*	Scottish Government Scottish Government
7	**AOB** No other business was raised.	