Reference: FOI.ICB-2627/054

Subject: Sodium Valproate

I can confirm that the ICB does hold the information requested; please see responses below:

QUESTION	RESPONSE
Please also apply this to any information held by your ICB following the ICB restructuring on April 1st 2026.	
1. Please provide a copy of the Action and Improvement Plan produced pursuant to Action 2 of the NatPSA by the 31 January 2024 deadline, or the nearest equivalent document your organisation holds.	BNSSG system wide action and improvement plan as per 30.1.24 – enclosed.
2. Please provide any entry or entries on your corporate risk register relating to valproate-containing medicines (including those recorded as sodium valproate, valproic acid, valproate semisodium, Epilim, or Depakote), added or active at any point between 1 October 2023 and the date of this request. For each entry, please provide the risk title and description, date first added, inherent and residual risk scores, recorded controls and mitigating actions, and current status, if closed, the date of closure and reason recorded. If no such entry exists or has existed in this period, please confirm this in your response.	Risk MO37 was added to BNSSG risk register in April 2023 but closed in July 2024. This was replaced with risk MO46 to include other teratogenic medications e.g. topiramate, in July 2024 and closed in February 2025. See extracts from risk register enclosed.
3. Please provide copies of any papers, reports or minutes from your Medicines Optimisation Committee or equivalent, or any sub-group or working group established to co-ordinate valproate safety, concerning	Minutes from the BNSSG Valproate Safety Working Group (which became the BNSSG CNS Teratogenic Medicines Safety Working Group) between October 2023 to March 2026 are enclosed (Docs 01-11)

valproate prescribing or patient outcomes, to address cost concerns you can simplify by identifying documents by keyword searches for “valproate”, “VPA”, “Epilim” and “valproic acid” from October 2023 to March 2026.	The BNSSG CNS Teratogenic medicines Safety Working Group reports into the BNSSG ICS Medicines Quality and Safety Group and so these minutes are shared with the Medicines Quality and Safety Group for information. There is reference to the Area Prescribing Medicines Optimisation Committee (APMOC) meeting within the risk register extract provided as part of question 2. Minutes from the meetings held in February, August and December 2024 are enclosed (Docs 12-14). NPSA alert was shared with the ICS Medicines Quality and Safety Group in January 2024 meeting (Doc 15) and update given in August 2024 (Doc 16). Please note that FOI requests and responses are publicly available and therefore personal information has been redacted. The ICB considers the names included in the enclosed document(s) to be personal information and therefore has applied a section 40 (Personal Information) exemption to this information.

The information provided in this response is accurate as of 1 June 2026 and has been approved for release by Dr Aananthakrishnan Raghuram, Chief Clinical Leadership and Delivery Officer (Medical) for NHS Bristol, North Somerset and South Gloucestershire ICB.

NPSA Alert Action and Improvement plan

** Please note where the term valproate is used this refers to sodium valproate, valproic acid and valproate semi-sodium (valproate)*

Overview

NPSA Actions https://assets.publishing.service.gov.uk/media/6565ddf162180b0012ce82fd/NatPSA-2023-013-MHRA.pdf)	Target Date	Date Completed	Current position - December 2023	Outstanding action	Progress update	
Designate a new or existing group to co-ordinate the implementation of the new regulatory measures in providers, with oversight from a senior quality group. This group should include (but is not restricted to): a. An appointed chair with delegated responsibility for the actions in this alert. b. Representation from clinical leads in all the specialities named above and any other relevant departments. c. A mechanism by which the group can involve and be informed by patients with lived experience.	31.1.2024	Complete - group in place	BNSSG ICS Valproate safety working group was established in June 2022. Roles and reponsibilities of the group members include: reviewing system pathways to ensure improvements as needed with clinical engagement from the group, better governance and better outcomes for valproate patients in BNSSG; action national valproate safety alerts and review any local issues or patient safety events (e.g., Datix) for shared learning. Meeting minutes feed into BNSSG ICS Medicines, Quality and Safety Group. Also reports/updates from the group are shared with groups including ICB Quality group, provider safety groups and ICB medicines optimisation programme board.	To review TOR with group to ensure still current.	30.1.24- Group meetings ongoing. TOR updated and reviewed at meeting, to be finalised in April 24 meeting.	
An appointed chair for this group with delegated responsibility for the actions in this alert	31.1.2024	Complete - chair in place	ICB Principal Medicines Optimsation Pharmacist to chair the meetings who will link with the Director of Pharmacy and Medical Director who sit on the ICB Executive committee	N/A	N/A	
Appoint ICB Executive Lead	31.1.2024	Complete	ICB Medical Director, will be executive lead supported by Chief Pharmacist BNSSG ICB	N/A	N/A	
Group to have representation from clinical leads in all the specialities named above and any other relevant departments	31.1.2024	In progress -key clinical leads part of group	As well as ICB representation, the group has representation from NBT (Neurology), AWP (Psychiatry/Learning disabilities/Autism), UHBW(Paediatrics), Sirona(community services), GP and Community Pharmacy Avon	To review groups link with contraception and sexual health team at next meeting. To ensure a Sirona representative and GP are invited following staff changes	Unity sexual health emailed re group and awating feedback. GP and Sirona invited. 30.1.24 - To investigate if a consultant/nurse in psychiatry is able to attend.	
A mechanism by which the group can involve and be informed by patients with lived experience	31.1.2024	A mechanism is in place but to review going forward.	Group can invite members of or email Health Watch for patient experience representation/input. Also previous patient survey was undertaken via GP practice links plus patient links also via secondary care trusts patient contacts.	Although links in place, need to review how and when this is used going forward.	30.1.24 Mechanism in place but to monitor as input needed.	
The group should be tasked with, and document, progress towards:						
a. Updating all local guidance and protocols relating to prescribing of valproate to reflect the new regulatory position, including definitions of the roles and responsibilities of clinicians and provider organisations, and the recording of compliance with the risk forms	Plan in relation to updating the guidelines in place by 31.1.2024. Individual guidelines to be updated but sign off linked to relevant governance committee dates. See detailed plan.	Ongoing	AWP and UHBW have Valproate Procedure in place and NBT plan to develop. ICS Aide Memoire was drafted prior to MHRA changes. Valproate safety information also available on the BNSSG Formulary website. Providers to update their local SOPs and group to update Aide Memoire once local processes confirmed following any changes. Formulary Valproate TLS status to be updated and Valproate Shared Care Protocols to be updated.	All guidance to be updated in line with new MHRA recommendations	30.1.24 - All SOPs being updated by providers and Aide memoire being reviewed and updated. Updated shared care protocol drafted. Once updated sign off via relevant governance committees.	
b. Commissioning work if necessary to understand the needs of the affected population, including those people most at risk of health inequalities.	To be scoped following provider feedback intially	Ongoing	Have some prescribing data and information from previous valproate audits but need to review in relation to health inequalities	To review population data to understand local valproate population better. BI have been contacted for some data - await data. Requires practices to agree with the data sharing.	30.1.24 - Awaiting the primary care data sharing agreements to be signed.	
c. Reviewing the results of local audit(s) of compliance with the existing PPP measures for girls and women of childbearing potential prescribed valproate.	Review of previous audit findings by 31.1.2024	Previous audit work has been reviewed. To consider future ongoing audits.	Audits have previously been undertaken in primary care 2016- 2022, so we are aware of the local issues and compliance with the Pregnancy Prevention Programme (PPP). However, going forward it would be important to reflect on previous audits and to consider re-audit to assess compliance with existing PPP measures for women and girls prescribed valproate	To consider re-audit in 2024/25	30.1.24 Previous audit data and learnings has been shared	
d. Commissioning/determining the local pathways of care for women of childbearing potential and girls in relation to the prescribing and review of valproate.	Providers to scope current pathways by 31.1.2024 and feedback issues	Ongoing	Current pathways known but providers reviewing pathways for inclusion of second specialist check/recommendations as per MHRA new guidance.	To be considered following local pathway review	30.1.24 Plan for 2 clinician reviews in place with all providers, some practicalities being worked through.	
e. Planning for and identification of clinical resource to meet the identified needs of the population and implement the new regulatory measures.	Providers to review current resource by 31.1.2024	Ongoing	Providers currently reviewing pathways in line with NPSA alert	15.1.24 NBT have put an MDT process in place for epilepsy patients, AWP and UHB reviewing pathways.	30.1.24 Plan for 2 clinician reviews in place with all providers, some practicalities being worked through.	

Detailed action plan

** Please note where the term valproate is used this refers to sodium valproate, valproic acid and valproate semi-sodium (valproate)*

Action Needed	Completed by	Target Date	Date Completed	Comments
Phase 1 - the initial phase of implementation of the new regulatory position will apply to all patients under 55 years newly starting valproate and the prevalent female population (girls and women of childbearing potential).				
Share NPSA alert with secondary care provider safety leads and primary care. Secondary care to disseminate to relevant parties. All providers to read and understand requirements of NPSA Nov 2023 alert. (Note - alert doesnt cover emergency situations where valproate is required)	All	01-Dec-23	28.11.23	Alert sent to ICB MOPs, Embedded practice pharmacists, PCN pharmacists and pharmacy technicians, MO team, Prescribing Leads. Alert sent directly to community pharmacies via NPSA alert cascade. Also sent to NBT Neurology Consultant, Neurology Pharmacist NBT and Clinical Lead Pharmacist Secure & CAMHS and Lead Pharmacist for Education and Training AWP on 28/11/2023
Share NPSA alert detail with BNSSG APMOC (Area Prescribing Committee)	ICB	07/12/2023	07/12/2023	Alert presented at APMOC on 07/12/2023
BNSSG ICS Valproate Safety Working Group to be set up	ICB	31-Jan-24	Complete group in place since June 2022	Group meets 2 monthly
Consider membership of ICS Valproate Safety Working Group and consider additional representation as appropriate	ICS Valproate Safety Working Group	31-Jan-24	Group has included key speciality representatives since set up in June 2022	To review the group links with contraception and sexual health teams at next meeting in Jan 24. Unity have been contacted regarding group. To ensure a Sirona representative and GP are invited following staff changes. Investigating a consultant/nurse psychiatrist to attend the meeting.
Review TOR for the group to ensure fit for purpose and reflects the NPSA alert	ICS Valproate safety working group	16-Apr-24	in progress	TOR reviewed at meeting on 30.1.24, final comments then to be signed off at April meeting.
Ensure group knows can access patient views via Health Watch as well as via direct patient contacts.	ICS Valproate safety working group	31-Jan-24	Previous patient survey conducted to understand the barriers to patients signing and returning their ARAF form to specialist teams 8 responses, 62% had an annual review with a specialist, 37.5% (3) received an ARAF . Of the 3 people who received the form – 1 received by post, 1 in person, 1 by email. All 3 patients were able to understand the ARAF form and reported to have returned the form. Healthwatch can be used to seek patient views but need to review how well this works and when input needed.	Highlighted at meeting on 30.1.24. Although Health watch know about, need to consider how best this is used.
Primary care initial data collection and evaluation to be completed to ascertain current valproate patient numbers (male and female < 55 years) per practice and indications the drug is prescribed.	ICB	31-Jan-24	Initial data collected	30.1.24 - Initial data collection undertaken. Identified large numbers of male patients on valproate (1050) and 295 females. Most common indication was epilpsy. Small numbers of children under 13 yrs prescribed valproate mainly for epilpsy. Await inequalities related data from ICB BI team once data sharing agreements signed off - see below.
In line with NPSA Alert all providers to consider local health inequalities in relation to valproate	Providers	31/02/2024	in progress	ICS has contacted the PHM team to obtain system level data. Aggregate ICB level data from system wide data system requires practice opt-out. PHM team are currently working through a generic opt-out that would allow us to use language and LD generically. Await consent and then data. 30.1.24 - awaiting data sharing agreement sign off
All providers to map their *current* valproate policies/pathways	Providers	31-Jan-24	Complete providers have have reviewed their current pathways (pre alert)	**UHBW** (Paediatrics) -Specialist Childrens Team manage their own valproate patients – clinicians are aware of national guidance however due to their age patients are not always eligible for Pregnancy Prevention Programme (PPP). **NBT** (Neurology) - Specialist teams (specialist nurse or consultant) book patients in for appointments and undertake reviews. Consultant secretaries support the initial follow up of non-attenders and return of ARAF forms. **AWP(mental health and LD)** -AWP have developed a new electronic editable ARAF form on RiO system at AWP (which mirrors the MHRA ARAF form wording). The editable ARAF form then pulls review due dates on to a ReportZone dashboard on the AWP intranet page. Teams are tasked with checking this dashboard to see when annual reviews are due. Relevant team reviews their patients. Patients not currently under AWP will need to be referred for review, those under AWP will be recalled for review.
All providers to review current pathways and changes needed to implement new NPSA guidance	Providers	31-Jan-24	in progress and now putting into action	30.1.24 - All have reviewed 2 prescriber review process and shared updated risk forms. **AWP** have set up a valproate working group to review alert and review processes. Valproate is moving to a "restricted category" of medications which means clinicians are required to complete an extra form on initiation. Approx 90% of female patients are now on the AWP dashboard showing when they're due for their review which is positive to monitor patients. Second specialist signature has been agreed to be set at a consultant level and they can ask other consultants in the teams, or they can go to different teams or different localities to get this sign off. AWP SOP being updated and then signed off and plan to adopt the BNSSG original pack risk assessment form. Also, AWP valproate webpage to be updated. **UHBW** MSO is liaising with relevant clinicians who review paediatric valproate patients. This involves coordinating a meeting with UHBW prescribers to iron out our internal processes and also prescribers for off label indications. Paediatric formulary status being reviewed. Developing a spreadsheet which will be used as a valproate register so that the team have a list of all of the patients, whether the patients have had an annual risk at knowledgement form with one signature or two signatures. An internal SOP is also being drafted to highlight which forms need to be completed etc to staff **NBT** have put an MDT approach in place to address the second signature recommendation. This will include consultants and specialist nurses. The MDT plan to meet every two weeks, and these cases will be discussed at the meeting. This will cover new patients and existing women of child bearing potential.
Providers to review staff capacity for implementing phase 1 where 2 specialists are required to review any new valproate patients. Which staff will be second signatures? Will this be via an MDT review or other?	Providers	31-Jan-24	Plans in place as above and now putting into action	As above
Following review of local processes, process for all patients under 55 years due to start valproate medicines will have 2 specialists reviewing medication options	Providers	31-Jan-24	Plans in place for 2 specialists	As above
Providers to update local SOPs	Providers	Plan in place by 31/01/2024, then to be signed off via local governance processes once suitable input	in progress	SOPs in processes of being updated .
Once new ARAF forms and educational materials have been issued nationally, ICB to share with all relevant prescribers for use in reviews. AWP to update their digital form with the new ARAFs once available.	Providers	31-Jan-24	New ARAF and RAF forms have been shared - complete. AWP digitial system - in progress - is being updated but have a plan to use paper forms in interim until digital system updated.	30.1.24 - New forms shared and will be used from 31.1.24. However AWP will need to use paper forms initially until their digitial form can be edited which may take time to be edited.
To update Valproate Aide memoire (which includes pathway overview) and appropriate governance route. Ensure the referral pathways are up to date.	ICS Valproate Safety working group	16-Apr-24	in progress	30.1.24 - Document being updated
Ensure patient information leaflets re valproate in easy read and mulitple languages are accessible	ICB/AWP	31-Jan-24	complete	
Highlight readcodes and Ardens template to primary care to help ensure a consistent approach to coding and allow better review of data. Remind primary care to keep a local registry of patients.	ICB	16-Apr-24	in progress - linked to aide memoire document	Will need to add to Aide Memoire and newsletter article
Investigate the Eclipse valproate module	ICB	31-Jan-24	Complete	30.1.24 Some eclipse data already available, and may be useful to review perioidically. Practices can access to review their data

To re-review valproate audit data and findings and ensure learning is taken forward	Valproate working group	31-Jan-24	Complete, previous audit results have been shared with the group	Audits done in 2020 and 2021. Findings have previously been shared with the group. To consider the potential for future audits
Ensure clear communications between sectors following review of these new patients	all	31-Mar-24	in progress	
Update the BNSSG formulary to reflect the consistent Amber 3 month TLS status of valproate for all indications and the move for migraine indication to a non-formulary status. AWP to ensure their medicines formulary aligns and reflects the NPSA alert recommendations	formulary team/AWP	31/02/2024	in progress	Status agreed at formulary meeting subject to shared care protocol being updated. BNSSG Shared care protocol agreed at February meeting. Minor tweaks and then will be uploaded to formulary website and TLS updated.
Update the BNSSG valproate shared care protocol	formulary team	31/02/2024	in progress	In progress, drafted and due specialist comments before sign off at formulary meeting on 6th February 2024 - Shared care protocol agreed at February meeting. Minor tweaks and then will be uploaded to formulary website and TLS updated.
Need to consider referral pathway for people not curently under a trust clinician - out of area patients, patients from abroad eg refugees	Valproate working group	16-Apr-24	in progress	to be discussed at valproate safety working group - eg women of child bearing age from abroad with no ARAF or clear notes may need to be reviewed as a new patient as it will be unclear what checks have been put in place.
Develop an original pack valproate dispensing risk assessment form to support the new legislation	ICB	To be signed off at next APMOC 1/2/24	in progress	Risk assessment form drafted and agreed by AWP, NBT, UHBW and comments included from Sirona. Plan to take for sign off at next APMOC. It should be noted that community pharmacy may not use the form as may use their company form or record directly onto the patient's pharmacy record.
Consider patient communications - individual discussions re risks. Also whether anything needed wider?	Valproate working group	31/04/2024	to do	
Consider any additional training needed for clinicians?	Valproate working group	31/04/2024	to do	
Monitor numbers of patients on valproate	Valproate working group	ongoing	being reviewed on a regular basis	
Monitor any incident reported to evaluate how the changes are being implemented	Valproate working group	ongoing	being reviewed on a regular basis	
Phase 2 -for girls and women already taking valproate the two-specialist system should be implemented at their next routine review.				
Edit current process and implement the 2 specialist check for women and girls currently on valproate at next review	Providers	31-Jan-24	Providers have a process in place for annual reviews	30.1.24 - Providers have plans in place and are editing SOPs to highlight the changes
Communicate review process to primary care once pathway confirmed	ICB	16-Apr-24	in progress	30.1.24 - Information shared re NPSA alert with primary care but once aide memoire agreed this is to be shared with primary care so all will be aware of roles and responsibilities.
Investigate current wait times for the local services so can give primary care/ patients an estimate of when annual ARAFs will be completed.	ICB/Providers	31-Jan-24	complete	30.1.24 - approx 6 weeks wait for epilepsy referral for new patients
Re-audit compliance with the existing PPP measures for girls and women of childbearing potential prescribed valproate.	ICB/Primary ca	Plan for project in PQS 24/25(April 24 - March 25)	to do	
Phase 3 - for men currently taking valproate the requirement for the two-specialist review will begin in the subsequent phase of implementation, which will take into account advice from healthcare professionals and patients developed in light of experience with the initial phase.				
To await national guidance regarding implementation	Valproate working group	TBC	to do	
Need to consider men taking valproate not currently in the system: 1. how we identify them, 2. is there capacity to see them	Valproate working group	TBC	to do	
Need to use the new national resources to support patients regarding the risks vs benefits once available	Valproate working group	TBC	to do	

Risks and Issues log

Date	Risk/Issue	Commentary
Dec-23	Patients may not engage - may not attend review appointments or return ARAF forms	AWP - send an electronic copy of the ARAF form to primary care so they are aware of the review in case patients doesn't return ARAF
Dec-23	No easy national digital solution (yet) for signing and returning of ARAF forms to all providers. Also, no local comprehensive system wide transfer of information	
Dec-23	Decision and communication of whether a patient has a permanent absence of risk in relation to pregnancy. This would include situations where patient has a changing level of capacity.	
Dec-23	Capacity to undertake the 2 specialist independent review process in male and females under 55yrs who are prescribed valproate	
Dec-23	Identification of exisiting male patients may prove complex, as many will not be under specialist care currently	
Jan-24	NBT have been experiencing recruitment issues to their epilespy specialist nurse post	

Workforce

Extract from risk register re valproate risks

Risk register enteries

Risk ICB/ System or Both	CMO / CNO	Ref CRR	Risk Description If (cause) then (risk event) resulting in (effect/impact)	Principle Objective ref	Date entered on register	Risk Lead (exec)	Risk Owner	Unmitigated likelihood	Unmitigated impact	Unmitigated risk score risk rating
SYSTEM	CMO	MO37	There is a risk associated with the MHRA Safety Alert for Sodium Valproate, which continues if it is not fully implemented despite ongoing work. Valproate is highly teratogenic and evidence supports that use in pregnancy can leads to physical birth defects and neurodevelopmental disorders.		Apr-23	CMO	Chief Pharmacist	3	4	12
Both	CMO	MO46	Due to the additional work required, there is a risk in relation to the BNSSG ICS's ability to implement and respond to national pregnancy prevention safety alerts . Valproate and topiramate NPSA have been issued but more may follow. As these medications are teratogenic if safety recommendationsare not followed this could potentially put patients at risk.		23.07.24	CMO	Chief Pharmacist	4	4	16

Management actions already in place to mitigate risk (current controls)	Current likelihood	Current impact	Current risk rating	Target risk score	Movement of current risk score	Oversight Committee
● Valproate working group in place ●Overall numbers of patients prescribed valproate has reduced since the initial alert was published ●GP Practices review patients on a regular basis to check for ARAF/PPP in place ●AWP have developed a new electronic patient database to ensure clear records of patients on valproate ●In May 2023, national decision support tools in relation to valproates use in epilepsy and bipolar disease were issued by NHS England. ●AWP's new valproate database in place and staff introducing to clinical teams. Need to monitor benefits and consider other providers in relation to a system wide database to support call and recall patients for their annual specialist reviews. virtual valproate reviews more streamlined. ●NHSE Valproate Decision Support Tools shared and being trialled by providers ●Sept 2023: MHRA published Full pack dispensing of valproate-containing medicines. This is guidance for dispensing of valproate-containing medicines in the manufacturer's original full pack, following amendments to the Human Medicines Regulations (HMRs).This will help ensure all patients receive the patient information leaflet as part of the Pregnancy Prevention Programme to help address concerns. ●NBT /UHBW/AWP have a valproate policy for staff in place. ●Multilingual leaflets in place ●Action and improvement plan drafted and updated following Jan Valproate Group meeting with detail of what providers are doing to meet the new requirements for valproate. To continue to be updated. ICS valproate risk assessment form signed off at APMOC and available for use/adapting by providers but need to develop a process to share information across the system. TOR updated. TLS status and SCP for valproate updated to Amber 3 months System valproate pathway due to be presented at August APMOC and safety reminder included in the BNSSG Safety Dashboard. Data reconciliation exercise undertaken so NBT and the Bristol Children's hosptial can review their patient lists.	2	4	8	1x4=4	↔	Medicines quality and Safety Group
ICS sytem safety group in place for valproate which now include topiramate going forward. Safety recommendations from alerts have been shared National resources and guidance has been issued from the MHRA BNSSG Valproate and topiramate resources approved at APMOC and added to the BNSSG Remedy page. These resources have been highlighted in the MO newsletter. The TLS of topiramate has been reviewed by the joint formulary and for adults with epilepsy this is now an amber initiated status.	2	4	8	2x4=8	↓	Medicines quality and Safety Group

Actions to be taken(as these are completed they should be moved to actions in place)	Comment on progress	will ICB action alone mitigate risk	Risk appetite	Risk open/closed	target date for completion	last reviewed	Other Directorates Involved
Suggestion to close risk and generate a new risk on the log relating to implementing wider pregnancy prevention programmes following the new topiramate safety recommendations and discussions within the Medicines Optimisation team. ●ICB to consider developing pregnancy prevention posters and contraception advice for patients prescribed teratogenic medicines.	July 2024 - Suggest closing this risk. Steps have been put into place to implement safe practices in relation to valproate prescribing. June 2024 - System valproate pathway drafted and planned to go to next APMOC. Continue to wait for national information on exisiting males. Data reconciliation exercise ongoing. May 2024 - Valproate group Terms of reference have been updated. National ICB Roles & Responsibilities template shared and compared to BNSSG draft Action and Improvement Plan. No new info nationally in relation to existing valproate male patients this is due soon. AWP valproate SOP has been updated, AWP currently still using the old version of ARAF form while they await IT upgrade in May 24. UHBW and NBT have also updated their valproate SOPs/pathways. SCP being updated. Datix continue to be reported to the ICB involving valproate mainly where GP practice have not received the ARAF form or patients have not yet been reviewed annually. April 2024 - Local providers have updated internal protocols. AWP now have around 95% of women on their valproate dashboard. Development of an ICS pathway with supportive information continues. Meeting planned to discuss original pack dispensing. Currently undertaking an exercise to reconcile the NBT patient valproate register with primary care records to ensure patients are called in for review. Still await national information regarding existing male patients on valproate. March 2024 - BNSSG system wide Valproate group continues to move plans forward. Concerns raised at MQS group that as a system we need to come up with an agreement on how we share the risk assessment of dispensing of valproate in non-original packs across the system. Working with Childrens hospital and practices to identify patients where no clear indication, or shared care is required. February 2024 - ICS Valproate Risk Assessment form signed off at	no		closed	Apr-24	Jul-24	
Work to raise public and patient awareness Work to support clinicians in relation to contraception and the Pregancy prevention programme. NHS England have developed a national easy read patient information in relation to valproate (for females). They plan to develop a leaflet for Males next.It is anticipated we will adopt the leaflet, following local governance sign off.	24/02/2025 As the target risk score has been met and organisational plans are in place to support the safety of the national safety alerts for valproate and topiramate, with a plan to adopt the national easy read valproate resources, we recommend a closure of this risk with ongoing monitoring through the system wide teratogenic medicines working group and Datix reports. If issues present then a new risk will be added. 14/02/2025 - Ongoing system meetings with providers to ensure processes in place and learning from Datix are shared. Discussions relating to patients who dont engage with the annual review process and steps to support clinicians and patients ongoing. RISK RECOMMEND TO CLOSE 23/1/25 Local guidance in place to support the safety recommendations for valproate and topiramate and this had been shared with providers.Systems in place in trusts and GP pactices to support patients. The national MHRA registry highlights that nationally there have been a reduction of pregnancies whilst on valproate in a 6-month period . Locally Datix reports are monitored. 19/12/24 Safety pack for male patients has been approved at APMOC and added to Remedy 18/11/24 A safety pack for male patients taking valproate has been developed and due to go to the December APMOC meeting. A topiramate resource to implement the new safety recommendations has been approved by APMOC and is now available on Remedy and has been highlighted to clinicians in newsletter. 22/10/24 - mitigated score revised as work is progressing to put safety plans in place 16/09/24: Information for primary care in relation to topiramate is being finalised. Patient numbers shared with practices. Discussions on going in relation to valproate and males and information pack to support clinicians to be drafted. Of those on valproate, approx 20% were classified as having a learning disability and so easy read documents are being re-reviewing by LD team.	no		close	2025	24/02/2025	

Notes (If there is more than one Directorate involved please state here)

BNSSG ICS Medicines Quality and Safety Group Subgroup: Valproate Safety Working Group

Date of Meeting: Tuesday 30th January 2024
Time: 10:30 – 11:30am
Venue: Microsoft Teams

Minutes

Present		
(Chair)	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Neurology pharmacist NBT	
	Consultant Neurologist, NBT	
	Epilepsy Specialist Nurse, NBT	
	Interim Medication Safety Officer, NBT	
	Medication Safety Officer, NBT	
	Clinical Lead Pharmacist, AWP	
	Medication Safety Officer & Clinical Governance Pharmacist, UHBW	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Deputy Chief Pharmacist, BNSSG ICB	
	Patient Safety Specialist & Clinical Improvement Lead. Medicines Safety Improvement Programme, NHS England	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
Apologies		

	Item	Action
1		
2		
3	**NPSA alert and national updates** highlighted the NPSA alert that was published 28th November 2023 and described the regulatory changes that they advised from January 2024, for oral valproate medicines: A. Valproate must not be started in new patients (male or female) younger than 55 years, unless **two specialists independently conside**r and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply. B. **At their next annual specialist review**, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for **a second specialist**	

	Item	Action
	signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes. The alert also highlighted that a new or existing group should be designated to co-ordinate the implementation of the new regulatory measures in providers, with oversight from a senior quality group. This action has been completed by through the work of this working group. This group is asked through the alert to update local guidance, review audit and other data and then agree an action and improvement plan. █ also provided an **update to the group in relation to males**, following the update on 15th January. A Study suggests there **may be an increased risk of neurodevelopmental disorders in children fathered by men on valproate in the three months prior to conception compared with men on other antiseizure medicines.** Around 5 children in 100 born to fathers treated with valproate around conception were diagnosed with a neurodevelopmental disorder. Compared to 3 in 100 children whose fathers were taking lamotrigine or levetiracetam around conception. This risk is much smaller than the risk associated with valproate in pregnancy. As a precaution, male patients on valproate who are planning a family in the next year should talk to their healthcare professional about their treatment. New ARAF form for men is only to be used for initiation of valproate, we still await further information around those existing valproate male patients. █ confirmed no additional recommendations have yet been made in relation to existing valproate males and so we wait further information. New valproate males are included in the new regulatory actions but the ARAF form for new males does not cover this issue. Infrastructure for new males is right infrastructure but information is lacking. A link to the New Zealand communications was shared by █ which is helpfully worded, so useful for the group to note. Sodium valproate (Epilim) use in people who can father children: important new safety information (medsafe.govt.nz) MHRA information: MHRA update on new study on risk in children born to men taking valproate - GOV.UK (www.gov.uk) **Provider updates on implementing the NPSA alert:** • **NBT –** have put an MDT approach in place to address the second signature recommendation. This will include consultants and specialist nurses. The MDT plan to meet every two weeks, and these cases will be discussed at the meeting. █ highlighted 2 issues, one is the quality of the data of knowing who these patients are and do we actually have the full case load of patients? keeping track of patients can prove difficult, particularly with the level of compliance for patients wanting to be part of this process. The other question related to the level of risk and when we decide not to prescribe medications. █ mentioned that he had started to draft a valproate SOP. The indication of migraines was discussed and where these reviews would feature. It was discussed that there will be historic patients on valproate for migraine. It was mentioned that if GPs referred them into neurology for second sign off and the response would potentially be to please stop the medication and consider other options for migraine. This would support the move to change the medication to a non-formulary status for this indication in BNSSG. • **AWP –** █ explained that their electronic valproate system requires an update because of the new ARAF form as the MHRA have decided to reword the form compared to the previous one.	

	Item	Action
	Valproate is moving to a "restricted category" of medications which means clinicians are required to complete an extra form on initiation. This is a bit like a checklist form to ensure all key requirements are met e.g. ARAF, RAF, has second specialist written the review in notes etc Approx 90% of our female patients are now on the AWP dashboard showing when they're due for their review which is positive to monitor patients. Second specialist signature has been agreed to be set at a consultant level and they can ask other consultants in the teams, or they can go to different teams or different localities to get this sign off. AWP SOP being updated and then signed off and plan to adopt the BNSSG original pack risk assessment form. Also, AWP valproate webpage to be updated. **Action:** ██ to share the AWP SOP once updated and signed off as the earlier version had lots of useful flow charts others may find helpful. • **UHBW –** ██ explained that work was underway, and that she had met with ██████ and ██ ████, the governance lead for paediatric neurology in the Children's Hospital, to discuss the alert and next steps. ███ is starting to develop a spreadsheet which will be used as a valproate register so that the team have a list of all of the patients, whether the patients have had an annual risk at knowledgement form with one signature or two signatures. An internal SOP is also being drafted to highlight which forms need to be completed etc to staff. ██ commented that having an electronic solution would be much easier, so disappointing that the ARAF form is for print out/paper solution. Also considering developing a clinical note that can be added to care flow/EPR system, which is auditable and can build dashboard from that, in a similar way to one that was done with isotretinoin. However, this may take time due to the launching of EPMA. Need to start recording what they are doing, hard to provide data when it is all on paper. There was discussion around the transition between paediatric and adult services and ██ mentioned that from a nursing perspective this seems to work well. ██ commented that there still seems to be a mindset for using valproate to treat epilepsy in children which needs to change as there are so few indications even within epilepsy for those situations where Epilim is the best treatment (small number of patients) but NBT are seeing patients come through where it is not clear why valproate has been used over anything else. There is a link with the nurses attending the Children's Hospital as part of the transition process. However, ██ mentioned that there's no reciprocal link, so NBT don't have any Children's Hospital staff coming to NBT for the second half of the transition and there are no consultant transition clinics. **Action:** ██ to check with colleagues if there are any issues re the transition process that we need to consider with the new recommendations and share at the next meeting. There was discussion relating to electronic systems and ██ commented that at the national valproate meeting they had advised this was not coming any time soon and would be very expensive to develop. ██ asked with a digital solution where would the national form be stored? If there was a national form that went into a central registry, this would solve a lot of problems. The Blueteq system, (a web-based portal which was primarily used by NHS England but which ICBs are now using in relation to high-cost drugs) was then suggested as a possible solution as this is a system that secondary care are using currently for other medications. A form can be built on there and it can have whatever information you want on there, but that could act as a register, although it wouldn't have patients' names, it has to be pseudo anonymized with NHS number and initials. It was unclear whether primary care could access and whether AWP use. It was also unclear about whether information could be uploaded to the system such as a signed ARAF form. **Action:** ████ to investigate the functionality of Blueteq for the next meeting **Data**	

	Item	Action
	shared some data that had been collated from primary care in relation to valproate prescribing numbers and the indications. Data was also shown from the epact dashboard. See slides. This data suggests that epilepsy is the most common indication for valproate followed by mental health indications. explained that she had put in a data request to the ICB BI team to gain some additional data re valproate prescribing but this was just going through the relevant permissions processes but hopefully should allow some overview of health inequalities. **TOR** mentioned that the terms of reference for the group needed to be updated to reflect the requirements of the NPSA alert. TOR edited so not specific to just females and so will cover all valproate patients. Some job titles and membership also updated. Avon LPC has also been updated to their new name Community Pharmacy Avon. commented that she had invited a GP to the meeting, but they had been unable to attend this meeting and that she had been in touch with Unity sexual health to see whether they'll be able to attend or whether they want to opt in. has also asked Unity for their advice on consent and sharing contraception information with primary and secondary care clinicians. **Action:** to follow up Unity. The TOR also include information regarding executive oversight for a governance purpose. **Action:** Any comments on the TOR to before the next meeting **Post meeting note:** suggested the addition of a nurse or consultant from psychiatry. **Action and Improvement plan** shared the ICS action improvement plan, which will be updated following the meeting and asked for any comments to be emailed to her or . **Action:** Any comments on the plan to be shared with	
4	**Aide Memoire** presented the Aide Memoire to the group and explained how this had been put on hold whilst we waited for recommendations from the MHRA. mentioned that national work was ongoing around roles and responsibilities, but we felt we sort of wanted something sort of local as well or at least in the interim, which we can include self-referral pathways as well as a bit of background information. The flow chart pathway has been edited and can be edited again further following discussions. The forms and resources links have been updated. **Action:** to compare roles and responsibilities with the shared care protocol to ensure they align Group suggested Aide Memoires are normally only a page or 2 in length, so this is more like a guideline and so need to consider purpose and overlap with other documents as we are in danger of having multiple documents and protocols. It was discussed that having one document that covers it all, that is the go-to reference for the source for how we manage patients on valproate is likely to have more impact than multiple documents. **Actions:** Review the aide memoire and purpose, could it be shortened to an overarching process? to meet to review in light of the SCP.	

	Item	Action
5	**Traffic Light Status** █ explained to the group that a while ago it was agreed that for adults, the traffic light status for all indications for valproate should change to amber three months once an updated shared care protocol was in place and for the migraine indication this would be changed to non-formulary for new patients. █ went through the shared care protocol which has already received comments from some of the members of the group and explained that this would be going to the Joint Formulary meeting in February for sign off. The shared care protocol aims to include all indications and both adults and paediatrics which was quite complicated to undertake. The document links with all the new risk acknowledgement forms and covers the NPSA alert information. Migraine dosing information has been removed as this indication will no longer be formulary. Wording in relation to the shared care protocol was discussed as it was felt by the group that there should be a stronger emphasis on review and stopping the valproate. █ commented that we need to be very clear and unambiguous and those patients who are still on it should be reviewed to look for an alternate, better treatment. In terms of monitoring, █ explained that they have looked at the SPS information for this and there was some recommendation to do regular LFTs but these monitoring may not be required from looking at the SPC, but it looks like it may originate from monitoring that's done for bipolar disorder for serious mental health conditions rather than for the medication. █ asked the group whether or not we can just include it for bipolar disorder in line with the monitoring that would be happening for those patients anyway or if there's any reason to put it in for other patients. Side effects have been edited in the SCP so there is a bit more information about side effects though with pancreatitis in terms of referring for urgent hospital admission, if they've got to keep pancreatitis and that's in line with Information about psychiatric disorders and suicidal ideation was also updated in the SCP. █ advised that she had added a bit more information about referral back to specialist if patient becomes pregnant or wanted to start a family. Additional information added in relation to contraception in line with MHRA advice. █ agreed with the way the contraception was worded. Any additional comments to be sent to █ ahead of the joint formulary meeting in February. █ added that the paediatric indications and traffic light status was to be agreed at the formulary meeting. **Action**: █ to email the paediatric neurology pharmacist to contact █ re the shared care protocol. There was discussion regarding contacting those practices with patients prescribed valproate for migraine indications and asking for these patients to be reviewed. **Action:** █ to investigate the best way to do this.	
	Valproate Original Pack dispensing risk assessment form From 11th October 2023, the Government amended the Human Medicines Regulations 2012 (HMRs) to require manufacturer's original full pack dispensing of valproate-containing medicines and the changes also enable pharmacists to supply up to 10% more than or less than the amount on a prescription of medicines other than those containing valproate, so that they can dispense a manufacturer's original full pack instead of splitting the pack.	

	Item	Action
	However, if there are exceptional circumstances to original pack dispensing then national guidance advises that a risk assessment should be put in place. SPS and NHS England were contacted to see if there would be a national form, however, no national risk assessment is in development and so MSOs in BNSSG agreed it would be helpful to have a standardised approach to this form/process across BNSSG. █ highlighted that she had worked with pharmacy colleagues from UHBW, NBT, AWP and Sirona to draft a risk assessment form that could be used in situations where original pack dispensing may not be appropriate and shared with the group. The group agreed to support the form. █ mentioned that Community Pharmacy Avon were also consulted about this form, however, they feedback that although this form will be available for community pharmacies, they may still choose to use their own in-house form or record directly on the patient's PMR. This form is going for approval at the February APMOC meeting. OP valproate exceptions risk assess **Post meeting note:** This form was approved by APMOC and will be added to the BNSSG formulary.	
6	**Datix** Due to timing of the meeting, it was agreed to share the Datix slides around for information – see slide deck.	
7	**AOB** • **Meeting frequency** █ asked the group if we should increase the frequency of the meetings, but the group agreed to stay with the 8-week frequency. **Action:** █ - Next meeting date to be shared for 8 weeks' time **Training** It was discussed that it might be helpful to consider clinician training once all SOPs and resources have been updated. For future discussion.	

Next Meeting – April 2024

Minutes: █ (Medicines Optimisation team, BNSSG ICB)

BNSSG ICS Medicines Quality and Safety Group Subgroup: Valproate Safety Working Group

Date of Meeting: Tuesday 16th April 2024
Time: 10:30 – 11:30am
Venue: Microsoft Teams

Minutes

Present		
(Chair)	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Neurology pharmacist NBT	
	Interim Medication Safety Officer, NBT	
	GP Partner in South Gloucestershire and Clinical Lead GP for prescribing in BNSSG ICB	
	Clinical Lead Pharmacist, AWP	
	Medication Safety Officer & Clinical Governance Pharmacist, UHBW	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Deputy Chief Pharmacist, BNSSG ICB	
	Patient Safety Specialist & Clinical Improvement Lead. Medicines Safety Improvement Programme, NHS England (Leads National Valproate Work)	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health	
	Community Sexual Reproductive Health Registrar, Unity Sexual Health, UHBW	
	Interface Pharmacist NHS Bristol, North Somerset and South Gloucestershire ICB	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
Apologies		

	Item	Action
1	**Welcome, Introductions and Apologies**	
2	**Minutes and Action log** No comments from the group on previous minutes. went through the action log and discussed the actions: • AWP SOP – This has now been updated and approved in March (after the addition of a section about people with long term impaired capacity) and will share with the group with the minutes. **Action:** to share the SOP with the group • BlueTeq – The Blueteq system had been investigated to see if it could support a system wide valproate database following a suggestion at the previous meeting. However, upon investigation, commented that it had some limitations locally. AWP and primary care don't have an account for	

	Item	Action
	this system and so if secondary care use it primary care won't be able to view it. Also, NBT can't see UHBW's account and vice versa. The ICB can only view an anonymised version of the data. Therefore, the **Blueteq system wouldn't support a system solution**, however, trusts with access to Blueteq could use to support their own internal recording of patients. • Terms of Reference - Thanks to those that had given comments on the Terms of Reference for the group, these were amended, and the finalised version shared with the group. A consultant Psychiatrist from AWP had been invited to attend the meeting and meeting invites shared, although they were unable to attend today's meeting. Representatives from Unity Sexual Health Clinic were also invited and are present at the meeting. • Action and Improvement Plan – no comments received from the group on this. • Valproate pathway /aide memoire document – █ and █ explained that they had tried to shorten following feedback at the last meeting, and this was to be discussed later in the meeting. • Migraine indication for valproate – this was to be discussed later in the meeting.	
3	**National and local updates** **Roles and Responsibilities document** – █ explained that there had been a national working group set up in January which █ had been attending that had been set up to draft a template document for ICBs to complete which highlights the roles and responsibilities relating to valproate across the system which could be used nationally. █ explained that a draft has now been put together and will be shared with the group for any feedback with the notes and action log. This information has been documented on an excel spreadsheet and each tab follows the patient journey. The template lists a lot of tasks, rather than being a high-level document. For example, the first tab relates to initiation, then treatment etc and the different healthcare staff involved. It then identifies the provider or organisation who would be responsible for that particular activity. One situation example includes if there's a change in the patient circumstance such as planning a family and pregnancy support. █ mentioned that one of the **key messages that came from the workshops was that every patient contact with the healthcare professional counts** and how it is a good opportunity reiterate the risks around valproate and to double checking if they've had the review, their annual risk acknowledgement form and signed it etc. **Action:** To share the draft national document with the group for comments, ideally with end comments given within a week. █ added that this was always intended to be **a template** and it's a halfway house between a long list of tasks and letting everybody locally define who that is and a very prescriptive list which would be impossible to try and design for the whole country, because everywhere is different. **Male patients and valproate** – █ asked █ if there was any information relating to existing males taking valproate yet and █ advised that we were a couple of days early as the Stakeholder network, which includes charities and other organizations as meeting on the 18th April and it is thought that the NHS/MHRA will announce their intentions on the prevalent males at this meeting. It is unclear what they will discuss at the meeting, but it is likely that they will include a requirement for new initiations to counsel men on the increased risk of neurodevelopmental disorders to their children if they conceive whilst taking valproate. This relates to information highlighting a 3% baseline risk and an increase to a 5% risk, if you're taking valproate compared to other medications such as lamotrigine. It can be complicated given the limited alternative medication options available for some patients especially in epilepsy. What will be discussed about prevalent males is unknown and so we will have to wait feedback from the meeting. **Provider updates on implementing the valproate NPSA alert:**	

	Item	Action
	• **AWP** – ■ explained that their SOP had been updated and circulated in AWP, they were still having to use the old ARAF form currently but covered off in our procedure that the two forms don't quite match and document the 2 signatures in the patient notes. AWP have now got around 95% of women on their dashboard. Webinars and communications have also been issued, with an audit of valproate prescribing is planned for the summer. ■ explained that they are awaiting a massive upgrade to the clinical notes system (around 1st May) but once this has been undertaken then the valproate work will be prioritised by the IT team. Once this is completed the new forms will be shared with primary care. If primary care, wish to know the two prescribers this can be provided on request as it is all documented in the AWP notes. On inpatient wards, they are seeing the valproate numbers decrease and ■ commented that she thinks we've only maybe had one female and one or two males started on it since February, which is really good. The group agreed it was positive to see other options being used for mental health patients. ■ highlighted to ■ that the ICB had received an email from a GP practice where they had received the old ARAF form from AWP, and they weren't sure if they were able to accept it or not? ■ commented that even with the old ARAF form it does highlight that the patient has had a review with a specialist, they are on PPP, the only thing the form doesn't have is the second specialist signature. ■ commented that they weren't sure what to do re the new ARAF form, they either pulled the dashboard which was 2 years' worth of work or carry on using old form temporarily. In the interim while they continue to issue the old ARAF form to practices, they have asked the specialists to document in the notes if the GP practice needs assurance. ■ advised to tell GPs if they are concerned whether a second specialist review has been done, to ask and AWP will be able to provide notes from clinical system. • **UHBW** – ■ explained that flow charts about what needs to happen with both male and female patients had been developed by UHBW. UHBW are proposing that new male and female valproate patients will be discussed at the peer review meeting, where all of the paediatric neurologists and clinical nurse specialists meet and the decision that Valproate, is the only effective and tolerated treatment will be made and documented at the meeting. The entry made into the medical records will include the names of those two independent specialists. Currently 2 signatures cannot be added to the actual internal prescription and so first prescription will only ever have one signature, which is why it's important that the peer review meeting is documented. UHBW have applied for a clinical note within their care flow system, but there's a backlog of requests and the wait time to get any new work or forms done is considerable. Existing female valproate patients will now be reviewed in clinic. The Chief Medical Officers (CMO) letter supported this and despite the perceived increase in workload the consultants understand the need to complete this work. The plan is that the consultant will see the patient in clinic., The clinical nurse specialist or children's epilepsy surgical specialist nurse will be the second independent specialist agreeing that valproate is the only option for continued treatment and will document that in record. If the nurse specialist cannot agree with the consultant that valproate is the only effective treatment option, then the patient will be put forward to the peer review meeting where it can be discussed with all of the consultants in the room. ■ commented that they think that they probably have a few of patients falling into that category where valproate has been commenced as a treatment option but was not the only effective one. ■ mentioned that she has met with the children's nurse specialists, and they are happy that professionally they can say no if they feel other medication options should be considered.	

	Item	Action
	The plan is for clinical notes within careflow to run a dashboard link that which will serve as the valproate register as well. Currently, UHBW are using an Excel spreadsheet as a valproate register as they don't have any other digital solutions. • **NBT –** ■ highlighted that NBT have put an MDT approach in place to address the second signature recommendation. This will include consultants and specialist nurses. An NBT protocol document has been drafted and is planned to go for sign off by the relevant committees shortly. This will then be shared with the relevant people in the trust. Linked to this it will be some reminders to clinicians that valproate shouldn't be prescribed for non-formulary indications. Currently using an Excel registry but work planned to check it is up to date. ■ asked the group about the scenarios whereby ITU patients who particularly post cardiac arrest, may have seizures that are then started on IV Valproate. It was discussed that this sits outside of the standard valproate pathway as would come under an emergency situation. At the point where a patient may need to be continued on long term therapy, it was commented that the adult physicians at UHBW say they would always liaise with North Bristol with the neurology team. ■ suggested ■ talk to ■. ■ asked if there was a joint status epilepticus guidance across the 2 trusts, but the group were not aware of a joint document. It was agreed that it would be helpful to have a joint status guideline across the trusts if one was developed. **Action:** ■ to liaise with ■ if a guideline is developed so this can be considered for a joint trust policy. • **Unity Sexual Health** ■ explained that Unity don't currently have a fast-track service for patients to be referred for contraception in order to commence teratogenic medication like valproate. ■ advised that Unity is not currently on the electronic referral system but are actively moving towards that at the moment. As part of the work, moving on to the referral system, they are looking to introduce a new referral category which is for urgent LARC initiation for people on a pregnancy prevention program. All agreed this would be a useful addition. **Data** ■ explained that some data had been requested from the ICB BI team relating to health inequalities however, this was not yet available with the appropriate data sharing permissions being obtained. ■ advised that a local EMIS search had been run and had shown 298 patients prescribed valproate overall aged 10 to 55 years, of those requiring a review 184 were identified and thankfully 0 patients identified as potentially pregnant. It was discussed that the reason the numbers for review was high may relate to a lack of consistent coding in the GP notes, but it is hoped this will improve when the pathway is issued and through a local safety dashboard that encourages practices to code ARAF and RAF forms on the system. ■ commented on the draft valproate pathway and the need for practices to run the EMIS searches and how it could be better incorporated into the safety dashboard? ■ not convinced that practices would routinely code patients despite it being in the safety dashboard. ■ commented that in previous years ICB have included valproate in the Prescribed Quality Scheme and generally recommend practices have a valproate champion to run searches and check valproate patients had appropriate PPP in place regularly. It will be important that we highlight the valproate EMIS codes and encourage their use going forward. Valproate searches are in the safety dashboard again this year but perhaps we could think about promotion around reviewing these searches. **Other - Topiramate**	

	Item	Action
	█ asked █ if there was going to be a PPP for topiramate and if so, would it be worth gathering the data around that at the same time as valproate or are they going to be treated as two completely separate things? █ commented that topiramate will likely have a pregnancy prevention programme by the end of this year and that it will include the same annual risk assessment forms. The big difference is that topiramate is mostly initiated in primary care for migraine with only the minority of it being initiated in secondary care for other conditions (e.g. epilepsy). This therefore puts quite an onus on primary care to manage the additional documentation. However, given the current pressures in primary care, managing an annual risk assessment form completion for patients may prove challenging especially given current variation in medication monitoring. █ highlighted another complicating factor would be that patients may be on multiple medications requiring them to be on pregnancy prevention programmes e.g. valproate, topiramate, isotretinoin), and this would require them to complete multiple separate ARAF forms which they may not be happy to do and will create extra administration. █ discussed that Topiramate is one of only four drugs that primary care has available for migraine. Although it's not a great drug, is probably one of the more effective and more beneficial and its first line according to NICE, although that is likely because the older drugs just don't have the evidence base that newer drugs have and so NICE always promote things with the with the stronger evidence base. █ commented that it would be useful to review topiramate numbers. █ commented that the numbers prescribed topiramate are considerably bigger, and actually the pregnancy exposures are considerably bigger, and for this it's just that the increased risk from topiramate is lower than it is from Valproate.	
4	**BNSSG Pathway and update letter** █ explained that feedback from the previous meeting had been taken on board to make it a shorter more readable document. █ talked the group through the pathway and explained that there would be additional supporting documents in relation to resources, coding, the shared care protocol etc that could be accessed separately, and so clinicians can focus on the pathway and then access the other information when required. It was discussed that the valproate referral information needs to be confirmed by providers before the pathway is finalised. █ agreed that the PCLS route would be correct for AWP or in Bristol it would be the Recovery and Assessment Teams. **Action:** █ to follow up with relevant people at the trusts to confirm the referral pathways. █ asked about the patients who would need referring into the trusts. █ explained that this would be patients new to the area or patients who are no longer come under the specialist's teams. █ explained that for AWP it depends on if a patient meets the threshold for care coordination. However, if a patient is taking valproate for bipolar, that's a serious mental illness for many patients and so they would meet the threshold and just stay on caseloads. This patient cohort would therefore remain on the system and so should be called in for annual review. We are aware that there are there are some people where primary care have been prescribing without secondary care input and so they just need to refer back in every year because there isn't a mechanism yet for kind of automatic recall for this group. █ mentioned that this had been raised with the Medical Director, however, it isn't possible to keep these patients who don't meet the threshold on the AWP caseload. █ explained that within mental health, the numbers for each practice that have patients who have been *discharged* from services is likely to be very small and so should be manageable. █ asked for data on those AWP patient numbers. █ suggested comparing the numbers that GP surgeries have and see how may are not on █ dashboard. **Action:** █ and █ to review the valproate data to assess the numbers that might need to be referred in BNSSG. █ commented that the wording in the pathway could be changed from 'girls' to 'females'. █ commented that the group that is often missed is 10-14 years with regards to contraception as the sexual health clinics	

	Item	Action
	are seeing with unplanned pregnancies risks in PAS. ██ commented that it was useful that the pathway referred to pre and post menarche rather than age, so that contraception can be clearly communicated. **Action:** ██ to make the changes to the pathway.	
5	**Valproate Original Pack dispensing risk assessment process** Due to time constraints, it was agreed this would be discussed outside of the main meeting. **Action:** ██ to arrange a meeting with ██ to discuss further.	██
6	**Traffic Light Status** ██ explained that the traffic light status for valproate, for all licensed formulary indications, is now Amber three months and the shared care protocols been approved and uploaded to the formulary website. No issues to date. Therefore 1 shared care protocol for adults and children for all indications (men and women). In relation to paediatric patients, a search was undertaken to identify patients without an epilepsy indication. This identified 11 patients, of which 9 actually had an epilepsy indication. Two patients had a bipolar indication but were under specialist teams. Therefore, it was agreed that the neuropathic pain and migraine indications that are on the formulary for existing patients only for paediatrics would now be removed as there's no children on them.	██
7	**Update from BNSSG Valproate Group following latest NPSA alert** ██ shared with the group the draft update that will be sent out to primary care to update them on the system valproate work to date following the publication of the NPSA alert.	██
8	**Pregnancy prevention posters and contraception advice** ██ explained that at previous meetings, it had been discussed that contraception was an area where we may need to do some additional work. ██ highlighted two posters (one for healthcare professionals and one for patients) that had been used by other areas and asked the group whether we should consider doing something similar? ██ explained that although these posters are useful, they are not specific to valproate. ██ advised that ██ had commented that the patient posters may be helpful to raise awareness. The example poster is good for general considerations when using medications and planning pregnancy, but there **may need to be a greater emphasis on the importance of actively preventing pregnancy and use of long-acting effective contraception with medicines such as valproate and topiramate.** The tone of the poster is more along the lines of "you're planning a pregnancy - lets optimise your meds" - but where a pregnancy prevention programme is indicated the messaging perhaps need to be stronger " you're on meds that can be harmful in pregnancy - lets optimise your contraception/ pregnancy prevention"? It was commented that clinician posters may be helpful too to act as an aide memoire. ██ agreed with ██ comments and that an aide memoire may be helpful and that we may need to be a bit more prescriptive around recommending effective contraception in certain groups in the information. It may also be **useful to have a list of drugs** whereby patients need to be on a pregnancy prevention programme contained within the information especially topiramate as they see lots of patients on this. **Action:** ██ to investigate further how the posters could be improved and used and bring back to a future meeting.	██
8	**Datix** Two Datix relating to valproate have been reported since the last meeting and were currently being reviewed. One related to a mental health patient has been registered with practice, taking Valproic Acid (Depakote) but missing the Valproate risk assessment for female patients. The second incident related to a patient of childbearing age on sodium valproate who was overdue a clinic appointment with Neurology for completion of pregnancy prevention paperwork (the pregnancy prevention risk acknowledgement form is currently 4 months overdue).	

	Item	Action
9	**AOB** █ highlighted that the Hughes report had now been published which discusses the options for redress for those harmed by valproate – see link for further information. https://www.patientsafetycommissioner.org.uk/our-reports/the-hughes-report/	

Next Meeting – Tuesday 2nd July 2024

Minutes: █ (Medicines Optimisation team, BNSSG ICB)

BNSSG ICS Medicines Quality and Safety Group

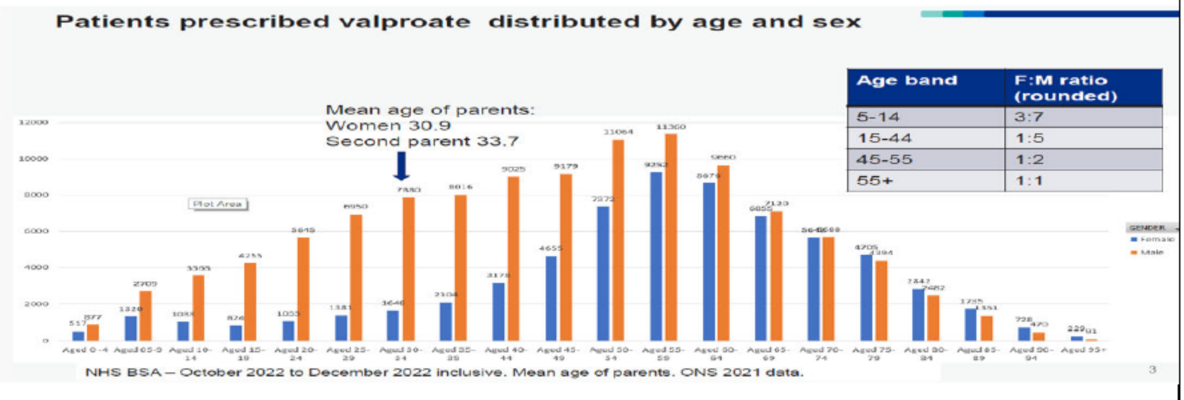
Subgroup: Valproate Safety Working Group

Date of Meeting: Tuesday 16th July 2024
Time: 10:00 – 11:00am
Venue: Microsoft Teams

Minutes

Present		
(Chair)	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Neurology pharmacist NBT	
	Interim Medication Safety Officer, NBT	
	GP Partner in South Gloucestershire and Clinical Lead GP for prescribing in BNSSG ICB	
	Medication Safety Officer, AWP	
	Patient Safety Specialist & Clinical Improvement Lead. Medicines Safety Improvement Programme, NHS England (Leads National Valproate Work)	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	
	Neurology Consultant, NBT	
	Community Sexual Reproductive Health Registrar, Unity Sexual Health, UHBW	
	Interface Pharmacist NHS Bristol, North Somerset and South Gloucestershire ICB	
	Medication Safety Officer, Sirona care and health	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Paediatric Neurology and Palliative Care Pharmacist, Bristol Royal Hospital for Children	
Apologies		
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	

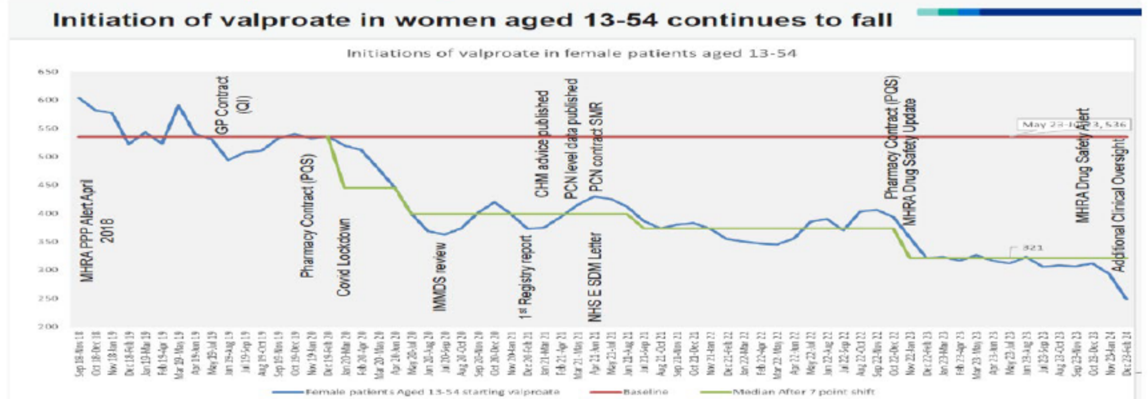
	Item	Action
1	**Welcome, Introductions and Apologies**	
2	**Minutes and Action log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. went through the action log and discussed the actions: • **Action 6 – Valproate Action and Improvement Plan** – this is ongoing which we will continue to update. Keep open. • **Action 12 - - To share the draft national ICB valproate roles and responsibilities template document with the group for comments, ideally with end comments given within a week.** Action complete and documents shared. This document will be going to August APMOC for sign off. Suggest close.	

	Item	Action
	• **Action 13 - █ to liaise with █ if a status guideline is developed so this can be considered for a joint trust policy.** █ has since left UHBW as MSO and the new MSO had not started yet. The action had not moved forward, and it is unclear who to link with at UHBW. █ commented that she would email █ █ at UHBW and copy in █, to see if he could advise if there was a current protocol or if UHBW followed NBT guidance. Also ask if they would be interested in collaborating on a joint protocol. **Action: █ to email █ and link █ into the email. Keep open.** • **Action 18 - █ to investigate further how the pregnancy prevention posters could be improved and used and bring back to a future meeting.** To bring to a future meeting, topiramate as well as valproate to be included. Keep open.	
3	**National and local updates** █ gave the group an overview of the work the group had undertaken to date and how BNSSG were shown to have relatively low prescribing of valproate when compared to other ICB areas. See slide set. Healthier Together Valproate Safety Grou █ commented on the system valproate pack, and asked how the SCP for valproate would fit in with the new valproate pack resources? █ felt that there were a lot of words and found the SCP slightly impenetrable which may make it difficult to get outcomes we want. █ thinks that the valproate pathway/pack needs to be rationalised to make it usable and helpful for clinicians and not just serving our purposes. █ commented that when the SCP gets reviewed, we will take those comments on board. █ discussed some slides that █ had presented at another national valproate meeting. These highlighted the distribution of national valproate prescribing. One slide (shown below) highlighted lower valproate prescribing rates in females compared to males. █ added that the data shows how conservative we are at prescribing valproate in women of childbearing age. It is also positive when you look at the change in prescribing rates for girls around the age of puberty where a drop is seen, which suggests paediatricians are being proactive. █ advised that initiations of valproate in children has remained relatively stable so a willingness to reduce valproate in the prepubertal years is really important.  █ then showed another slide (shown below) with a timeline overview of how safety alerts, lockdown and other events had affected valproate prescribing. Overall, there does seem to be a reduction in prescribing of	

	Item	Action

valproate with reductions also aligning with MHRA safety alerts. It is unknown whether this reduction in prescribing will continue.

National Valproate Update



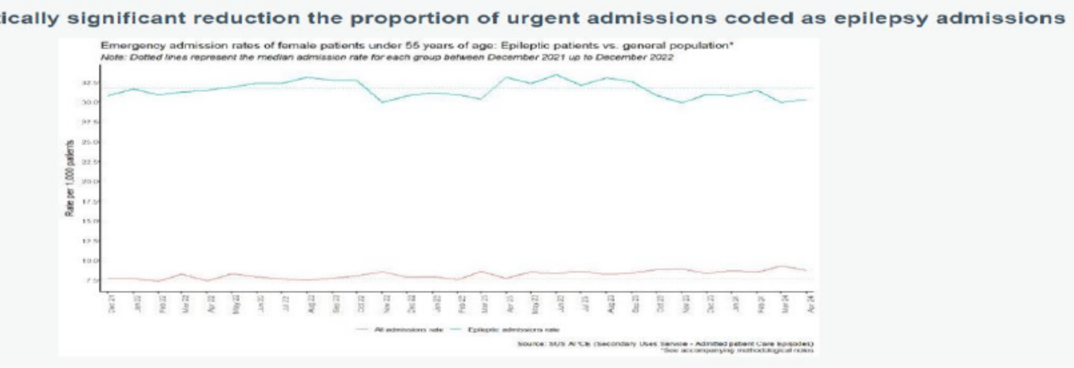
There have historically been discussions around whether reducing valproate prescribing will result in unintended harms for patients.

█ commented that there are continually increasing urgent hospital admissions for all women under 55yrs since December 21, but we are in general admitting and seeing more patients than we have previously. The rate of admissions for people who are admitted with epilepsy conditions is much higher than the general population. Epilepsy is a long-term condition and so this would be expected, and this data would suggest the epilepsy admissions is following the trend of the national increase in admissions, but data is showing that the proportion of people who are admitted for epilepsy related conditions has reduced and has stayed down for the last 7 data points (statistically significant). See graph below.

Urgent Epilepsy Admissions

Likely lead indicator for SUDEP.

Statistically significant reduction the proportion of urgent admissions coded as epilepsy admissions



Conclusions may be difficult to make around this, however, it is helpful to show that the data has not increased to show increased admissions related to the valproate safety recommendations, suggesting epilepsy control hasn't worsened.

- **National review of patients prescribed valproate in pregnancy in the last 18 months**

█ highlighted that NHS England were looking into the pregnancy valproate exposures as nationally in the last 18 months there have been potentially 49 exposures to valproate. However, 10 of these patients had a prescription for valproate only for the first or last month of their pregnancy and so may not have been associated with an actual exposure. ICBs are being asked to review patients who have been potentially exposed to valproate during pregnancy. █ confirmed that BNSSG have not had a patient highlighted.

	Item	Action

National Valproate Update

Exposed Pregnancies

Number of women prescribed a medication in a month in which they may have been pregnant

17 pregnant women received valproate in last 6 months			
Epilepsy	Bipolar	Both	Neither
17	0	2	0
For 12 of 17 this is their first pregnancy			
8 have had treatment changed since conception			

Patients prescribed Valproate in the last 18 months in at least 1 month that they may have been pregnant	49
Number prescribed in multiple months	28
Number prescribed in only 1 month (Any month)	21
Number prescribed in only first or last month	10

Data does not show if pregnancies were carried to term or led to live births. Prescribing in first or last month may have been before conception of after delivery. Prescribing is not a strong indicator of in-utero exposure. i.e. this is likely to be an overestimate of exposure.

asked what the baseline number of people on valproate medicines was for the 49 exposures was? advised that there were approximately 17,000 patients, so exposures are relatively small. It is therefore difficult to say if this number could be reduced or if interventions would have helped prevent a pregnancy or whether this was chance.

Interestingly, in the general population a cohort of 17,000 women of childbearing age will have around 600 children. So, when you look at 17 compared to 600, that is a lot of women who are avoiding pregnancy whether that is a good thing or bad thing.

- **Valproate and existing males**

There are significantly more males (49,160) prescribed valproate than females (16,953). In January 24, the MHRA highlighted the risks associated with males and as a result the valproate risk assessment form for initiation of valproate in men (RAF) was introduced. However, the advice for existing valproate males was not confirmed.

We are expecting the July 24 Drug Safety Update to publish further information for this group/existing men on valproate. It is expected this will include the need to have a review to highlight the risks to male patients.

However, the update may not confirm how frequently this should be discussed with the patient or where in the patient journey this should be discussed. commented that if you were to think about a cut off age, 2.5% of men father children after the age of 55 years so 97.5% under 55 years fathering children, this will be a significant number of a patients for neurology to review and have these discussions and so as a result it will be unlikely that there will be an annual review that needs completion for existing valproate males. It may be a letter is sent to patients highlighting the risks associated with the medication. It is unlikely there will be a specific RAF form for existing valproate group as the MHRA are describing this as a *precautionary* measure.

It was discussed that there are still ongoing discussions regarding the size of the risk associated with this group of patients.

highlighted the risks associated with males who are not taking their responsibilities around valproate seriously but will potentially father children and it will be hard to protect the unborn foetus. agreed that managing the contraception of the male population is a different conversation and it was commented that this is a very different risk because it is, it is a risk that is passed on and it is essentially passing on the risk of a genetic disorder. However, part of the risk relies on the autonomy of the male to decide who he tells, which may be an uncomfortable conversation. It's our job to encourage valproate males to follow behaviours that we would want to see.

asked if she had had many conversations with males regarding contraception due to them being on teratogenic medications like valproate? LF commented that one of the things that she asks every patient seen, if they say they're sexually active, is what contraception does your partner use and is amazed at how many

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	don't know. ▇ commented that it is important to normalise these conversations. It's a fine line because we don't on the one hand want the men to be reproductively coercing their partners into taking something but on the other hand, they should be interested, and they should be involved in some of those conversations. So, the role within sexual health is to try and help people navigate that fine line, but also try and normalize the conversation. They should be talking to partners about this because it affects them both potentially. However, to date ▇ hasn't seen male patients or any patients specifically taking valproate to have these conversations. ▇ commented that we know that it can cause infertility and that it can be toxic to the testes we don't know what impact that has on the unborn child. ▇ commented that by the end of the month we will know as will be published which will make it easier to explain the risks. ▇ commented that at a conference he attended where the authors of the study were in attendance, he commented that the data was queried however, it is unlikely the stats are going to change, but the granularity to the data is poor because it was done as an AI search of national data. So, the issue in the field is going to be that people aren't quite convinced which cohort this applies to or whether the risk is universal or not. So, there's less enthusiasm for this, which is going to be a barrier to it being rolled out effectively. The patient numbers in this group are massive and practically no department has got capacity to cope with this, and this will be the biggest barrier. **Action 19: Await the MHRA Drug Safety Update recommendations for existing males on valproate and take actions as appropriate. This could include a draft letter to highlight the risks for patients.** ○ **Southampton's approach to valproate registers** ▇ commented that at a regional Medicines Safety Officer day, the Consultant Pharmacist MSO for Southampton mentioned that apparently secondary care in their trust are not trying to keep a list of all the patients on valproate who might need them to do an annual review, they're leaving it to the GP's to feed those patients in on the basis that that list can never be comprehensive because people are moving in and out of area and the one definitive point of contact is the GP as they prescribe the medication on an ongoing basis. It was flagged for discussion as this is a controversial viewpoint from quite a large secondary care centre with a Consultant Pharmacist leading this. ▇ added that when the Consultant Pharmacist was pushed on it, the MSO did infer that they did hold some sort of a database of patients which had been reviewed within the system. ▇ mentioned that she understood that they were doing the work but not providing the assurance, so reviews were being undertaken, they had a system but were not putting their hands up to say that they were assuring the process. ▇ commented that as a system you can only action patients that are know about, so if new patients come into the system they will need to be referred, but is important to have some recall system otherwise the additional referral workload would be high. ▇ asked if the regional MSO Southampton Consultant Pharmacist had mentioned what the barriers are for having a recall system for patients? ▇ mentioned that the people that move around would be a small percentage of people on valproate and so there can be a safety net there but would be important to have a recall system for those that under their care. ▇ commented that the inference was that the patients were closer to their GPs, and they could monitor patients on the valproate patient list easier than secondary care. ▇ commented that when he needs to see this patient in a year for follow up, nothing happens, and they might come back in 18 months to two years and so this is why we've had to put in more active systems. Other neurologists and other centres would agree. It's just that the capacity for follow up is completely inadequate.	

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	So, when you say you need to see someone at a year, it doesn't happen at a year and that's the fundamental barrier. █ commented that the view from primary care would be that if they're under the care of the specialist team, the expectation would potentially be that that recall system is in place within that team. █ mentioned that there will be people who are lost to follow up and who you know don't attend or move areas and so they will always be a necessity for some patients to be referred back into the system. At NBT, they have tried to take this out of the clinics because that system doesn't work, so there will be an actively managed list, where there will be a nurse, who's got dedicated time to pull the patients back just for the ARAF process, almost separate from clinical care, as that's the only way we can practically achieve that. But it, but it's worth noting that there was no resource to achieve that, with the resource needing to be funded out of something else we've had to do to pay for that. Part of the issue, as this is a large piece of work, is funding. █ commented that when they looked at the systems in place originally, one was where general practice refers the patient in every year and the other was the where acute trust keeps a list of patients and manage it on their behalf. And of course, neither system worked well. Therefore, a hybrid system whereby secondary care keeps a list, but GP practices still refer in the people who fall through the net. Nationally, that is where most people are settling because of this issue and due to a rolling recall program for long term conditions in secondary care being unusual. This is why a systems approach is needed – GPs need to be able to refer in those patients who have fallen through the net and hospitals need to be able to manage the system to get patients in as frequently as needed. It would be important for there to be an understanding of the time frames and processes, so that if the acute trust can't review all the patients in a year, they might be able to get them through them in 15 months so ideally primary care are aware how long they will potentially be going to hold this risk. █ commented that what █ said as being well articulated and reasonable and the understanding of both sides. Is there a way that secondary care can let GPs know that secondary care is trying to review patients but experiencing difficulties. Therefore, Secondary care are asking for primary care help, i.e. if there are any patients who have fallen through the net please can you refer them in for review. However, this would be hard to articulate in a newsletter. █ commented that the system at NBT as of 2 weeks ago is that they have tried to update their database of valproate patients with help of ICB. █ advised that they will have a nurse who's going be dedicated this to doing this one day a week, which is probably the resource that it takes to manage this cohort and recall them back to a clinic and make sure the forms are being signed. So, the reality is going forward and the reason we've had to set this process up, is because it was almost impossible to see the patients at 12 months. So, the system going forward will be they will be recalled back actively just for the form to be signed, but not for any other clinical care in that encounter. If a patient for example in three months from now, has breached their 12 months, then the chances are there's a reason for that. E.g. they've DND, haven't wanted to come, aren't known to NBT for whatever reason, so █ thinks that NBT will probably have to be slightly more actively suggesting the GP's do contact them if there's a lapse once this is fully established. █ commented that that would be important to communicate to primary care otherwise primary care feel like nothing is being done and that it is all on them. █ commented that GPs will likely be happy to be a safety net	

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	for those patients who fall through the cracks as long as they know there is a system in place, but it's not all on GPs. It was discussed that it will be important to highlight this part of the NBT pathway, however, not immediately as the appointed nurse has just gone on sick leave. █ commented that our local systems seem helpful overall with AWP utilising an electronic database for recall and NBTs new dedicated nurse system will hopefully support the patient recalls going forward with the GP practices supporting those who fall outside.	
4	**Valproate BNSSG system resource to support the national safety recommendations** █ thanked everyone for their feedback and explained that this resource was due to go to APMOC in August.	█
5	**Valproate Data Reconciliation** • NBT • Bristol Children's Hospital A data collection exercise has been undertaken and information shared with NBT and the children's hospital to review their patient lists.	█
6	**Datix /Ulysses** – shared learning from events – All providers █ explained there had been no recent valproate or topiramate learning events to share with the group.	█
7	**Topiramate** SBAR Topiramatev2.1.docx • Overview of alert █ shared an SBAR relating to topiramate with the group and highlighted that a new safety alert has been issued by the MHRA in relation to the prescribing of topiramate in pregnancy and females of childbearing potential. The group therefore need to consider how we can ensure the new safety measures for topiramate are safely introduced into the BNSSG area. Topiramate is a medication licensed for use in epilepsy and for the prophylaxis of migraine headaches after careful evaluation of alternatives. It is known that nationally this medication is used in indications outside of license such as for tics in Tourette's syndrome. Initial safety warnings about topiramate use in pregnancy and in females of childbearing potential were published in January 2021, following a review of antiepileptic drugs in pregnancy, which highlighted an increased risk of major congenital malformations. Prescribers were asked at the time to ensure that patients were fully informed of the associated risks if taken in pregnancy at initiation and as part of annual reviews. However, the new safety advice relates to introducing a pregnancy prevention programme for those women of childbearing potential. New annual risk awareness forms have been introduced alongside national guidance for health care professionals.	█

	Item	Action
	A specific timeline has not been issued to implement these safety recommendations by the MHRA or NHS England and no additional funding provided with NHS England suggesting this would fall under current contracts. The initial alert has been shared with various parties, but additional supportive information will be required. The safety alert seems to indicate that the responsibilities for reviewing topiramate prescribing where the indication is epilepsy falls to the specialist clinician (currently TLS amber specialist recommended in BNSSG), however for the indication of migraine prophylaxis it falls to a healthcare professional to review (currently TLS Blue). This is currently mainly prescribed by primary care. **Data** From a review of local data from EMIS, we have around 763 adult female patients prescribed topiramate and 35 female children aged 0-17 years. 11% of the adult topiramate patients, 81 patients, were coded as having this for epilepsy indication. With 89% of adult patients having topiramate for another indication such as migraine. Of patients prescribed topiramate 630 patients had a code of migraine in their notes. For children it was noted that 13 patients (51% of children) on topiramate were having it for an epilepsy code. This is just based on EMIS coding that might be slightly different where we haven't done the full audit yet. █ commented that 4 adults on topiramate were also potentially having topiramate related to their Tourette's. So potentially there will be some unlicensed prescribing in our local area and so monitoring of this group will need to be considered. **Traffic light status (TLS)** Traffic light status was discussed with the group as this needs to be clarified to support patient management. **Paediatric** For paediatric patients, the TLS amber 3 months for both indications. It was agreed that this was a sensible TLS and should continue without change. **Adult epilepsy** For adults, for epilepsy, it is classified as amber (specialist recommended). It was discussed that this will need a review as with it only be a specialist recommended drug, secondary care will not have these patients under their care and so won't be able to undertake routine reviews etc. █ commented that topiramate was suggested as a drug to avoid as far back as the 2012 NICE Guidance for Epilepsy. Data about safety and pregnancy has been available for a number of years and so the current epilepsy patients on this medication will likely be historic patients who would benefit from a review as this is not routinely used in practice currently. █ described the two indications it may be prescribed in, are patients who have had trouble with weight gain on the other antiseizure drugs and so topiramate was chosen as an appetite suppressant. The second is the group of patients who have severe migraine as well as epilepsy. But the reality is there are better drugs for both indications. █ asked whether this group of patients on topiramate for epilepsy should be referred in for a review of their topiramate with neurology. █ agreed as he didn't see any other option and mentioned that we don't know what proportion will be under neurology's care from historic prescriptions. It will be likely that patients will have been on it for many years and just no one has felt the need to change the medication. █ commented that following review any patients that needed to continue may therefore come under the new valproate nurse role.	

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	In relation to traffic light status for epilepsy, ■ discussed that the amber status for valproate makes sense as there are monitoring requirements as well as the pregnancy prevention programme, however, if topiramate was to be started by secondary care it would be likely have been dose titrated prior to transfer to GP, In which case Amber specialist initiated might be the way to go if we were to change the traffic light status rather than requiring a shared care protocol. ■ commented that it is unclear however what would need to be included in any shared care protocol for topiramate apart from information around the pregnancy prevention program. ■ suggested having one paragraph that says this shared care protocol is designed to prevent people from prescribing topiramate. ■ mentioned that SCP can have different purposes as many of the new antiseizure drugs have no monitoring requirements but are still amber 3 months shared care. ■ asked ■ if he thought that topiramate for epilepsy needed a SCP given that for migraine it likely won't need a SCP? Is there a need to make it shared care? If there isn't really a need for a SCP then ■ not sure that we need to change the TLS beyond maybe making it amber specialist initiated if the specialist did initiate it would be stabilised, before the GP takes it over. ■ commented that some of these will likely be reviewed over time. ■ suggested as a minimum it should be amber specialist initiated but could be shared care as we would want to put something n in place that reduces the number of future prescriptions. ■ happy for there to be a SCP for topiramate for epilepsy if that is something that clinicians feel strongly about. If topiramate stays TLS blue for migraine anyway, that will be something that clinicians are familiar with. **Adult migraine** For migraine prophylaxis, topiramate is commonly prescribed by primary care and is currently classified as Blue in the traffic light system for adults. ■ asked the group how they felt about primary care maintaining this? Any changes to formulary status and changes to the migraine pathway could impact on existing services. Not sure if there is capacity for secondary care to pick these patients up if status changed and GPs are used to the drug however, they would need to now have patient conversations incorporating risks. There is also a need for clinicians to try 3 options for migraine prophylaxis before considering treatment with Calcitonin Gene-Related Peptide (CGRP) monoclonal antibodies (MABs) in the BNSSG local migraine pathway. There are currently only 5 options on BNSSG formulary before the option for trying a MAB, these include propranolol, candesartan, amitriptyline, topiramate, lamotrigine so we need to consider impact of this with specialist teams and primary care. ■ suggested that his initial thought is that could be reasonable for the migraine cohort because primary care are used to it, especially the cohorts that don't need to be on a PPP, a worry is those that want to stay on it, that are within the PPP cohort and where they sit and sort of getting a referral along for that specific cohort might be the way and if that affects the TLS status past that and not sure it does. ■ commented that there isn't a specific migraine team who looks after migraine currently. ■ agreed and advised that there isn't a specific consultant team for headache only a specialist nurse who runs the MAB clinic. ■ commented that it is complex to know how this should be approached because of the scale of the problem and because topiramate is effective as a treatment for migraine. If it didn't have the stringent requirements for the CGRP MABs, then that's your solution as they're better, they have fewer side effects. However, this would be phenomenally expensive for the NHS, but that's the	

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	ultimate outcome here is all those topiramate patients would ultimately be changed to the monoclonal antibodies. However, it should be noted that they're not safe in pregnancy either so doesn't solve the problem. Therefore, potentially patients that cannot be changed to the other first line drugs in primary care will need to be referred back. █ summarised that the initial advise therefore for primary care would be to review the topiramate patients they have and consider them for an alternative that can be prescribed in primary are in the first instance. █ asked if there would be a situation where a patient wanted to continue on topiramate as they feel it is helping and were happy to go on PPP – where should these patients sit? █ asked █ what the conversation is nationally about managing the topiramate PPP within primary care, as there are some concerns locally already, but being pragmatic and has already been said, it could be quite big cohort and if well managed from a prophylaxis point of view and good adherence to contraception that is something that could continue but there may be some apprehension with the PPP. █ suggested the national feeling is begrudging resignation, the fact that general practice will have to do this because they initiated it and so therefore, they can't hand on the responsibility for monitoring it to anybody else and again we have known about these risks for many years. It's just that we're now adding a bit of paperwork. █ has had a lot of conversations with primary care contracting to ask if it is in the standard contract and they confirmed that it was included in standard contract, that it was a rolling recall program with consent or documented consent, and that was part of standard business. Contracting also highlighted that it was very unlikely to get a directed enhanced service negotiated. Having a conversation with the patient about the risk to children, people are telling █ that is something that general practice would be able to do and keeping the documentation is something they can do, and it really just comes down to the capacity issue as general practice is a fantastic place to have a conversation about highly effective contraception. █ suggested he can see some pushback from GPs. █ suggested that it is both helpful and unhelpful that the MHRA haven't said how frequently you need to see the patient. It's helpful in that gives us flexibility, but it's unhelpful because there'll be a cohort of patients who just don't get seen. █ highlighted that she was wondering about the numbers as topiramate is something that we see more commonly prescribed in women presenting to Sexual and Reproductive Health services. Within the last few months, there was a lady that presented to our pregnancy advisory service and she chose to have a termination of her pregnancy not because of the medication because she had no idea that that would be a problem for her, but I think there will be a consideration, if we start to get the numbers, as potentially this will be something that's more affecting, more people across BNSSG than valproate. **Contraception and topiramate** █ highlighted the difference between valproate and topiramate from a contraceptive perspective. Topiramate is considered to be an enzyme inducing agent and so we would not recommend the use of the implant as an effective form of contraception for topiramate, but the implant is highly effective version for somebody on valproate which isn't on an enzyme inducing agent, so that's just one distinction to make.	

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	The other thing to highlight as well is that we've been alerted to the fact that there is a patient guide for the topiramate pregnancy prevention program, which contains a slight inaccuracy which seems to imply that the vaginal ring is a form of a barrier method. So, this has been highlighted with the MHRA. So please note that there is an error on page four of the document which says, 'using an additional barrier method such as condoms or vaginal ring may be necessary' is not correct because the ring is not a barrier method. █ agreed that it would be important to highlight information around contraception to clinicians. It was discussed that █ to put some different scenarios together and potential processes and share with relevant people outside the meeting. **Action: Scenarios to be drafted and shared with relevant colleagues for discussion**.	
9	**AOB** █ asked what she should do with the topiramate leaflets knowing they had a mistake on them, █ commented that the faculty have addressed it with the MHRA, the Faculty of Sexual and reproductive healthcare, have highlighted it but it is unknown how long it will take for this to be actioned.	

Next Meeting – 10th September 2024

Minutes: █ (Medicines Optimisation team, BNSSG ICB)

BNSSG ICS Medicines Quality and Safety Group Subgroup: Valproate Safety Working Group

Date of Meeting: Tuesday 10th September 2024
Time: 10:30 – 11:30am
Venue: Microsoft Teams

Minutes

Present		
(Chair)	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Neurology pharmacist NBT	
	GP Partner in South Gloucestershire and Clinical Lead GP for prescribing in BNSSG ICB	
	Lead Pharmacist- Medicines Safety, Governance and R&D, AWP	
	Patient Safety Specialist & Clinical Improvement Lead. Medicines Safety Improvement Programme, NHS England (Leads National Valproate Work)	
	Clinical Lead Pharmacist Secure & CAMHS and Lead Pharmacist for Education and Training, AWP	
	Epilepsy surgery ANP, NBT	
	Medication Safety Officer, Sirona care and health	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Paediatric Neurology and Palliative Care Pharmacist, Bristol Royal Hospital for Children	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Deputy Chief Pharmacist and MSO, BNSSG ICB	
Apologies		
	Neurology Consultant, NBT	
	Epilepsy Specialist Nurse, NBT	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	
	Community Sexual and Reproductive Health Registrar	

	Item	Action
1	**Welcome, Introductions and Apologies**	
2	**Minutes and Action log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. went through the action log and discussed the actions: • **Action 6 – Valproate Action and Improvement Plan** – this is ongoing which we will continue to update. Suggest close on the action log. • **Action 13 to liaise with if a status guideline is developed so this can be considered for a joint trust policy.** – Suggest close as linked with .	

	Item	Action
	• **Action 18 - ■ to investigate further how the pregnancy prevention posters could be improved and used and bring back to a future meeting.** To bring to a future meeting, topiramate as well as valproate to be included. Keep open. • **Action 19 - Await the MHRA Drug Safety Update recommendations for existing males on valproate and take actions as appropriate. This could include a draft letter to highlight the risks for patients.** DSU now published and group to discuss actions to take as part of the meeting. • **Action 20 -Topiramate scenarios to be drafted and shared with relevant colleagues for discussion, with an aim of supporting primary care with their topiramate patients.** Suggest close, scenarios drafted and changes made following feedback.	
3	**National and local updates** **Provider updates on the valproate alert:** **AWP** – Valproate dashboard in place and being used, highlighting patients as 'red' when no in-date review. Now currently maintaining it and getting ongoing staff engagement. A communication has been drafted to prescribers to remind them of the dashboard principles and encourage AWP staff to engage with the dashboard and its importance. The valproate doesn't just sit with pharmacy, so needs good engagement with MDTs being used for reviews. **NBT** – Nurse (Gianne) now in post to support the valproate reviews and completion of the ARAFs, early days but working well. **BCH** – Trying to get an electronic risk assessment form set up but not available yet, but the doctors are all aware completing the forms. A temporary register is also in place. Hoping the electronic forms will become their register in the future. **Local updates** ■ informed the group that the valproate support resources which the group had worked on had been approved by APMOC and were published in the CNS guidelines section on Remedy. She thanked the group for their input and support with these documents. **National updates** ■ explained that the September Drug Safety Update which had been recently published had highlighted the concerns around valproate in men. See update and slides below. This alert is based on a retrospective observational study which has indicated a possible association between valproate use by men around the time of conception and an increased risk of neurodevelopmental disorders in their children. The guidance advises clinicians to inform male patients who may father children of this possible increased risk and the recommendation to use effective contraception during valproate treatment and for at least 3 months after stopping valproate. This guidance is in addition to the existing safety recommendations around valproate. ■ commented to the group that in BNSSG we have approximately 1681 males prescribed valproate (subject to coding). This is considerably higher than the number of women on valproate. Healthier Together Valproate Safety Grou	■ ■ ■ ■ ■

	Item	Action
	Resources to support the valproate safety recommendations in men explained that the MHRA have already published some resources to support clinicians around the recommendations which can be used to communicate risks. A document to visualise the risks: Visual_risk_communication_diagram_to_be_used_by_a_healthcare_professional_when_counselling_on_the_risks_PUBLISH.pdf (publishing.service.gov.uk) As well as a document to highlight contraception: Advice_for_male_patients_on_valproate_to_use_contraception_PUBLISH_.pdf (publishing.service.gov.uk) advised that discussions within NHS England have included that primary care is the first point of contact where these patients would likely turn up with their queries and that secondary care wouldn't have capacity for these patients to be referred in. Therefore, some questions and answers have been developed to support clinicians, but they are not NHS England Official documents because they will be unlikely to be signed off by NHSE in a timely way. Ideally these FAQs should come from a Royal college, but this will likely take months and so the FAQs were developed collaboratively to ensure general practice had something to refer to. Therefore, local systems can adopt these to support their implementation of the recommendations. Valproate QA Paternal Risk v0.5.doc It was agreed that the group felt these questions looked useful and so would be good to adopt a local version. commented that the question that feels most uncomfortable is the one around "my child has been affected", so this may need to be carefully considered or even removed. Initial feedback on this question has been around where patients can be sent for review or long waiting times to be seen by a psychiatrist with expertise in learning disabilities. If BNSSG ICB could do anything locally that would be helpful. also mentioned a flow chart that had been drafted and was available for local adaptation. One flow chart considers the male or trans female on valproate and the other the female or trans male with a partner on valproate. It was agreed that this may also prove useful locally. General Practice Responses to Paternal advised that the ICB had been trying to develop an EMIS search to highlight patients potentially at risk and however searching for trans female patients is proving challenging as it relates to coding rather than being an option on 'gender'. agreed and commented that this is tricky because general practice systems record the sex as recognized, not the sex as birth. In addition, patients get a new NHS number when they transition which	

	Item	Action
	means that their previous records become opaque. ■ had not heard of any work arounds for this and so may require the practice to identify and know their patients. **Action:** ■ to draft a pack to support the valproate safety recommendations in men and share with the group for comments. ■ asked if the documents on remedy will need to be updated following the male alert and ■ commented that it may only be the pathway that might need a minor tweak. **Action:** ■ to review and edit current pathway wording where required in relation to male risks.	
4	**Data** ■ showed the group the current prescribing data, which shows BNSSG to be relatively low prescribers of valproate in females aged 13-54yrs per 1000 population when compared with other areas and that there had been a reduction over time which is positive. Prescribing in children 0-12yrs is also relatively low when compared to other areas. ■ then explained to the group that she had requested some data from BI in relation to **learning disabilities**, **socioeconomic deprivation** and **spoken language**. It was discussed that the percentage of **valproate prescribed in those with learning disability was around 21 %** and had been relatively consistent over the last year. It was also noted that half of the prescriptions for valproate or valproic acid were given to individuals living in the top 40% of the most deprived areas (29.5% in the most deprived, and 23% in more deprived than average). There was a range of spoken languages noted with the most being British language group but also reasonable numbers in eastern European and middle eastern. The group discussed that we have patient information leaflets available in different languages including Russian, Romanian and Arabic and also in easy read format. ■ commented that it would be important to review/update these easy read leaflets to ensure still fit for purpose. **Action:** ■ to reach out to the LD consultants to find some volunteers to review the easy read ARAF we currently have. It was also discussed that a template document had been developed to help clinicians have discussions around sexual health with people with autism and learning disabilities. It includes easy read questions and came from focus groups with people with learning disability and including some who also had epilepsy, words being used in the leaflet are their words. ■ highlighted that the focus groups had highlighted that they feel uncomfortable when the health care professional feels uncomfortable and so they suggested that the HCP prepares in advance of having these conversations and the other was to ask the patient how the conversation could be done better next time. It was agreed this looked like a useful document. Educational Resource for autism and or LD.p ■ shared how she had been experiencing feedback from LD teams that they are unhappy about risk forms being signed off by a responsible person and the implications around this, so they have had to add some wording in the AWP procedure that the person signing off has been given the information but not necessarily that they're consenting on the patient's behalf, AWP are using a best interests decisions for patients that lack	

	Item	Action
	capacity and can't make decisions around valproate. ■ also mentioned that there's also been a lot of feedback about people with really severe LD that are in supported accommodation 24/7 where the risk of risk of pregnancy would only occur as part of a criminal act and how the clinicians approach the risk form in that instance, because if they're in 24 hour housing, we obviously don't want to force contraception on people if the only way they would get pregnant would be through a criminal act and so that's been quite challenging. ■ agreed and discussed that a best interest decision would likely be the best approach. The other challenge is how we eliminate the assumptions on people's sexuality because of their learning disability or intellectual disability? ■ agreed saying that they are reviewing every year and doing it as part of best interest decision involving the patient as much as possible, as much as they're able to understand as well as carers and family. A pragmatic approach about in relation to how often they repeat the risks, taking into account if it's going to cause them distress, changes in capacity, housing situation etc.	
6	**Datix /Ulysses** – shared learning from events – All providers ■ explained there had been no recent valproate or topiramate learning events to share with the group.	■
7	**Topiramate** **Formulary status update** For **adult epilepsy** patients, the TLS was agreed to be changed from Amber recommended to [Amber Specialist initiated]() at the September JFG meeting. This should support with recalls for ARAFs and allow secondary care to ensure if topiramate is the most appropriate medication for the patient. **No change for paediatric patients or adult prophylaxis of migraine.** **Topiramate and pregnancy** Following the recent safety recommendations, we wanted to ensure there wasn't any pregnant patients identified on topiramate who weren't aware of the concerns. We therefore ran a search and identified 4 patients who were potentially pregnant and asked practices to review. On patient who was taking topiramate for seizures was to continue throughout pregnancy due to seizure risk but was having a consultant led pregnancy with additional scans and support. Another patient taking for seizures had an unplanned pregnancy, stopped the topiramate at 4 weeks as part of a review and has had multiple scans and no concerns raised about the baby. Two other patients were taking for migraine and they stopped the topiramate upon realising they were pregnant. One of these was referred to neurology as also had seizures. ■ advised that this search will be reviewed periodically to check if any new reports come through and shared with practices. **Draft resources** At the last meeting scenarios were drafted and a document developed to help aid clinicians reviewing their topiramate female patients. Thank you for your comments and feedback, we have tried to edit this document to reflect this. To further support this a document with additional information was also developed and shared with the group. ■ asked if patients are on both topiramate and valproate do they need to complete two forms, ■ responded to say unfortunately yes, they will need an ARAF for valproate **and** topiramate.	■

	Item	Action
	■ commented that he has had some GP feedback that some don't feel confident completing the ARAF form or giving contraception advice but appreciated that others will, but wondered if there was an alternative option for GPs who don't feel comfortable completing the forms? ■ advised that there isn't really an alternative option for completion of the forms, there isn't a consultant who reviews migraines specifically, only an advice and guidance service who could help potentially. The sexual health service Unity may be able to support with the fitting of highly effective contraception, however the responsibility for the topiramate annual review should be undertaken by the specialist prescriber or healthcare professional in primary care (depending on the topiramate indication). Ardens topiramate templates were mentioned, and it was commented that ■ are just confirming what these look like on the GP practice system – linking in with Ardens. **Action:** ■ to confirm information around Ardens templates and expand how clinicians can document contraception in the topiramate resource. Plan to take the topiramate pack to APMOC for October. ■ talked though the support tool. ■ mentioned that it would be good to clarify Unity's role in the pathway. ■ asked about ARAF forms for non-licensed indications and ■ advised that unfortunately this would need to be created as one has not been developed nationally. There was a discussion around future pregnancy prevention programmes but no more are known about currently. ■ commented that he had reviewed AWP data and can confirm that they are not currently prescribing topiramate for indications other than epilepsy or migraine prophylaxis.	
9	**AOB** It was noted that the group was happy to change the group name to include both topiramate and valproate going forward.	

Next Meeting – 5th November 2024

Minutes: ■ (Medicines Optimisation team, BNSSG ICB)

BNSSG ICS Medicines Quality and Safety Group Subgroup: CNS Teratogenic medicines Safety Working Group

Date of Meeting: Tuesday 5th November 2024
Time: 10:30 – 11:30am
Venue: Microsoft Teams

Minutes

Present		
(Chair)	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist, BNSSG	
	Neurology pharmacist NBT	
	GP Partner in South Gloucestershire and Clinical Lead GP for prescribing in BNSSG ICB	
	Lead Pharmacist- Medicines Safety, Governance and R&D, AWP	
	Neurology Consultant, NBT	
	Epilepsy Specialist Nurse, NBT	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	
	Medication Safety Officer, Sirona care and health	
	Medicines Safety Officer, NBT	
	Medicines Safety Officer, UHBW/NBT	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Team Administrator, Medicines Optimisation team, BNSSG ICB	
Apologies		
	Practice Clinical Pharmacist	
	Paediatric Neurology and Palliative Care Pharmacist, Bristol Royal Hospital for Children	

	Item	Action
1	**Welcome, Introductions and Apologies**	
2	**Minutes and Action log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. went through the action log and discussed the actions: • **Action 21 – to draft a pack to support the valproate safety recommendations in men and share with the group for comments.** – This action has been completed as a pack has been drafted and shared with the group, for discussion in the meeting today. Pack will be taken to APMOC in December 24 for sign off. **Suggest close** on the action log. • **Action 22- K to review and edit current valproate pathway wording where required in relation to male risks.** – **Suggest close** as minor tweak has been made to current pathway. • **Action 23 - to reached out to the LD consultants to find some volunteers to review the easy read resources we currently have.** has now gone on maternity leave and so this action has moved to	

	Item	Action
	▇. ▇ reached out to the AWP LD lead and had some comments back but not all and so ▇ will collate the responses and share with the group. **Keep open** • **Action 24 - ▇ to confirm information around Ardens templates and expand how clinicians can document contraception in the resource. Plan to take the topiramate pack to APMOC for October.** Suggest close, ▇ contacted Ardens and included the information re Ardens Topiramate EMIS searches and templates into the topiramate pack which is now available on the [Remedy]() website following approval at APMOC.	
3	**Provider updates** **AWP –** ▇ explained that ▇ had now gone on maternity leave and so he will be leading on this work in the interim supported by the perinatal pharmacist. He explained that AWP were looking at out of date ARAF forms on a quarterly basis and reporting to their executive board, and had noticed an improvement, which was positive. Slowly implementing topiramate recommendations, but no initiations of this medication from an AWP perspective currently. Trainee pharmacist had completed a data collection audit looking at the quality of ARAF Forms, so this will highlight if the clinicians completing the forms correctly, for example is contraception being recorded, are two signatures on the form? The pharmacist is due to write this up in March 2025 and so can be shared with the group in April 2025 and any improvements taken forward. **NBT** – ▇ commented that ▇ is now in post managing the spreadsheet of women on valproate and topiramate, ensuring they are up to date. ▇ mentioned that he had given a lecture at a regional Neuroscience meeting to highlight the safety changes around valproate and topiramate. However, had been met with some resistance, especially in relation to valproate in men. An Australian study had been published around the last month or so and suggests that there was no increased risk in men and valproate. So, this is becoming an increasingly contentious area. There is a lot of push back despite this being part of the regulatory framework. In relation to topiramate, NBT are receiving referrals from GPs which are being slotted into routine appointments as not specific national timeframe for this work. ▇ commented that she has noticed that many male patients are furious in relation to the safety recommendations, especially if they have already had children whilst on valproate or topiramate or sperm count concerns but ▇ has been advising these patients about the contraception requirements and the option to discuss changing medication in the future if they wish to start a family. **UHBW** – ▇ commented that they had been reviewing their registers and were investigating electronic options. Also going to be doing some work around reviewing some local procedures around medicines and try to point to the system guidance, because although the information is available on remedy, some clinicians may find it difficult to locate. ▇ plans to meet with ▇ to see if any joint working is possible. ▇ mentioned that in relation to the male valproate guidance it may be helpful to include information from the Children's hospital for example to support parents if have got questions for the paediatric cohort and so ▇ can support that workstream.	▇ ▇ ▇ ▇ ▇

	Item	Action

Unity – █ mentioned that clinicians are asking people now about the safety recommendations, but it hasn't really come up that much in this sector. █ asked about LARC referral and █ mentioned that they have now moved on to an electronic referral system, so they are now getting referrals in via that route. There is a section for urgent LARC referrals but as this hasn't been overly communicated this may not be being used. There may also be complications due to collective action and referral forms.

Primary care – █ mentioned that from a valproate perspective things seem to be working quite well but is potentially simpler from a GP perspective. In relation to Topiramate, █ hadn't noticed any noticeable push back but commented was early days.

█ mentioned that his colleagues were receiving referrals from GPs in relation to topiramate started in the community. His understanding that if for migraine GPs should be able to review and complete the paperwork is this correct? █ agreed that in this situation, it was agreed that primary care would do this. █ advised the only exception to this is if the treatment was not controlling their migraine and may need support or advice from secondary care, but otherwise primary care should manage. █ commented that if there's an active decision, then we're happy to see them, albeit after a likely delay, but those patients where there isn't an active decision, they're staying on topiramate for migraine, secondary care don't have capacity to review.

Sirona – Nothing to report.

National updates

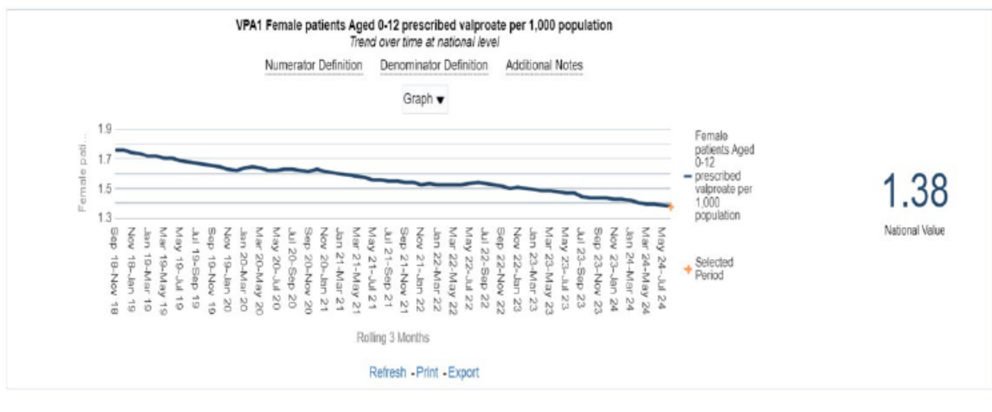
█ highlighted to the group that the BNF and BNF-C now include information relating to the MHRA safety advice about valproate use in men. This mentions that health care professionals should advise patients who may father a child about the risks of treatment, use of effective contraception and the need to refrain from sperm donating.
It also highlights that males who are planning a family should discuss alternatives with a specialist.

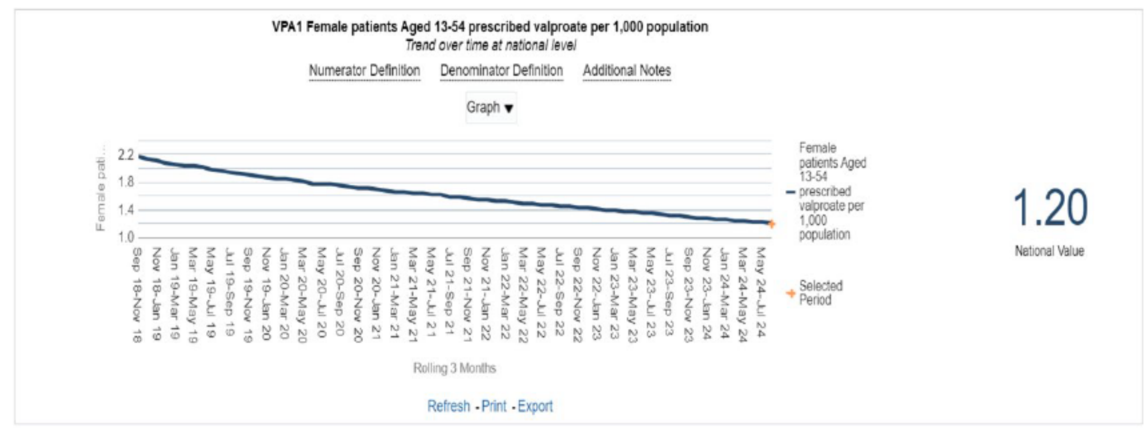
No other national updates noted.

Data

█ show the group current valproate prescribing trends from epact2, which continue to show a **reduction** on patient numbers although the decline is slowing.

Female patients aged 0-12years per 1000 population June-August 24:



	Item	Action
	Female patients aged 13-54 years per 1000 population June-August 24:  discussed how she had run some EMIS searches to investigate how contraception was being used with valproate. Of the women aged 10-55years, approximately 44% were prescribed an implant, levonorgestrel IUD, Depo-Provera injection or copper coil. explained that her search may not be completely accurate due the different EMIS codes that may be used but provides a rough estimate of those using LARC. Similarly, around 45% of those prescribed topiramate were prescribed a LARC method of contraception, excluding the implant (due to the potential interaction). also mentioned that she had reviewed the numbers of males prescribed valproate and this had shown a decrease with 1681 patients on 8th September 24 and now 1647 patients on 4th November 24. also advised that the number of women prescribed topiramate had reduced, with 756 patients aged 18-55yrs on 8th July 24 and now 703 patients on 4th November 24. It would be useful to monitor patient numbers going forward.	
4	**Male valproate resources** discussed the draft resource pack that had been shared with the group and sought their comments and amendments prior to taking to APMOC for approval. explained how this had been done in a similar style to the previous pack, with the separate sections to make the information easier to access. It was mentioned that these had been based on the NHS England resources mentioned at the previous meeting. As part of the discussions, mentioned that CPPE had developed a training package for pharmacists and pharmacy technicians in relation to having these difficult conversations. This was co-written with a lot of patient representatives, and it's trying to support and encourage people who might not see themselves as specialists, so they might feel better able to have these conversations with patients. mentioned that we can make sure this is clear in the FAQs that the CPPE training is for pharmacists and pharmacy technicians. mentioned that the LD resource in the pack was designed by CPPE originally as well as with NHS England. **Action 25:** Check the CPPE training is included in the FAQs and that it is clear that it is available for pharmacists **and** pharmacy technicians. The roles and responsibilities document was discussed to assess if it was in line with local processes and whether anything had been missed. commented that most of the things discussed are included in the different pathways, but one other pathway that could be included could be a referral to a sexual health practitioner.	

	Item	Action
	Action 26: ██ to edit the pathway to include the option to refer to sexual health team In relation to the GP practice text message, ██ advised it would be helpful to discuss this with the UHBW paediatric Neurology pharmacists to see if a paediatric version of the message would be beneficial to support parents in case of any queries etc. **Action 27:** ██ to link with ██ in relation to paediatric messaging in the valproate pack. ██ raised the issue of patients with learning disabilities on valproate whose epilepsy is well controlled on valproate, but they are hesitant to go on or don't want to take contraception. Is it sufficient to take the family's word that they will monitor the patient? How best can this type of encounter be discussed with the family and patient. ██ mentioned that there is a national valproate meeting soon so can raise the issue there. **Action 28**: ██ to ask at the regional valproate meeting about contraception and learning disability patients and any resources. Also ask ██ if AWP have any advice. ██ asked ██ is Unity have any specific resources to discuss contraception with this patient group? ██ advised that they do see people who do have learning difficulties or disabilities, who want to be on contraception and so it is a very different conversation to one where people don't want to take contraception. These conversations can involve a lot of discussion, and if we can assess them to have the capacity to consent, then we're happy to give it, but the issue ██ is talking about is a very difficult, different scenario. It is important that patients are not coerced into having contraception and that whatever we do is something that the patient's consents to and it is their choice. ██ gave the example of where they have declined to fit a coil in somebody that was referred to them who was absolutely terrified about having a coil because they didn't feel that the patient was giving her full consent for that, so they opted not to. However, it is a very difficult conversation and even more so when the patient may have learning difficulties/doesn't have full capacity. ██ mentioned that the use of topiramate and valproate is linked to some evidence of increased fracture risk and we know that with depot there's an increased risk of reduced bone mineral density, so there's some concern about the potential combined effect. The clinical effectiveness unit at the Faculty have reviewed the evidence to say, well, should we not be recommending Depo -Provera to these patients and they haven't come up with that conclusion because the evidence is patchy and not terribly robust. But nevertheless, when you're having these conversations with people about risk these issues come up and when it's not 100% clear, it makes it even more tricky. Therefore, it is important to document all conversations stating that the new risks have been highlighted to patients and carers as appropriate. This is also tricky as the risk is not directly to the patient but to any children they may conceive whilst taking valproate. ██ commented that the pack information looked comprehensive. ██ commented that the best way to get rapid neurology advice is via the electronic advice and guidance service, which is usually responded to within 24 hours other than weekends. This may be helpful for someone who is demanding to come off their valproate because they want to conceive shortly so they can get an alternate plan. **Action 29:** ██ to review the pack to include this advice and guidance information for neurology patients.	
7	**Topiramate** ██ highlighted that the topiramate information pack and scenarios which had been discussed at the previous meeting, has now been approved at APMOC and has been added to Remedy in the guidelines section.	

	Item	Action
	See: 4. Central Nervous System Guidelines (Remedy BNSSG ICB). █ also mentioned that there is a new safety page on Remedy which also links to this information, see: Medicines Quality and Safety (Remedy BNSSG ICB)	
	Datix /Ulysses – shared learning from events – All providers █ explained there had only been one valproate Datix since the last meeting, this Datix was a report from a GP practice which related to an ARAF form which the practice had not received and had tried to contact the provider. Upon investigation, the review and form had been completed but just hadn't been sent to the practice. This opened a discussion regarding whether Datix was the correct route for this type of query. Two other Datix reports relating to topiramate were mentioned, one where the clinical indication for the topiramate was unclear and another related to the paediatric reconciliation exercise where a patient had topiramate on their medical record listed as a hospital item but was no longer being prescribed so was useful to tidy up the patient records to prevent confusion.	█
	Updated Terms of Reference █ went through the updated terms of reference for the group which had been shared when the group papers were circulated. The group name had been changed to the teratogenic medicines' safety working group to include both valproate and topiramate. Other tweaks were minor within the document, with the membership and quoracy remaining similar. The group remained happy with the currently frequency of meetings. There was a discussion regarding what medications the group included, and it was discussed that currently it focuses on the neurology medications. There was a suggestion that it could be called the Teratogenic CNS medicines safety group. █ mentioned a research group at Bath university who look at drug safety in pregnancy, whom she is working with as it may link with some of the work this group have been undertaking. It was agreed that it would be useful for █ to invite. **Action 30:** █ to invite a member of the Bath University research group to a future meeting to share the work they have been undertaking.	
9	**AOB** █ asked whether the men in valproate study had been published yet? █ to check with █. █ asked █ to share the reference for the Australian journal article so the group can review. **Action 31**: █ to ask █ about whether any valproate and men studies have been published. **Post meeting note:** █ contacted █ and he was not aware of the Scandinavian studies being published in a peer reviewed journal as yet and MHRA has not released the data. **Action 32**: █ to share the reference for the Australian valproate study with the group.	

Next Meeting – TBC

Minutes: █ (Medicines Optimisation team, BNSSG ICB)

BNSSG ICS Medicines Quality and Safety Group Subgroup: CNS Teratogenic medicines Safety Working Group

Date of Meeting: Tuesday 7th January 2025
Time: 10:00 – 11:00am
Venue: Microsoft Teams

Minutes

Present		
(Chair)	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist, BNSSG	
	Neurology pharmacist NBT	
	GP Partner in South Gloucestershire and Clinical Lead GP for prescribing in BNSSG ICB	
	Lead Pharmacist- Medicines Safety, Governance and R&D, AWP	
	Epilepsy Specialist Nurse, NBT	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	
	Paediatric Neurology and Palliative Care Pharmacist, Bristol Royal Hospital for Children	
	Medicines Safety Officer, UHBW/NBT	
	Patient Safety Specialist & Clinical Improvement Lead. Medicines Safety Improvement Programme, NHS England.	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
Apologies		
	Practice Clinical Pharmacist, Clinical Pharmacist Ardens for EMIS web	
	Medicines Safety Officer, NBT	
	Team Administrator, Medicines Optimisation team, BNSSG ICB	

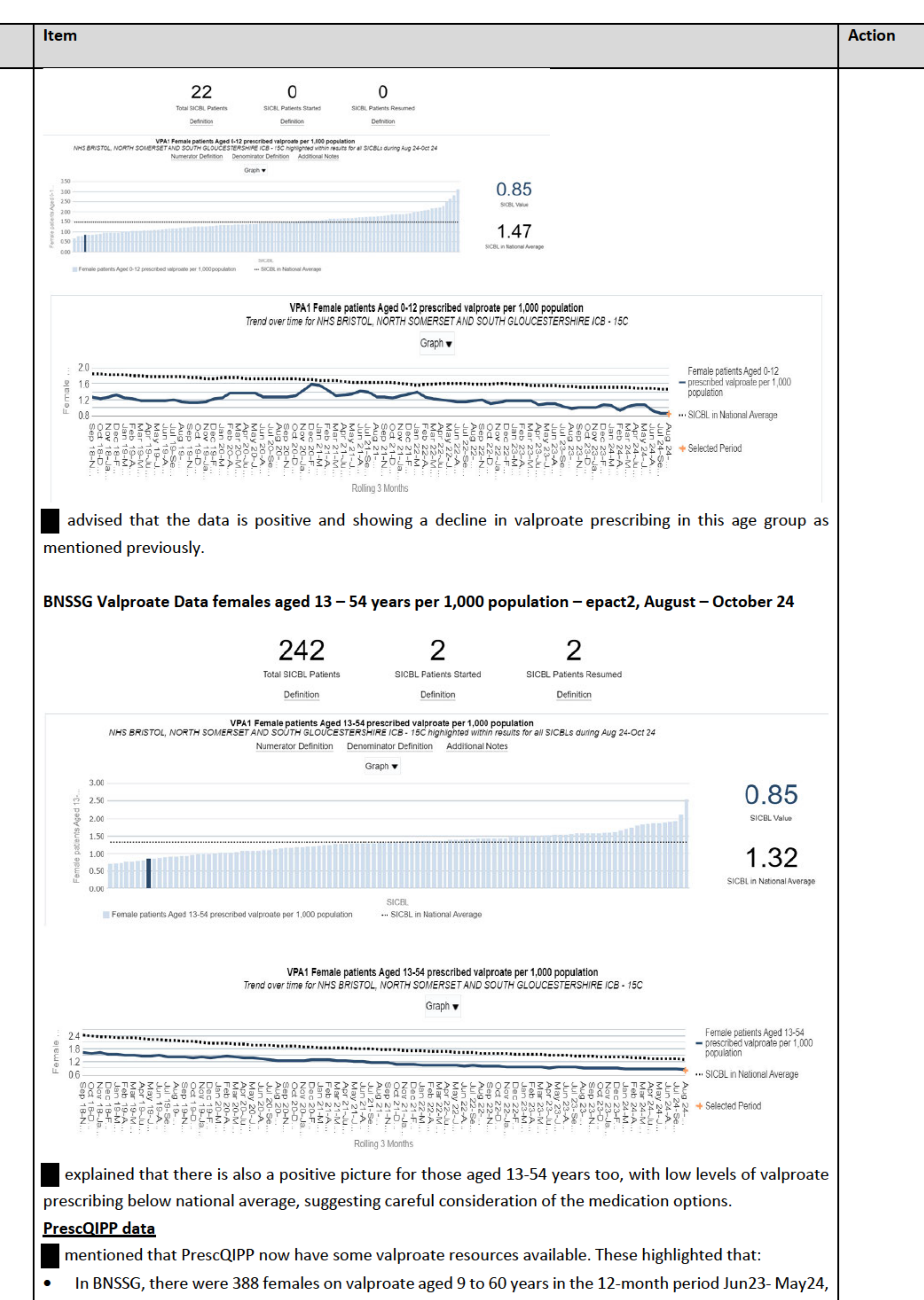
	Item	Action
1	**Welcome, Introductions and Apologies**	
2	**Minutes and Action log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. went through the action log and discussed the actions: • **Action 23 - to reached out to the consultants to find some volunteers to review the easy read resources we currently have.** This was further discussed as Manchester LD leaflet wording had not been agreed by the group, and due to legal technicalities with the Choice and Medications leaflet which AWP subscribe to, this can only be used by its subscribers and so not shared wider for example on the ICB website. highlighted that his colleague in NHS England South East Region had completed an extensive quality and safety improvement project to develop an easy-read leaflet for people taking valproate. This had been developed alongside clinicians and experts by experience, including people with learning disabilities, to ensure it is as informative and accessible as possible. As	

	Item	Action
	this has been developed by NHS England, this would be available for ICB areas to use without a license/cost. Suggest close action and start new action. **New Action (Action 33): ■ to contact ■ about the leaflet and when this may be available.** ***Post meeting note:*** *■ emailed ■ and the leaflet has been finalised – see attached document with link to finalised leaflet* • **Action 25 - Check the CPPE training is included in the FAQs and its audience is clear i.e. applies to pharmacists and pharmacy technicians**. Actioned FAQs clarified suggest close • **Action 26** - ■ **to edit the pathway to include the option to refer to sexual health team** Referral to sexual health included in the pathway suggest close • **Action 27 -■ to link with ■ in relation to paediatric messaging in the valproate pack** Action complete, suggest close • **Action 28 - ■ to ask at the regional valproate meeting about contraception and learning disability patients and any resources. Also ask ■ if AWP have any advice** Discussed in meeting, suggest close. • **Action 29 ■ to review the pack to include advice and guidance service information for neurology patients** Action complete, suggest close • **Action 30■ to invite a member of the Bath University research group to a future meeting to share the work they have been undertaking.** ■ discussed with ■, who unfortunately was unable to attend the January meeting but hopes to attend the following meeting, keep open. • **Action 31 - ■ to ask ■ about whether any valproate and men studies have been published** ■ commented that the Scandinavian studies have not been published in a peer reviewed journal yet and the MHRA has not released the data. Suggest close action. • **Action 32 ■ to share the reference for the Australian valproate study with the group**. This action was outstanding, keep open.	
3	**Provider updates** **UHBW Bristol Children's Hospital-** ■ explained that there hadn't been much change since the previous meeting and that they were continuing to investigate electronic valproate form. ■ mentioned that there had been a decrease in valproate prescribing in those aged 12 years or under which may potentially suggest that prescribers are carefully considering the medication choices when valproate is a potential treatment option. ■ agreed that there were more discussions ongoing in relation to medication choices. **AWP –** ■ discussed that AWP were continuing to monitor compliance on their valproate dashboard in relation to out of date ARAF forms on a quarterly basis, quarter 2 data had shown an improvement, which was positive, quarter 3 data is due to be reviewed. The trainee pharmacist who had completed a data collection audit looking at the quality of ARAF Forms of the patients on the dashboard is due to return in March and so the results will be written and recommendations presented on their return. However, as the raw data is available ■ mentioned that they are proactively	

	Item	Action
	discussing the findings with individual clinicians e.g. where compliance isn't 100% mainly around second signature. Due to the geography of AWP, this is a large task. ■ mentioned that this is further complicated when reviewing learning disabilities clinicians as some come under Sirona and others AWP governance. It was suggested ■ link with ■ the MSO at Sirona. ■ mentioned that some patients were being prescribed valproate for epilepsy and reviews and ARAF forms completed by clinicians in the learning disability team. ■ commented that this makes it complicated when considering who is responsible for the compliance of these patients. ■ asked about the use of electronic ARAF forms and how AWP gets patients to sign the form. ■ advised that it is electronic as the information feeds into the electronic dashboard but would double check around the signatures. ■ mentioned that she thought that ■ had been in touch with the MHRA in relation to signatures and they confirmed a wet signature isn't required. ■ confirmed that she also had information from the MHRA on this and so will share with ■ and ■. ■ asked if ■ could share the email from the MHRA around wet signature. ■ commented that having that documentation in the records if a patient said that they didn't consent to that afterwards it is a bit trickier if the ARAF form isn't signed. Also is it appropriate to bring patients back into clinic if they have complex needs once a year. It would be helpful to know the medico-legal position further down the line around not having a signature on the form. **Action 34:** ■ to share MHRA information regarding signatures with ■ and ■ ■ mentioned that the regulations were all encompassed in the SPC for Valproate, and this does not say that the patient needs to sign a consent form, so therefore clinicians can't be held to having to have a patient sign the ARAF. The only difficulty that ■ sees relates to when the GP receives the ARAF, and it hasn't got the patient signature on. How do we verify to the GP that the patient was involved in the conversations? However, this can be done in any way that might work in local systems. It can make it difficult for the GP not knowing who has signed the form on their behalf e.g. if it is a carer and what discussions were had. Leaving the signature blank is still within the regulations. ■ asked how the UHBW dermatology team get signatures in relation to isotretinoin and ■ mentioned that these are undertaken at face-to-face meetings either at initiation or at an annual review meeting. ■ not clear if the valproate annual review will always be face to face. ■ mentioned that in relation to learning disability patients, there's no problem with LD specialists prescribing valproate for epilepsy related conditions. The only question that could be asked - was the prescribing by an LD physician comparable to the prescribing of a Neurologist or an Epileptologist? So that we know when the LD clinician was prescribing that they were considering a full range of medication options. Is the clinical standard the same? There is a risk that the clinicians are happy prescribing valproate as they are familiar with the medication but wouldn't really want to prescribe anything else because they're not experienced with the other medications meaning that their default was valproate and so this is something we would want to be considered. This is why it may be important for clinicians in this situation to link with other specialists or be part of an MDT, so they have a sounding board elsewhere. However, the *pathway* could be seen as a better one for the patient only seeing one clinician in an appointment where all things are covered.	

	Item	Action
	██ commented that he would like to think that the cases he has seen would have included neurology input into any prescribing decisions. It was more an issue around the management of the ARAF forms that they were happy to make those decisions. ██ also told the group that they have created a new pharmacist post at AWP, for an LD specialist pharmacist which didn't exist previously, so this will be helpful. The group agreed it was positive to see new roles in this area. **NBT** – ██ mentioned that they had recently reviewed a couple of cases whereby receipt of ARAF forms had been delayed but upon investigation, it looked as though these delays were for a variety of reasons some relating to secondary care, some primary care and some due to patients not returning paperwork or engaging with appointments. ██ commented that the current problems relate to engagement, with appointments being offered but patients or parents not confirming if they will attend or not, which could potentially lead to a wasted appointment if they don't attend. A lot of time is being spent chasing appointments etc. However, clinicians are more pro-active now in terms of counter signing the ARAF forms. ██ asked the other providers if they had any suggestions with how to manage patients who do not attend their review appointments. ██ commented on how sending invites in different ways such as email, text reminders, phone calls can help as well as considering any language issues but agree it can be very time intensive, especially if the patient is not keen on coming for an appointment. ██ mentioned the recent Nottingham report where it looked at concordance issues with patients, not just in relation to mediations but also appointment attendance. AWP are completing a bit of work around this not just valproate but patient adherence to appointments, but it is a big piece of work and what systems are in place to address missed appointments. ██ mentioned that they were looking at formulating an electronic valproate checklist form like the one used in NBT for isotretinoin, so not solely relying on uploading the hard copy of the ARAF as a record. However, not all staff may be onboard with this form currently so needs further discussion but could be helpful for example to clarify about patient discussions and if remote/ face to face appointment. ██ mentioned that in sexual health services, they offer flexibility in relation to timing and location (due to having multiple bases), with teenagers (who have a high rate on non-attendance) having specific teenage pregnancy outreach nurses that can also provide the option of telephone appointments. Text reminders are used and where the wait is very long but high DNA rate they phone the patient, the day before, but this comes down to available resource and investment to ensure patients comes and then if they are not attending, work to refill the appointment slot. ██ commented on 2 learning points from other areas, point one, understanding getting the patient to attend the consultation must be an 'every contact counts' approach by the whole system. Once you understand who sees the patient e.g. community pharmacist, GP then it can be considered what part can they do – e.g. part/step 2 of the ARAF form must be done by a specialist, but discussion of risk and contraception discussion in part/step 3 of the ARAF form can be done by other people. Is it better to have the risk managed and have a partial ARAF rather than no ARAF in patients who are constantly not attending appointments. Point two is that some other areas have seen GPs complete the risk section but not the specialist assessment. No one has involved the sexual health services or community pharmacy teams yet (depends on where the patient is presenting) but a whole system approach should be considered.	

	Item	Action
	■ asked ■ if perhaps the local picture could be broken down, could we look at the trends of people who didn't attend to align focused work? ■ mentioned the BNSSG valproate patient survey previously undertaken which looked at the barriers to the form being completed but perhaps we could look at the survey again with an appointment focus instead of an ARAF focus. **Action 35:** ■ to share the previous patient survey findings with the group **Unity** – ■ mentioned no updates to report **Primary care** ■ mentioned that no problems arisen recently. In relation to the issues, for other medicines when there is non-attendance such as for monitoring etc they restrict or modify the medication issues/ amount given to the patient, but you can't necessarily do this for valproate due to the higher risks of harms. Similar to what others have mentioned, primary care does use a proactive calling approach in these cases. In terms of not having multiple contacts, for example in the LD example ■ mentioned, the reassurance that the GP would need would be around the right steps taking place with assurance that the counselling has taken place on initiation and annual reviews. **National updates** No national updates noted at the meeting. ■ mentioned the MHRA are reviewing if the safety alert has been effective and the registry highlights that nationally we have seen a reduction from 15 -17 pregnancies whilst on valproate in a 6-month period to 11 pregnancies. So, this is 11 pregnancies in 19,000 women so very small number of pregnancies exposed to valproate. Now waiting for sign off to do a review of the 60 cases over the last 2 years case reviews –this will help to inform if future work is needed, were these informed choices? if so then this is reassuring or if not, is further work needed. Although 11 cases/exposed pregnancies out of 19,000 women are small in number if these patients hadn't been informed then it might highlight a gap. No work around adverse consequences of the changes yet such as sudden epileptic death, suicide etc, so this is still an unknown. Internationally, we are now lower in relation to valproate pregnancies than Denmark and Germany who were noted to be better than England previously, so this is positive to note.	
4	**Male valproate resources** ■ advised that the male valproate resources had been approved at APMOC and had been added to the Remedy website.	
	Data **Epact2 data** **BNSSG Valproate Data females aged 0 – 12 years per 1,000 population – epact2, August – October 24**	



	Item	Action

█ advised that the data is positive and showing a decline in valproate prescribing in this age group as mentioned previously.

BNSSG Valproate Data females aged 13 – 54 years per 1,000 population – epact2, August – October 24

█ explained that there is also a positive picture for those aged 13-54 years too, with low levels of valproate prescribing below national average, suggesting careful consideration of the medication options.

PrescQIPP data

█ mentioned that PrescQIPP now have some valproate resources available. These highlighted that:

- In BNSSG, there were 388 females on valproate aged 9 to 60 years in the 12-month period Jun23- May24, who have not been prescribed any contraception within the last 5 years.

	Item	Action
	• In BNSSG, there were 1216 males under 55years on valproate in the 12-month period June 23 – May 24. ■ mentioned that it maybe we want to revisit those patients that haven't had contraception and were on valproate to ensure it is an informed choice and not missed. ■ mentioned that the Prescqipp data comes from epact2 items so any contraception given from outside the GP practice e.g. from a contraception/sexual health clinic may not be picked up, also personally administered items such as some contraceptive injections may not be seen in the data. So, the data could be showing some false negatives for people who were actually on contraception, however, is still a useful piece to look at and whether there is variation across BNSSG. ■ mentioned that those over 55years don't usually need contraception and so this may also be affecting the data too. **Action 36:** ■ to investigate trends around those patients without contraception prescribed valproate	
	VIQI November 24 ■ explained that she raised the group's question relating to what clinicians should do when they're reviewing patients with LD who didn't want to go on contraception to ensure that they'd understood the risks, and they were happy to keep taking their valproate/topiramate medication despite not being on contraception. A summary of the discussion around this question can be seen in the attached document. Notes from the Nov 24 VIQI groupv2.docx ■ advised that this prompted a wider discussion at the meeting. However, the group commented that there should be a framework to ensure that clinicians have had that good quality conversation with the person with Learning Disabilities. If the clinician thinks that that person with LD has capacity and that they can make that decision regarding contraception, that that is fine but ensure it is documented. ■ mentioned that example of cohesion had been discussed by other areas. ■ advised that the meeting is available on NHS Futures and so people can sign up and listen into the meeting if they wanted to. See: https://drive.google.com/file/d/10CvMPSGJQgCrLnbDly1jtuW3AUL-8iZO/view	
	Valproate original pack form amendment & SPS recommendations re valproate stability ■ explained that previously the group had developed an original pack dispensing form to support valproate dispensing, for example if it was unable to be given in an original pack, following the publication of the valproate safety recommendations. It has since been highlighted that the Specialist Pharmacy Service (SPS) website now states that valproate should not be added to a Monitored Dosage System (MDS) as the preparations are hygroscopic which could affect the medication release profile. It was therefore suggested that appendix 1 of the BNSSG Valproate OP form was edited to remove the line which said, '*Patient supplied medication in a monitored dosage system (MDS)/compliance aid*' so we are not overly promoting this, however, if following a risk assessment, it was deemed appropriate to provide in an MDS, this could still be added in the 'other reason section'. A link the SPS website is also included. An additional change was also proposed to 'Other reason the patient is unable to manage valproate separately' to 'Other reason the patient is unable to manage valproate in an original pack' and this was agreed by the group. ■ advised the group that any further comments should be sent to her by the end of the week and then the version will be taken as final and replace the previous one. **Action 37:** Any final comments to be shared with ■ on the Original pack document by the end of the week.	

	Item	Action
7	**Topiramate** No specific comments to note in relation to topiramate	
	Datix /Ulysses – shared learning from events – All providers █ explained there had only been one valproate Datix to the ICB and no topiramate reports since the last meeting, this Datix related to a patient who had been re-referred to neurology as they had no Pregnancy Prevention plan with regards to Valproate. This referral had then been rejected by neurology with the comment: patient discharged in 2016. Does not need an appointment as per request. The patient had been taking for epilepsy. This is currently being investigated by the relevant secondary care patient safety team. █ commented that she had been reviewing incidents and noted that there had been 6 incidents in quarter 3 for UHBW relating to valproate. These related to missed doses, incorrectly giving semi sodium valproate instead of valproate, patient labelled medication being returned into the general stock, so generally quite reassuring as a small number of low-level incidents given the total number of UHBW incidents. █ highlighted that one incident had been reported nationally of a patient who died of sudden epileptic death, whilst they were transitioning from one medication to another for their epilepsy, the report didn't say it was valproate, but it seems very likely that it was either valproate or topiramate. It is well known that there is a risk of harm when changing medication and hence close monitoring etc is required. █ mentioned that it hasn't been shown to increase the risk of death, but it does increase the risk of harm and so potentially the studies weren't powered enough to show an increase in death when you change medicines. Given there has been a lot of changing of medication across the whole of the country, this incident was important to note and good to monitor to ensure we are reviewing the potential harms associated with the valproate/ topiramate safety alerts.	█
9	**AOB** **New sodium valproate information hub launched by the Welsh government** █ shared a link with the group about the new Welsh valproate hub, this has information in Welsh and English. It usefully groups key information about valproate in one central place. See: New sodium valproate information hub launched - All Wales Therapeutics and Toxicology Centre Sodium valproate - All Wales Therapeutics and Toxicology Centre **Terms of Reference** The finalised TOR had been shared with the meeting papers; these will be deemed as final unless any further comments received.	

Next Meeting – 11th March 2025

Minutes: █ (Medicines Optimisation team, BNSSG ICB)

BNSSG ICS Medicines Quality and Safety Group Subgroup: CNS Teratogenic medicines Safety Working Group Minutes of the meeting held on Tuesday 11th March 2025 at 10am-11am, MS Teams

Minutes

Present		
(Chair)	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Medicines Safety officer, Sirona	
	Neurology pharmacist NBT	
	Team Administrator, Medicines Optimisation team, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist, BNSSG	
	Lead Pharmacist- Medicines Safety, Governance and R&D, AWP	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
Apologies		
	Practice Clinical Pharmacist	
	Interim Medicines Governance Pharmacist, NBT	
	Patient Safety Specialist & Clinical Improvement Lead. Medicines Safety Improvement Programme, NHS England.	
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	
	Paediatric Neurology and Palliative Care Pharmacist, Bristol Royal Hospital for Children	
	Paediatric Renal, Neuroscience and Palliative Care Pharmacist, Bristol Royal Hospital for Children	
	Pharmacy Governance Lead and Hospital Group Medication Safety Officer, UHBW/NBT	
In attendance		
	Senior Lecturer, Department of Life Sciences, University of Bath	

	Item	Action
01	**Apologies, Declarations of interest** █ shared the apologies as noted above. No declarations of interest were declared.	█
02	**Minutes of last meeting and Action Log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. █ went through the action log: • **Action 30- █ to invite a member of the Bath University research group to a future meeting to share the work they have been undertaking.** This can be closed as on the agenda for this meeting. • **Action 32 - █ to share the reference for the Australian valproate study with the group**. This action was outstanding, keep open • **Action 33- █ to contact █ about the valproate leaflet aimed to support discussions with LD patients and investigate when this may be available**. This can be closed as actioned and leaflet shared with group, for discussion at the meeting. • **Action 34 - █ to share MHRA information regarding signatures with █ and █**. Action complete, this can be closed. • **Action 35 - █ to share the previous patient survey findings with the group.** This can be closed as action complete • **Action 36- █ to investigate trends around those patients without contraception prescribed valproate.** Some data in this area to be discussed at the meeting. • **Action 37- Any final comments to be shared with █ on the Original pack document by the end of the week (by 13/1/25).** Action can be closed, document updated and finalised, shared with group and added to Remedy.	
03	**Teratogenic Medicines Research Feedback from University of Bath** █, Senior Lecturer from the University of Bath presented on primary care data for health research, with a focus on some studies which related to potential medication harms in pregnancy. █ presented the embedded presentation to the group. (*Nb. Presentation information not for wider sharing outside of the teratogenic medicines group*). Bristol_11MAR2025_ McGrogan1.pptx █ gave an overview of how data from the Clinical Practice Research datalink (CPRD) was used and reviewed. CPRD collects anonymised patient data from a network of GP practices across the UK, although mainly from England. It is a very	

	Item	Action
	rich dataset and pregnancy cohort data can be reviewed although some data cleansing can be needed. Two studies were discussed. The first study, ran for approximately 20 years and is about to be submitted, this study focuses on immune-mediated inflammatory diseases in pregnancy, including psoriatic arthritis, psoriasis, spondyloarthritis and inflammatory bowel disease. This data is currently being finalised; however, it suggests a reassuring message. Potential outcomes such as major congenital malformations and pregnancy loss were reviewed and the results didn't highlight anything which in a pregnancy study is good news. A small increased risk of pregnancy loss in IBD was noted but existing literature suggests this is known. The second study, which may be of more interest to the group, is the ongoing research on epilepsy treatments during pregnancy. The study reviews women with epilepsy diagnosed prior to pregnancy, prescribed an antiseizure medication as well as those without an antiseizure medication and looks at a range of potential outcomes including pregnancy loss, neurodevelopment disorders and foetal valproate syndrome. The data review also includes pre-pregnancy data, during pregnancy data and data post pregnancy. While some preliminary numbers are available, they are not yet confirmed and should not be quoted. The results are expected later in the year and will be interesting to compare with European data. █ stated that the study findings would be of interest to this group and so it would be helpful to invite █ back at the end of the year to share the results. **Action: Invite █ back to the group at the end of the year.**	
04	**National and local updates** **NBT** █ mentioned that electronic valproate checklist form was still being investigated. It was mentioned that █ has been looking into whether there is a need for patients/carers to sign the valproate Annual Risk Acknowledgement Form. █ explained they had contacted the MHRA about this and they had confirmed the following; *"The purpose of the ARAF is to support and record the discussion between the patient and prescriber about the risks of valproate. It is not a formal consent form and there is no legal requirement for the patient or carer to sign the form, however the patient or carer is asked to sign the form as a record that they have had a discussion of the risks with the prescriber. The patient/carer should be provided with a copy of the form as a record of the discussion."* █ commented that this suggests that best practise would be to have a signature so that you know there is a clear record of what was discussed, but legally, if you can't get the signature, you're not going to have an issue, as long as information has been shared with the patient, and it is documented.	

	Item	Action
	AWP [redacted] provided an update for AWP; he mentioned that the trainee pharmacist is now back and has written up the draft audit which reviewed the quality of ARAF completion. This is aimed to be presented at the AWP MOG at the end of March. It was agreed that it would be useful to share the findings with the group. **Action: To invite the AWP trainee pharmacist (or [redacted]) to the next meeting to share the audit findings**. [redacted] mentioned that they have identified a cohort of patients with learning disabilities who are not on Rio and technically come under Sirona. It is complicated but [redacted] and [redacted] are trying to work together to ensure good governance and monitor ARAF completion compliance. [redacted] mentioned that improvements in ARAF completion are being seen, and it is thought this is likely due to using their Locality Pharmacists, so they only have a few patients to discussed with the consultants. They also have a local procedure in place to support them too. This appears to be working well given the geographical spread of AWP. **Sirona** [redacted] mentioned that they had been looking into the governance into the patient group [redacted] had mentioned. They plan to discuss the details with the services involved to work a way forward. **VIQI update** [redacted] provided feedback from the VIQI meeting in February. She explained that there had been a discussion about the easy read valproate leaflet that had been developed by [redacted] in NHS England with clinicians and experts by experience, including people with learning disabilities, to ensure it is as informative and accessible as possible. NHS Creative had supported the artwork in the leaflet and the translated materials. Following the development of this easy read leaflet they hope to develop a similar leaflet aimed at male patients. The group discussed adopting this leaflet and there was agreement from all parties in the meeting. It was agreed for this to be added to Remedy and to also be re-shared with the group so providers can save and use as needed. **Action: [redacted] to add a link to the valproate easy read leaflet and translated resources on Remedy.** The leaflet can be accessed via the following website: Valproate - Welcome [redacted] queried about a card being given out when valproate prescriptions are dispensed. [redacted] has added this to their SOP. [redacted] mentioned that these are included in the risk materials, a patient card which highlights contraception and pregnancy prevention. Some community pharmacies may provide, or they can be issued via a clinician as a printed copy or an electronic version. [redacted] mentioned that nationally there is still a wait for the MHRA to agree with the manufacturers about the update to the risk materials in relation to males and the neurodevelopmental disorder risks. [redacted] also mentioned that at the VIQI meeting some areas of the country were experiencing issues with primary care refusing to prescribe valproate unless a valid	

<table>
<tr><th></th><th>Item</th><th>Action</th></tr>
<tr><td></td><td>ARAF was in place and so had become a 'red' drug. Locally we have not seen this in BNSSG, with both AWP and NBT having systems in place to support these forms.

There had also been discussions in relation to patients who serial DNA appointments and how clinicians are having difficult conversations. No easy solution identified but clinicians trying to have conversations in a different way, different communications, with different clinicians e.g. secondary care clinicians, GPs, Pharmacists all reiterating the safety messages, which is important as when people are having valproate for epilepsy, this can't be stopped suddenly due to the risk of seizures.

<u>Drug safety update</u>

█ highlighted the February 25 Drug Safety Update which had a focus on valproate. This update explained that the CHM has advised that a review by two specialists is required for initiating valproate in patients under 55 years of age but not for men who are already taking valproate.

█ explained that they had developed three infographics to clarify in which situations review by two specialists may be required:
• for female patients under 55 years old
• for male patients under 55 years old
• for male and female patients 55 years and older

█ mentioned that these documents will be added to Remedy. It was agreed these are a helpful summary and are in line with our current local pathways.</td><td></td></tr>
<tr><td>05</td><td>Data Review

█ shared data regarding the prescribing of valproate in comparison to other ICBs and BNSSG continue to show low numbers below the national average for both adults and children, which is positive. See slide set:

Teratogenic Meds Safety Group March 2

█ also showed some data from EMIS to the group. This is a search which a London ICB had used to review their data. The data does rely on coding so there are limitations to this information but provides a helpful overview. █ raised that there may be some data missed from other clinics that may not be communicated to the GP (and their EMIS system).

The data shows 253 patients prescribed valproate currently, with 106 of these having an ARAF on their record but only 57 of these patients having their ARAF recorded as being in the last 12 months. It may be that these forms are not being coded or potentially saved in a separate area so not identified by the search, but it does highlight that it would be helpful for us to encourage better coding in this area. Contraceptive advice was also noted to be lower than expected, however, this again may relate to how it is coded as some clinicians may free type in the notes.</td><td></td></tr>
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	Item	Action
	In relation to contraception, the search would suggest low numbers of highly effective contraception being prescribed but again may come down to coding or prescribing from other clinics. The indication data, however, did reflect on what we expected with most patients on valproate being prescribed it for epilepsy with the second most common indication being bipolar. See slide set. Further work may be needed to understand our data a bit better. However, it might be timely to send a reminder to code ARAF forms once received on the EMIS system.	
06	**Datix / Ulysses** ■ stated one Datix was received since the last meeting. This case revolves around a postmenopausal patient who underwent menopause at 40years and is no longer of childbearing potential. There seems to be a discrepancy regarding the completion of ARAF form, which wasn't done during the patient's visit to neurology in July 24 due to the patient being post-menopausal. However, the practice felt that the patient still required an ARAF completing as they feel the shared care protocol asks for this. ■ explained that the shared care protocol might need to be tweaked to ensure there is clearer guidance for cases where there is no risk of pregnancy, such as in postmenopausal patients. Existing guidance, including resources like EMC for valproate and recommendations from the Royal College, suggests these patients may not need referral for an ARAF to be completed on an annual basis but the interpretation appears inconsistent. An email was sent to the epilepsy nurses for clarification and agreement and national guidance shared with the GP practice. The discussion highlights a need for reviewing the wording and clarity in shared care protocols to avoid misunderstandings in similar cases. **Action- ■ to review the wording on the SCP in case of any required amendment.**	
07	**AOB** NICE guidance ■ shared the updated NICE guidance - Epilepsies in children, young people and adults (NG217) and explained that the update now included the MHRA safety recommendations in relation to valproate and topiramate. Related articles in the news ■ also mentioned the BMJ and Guardian articles which discussed an analysis of the use of sodium valproate and other antiseizure drug treatments in England and Wales based on national level electronic health records. The findings show that the rates for use of sodium valproate by women, including during pregnancy, decreased, in response to warnings about its effects, but the map reveals clear differences in dispensing patterns to women of child-bearing age, with the highest rates being found in local authorities in the north-west and across coastal regions in the east. These variations highlight potential inequalities that need further investigation, the researchers warn. Incident use was also reduced in men but remained at much higher levels than in women.	

	Item	Action
	It was also interesting to note that the analysis the research showed that between 2019 and 2023, new use of sodium valproate fell from 7 to 5 per 100,000 women in those aged 15-19, from 11 to 7 in those aged 20-29, and 14 to 7 in those aged 30-39. Pregnancy rates fell from 6.0 to 5.2 per 1,000 women dispensed sodium valproate over the same period. There was no clear evidence that epilepsy-related deaths increased in women aged 15-49 during 2015-2022, but there was some evidence for a slight increase in men aged 15-49yrs during the period April 2018 to December 2022. For further information see: Use of sodium valproate and other antiseizure drug treatments in England and Wales: quantitative analysis of nationwide linked electronic health records | BMJ Medicine Scientists map use of epilepsy drug in England and Wales linked to birth defects | Medical research | The Guardian **Future meetings** It was also noted that further meeting dates need to be shared for future meetings. **Action: Dates for further meetings to be sent out.**	
	Date of next meeting: To be confirmed	

Team Administrator, Meds Ops
March 2025

BNSSG ICS Medicines Quality and Safety Group
Subgroup: CNS Teratogenic Medicines Safety Working Group
Minutes of the meeting held on Tuesday 13th May 2025 at 10am-11am, MS Teams

Minutes

Present		
[redacted] (Chair)	Principal Medicines Optimisation Pharmacist, Medicines Optimisation team, BNSSG ICB	[redacted]
[redacted]	Medicines Safety Officer, Sirona	[redacted]
[redacted]	Neurology Pharmacist NBT	[redacted]
[redacted]	Team Administrator, Medicines Optimisation team, BNSSG ICB	[redacted]
[redacted]	Senior Medicines Optimisation Pharmacist, BNSSG ICB	[redacted]
[redacted]	Lead Pharmacist- Medicines Safety, Governance and R&D, AWP	[redacted]
[redacted]	Senior Medicines Optimisation Pharmacist, BNSSG ICB	[redacted]
[redacted]	GP Partner in South Gloucestershire and Clinical Lead GP for prescribing in BNSSG ICB	[redacted]
Apologies		
[redacted]	Patient Safety Specialist & Clinical Improvement Lead. Medicines Safety Improvement Programme, NHS England.	[redacted]
[redacted]	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	[redacted]
[redacted]	Paediatric Neurology and Palliative Care Pharmacist, Bristol Royal Hospital for Children	[redacted]

	Item	Action
01	**Apologies, Declarations of interest** [redacted] shared the apologies as noted above. No declarations of interest were declared.	[redacted]
02	**Minutes of last meeting and Action Log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. [redacted] went through the action log:	

	Item	Action
	• **Action 36-** *Investigating trends around patients without Contraception* – There is ongoing work. Potentially a small audit or data collection around the reasons people aren't taking up contraception could shed more light- action ongoing. • **Action 38** - *Invite ██ back to the group at the end of the year*- Keep open to act as a reminder. • **Action 39** - *AWP Trainee Pharmacist sharing audit findings* – Audit findings currently going to internal governance meetings at AWP. To report back at a future meeting. • **Action 40** – *Valproate easy read leaflet.* Good resource, added to remedy. Action agreed to close. • **Action 41** – *Review wording on Shared Care Protocol (SCP).* This is linked to a Datix. Practice hadn't realised that if the absence of risk is permanent a yearly review and completion of an ARAF isn't required (after the initial completion of the form), the SCP was not that clear on this. SCP has been updated for clarity, changing wording around if the absence of risk of pregnancy is permanent. It has been sent to the formulary team and to be taken to Joint Formulary group for sign off. Action agreed to close. • **Action 42** – *Future dates* – These have been sent out. Action agreed to close.	
03	**National and local updates** **NBT** ██ provided an update; she commented that they are now seeing a few patients on the wards at NBT being started on Valproate. She queried whether an ARAF needs to be completed while an inpatient or on discharge? ██ suggested that in general the form should be completed at the time of prescribing as it will confirm that 2 consultants have reviewed the patient for suitability of prescribing. It may be reasonable to assess whether it is likely to be used long term or if it is a short-term dose for an emergency situation which won't be continued but should be completed prior to any discharge. ██ suggested that this scenario can be used for any medicine so the argument for not doing it at prescribing is small so the form should still be completed unless it is used in an emergency situation such as ICU. ██ seconded this and commented that the MHRA flow charts are quite useful for reviewing what needs to be undertaken. If an ARAF is not completed and patient counselled, it risks the patient slipping through the net. ██ mentioned that there would likely be an expectation by primary care that if a patient was discharged on valproate as a new medication an ARAF would have been completed. ██ mentioned that although they have a process flow chart it doesn't go into this level of detail. **Action:** ██ to see if there was anything specific stated in guidance about IV valproate **Post meeting note:** The RCOG guidance 2019 says the following: *"5.11.1 Status epilepticus Although NICE protocols for the management of this acute medical emergency do not include valproate, its intravenous formulation (and those of other antiepileptic drugs) is not uncommonly used for status epilepticus (48). Best interest considerations will apply in the acute setting. Whilst an urgent pregnancy test is not always part of protocols for treatment of status, it would be prudent for this*	██

	Item	Action
	to be included and should be undertaken if valproate is to be used but should not delay treatment of this life-threatening emergency. Antiepileptic drugs introduced for seizure control in status may or may not be continued on recovery, and discussion will need to include following the usual PPP if valproate continuation is being considered" The updated NICE guidance on epilepsy(NG217) says the following: *If convulsive status epilepticus does not respond to 2 doses of a benzodiazepine, give any of the following medicines intravenously as a second-line treatment:* *• levetiracetam* *• phenytoin* *• sodium valproate (follow the Medicines and Healthcare products Regulatory Agency safety measures and precautionary advice for sodium valproate in box 2).* **AWP** ██ commented that AWP have shown a good improvement now at 85% (for quarter 4) which is up from where they were in Quarter 1 for ARAF compliance based on data from their dashboard. This will continue to be a quality priority for next year (25/26) as ideally this percentage should be as close to 100% as possible. A Trainee Pharmacist audited the quality of the completion of these annual risk assessment forms (findings currently going through internal governance), and this highlighted a lack of compliance with the quality of the ARAF with areas identified such as missing a second signature from the form or the contraception section not being fully completed. All consultants identified in the audit have since been contacted with the audit feedback and recommended actions shared with them. Many of these areas have already shown an improvement. ██ mentioned that when they went back to the consultants about the valproate patients, some of the patients had stopped valproate and so allowed a data quality exercise to be undertaken with the records on the database being updated. It was noted that consultants have been actively switching patients from valproate to alternative medications, following the MHRA recommendations being introduced which was positive. ██ mentioned that AWP are in the process of updating their valproate procedures since the MHRA infographics have come out and made it clearer on the action to take where there is the absence of risk of pregnancy. An audit may be conducted again next year to monitor the quality, but this is to be confirmed. ██ asked if there were any areas that were highlighted in the audit that might benefit from a future audit? ██ mentioned that the prescribing in learning disability patients may be useful to re-review due to the complexity of these cases. However, these consultants now fall under Sirona governance. **Sirona** ██ advised that the consultants have been asked to report on which patients are prescribed valproate by the end of the month to ensure Sirona has an accurate record of these patients and that the correct processes can be followed. **Primary care** ██ mentioned that there was nothing specific to report from a primary care perspective. ██ mentioned that they would be highlighting teratogenic medicines and contraception at the Unity sexual health study day for primary care clinicians.	

	Item	Action
04	**Data Review** [redacted] shared the data in the different age categories and prescribing trends reviewed relating to patients prescribed valproate per 1000 population. It was noted that BNSSG remains low prescribers of valproate when compared to the national average. See slide set. Teratogenic Meds Safety Group May 202	
05	**Datix / Ulysses** There has been one Datix relating to valproate (as mentioned earlier), which related to an ARAF not being completed on an annual basis for a patient, however, the patient had been through the menopause. This is therefore classed as a permanent reason for reproductive risks not to apply and so an annual risk assessment form not required to be completed as per the MHRA guidance. The infographics were useful to explain this and was shared with the GP practice. The confusion had arisen from the Shared care protocol (SCP); therefore, the SCP will be edited to provide clarification regarding this situation. (See slide set in section 4). [redacted] and [redacted] discussed the proposed changes to the SCP with the group which included adding the MHRA infographic links, the NHS England easy read leaflet as well as a paragraph on what is required when there is a permanent reason the reproductive risks do not apply. The group agreed with these amendments. It was discussed that this updated SCP will be taken to the next BNSSG Joint Formulary Group for sign off.	
06	**AOB** Meeting frequency [redacted] suggested reducing the frequency of the meetings. It was agreed to cancel the July meeting and then have the September meeting as the next meeting. Then the group will move to quarterly meetings (which will be in line with other quality working group meetings).	
	Date of next meeting: **9th September** 2025 10-11am (**Please note the July meeting has been cancelled**)	

Team Administrator, Medicines Optimisation
May 2025

BNSSG ICS Medicines Quality and Safety Group Subgroup: CNS Teratogenic Medicines Safety Working Group

Minutes of the meeting held on Tuesday 9th September 2025 at 10am-11am, MS Teams

Minutes

Present		
(Chair)	Principal Medicines Optimisation Pharmacist, Medicines Optimisation team, BNSSG ICB	
	Paediatric Neurology and Palliative Care Pharmacist, Bristol Royal Hospital for Children	
	Medicines Safety Officer, Sirona Health and Care	
	Neurology Pharmacist, NBT	
	Team Administrator, Medicines Optimisation team, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Lead Pharmacist- Medicines Safety, Governance and R&D, AWP	
	GP Partner in South Gloucestershire and Clinical Lead GP for prescribing in BNSSG ICB	
Apologies		
	Consultant in Sexual and Reproductive Health, Unity Sexual Health, UHBW	
NBT Epilepsy Nurses	Neurology, NBT	
	Patient Safety Specialist & Clinical Improvement Lead, NHS England	

	Item	Action
01	**Apologies, Declarations of interest** shared the apologies as noted above. No declarations of interest were declared.	
02	**Minutes of last meeting and Action Log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. went through the action log:	

	Item	Action
	• **Action 36 [redacted] to investigate trends around those patients without contraception prescribed valproate** On going to be partially discussed with the data review. Remains open. • **Action 39 To invite the AWP trainee pharmacist (or [redacted]) to the next meeting to share the audit findings.** On agenda today, suggest close. • **Action 41 [redacted] to see if there was anything specific stated in guidance about IV valproate** Update on action log. Agreed to close.	
03	**National and local updates** • Changes to National Risk Minimisation materials [redacted] discussed the national updates to the national risk minimisation materials, highlighting the changes. The ARAF forms were updated in May 2025. A new section has been added to the form under the second specialist with the date of the second specialist review to be added to all forms going forward. Wet signatures are no longer required so it can be done electronically. The PREVENT section has been expanded including that the patient understands the risks and the patient needs to sign the form if PREVENT does not apply to them. The male RAF form has been expanded around conception, infertility and potential risks to children born to fathers taking valproate. No comments raised. See forms attached. ARAF Female 202506 changes from previou RAF Male initiation 202506 changes from • MHRA 'shares concerns' over failure to meet epilepsy drug prescribing target An article from the Pharmaceutical Journal was shared with the group entitled *'MHRA shares concerns over failure to meet epilepsy drug prescribing target.'* Locally it was discussed that valproate prescribing has reduced by a reasonable amount over the years, but nationally the picture is not the same with variation across the country. In the article it was noted that there has been a 45% reduction so nationally the reduction target of 50% by the end of 2023 had not been met. The article commented that they appreciate there are a small number of women who will be unable to switch or try alterative medication without success. The article also flagged that some women were not asked to complete the acknowledgement of risk form, locally we do try to ensure this takes place across the system. MHRA plan to keep the regulation of valproate under close scrutiny and will continue to support the clinical care of patients ensuring the latest safety information is available to prescribers. • Provider updates **Sirona** [redacted] explained that work has been ongoing in this area within Sirona. Of the six consultants based within the learning disability team, four of them have come back to [redacted] about using the valproate risk assessment forms. One highlighted that they had a patient who was unlikely to change and so wouldn't need an ARAF and so it was	[redacted]

	Item	Action

explained to them that the completion/review of the ARAF should routinely be a yearly occurrence regardless. The two outstanding consultants are being chased.
Action: ███ to check if the new valproate resources are being used/available within the Sirona team.

BRI/UBHW
███ explained that she and ███ had met with ███ (Medicines Safety Officer) to review current processes and put plans in place. They are trying to implement an electronic ARAF form and are just undertaking some final amendments. They are planning on having a local SOP to bring together all of the teratogenic medicine guidance and recommendations to point doctors in the right direction of the BNSSG guidance.

NBT
███ agreed with what ███ had said and confirmed the plan to meet ███ and ███ regularly to progress the move to electronic forms. ███ advised that she was unable to comment on the how the Epilepsy team were managing with the ARAF completion as they are using paper ARAF forms. ███ asked if there was any backlog of ARAFs for the epilepsy team.
Action: Check on progress with Epilepsy team on ARAF completion.

AWP
███ advised that there had been an increase in compliance of the completion of ARAF forms within deadlines at AWP, with a rate of 95% completion for the last quarter on the dashboard. This had been one of the quality priorities for AWP. ███ mentioned that the number of patients overall on the dashboard had reduced with some patients stopping valproate and being prescribed alternative medications. ███ provided a summary of the audit findings, highlighting the main gaps on ARAFs were missing secondary prescriber and patient/representative signatures. The results from the deep dive were held on a spreadsheet and addressed individually. The new educational materials are all in place. The electronic ARAF system is on the patient management system and is currently in the process of being updated. It is noted that in the interim period, they will carry on using it but with the information being recorded separately.

Primary care
No formal feedback has been received in relation to ARAFs. ███ advised that in general it appears to be going ok with the new materials being available in primary care. BB raised about Ardens template being embedded in EMIS.

Action: ███ to check if there is an Ardens template on EMIS in relation to valproate.
Post meeting note: Both a valproate and topiramate review template is included on the GP IT system. There is a resources section on the template with some links, and the user would have to link on the 'Resources' tab to see them.
See example of the valproate template below:

	Item	Action
	Shared care protocol █ and █ explained that they had been contacted about the valproate shared care protocol. The links have been updated to link to the new 2025 valproate resources. However, it was also noticed that there is a slight difference in blood monitoring from shared care protocol to the monitoring advice on the Specialist Pharmacy Service (SPS) website (although matches with the summary of product characteristics). █ has emailed the SPS team to enquire about the difference and any supportive information but no response at the time of the meeting. █ shared the SPS website monitoring information for valproate. It states under ongoing monitoring that every six months and then annually BMI, full blood count and liver function tests should be monitored. BNSSG doesn't advise this for all patients so have asked where the evidence is as it is not on the summary of product characteristics or BNF. Opened to the group to see if they undertake LFTs and FBCs annually, if so the shared care protocol may need to be updated. █ went through the shared care protocol. It currently only states for adults for the first 6 months of treatment and then before surgery or following spontaneous bleeding or bruising. There is a separate section for bipolar monitoring and so this monitoring would be covered if a patient is having for this indication. █ to await the response from SPS and liaise with the formulary team/members of the group where required. However, the links to the updated resources will be undertaken to ensure it has the current information. **Post meeting note:** SPS responded to say that the recommendation appears to come from NICE CKS last updated in May 2025, https://cks.nice.org.uk/topics/bipolar-disorder/prescribing-information/valproate/ **1. How should I monitor someone taking valproate?** • Before starting treatment, a full blood count, baseline liver function tests (LFTs), and body weight or body mass index (BMI) are usually measured. • Ensure that LFTs, BMI, and a full blood count are measured 6 months after treatment has been initiated, and every 12 months thereafter. • Valproate levels are not routinely measured unless there is evidence of ineffectiveness, poor compliance, or toxicity is suspected.	
04	**Topiramate – one year on since safety recommendations introduced in June 24 – how are we doing? Any further work needed?** █ and █ shared a presentation showing the background to the topiramate safety recommendations following the June 2024 Drug Safety Update, the actions taken locally to date and presented figures from 2024 compared to 2025 (approximately one year after the alert). It shows that the numbers of patients prescribed topiramate overall are coming down.	

	Item	Action
	See slide set: Teratogenic Meds Safety Group Sep 25.p ■ mentioned that from a BCH perspective, the consultants have been reviewing the continued need for topiramate in female patients and stopping it where appropriate, particularly in those prescribed it for migraine. There have also been emails from them asking where to find the topiramate form which is a positive sign that they are completing the paperwork. ■ confirmed earlier comments about creating SOPs to point people in the right direction and that clinicians have been asking for the paperwork. They are definitely reviewing the patients and the ones that are continuing it are for epilepsy where it is the best drug, and they want to continue. It is now rare to start it for migraine. ■ mentioned that she had seen a recent Datix form from a GP practice, where they'd noted that patients had been reviewed by neurology and had started on topiramate for prophylaxis of migraine. However, the risk-based conversations had not been documented on the discharge letter in particular the conversations around contraception and the risks around the medication. ■ asked if this information would usually be included in hospital information/communication to primary care? ■ mentioned that that BCH, clinic letters should state if they've been through the information with the patient and the letters generally they do. ■ mentioned she was unsure but expected it would be similar for NBT and advised that they rarely see topiramate initiated in migraine patients anymore. ■ will check with the clinicians starting topiramate at NBT. From a primary care perspective, it was reported that there hasn't been any significant pushback to the topiramate protocol nor patient dissatisfaction to date, which is positive. ■ raised that they had received a query regarding ARAF forms for those who lack capacity and aren't sexually active, should at least one form be completed? Could a discussion be completed online rather than face to face for those who would find an appointment to fill this out too distressing. ■ mentioned that individual assessments will be important, and ■ raised this is also an issue for them and hasn't formally been addressed. It remains a grey area, and so it would be important just to document as much as possible.	
05	**Data Review** See data in slides (section 4) ■ shared data for female patients either aged 13-54 years and 0-12 years who had been prescribed valproate (per 1000 patients) and highlighted that BNSSG prescribing had remained under the national average and that the 0-12 years trendline has reduced slightly, and for adults it has reduced. ■ and ■ did a further data search through EMIS comparing February to August 2025 and the valproate patient numbers have decreased. The number of completed ARAF forms had increased in this period with121 patients having an ARAF on record in August, however, only 71 had it in the last 12 months. This data is subject to coding within primary care and potentially some forms may have just recently expired. The	

	Item	Action
	EMIS search is also not picking up the contraceptive advice and counselling as it is showing that it has gone down. However, again this is likely due to how this is coded by primary care. The data showed a slight increase in patients with migraine being prescribed valproate, however, the deep dive into migraine showed 13 patients, and 9 of these have been looked at, with 6 patients also having epilepsy, 1 had bipolar, leaving only 2 that were just for migraine. 6 of these patients are under specialists, 2 have recently been discharged, and 3 not. For the two patients solely with an indication of migraine, 1 is under a specialist and 1 had been discharged from specialist in March 2025, as the patient didn't attend the appointment following referral by GP. A deep dive of 3 GP practices and 20 patients prescribed valproate showed the indication for the valproate to be epilepsy for 14 patients, 2 patients had bipolar, 1 for migraine,1 for seizure prevention, 1 for cerebral palsy and 1 for paranoid schizophrenia. Of these 11 had an ARAF and 9 had no ARAF on record and only 5 of the patients with an ARAF had this from the last 12 months. There was a discussion regarding patient decline of the pregnancy prevention programme or where it is declared a patient doesn't need the pregnancy prevention programme. ██ mentioned patients in a single sex setting and how it may be reasonable for them to not need the pregnancy prevention programme whilst in this setting, however, it is important to ongoingly review the patient as they may not be able to always stay in that setting, and ARAF still needs completing to document that annually to support you. ██ also commented that in paediatrics this is also important as you don't know when menstruation will start.	
06	**Datix / Ulysses** ██ confirmed that there was just one report whereby a female of childbearing age had been prescribed topiramate by Neurology for migraine in secondary care but there was no mention of the teratogenic effect or the need for specific types of contraception whilst on the medication in the clinic letter. The patient confirmed that they had come off the medication as they had an adverse reaction. However, this report highlights the importance of ensuring that patients receive the appropriate counselling around the risks of teratogenic medicines and that any information provided to the patient is shared information between care sectors.	
06	**AOB** • **World Patient Safety Day – 17 September 25** World patient safety day 17th September this year is dedicated to 'safe care for every newborn and child'. • **SPS guidance on switching anti-epilepsy medication updated** SBS specialist pharmacy services website has just updated their guidance around switching and between generic and branded. It highlights that switching between different manufacturers' anti-seizure medicines requires individual assessments and careful consideration about whether it will be suitable. • **Carbimazole or thiamazole (synonym: methimazole)-containing products: Risk of acute pancreatitis and strengthened advice on contraception**	

	Item	Action
	Carbimazole and thiamazole have had strengthened advice on contraception as they have been found to cause congenital malformations when administered during pregnancy, particularly in the first trimester of pregnancy and at high doses. • **Additional actions to take following the meeting** **Action:** A newsletter update with reminder of topiramate and valproate resources will be a good idea to support reviewing and completing ARAFs where appropriate especially for primary care.	
	Date of next meeting: Tuesday 2nd December 2025, 10am	

Team Administrator, Medicines Optimisation
September 2025

BNSSG ICS Medicines Quality and Safety Group Subgroup: CNS Teratogenic Medicines Safety Working Group

Minutes of the meeting held on Tuesday 2nd December 2025 at 10am-11am, MS Teams

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Minutes

Present		
████ (Chair)	Principal Medicines Optimisation Pharmacist, Medicines Optimisation team, BNSSG ICB	█
████	Neurology Pharmacist, NBT	█
████	Advanced Clinical Practitioner (Epilepsy Surgery), Epilepsy Nursing Lead, NBT	█
████	Medication Safety Officer, AWP	█
████	Senior Medicines Optimisation Pharmacist, BNSSG ICB	█
Apologies		
████	Associate Specialist, Co-SAS Tutor for UHBW, General Training Programme Director for DCSRH and CoRSH LOC, BNSSG area and Yuno Sexual Health and BNSSG Pregnancy Advisory Service	█
████	Clinical Pharmacist, AWP	█

	Item	Action
01	**Apologies, Declarations of interest** █ shared the apologies as noted above. No declarations of interest were declared.	█
02	**Minutes of last meeting and Action Log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. █ went through the action log: • **Action 36 ███ to investigate trends around those patients without contraception prescribed valproate** On going, suggest close but consider in ongoing reviews. • **Action 38 Invite █ back to the group at the end of the year** To consider inviting █ at next meeting.	█

	Item	Action
	• **Action 43 [redacted] to check if the new updated valproate resources are being used/are available within the Sirona team.** [redacted] has now left post with Sirona, [redacted] to check with Sirona colleagues. • **Action 44 [redacted] to check with the Epilepsy team how ARAF completion was going, any delays or issues?** Suggest close, [redacted] discussed as part of NBT update. • **Action 45 [redacted] to check if there is an Ardens template on EMIS in relation to valproate and share with [redacted]** Both a valproate and topiramate template are available on EMIS. There is a resources section on the template with some links, and the user would have to link on the 'Resources' tab to see them. A screen shot was shared with [redacted]. Suggest close action. • **Action 46 [redacted] to draft a newsletter article for the MO or safety newsletter to remind clinicians about the topiramate and topiramate resource** Suggest close, newsletter article published in MO newsletter.	
03	**National and local updates** **National updates** • **BNF update to valproate safety materials** [redacted] highlighted to the group that the BNF had now been updated to include the updated valproate safety advice. • **PrescQIPP – developing resources to support prescribing of Teratogenic Drugs** [redacted] highlighted that PrescQIPP were in the process of developing resources around prescribing teratogenic medicines. The medications included in the resources will be wider than valproate/topiramate for example anticoagulants and ACE Inhibitors, although they were planning an Antiepileptic drugs (AEDs) document as well. These resources will potentially be useful resources to highlight alternative medications and to highlight potential risks or any pre-pregnancy advice. Publication date not yet known but [redacted] will share with the group once available. **Local Updates** **Sexual Health (Yuno)** [redacted] flagged to the group that although [redacted] was unable to make the meeting she had highlighted that Yuno sexual health is moving to a system to allow patients to self-refer for routine (non-complex) LARC procedures - so if anyone needs a LARC due to their meds this could be a route in the new year. **NBT** [redacted] mentioned that Gianne who previously attended these meeting has now gone on maternity leave. She updated the group to explain that they are in the process of trying to implement an electronic ARAF form to support patient reviews. She explained that they are experiencing ongoing difficulties in identifying and tracking new patients started on valproate. The team currently relies on manual processes and spreadsheets, which are not always up to date or comprehensive.	[redacted]

	Item	Action
	It was discussed that AWP have an electronic system already in place, which is generally working well, so hopefully if the electronic form can progress this may help patient recalls and reviews. ██ shared that their electronic form linked to a portal, so once the form is completed which should be done on initiation, it will then automatically put them onto the portal. This portal is then able to show the number of days until the patient needs to be reviewed in relation to their ARAF and valproate reviews. Locality Lead pharmacists for each area in AWP then add the relevant data into their quarterly report so that overdue patients can be monitored. ██ also mentioned that sometimes patients can be highlighted as red when they have had an ARAF form completed but consultants had done this manually rather than using the electronic form. It was therefore discussed that once NBT had their electronic form it maybe possible to link it to a database. ██ suggested that if NBT had a lead digital pharmacist then they could discuss with the AWP digital lead to share ideas. ██ to contact ██ for contact information if needed. ██ also mentioned that once clinicians start to use the digital form then prefer it and don't tend to go back to the manual paper form. The initial communication is the challenge. ██ mentioned that it can be complicated in a large trust due to the number of clinicians and wards involved. ██ gave an example of a patient started on IV valproate in the Emergency Department (ED) as an emergency, under neurology advice although the neurology team only saw as an emergency rather than ongoing review case. The patient then got discharged on oral valproate, however, the responsibility for completing the ARAF form was unclear among multiple teams, leading to missed reviews and gaps in follow-up, because the ED clinicians would not have completed the ARAF risk assessment due to the patient having the medication as an emergency. This was not a recent case but highlights some of the issues and was identified by a GP requesting an ARAF. ██ mentioned the electronic prescribing system should help overall but doesn't flag new patients. It was discussed that if the form could be edited to show it was a new patient, this may help, but it was not clear if this was possible. ██ mentioned she would chat with ████████ their MSO and link with AWP if needed. **Action 47:** ██ to discuss the electronic ARAF form and new patients with ██ from UHBW **AWP** ██ mentioned that █████████ will be leaving AWP and that ██ will now be attending these meetings. Valproate reviews generally going well with the electronic database system as mentioned previously. ██ also reported that AWP had completed an audit of valproate prescribing and found instances where original packs were split without the required risk assessment form being completed. Risks were being mitigated by labels being added to split packs and use of the leaflet, but it has prompted efforts to improve governance by ensuring forms are completed before splitting. It can be difficult to decide whether you need to complete a form every time you're splitting a pack or whether a review date can be added to the original risk assessment form. This arises in AWP when people go on leave for a night but wouldn't be appropriate to send them away with a full pack.	

	Item	Action
	██ explained that NBT generally avoids splitting packs for valproate, supplying original packs unless a specific request is made. **Primary care** No specific feedback to share with the group.	
04	**Terms of reference for the group** The group confirmed current membership, including representatives from NBT, AWP, UHBW/BCH, and sexual health colleagues, and discussed the inclusion of additional stakeholders as needed for specific topics. It was agreed to shift from bi-monthly to three-monthly meetings, with ██ suggesting scheduling meetings after the end of each quarter to allow time for data review and reporting. ██ to review future meeting dates and circulate to the group. It was also agreed to include any references to recent national safety guidance that are not currently included. There was discussion about widening the group to include all teratogenic medicines, but it was discussed that different representatives would be needed and that there wouldn't be an easy way to arrange the meetings and so to leave it as CNS teratogenic medicines for now and to re-review in the future. **Action 48:** Updated version of the TOR to be shared with the meeting notes for approval from rest of the group.	
05	**Data Review** See data in slides Teratogenic Meds Safety Group Dec 25.p ██ presented local prescribing data for valproate, showing that rates remain below the national average for key age groups, with a downward trend in new initiations and overall use, which is in line with national guidance.	
06	**Datix / Ulysses** ██ advised the group that there had been one incident reported by a GP practice since the last meeting. This involved a GP Practice who had been struggling to get annual risk assessment/PPP for a patient who is under Neurology on sodium valproate. The patient was a 36-year-old female, with learning disability, under Consultant Neuropsychiatrist Department of Neuropsychiatry. The GP practice had been chasing the specialists for the Annual Risk Acknowledgement Form for sodium valproate since 2022, with letters to neurology and neuropsychiatry were sent on: 4/1/2022; 21/4/2022; 21/8/2023; 11/12/2023; 4/9/2024 The ICB shared the Datix with the trust specialist and patient safety team for review and prompt action was taken by specialist team. It was identified that this patient DNA'd an appointment in February with Neuropsychiatrist, she has another	

	Item	Action
	appointment scheduled for 9th December 2025. A note was added to patient notes to make sure Consultant aware that the patient needs a valproate ARAF done when they see her in December. **Action 49:** ██ to check if primary care colleagues receive information from the acute trust/specialist team if a patient DNAs	
07	**AOB** • MHRA Sep 25 Safety Round up - https://www.gov.uk/drug-device-alerts/mhra-safety-roundup-september-2025 MHRA has published the first in a series of reports on trends in valproate prescribing as derived from the Clinical Practice Research Datalink (CPRD), in females and males in England. Data from January 2018 to June 2024 and shows significant reductions in new and overall prescribing in both females and males aged 16-44, with notable shifts away from valproate as a first-line treatment. • PJ article - Valproate has no significant impact on male fertility, study finds' This retrospective cohort study from researchers at University of Liverpool looked at analysis of data from 91,917 men who had taken valproate and compared with data from 535,803 men who had not. The study results suggested that there was no significant difference between the two groups— who had been diagnosed with either epilepsy or bipolar disorder — in infertility diagnoses, sperm counts and testicular atrophy. The reproductive hormone levels remained within normal ranges in both cohorts. The article also mentions the importance of considering the wider picture of what else may be causing infertility. For example, epilepsy, in and of itself, can affect fertility rates, which are two-thirds lower in men with epilepsy than without. See article: PDF pharmaceutical-journal.com-Valproate has • MHRA Drug Safety Update ██ mentioned the Drug Safety Update regarding updated advice around isotretinoin prescribing and the request for a survey completion by services. • Patient Safety Commissioner (PSC) Impact Report Sep 25 ██ mentioned that the Commissioner welcomes the improvement in safe prescribing of valproate and safety initiatives brought in by partner organisations, including NHS England and the MHRA. When the PSC role started in post in 2022, three babies a month were born exposed to valproate. First quarter data shows: • a 53% reduction in initiation in girls aged 0-12 • a 60% reduction in women aged 13-54 started on valproate • a 65% reduction in women re-starting valproate after a break of 6 months	

	Item	Action
	• at least 9 out of 17 mothers have active management of valproate if it was prescribed during a month when the woman was pregnant – this may include post-natal prescribing • and hospital admissions for women with epilepsy aged 13-54 have not been affected by these changes.	
	Date of next meeting: TBC	

Principal Medicines Optimisation Pharmacist
December 2025

BNSSG ICS Medicines Quality and Safety Group Subgroup: CNS Teratogenic Medicines Safety Working Group
Minutes of the meeting held on Tuesday 24th February 2026 at 10am-11am, MS Teams

Minutes

Present		
(Chair)	Principal Medicines Optimisation Pharmacist, Medicines Optimisation team, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist	
	Advanced Clinical Practitioner (Epilepsy Surgery), Epilepsy Nursing Lead, NBT	
	Medication Safety Officer, AWP	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Prescribing Lead GP, BNSSG ICB	
Apologies		
	Associate Specialist, Co-SAS Tutor for UHBW, General Training Programme Director for DCSRH and CoRSH LOC, BNSSG area and Yuno Sexual Health and BNSSG Pregnancy Advisory Service	
	Neurology Pharmacist, NBT	
	Patient Safety Specialist & Clinical Improvement Lead, NHS England	

	Item	Action
01	**Apologies, Declarations of interest** No declarations of interest were declared.	
02	**Minutes of last meeting and Action Log** No comments from the group on previous minutes and they were deemed to be an accurate reflection of the meeting. went through the action log: • **Action 38 Invite back to the group at the end of the year** To consider inviting for the next meeting.	

	Item	Action
	• **Action 47 ▇ to discuss the electronic ARAF form and new patients with ▇ at UHBW** ▇ not at the meeting, ▇ to email ▇ for an update. • **Action 48 Updated version of the TOR to be shared with the meeting notes for approval from rest of the group** This is on the agenda today and TOR was shared with group. Close item. • **Action 49 ▇ to check if primary care colleagues receive information from the acute trust/specialist team if a patient DNAs** ▇ informed the group that it has been confirmed that locally the specialist teams usually send communication to the GP practice if a patient DNAs their appointment. It was agreed to close.	
	Matters arising **Terms of reference – for final approval** The amended terms of reference for the group had been shared with the papers and ▇ highlighted the changes which had been made following the previous meeting including the change in meeting frequency to every three months. ▇ explained that the group continues to report to the BNSSG Medicines Quality and Safety group, with minutes also shared with the Area Prescribing Medicines Optimisation Committee and other relevant meetings, and encouraged members to suggest updates to the group's aims as its focus evolves. It was mentioned that the frequency may need to be re-reviewed in the future. The group accepted the updated terms of reference. **Electronic ARAF forms** ▇ mentioned that NBT and UHBW had been reviewing the NHS England valproate digital platform tool's functionality and costs in comparison to an internally developed version. Pharmacy representatives from UHBW/NBT were not present at the meeting so ▇ to check with ▇ if any update. **Action: ▇ to email ▇ for an update (links to action 47)**	
03	**National and local updates** **Local Updates** **AWP** ▇ provided an update from AWP, reporting a significant reduction in women on valproate with only about 18 patients remaining, attributing this to ongoing monitoring and review processes. AWP continue to monitor the percentage of patients with an in-date ARAF but mentioned some challenges with the dashboard data where patients remain listed after prescribing is transferred to GPs, however, it is easier to monitor and review patients now the numbers have reduced. ▇ commented that a recent re-audit of the quality of ARAF completion had been undertaken, following an informal student audit, which noted gaps such as missing reasons for not requiring contraception and incomplete specialist information. The	

	Item	Action
	results of the more official re-audit (completed by [redacted]) will be shared with the group at a later date. [redacted] highlighted the importance of high-quality ARAFs for GP acceptance, noting that incomplete forms can lead to issues during handover, and that the smaller patient cohort now allows for more manageable quality checks. [redacted] also mentioned an audit that had been undertaken of packing down valproate with data collection being reviewed. **Action 50: [redacted] to share valproate audit results with the group when available** **NBT** [redacted] mentioned that [redacted] now has a new role and so won't be able to attend this group going forward. [redacted] will be the new Neurology Pharmacist, although may not be able to attend these meetings, however [redacted] continues to cover both trusts in her role as Medicines Safety Officer. [redacted] shared NBT's approach to valproate monitoring, including the implementation of new weekly alerts which started in January for inpatients prescribed valproate so an ARAF can be completed prior to discharge, which is working well. Patient non-attendance is also a challenge but follow up processes are in place and follow up can be tailored to the patient. Follow up letters are often sent for any missed appointments to highlight the importance of the missed appointment to the patient. [redacted] commented that the database is working reasonably well in relation to the annual ARAF reviews. **Primary care** [redacted], representing primary care and the ICB, confirmed he was not aware of any complaints or negative feedback regarding valproate processes.	
05	**Data Review** See data in slides: Teratogenic Meds Safety Group Feb 26.p [redacted] presented local prescribing data for valproate prescribing from epact2, which showed that valproate prescribing rates for females aged 0 -12 yrs and 13-54 yrs remain below the national average, with a general downward trend in new initiations and overall use since the safety work started, which is in line with national guidance and suggests that patient risk assessments and discussions are being undertaken . No new initiations were shown in the last 3 months for those aged 0-12yrs. [redacted] also mentioned that locally there is a BNSSG safety dashboard which asks practices to review several medication related safety areas and one area included highlighting the risk in relation to pregnancy for topiramate and pregabalin	

	Item	Action
	patients. Although some slight variation in the data month on month, it has remained relatively consistent in relation to pregabalin patient numbers but the numbers of patients on topiramate (females aged 10-55yrs) has shown a decrease slightly from April 2025 (653) to February 2026 (621). Some of this may relate to patients who were having for migraine and since reviewed and changed to alternative medication options.	
06	**Datix / Ulysses** █ described a Datix incident reported from a GP practice where a 36yr patient was started on topiramate for migraine prophylaxis without appropriate counselling or documentation on pregnancy risks or contraception, which was identified and addressed by the GP practice and flagged for learning at UHBW. █ emphasised the importance of documenting counselling on teratogenic risks in discharge and clinic letters to ensure primary care are aware of discussions and can provide appropriate follow-up. █ summarised two cases (█ and █) which had similar themes where lack of timely access to antiepileptic medicines contributed to patient deaths, prompting NHS England to issue guidance to community pharmacies on the importance of time-critical medicines. The group reviewed the NHS England alert which has gone to community pharmacies, which included the MISSED mnemonic for time-critical medicines and recommendations for pharmacies to manage supply issues, communicate with prescribers, and support patients. PDF Operation note re CM Case 20260203 F It was discussed that there have been a number of medication supply issues over recent months. It was hoped that this alert will raise the importance of time critical medicines and help patients. █ reported that patients continue to face challenges obtaining epilepsy medicines, with the team supporting them in sourcing alternatives. Tools like the Charlie cards (cards which support patients request a minimum emergency supply from pharmacies, to cover them until they receive their regular prescription) are also being seen and used to facilitate patients access to their medicines provided conditions are met.	
07	**AOB** **Medication Shortages:** █ flagged current supply shortages of sodium valproate and phenobarbital, outlining available alternatives and the need for careful management, especially for patients on category one antiepileptics like phenobarbital. • MSN for Phenobarbital 30mg and 60mg tablets:	

	Item	Action
	MSN_2026_010 Phenobarbital 30mg a Currently 100 patients prescribed this medication in BNSSG. • MSN for Sodium valproate (Epilim Chronosphere®) 100mg modified-release granules sachets sugar free: MSN_2026_012 Sodium valproate (Ep Currently only 9 patients prescribed this medication in BNSSG. **Valproate warning labels** ██ had received some feedback from a community pharmacy that they had been having issues obtaining the valproate dispensing warning labels. The group discussed the continued use and availability of warning stickers on valproate packaging in pharmacies, with ██ confirming their ongoing use at AWP and agreeing to check if they had noticed any supply issues within the wider pharmacy team. ██ mentioned that she would raise the topic at a national VIQI meeting. ***Post meeting note:* ██ *confirmed that AWP have plenty of labels so have not tried to order recently so not be aware of any current issues.*** **Action 51: ████ to raise at the next VIQI meeting** **MHRA, Drug Safety Update**, Isotretinoin – changes to prescribing guidance and additional risk minimisation measures, January 2026 ██ highlighted the drug safety update and that following a recent review by the CHM of the impact of these risk minimisation measures, the MHRA have now advised that the second prescriber requirement for under 18 year olds is no longer required and has been replaced with alternative risk minimisation measures. The Acknowledgement of Risk Form for all patients prescribed isotretinoin has also been updated as part of this process and a patient information video has been produced by the British Association of Dermatologists with oversight from the MHRA and CHM, to explain the risks associated with isotretinoin treatment in an accessible format. The update also suggests there will be a clinical audit planned for 2026. **UKMEC update** UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) | CoSRH, updated December 2025 ██ mentioned that the UKMEC guidance had been updated in December and so might be useful for clinicians to be aware of when considering contraception methods. The update includes information about new conditions such as multiple sclerosis as some evidence exists that individuals with multiple sclerosis (MS) are at	

	Item	Action
	higher risk of venous thromboembolism (VTE) than those without MS. This is likely due mostly to immobility. There is therefore the need to differentiate individuals with MS with prolonged immobility from those without. Also, observational studies found evidence of a small increased risk of VTE with DMPA use compared to no hormonal contraception. The overall risk remains low and is likely to be lower than the risk of VTE with combined hormonal contraception. Conditions and characteristics that also increase a person's risk of VTE have been reviewed throughout the UKMEC and categories have been upgraded. 'Multiple risk factors for VTE' has also been added. Also updates in relation to stroke and anxiety/depression as well as changes such as inclusion of E-cigarettes, NICE classification of blood pressure and language used.	
	Date of next meeting: 19th May 2026	

Principal Medicines Optimisation Pharmacist
February 2026

BNSSG Area Prescribing Medicines Optimisation Committee (APMOC)

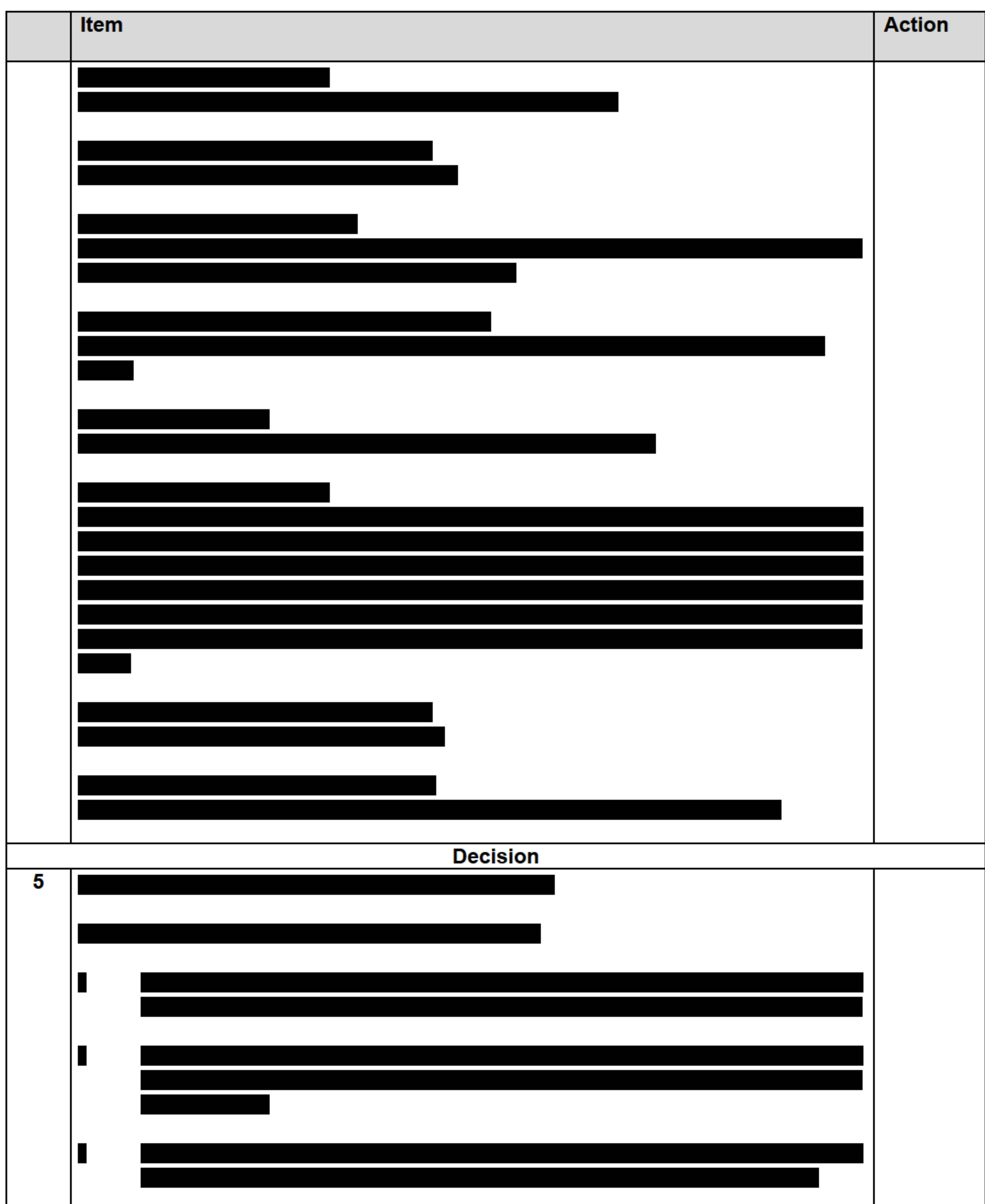
Minutes of the meeting held on Thursday 1st August 2024

Time: 13:30 – 16:00
Location: Microsoft Teams

Minutes

Present		
████ (Chair)	Chief Pharmacist, BNSSG ICB	██
████ (Minutes)	Team Administrator, BNSSG, ICB	██
████	Interface Pharmacist, BNSSG ICB	██
████	Prescribing Clinical Lead, BNSSG ICB & OneCare	██
████	Principal Medicines Optimisation Pharmacist, BNSSG ICB	██
████	Deputy Chief Medical Officer, BNSSG ICB	██
████	Health Watch Representative BNSSG	██
████	Senior Medicines Optimisation Pharmacist, BNSSG ICB	██
████	Principal Medicines Optimisation Pharmacist, BNSSG ICB	██
████	Principal Medicines Optimisation Pharmacist, BNSSG ICB	██
████	Consultant in Acute Medicine, NBT	██
████	Principal Medicines Optimisation Pharmacist, BNSSG ICB	██
████	Principle Pharmacist - Pharmacoeconomics, NBT	██
████	Pharmacist, Sirona	██
████	Director Pharmacy, NBT	██
████	Director of Pharmacy, UHBW	██
████	MO Pharmacist, AWP	██
████	Medicines Governance Pharmacist, Sirona	██
████	MO Pharmacist, BNSSG ICB	██
████	Senior MO Pharmacist - Diabetes Lead, BNSSG ICB	██
████	MO Pharmacist – Respiratory, BNSSG ICB (for Asthma item)	██
Apologies		
████	Clinical Pharmacist and Non-Medical Prescriber	██
████	Head of Medicine Optimisation, Sirona	██
████	Chief Medical Officer	██
████	Meds Op Pharmacist, AWP	██
████	GP and Clinical Commissioning Policy Lead BNSSG ICB	██
████	GPN Nurse – BNSSG ICB	██
████	Clinical Pharmacy Manager, UHBW	██
████	Interface Pharmacist, BNSSG ICB	██
████	Principal Medicine Optimisation Pharmacist – BNSSG ICB	██
████	ICS Community Pharmacy Clinical Lead, BNSSG ICB	██
████	Specialist Pharmacist High-Cost Drugs BNSSG	██

	Item	Action
1	[redacted]	
2	**Declarations of Interest** No conflicts of interest were identified.	
3	[redacted]	
4	[redacted]	



	Item	Action
	Decision	
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	Item	Action
	[redacted]	
[redacted]	[redacted]	
5.2	[redacted]	
5.3	**Implementing Valproate Safety Recommendations and Support Documents** [redacted] presented to the group. In November 2023 the NPSA published an alert regarding valproate and asked ICB's and healthcare systems to implement safety recommendations relating to valproate, including pregnancy prevention programme, and to have an Improvement Action Plan. A Valproate Safety Working Group has been set up which includes representation neurology, NBT, AWP, children's hospital, sexual health consultants, Sirona and ICB. This Group have pulled together a pack of information to support primary care with prescribing and to highlight the processes	

	Item	Action
	that are in place. This information is spread across 11 documents for ease of reference for prescribers when in consultation with patients. ███ presented the documents to the group. ███ highlighted his concerns of potential patients falling through the net. ███ stated she did not think this should happen due to patients being under a specialist with the medication being TLS amber. ███ stated should any incidents arise, these would be discussed and reviewed by the Valproate Safety Working group and the documents will be reviewed on an ongoing basis. ███ stated this will also be monitored via the Safety Dashboard. ███ stated in the future there could be a national benchmark for the percentage of patients that have been reviewed annually so suggested we start to think about how we can capture and review these figures with the trust and look to have regular updates. ███ stated a recent data exercise has been carried out with the children's hospital to ensure their patient lists are up to date. The national team are reviewing patients who have been pregnant and potentially exposed to valproates and made a request for the relevant ICB to carry out a deep dive audit on those patients. BNSSG was not one of the ICB's listed. **The group were supportive and approved the Valproate Safety Recommendations and Support Documents and the documents can be published**	
5.4 5.4a 5.4b 5.4c 5.4d	███ █ ███ █ ███ █ ███ █ ███ ███	
5.5	███ ███	

	Item	Action
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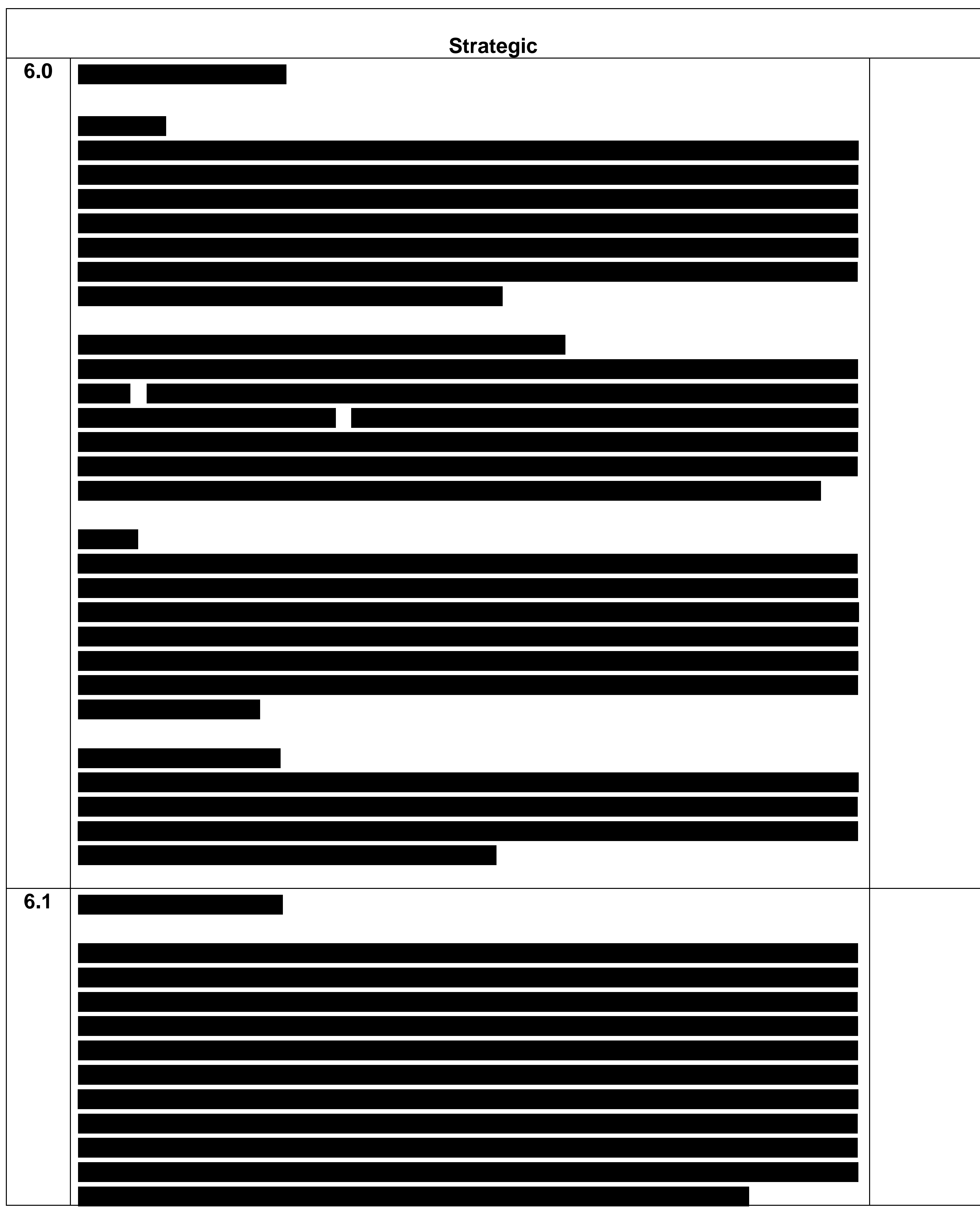

Strategic		
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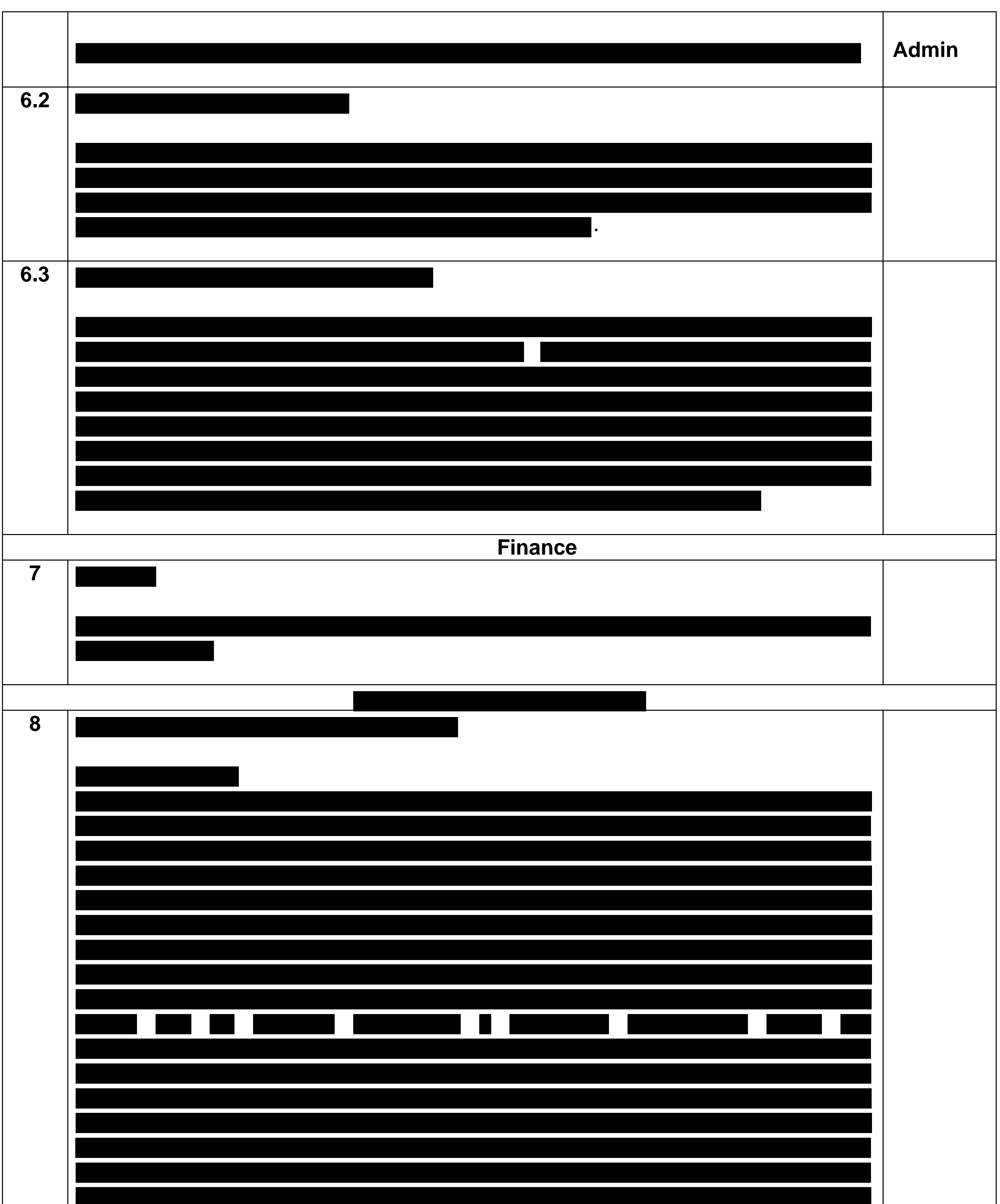

		Admin
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	Finance	
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	[redacted]	
9	[redacted]	
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11	[redacted]	
12	[redacted]	
13	[redacted]	
	[redacted]	

[redacted]
Team Administrator
BNSSG ICB
August 2024

BNSSG Area Prescribing Medicines Optimisation Committee (APMOC)

Minutes of the meeting held on Thursday 1st February 2024

Time: 13:30 – 16:00
Location: Microsoft Teams

Minutes

Present		
(Chair)	Chief Pharmacist, BNSSG ICB	
(Minutes)	Executive PA, BNSSG, ICB	
	Medicines Optimisation Pharmacist, BNSSG, ICB	
	Interface Pharmacist, BNSSG ICB	
	Health Watch Representative	
	Consultant in Acute Medicine, NBT	
	Clinical Pharmacist and Non-Medical Prescriber	
	Deputy Chief Medical Officer, Primary and Community Care, BNSSG ICB	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	Formulary Pharmacist, NBT	
	GPCB Clinical Lead, BNSSG ICB & OneCare	
	Medication Safety Officer, Sirona	
	Director of Pharmacy, UHBW	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	GP and Clinical Lead in Exceptional Funding and Policy Development, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Medicines Optimisation Pharmacist, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist - Diabetes Lead, BNSSG ICB	
	Consultant Chemical Pathologist, UHBW	
	Medicines Optimisation Pharmacist, BNSSG ICB	
	Programme Officer, Medicines Optimisation, BNSSG ICB	
	ICS Community Pharmacy Clinical Lead, BNSSG ICB	
	Chemical Pathology, NBT	
	Consultant Rheumatologist, NBT	
	Interface Pharmacist, BNSSG ICB	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Clinical Pharmacy Manager, UHBW	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
Apologies		
	Clinical Pharmacy Manager, UHBW	

	BNSSG ICS General Practice Nurse Strategic Lead	
	Lead Consultant, Medicines Optimisation, UHBW	
	Deputy Chief Nursing Officer	
	Clinical Lead for the BNSSG Referral Service, BNSSG ICB	
	CMO, BNSSG ICB	
	Chief Officer, Community Pharmacy Avon	
	GP registrar, BNSSG ICB	

	Item	Action
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2	**Declarations of Interest** No conflicts of interest were identified.	
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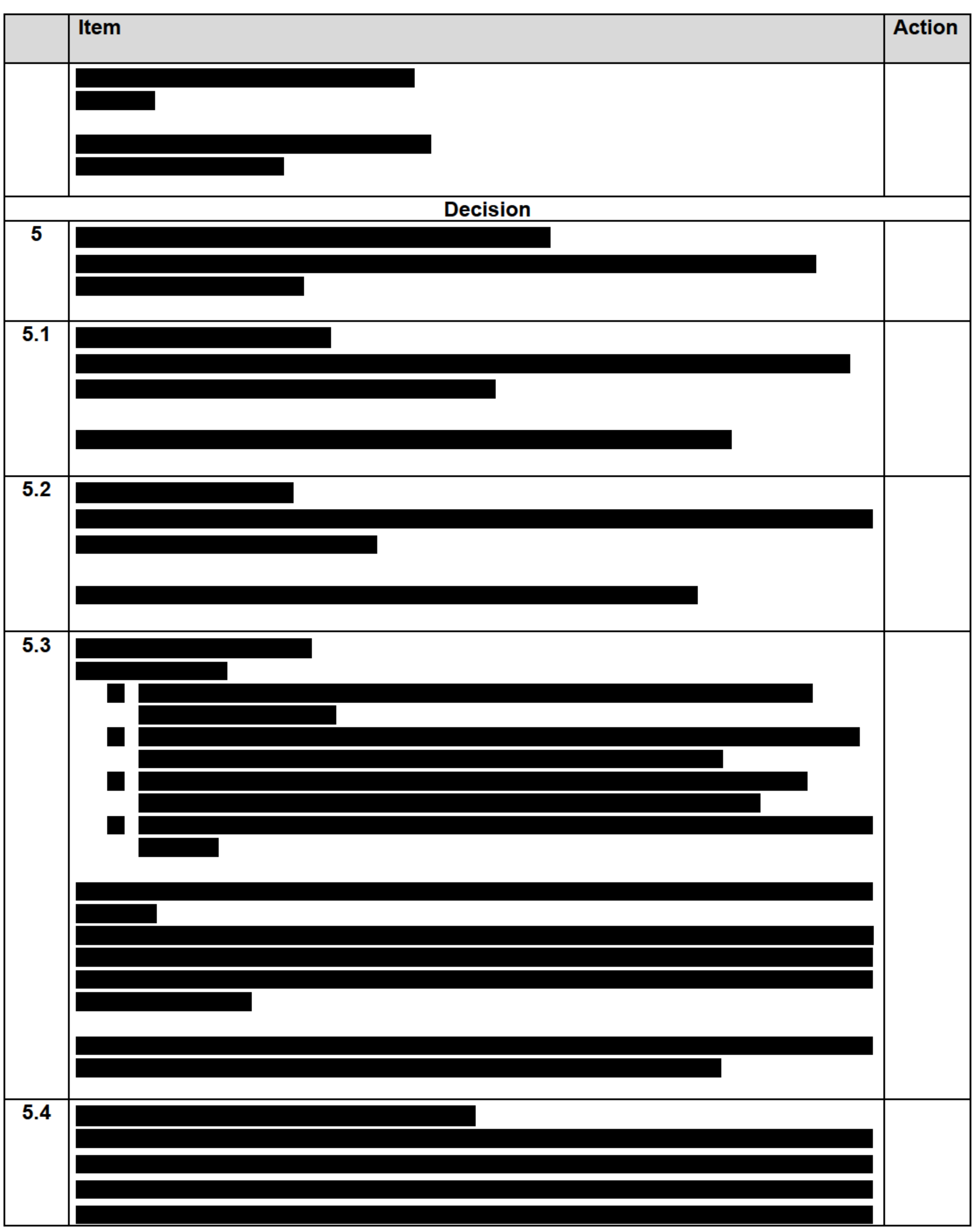

	Item	Action
	Decision	
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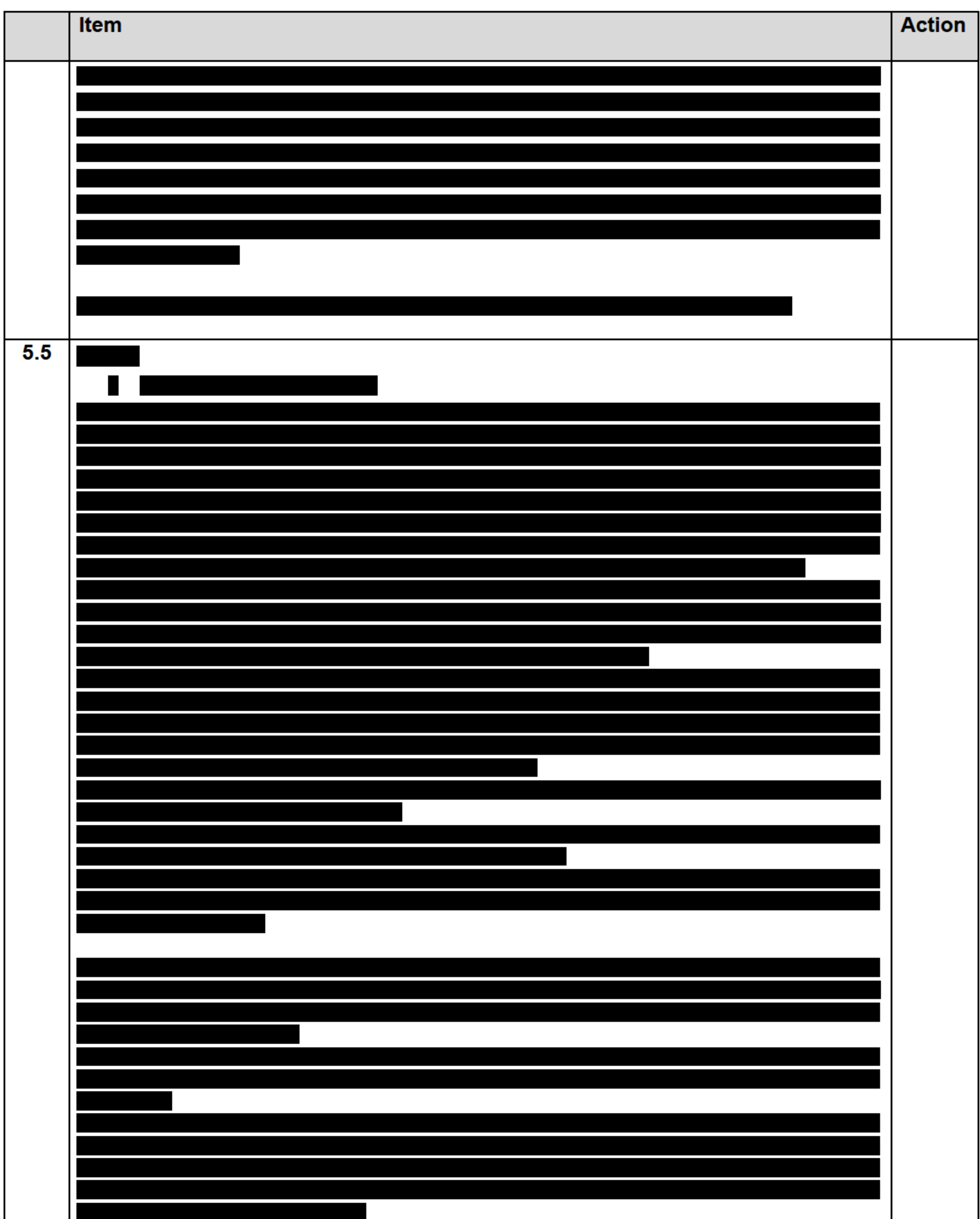
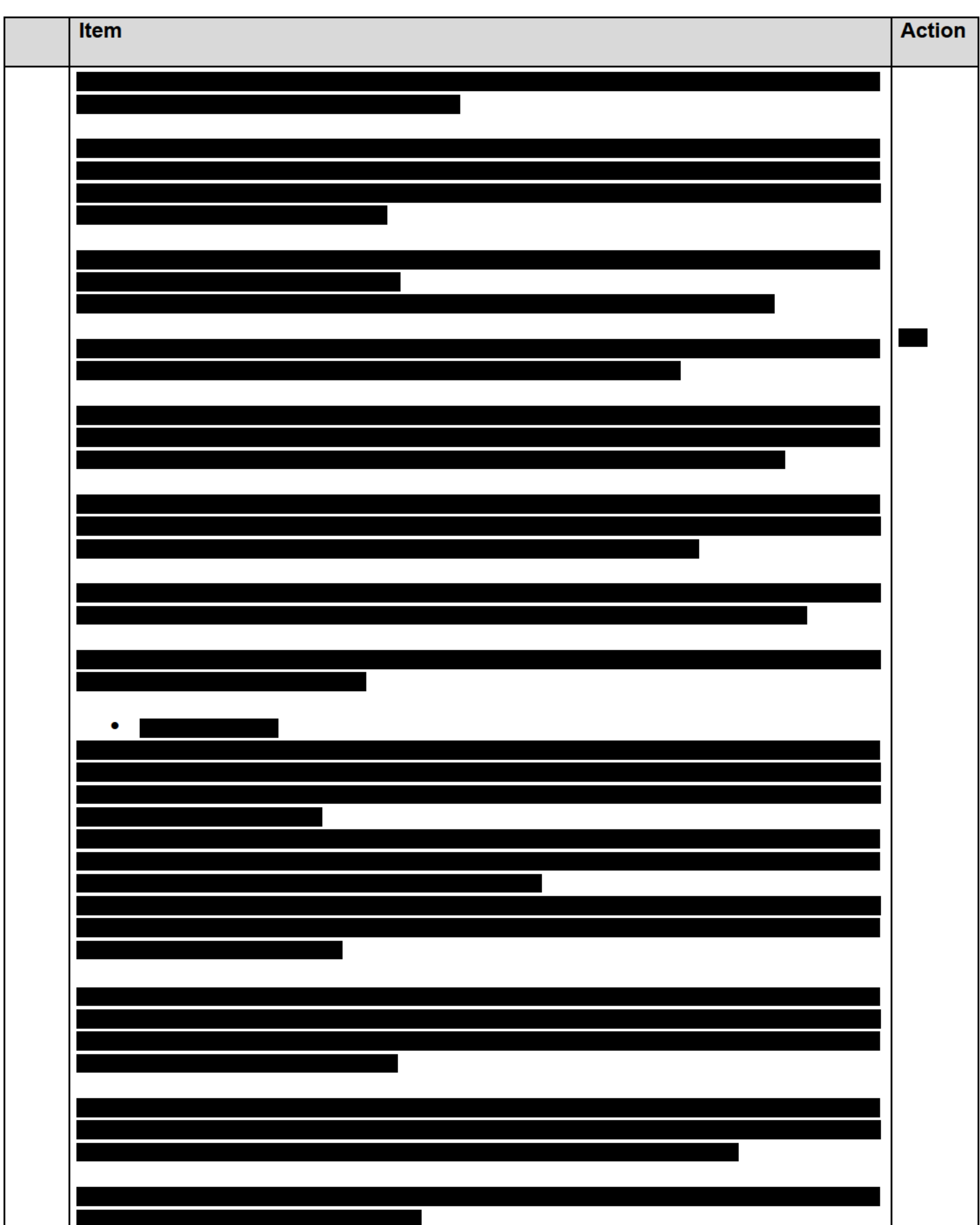
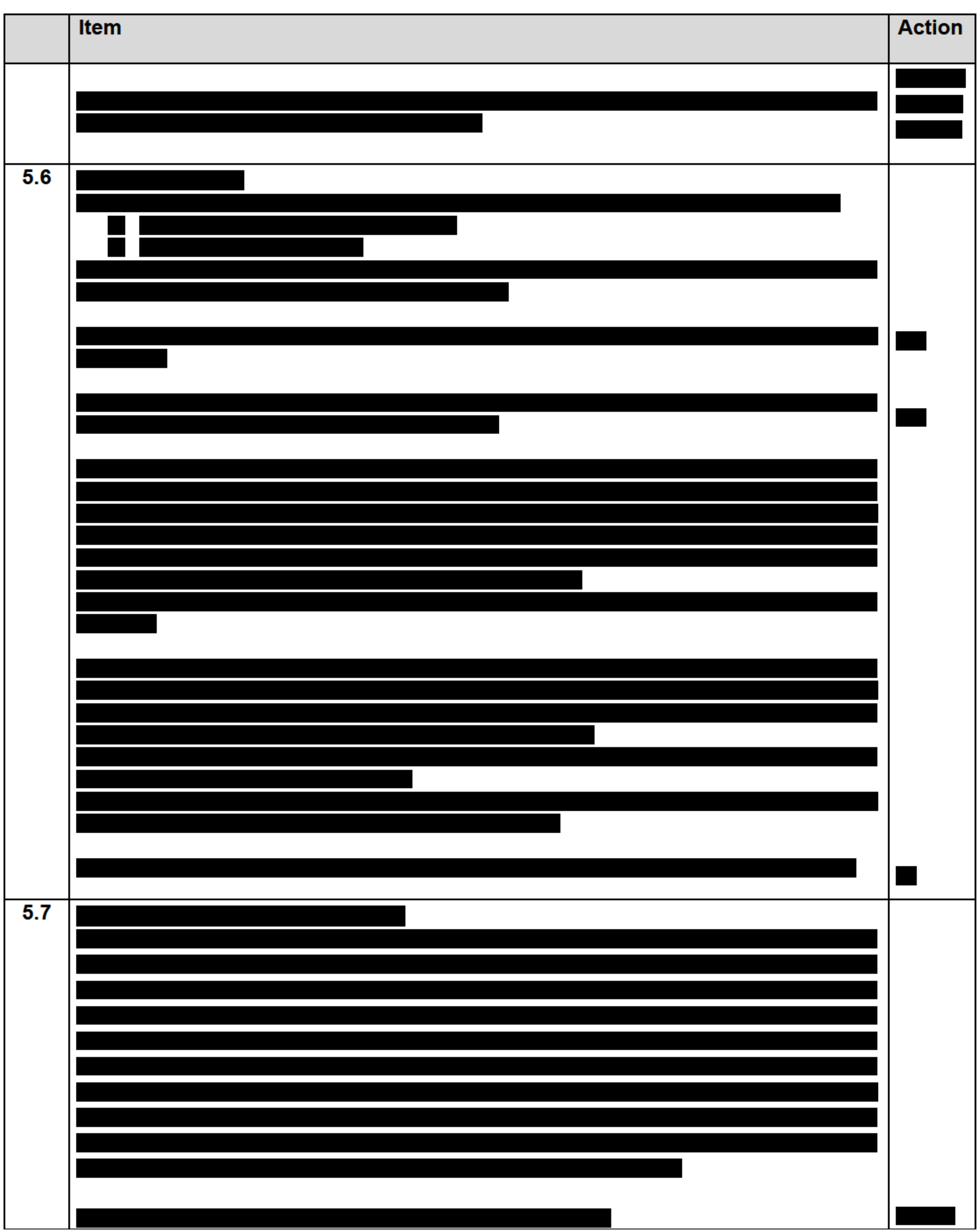


	Item	Action
5.5		

	Item	Action





	Item	Action
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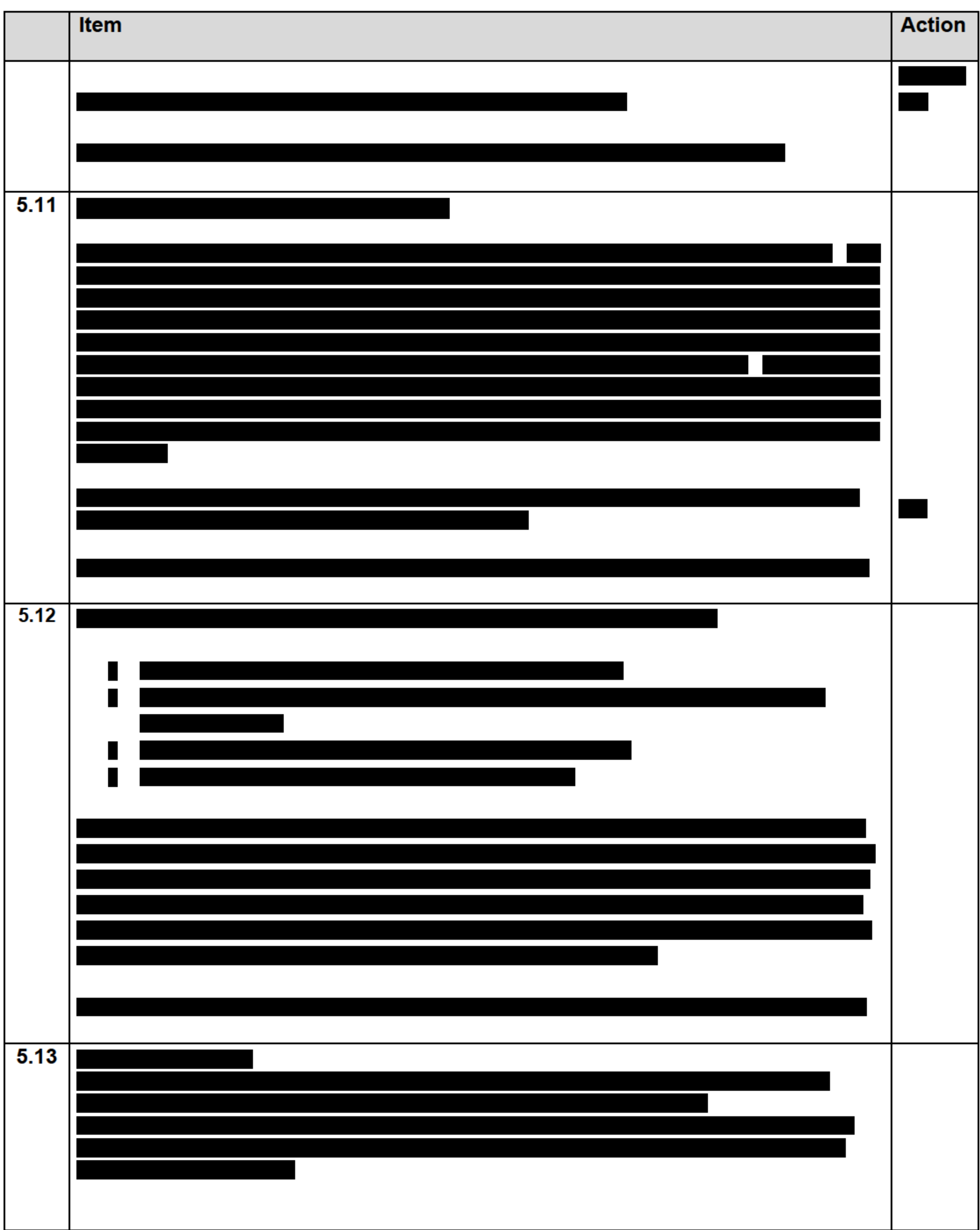
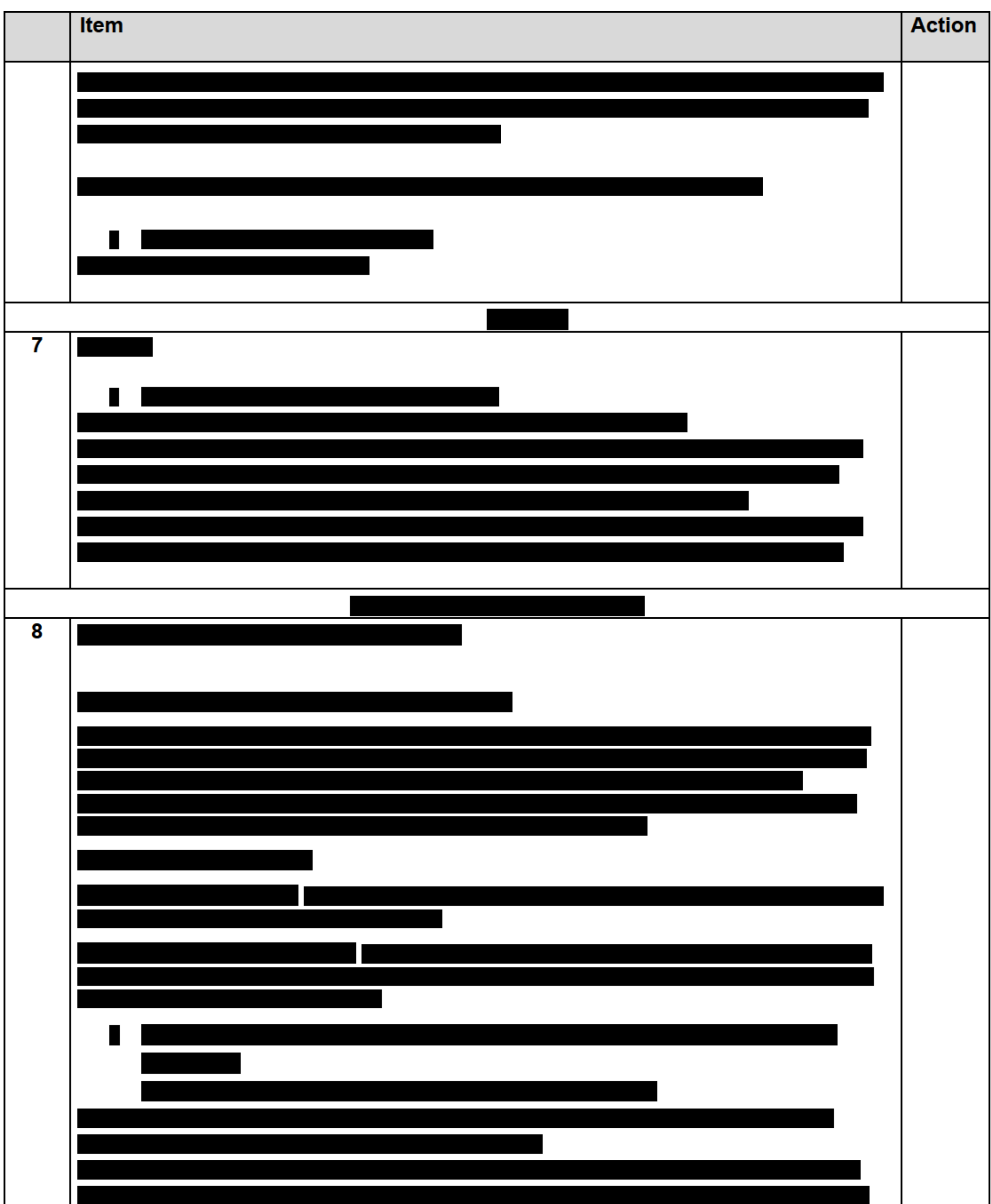
	Item	Action
	[redacted]	
5.8	[redacted]	[redacted]
5.9	**Valproate Original Pack Dispensing Risk Assessment Form** [redacted] presented and discussed the Valproate Original Pack Dispensing Risk Assessment Form with the group. [redacted] advised in October 2023 the legislation changed regarding valproate. The new Government ruling states that community pharmacy should dispense full original packs of valproate. Full warnings and risk information on valproate medication is to be made available on the label for the patient to see. There are exceptional circumstances to this rule, but a risk assessment must be carried out in order for it to be legal. This checklist has had input from [redacted], [redacted] (Medicines Optimisation Pharmacist), MSOs, valproate team and AWP to provide a consistent approach across the system. **The group approved the consistent approach change to the risk assessment form.**	
5.10	[redacted]	[redacted]



	Item	Action
5.11		
5.12		
5.13		

	Item	Action
5.14		
	Strategic	
6.0	**MHRA NPSA on Valproate** [Valproate-report-review-and-expert-advice.pdf (publishing.service.gov.uk)](Valproate-report-review-and-expert-advice.pdf) updated the group for assurance of all the actions currently taking place in line with the MHRA NPSA alert on valproate. An implementation plan is in place, that a working group is overseeing. Currently nothing to escalate to APMOC.	
6.1		



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	Item	Action
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	Standing Items	
11		For Information

	Item	Action
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February 2024

BNSSG Area Prescribing Medicines Optimisation Committee (APMOC)

Minutes of the meeting held on Thursday 5th December 2024

Time: 13:30 – 16:00
Location: Microsoft Teams

Minutes

Attendees		
(Chair)	Chief Pharmacist, BNSSG ICB	
(Minutes)	Team Administrator, BNSSG, ICB	
	ICS Community Pharmacy Clinical Lead, BNSSG ICB	
	Clinical Pharmacist and Non-Medical Prescriber	
	Prescribing Clinical Lead, BNSSG ICB & OneCare	
	Principal Medicine Optimisation Pharmacist – BNSSG ICB	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	Deputy Chief Medical Officer, BNSSG ICB	
	Interface Pharmacist, BNSSG ICB	
	Clinical Pharmacy Manager, UHBW	
	Principle Pharmacist – Pharmacoeconomics, NBT	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	General Practice Nurse Lead, BNSSG ICB (part of the meeting)	
	Director Pharmacy, NBT	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	Consultant in Acute Medicine, NBT	
	Medicines Optimisation Pharmacist, BNSSG ICB	
	Pharmacist, Sirona	
	Principal Medicines Optimisation Pharmacist, BNSSG ICB	
	Chair, LMC	
	GP and Clinical Commissioning Policy Lead BNSSG ICB	
Apologies		
	Director of Pharmacy, UHBW	
	Medicines Optimisation Pharmacist, AWP	
Presenters		
	ST5 in Chemical Pathology	
	Consultant Chemical Pathologist, Severn Pathology, NBT	
	Senior Medicines Optimisation Pharmacist (Respiratory Lead) BNSSG ICB	

	Item	Action
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2	**Declarations of Interest** No conflicts of interest were identified.	
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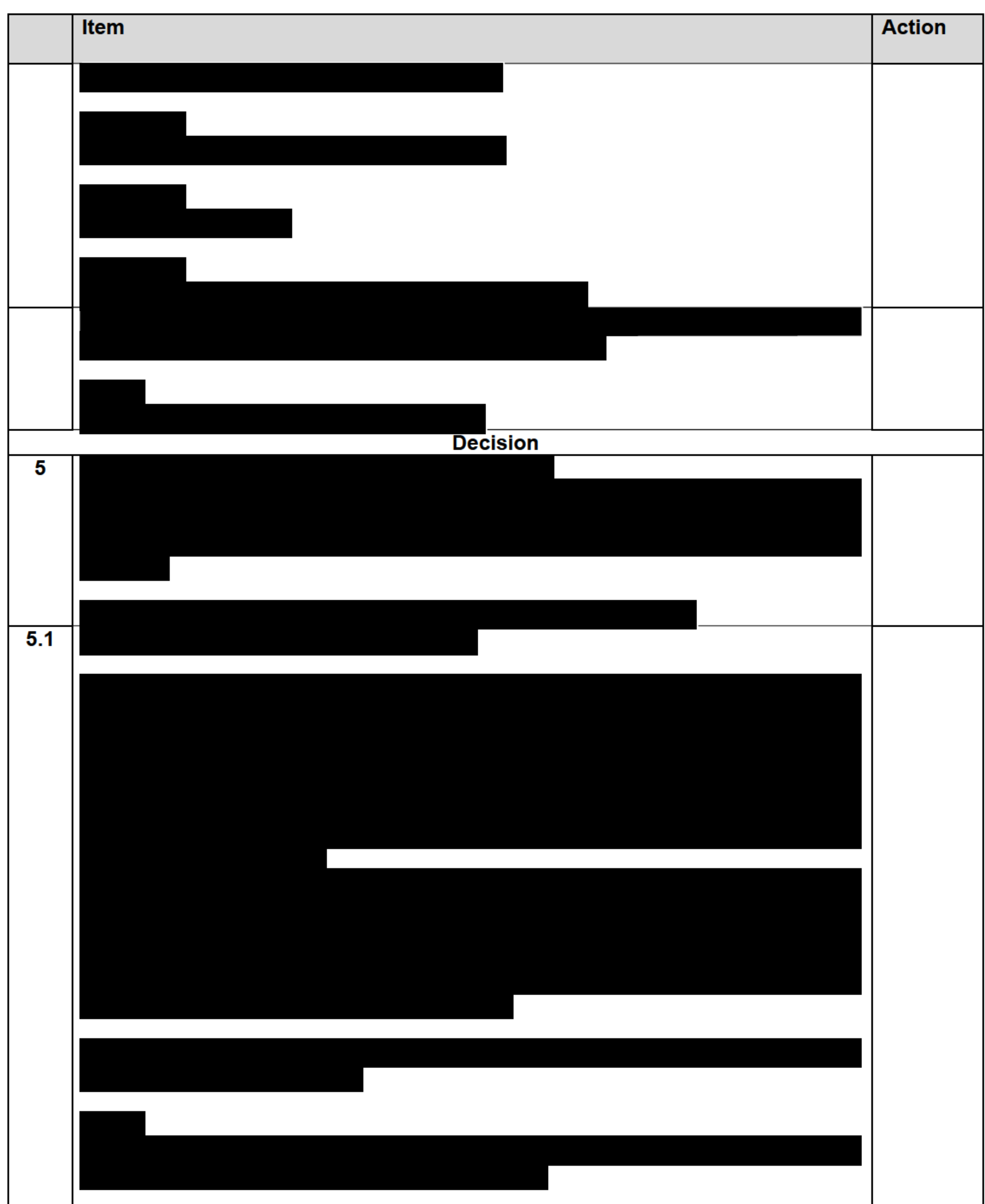

	Item	Action
	Decision	
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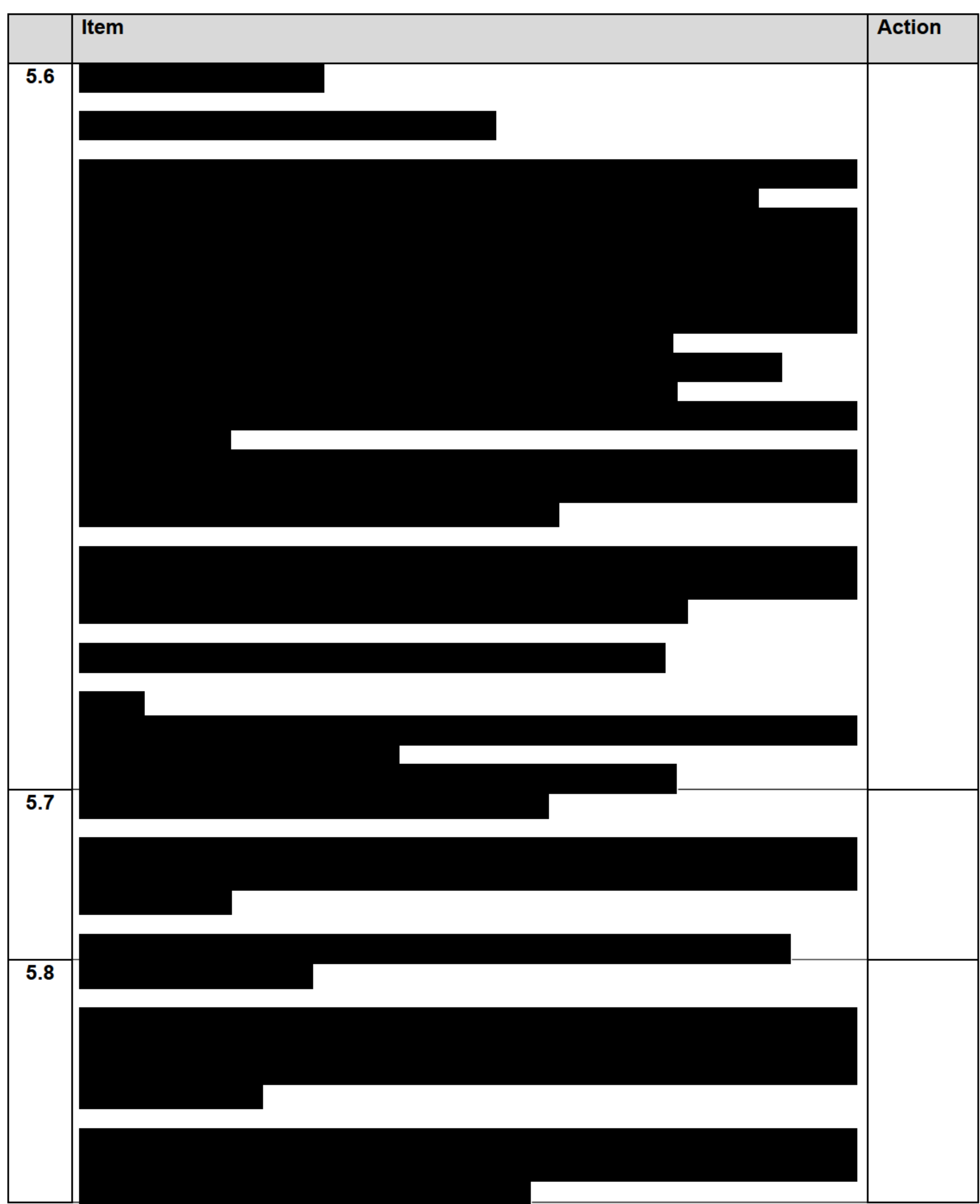
	Item	Action
5.2	[redacted]	
5.3	[redacted]	
5.4	**Valproate paternal risk safety pack** [redacted] set the scene and the background for this. The information has been going out to patients in different formats including text messages, examples of these are in the pack, flowcharts showing different options, questions to ask which have been approved by those with learning difficulties. It has also been through the Teratogenic Drug safety group. [redacted] commented that the evidence isn't overwhelming, but we are going on the national guidance on this. As more evidence is received this can be reviewed as no published data has been seen. **The group agreed this resource.**	
5.5	[redacted]	



	Item	Action
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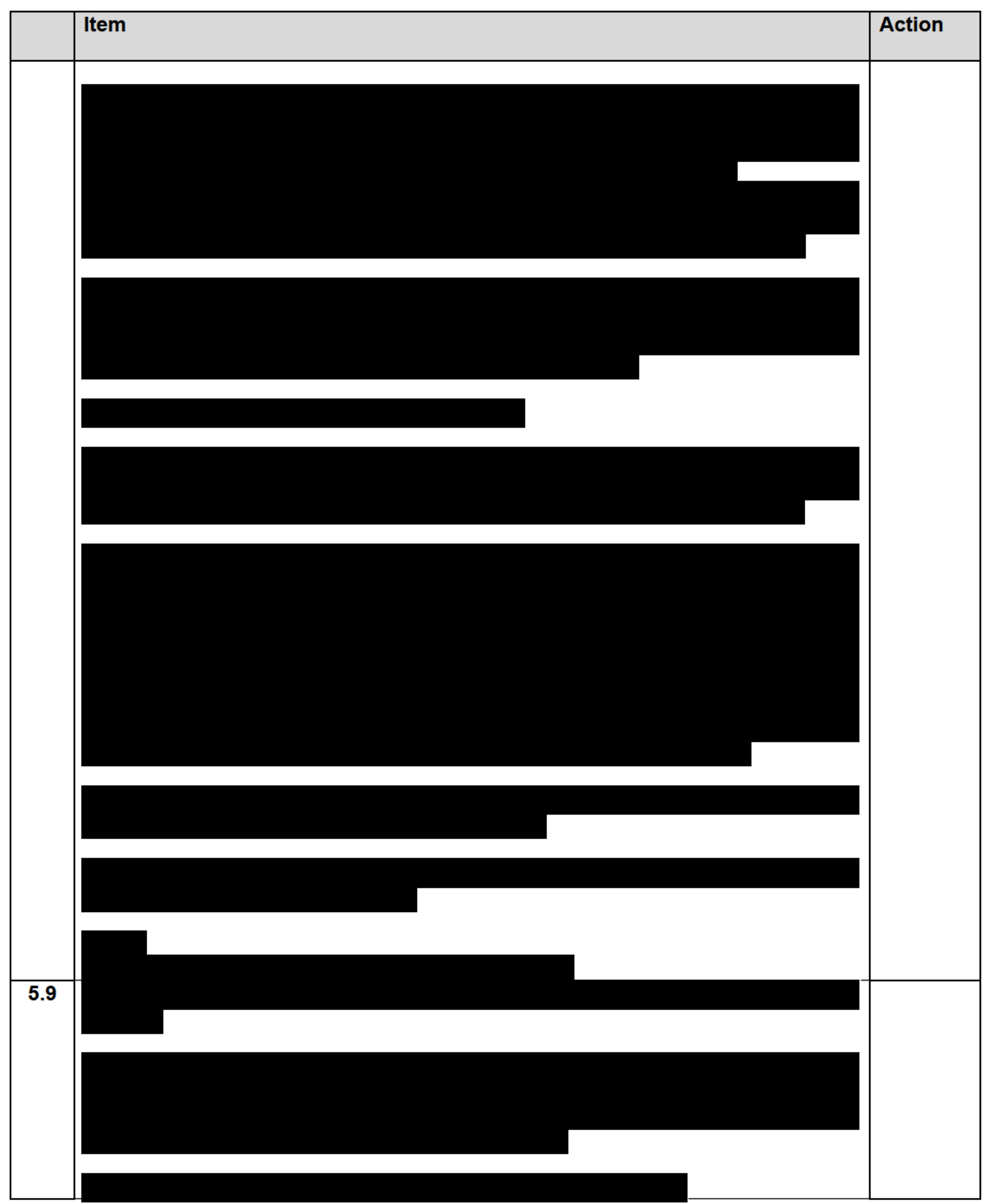
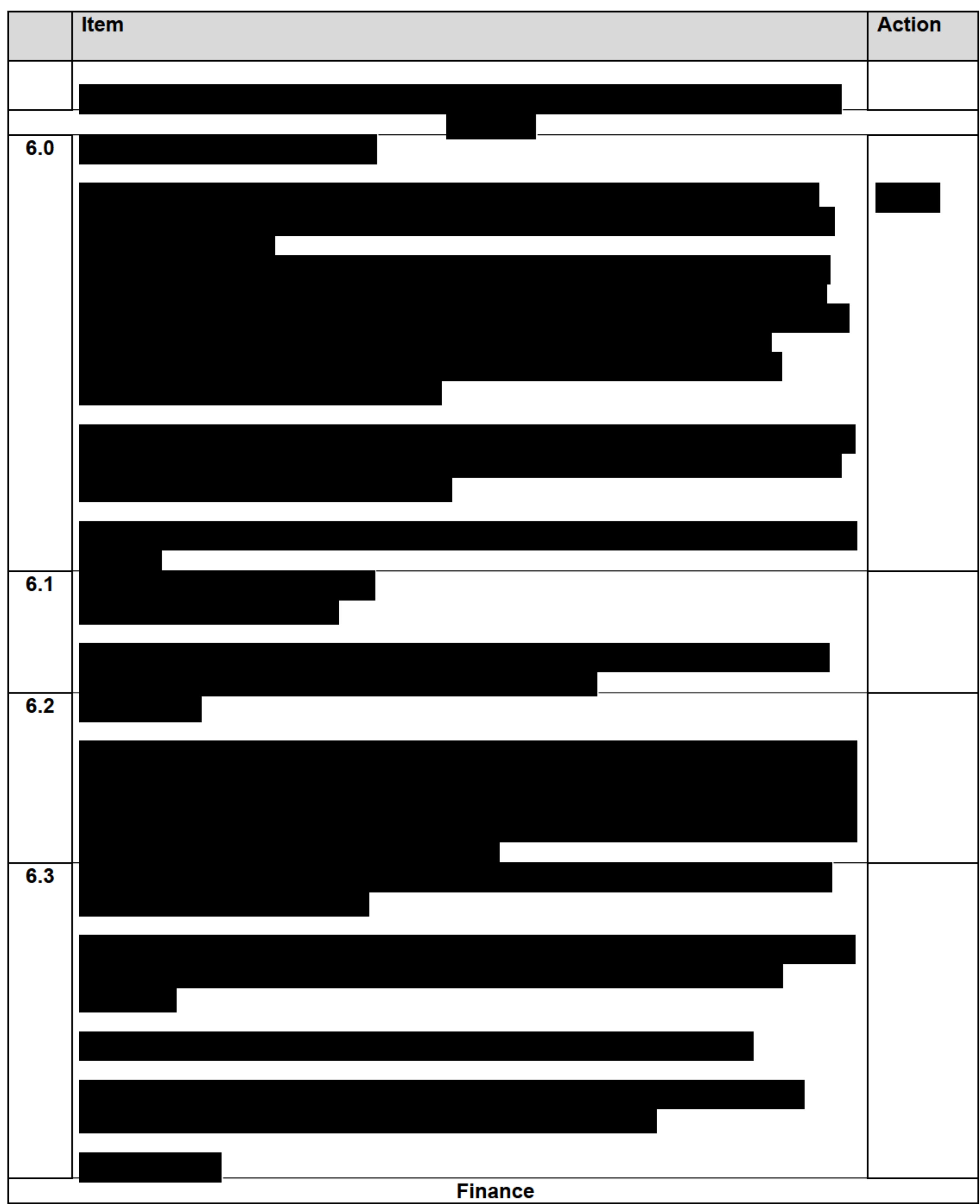
	Item	Action
		
5.9		



	Item	Action
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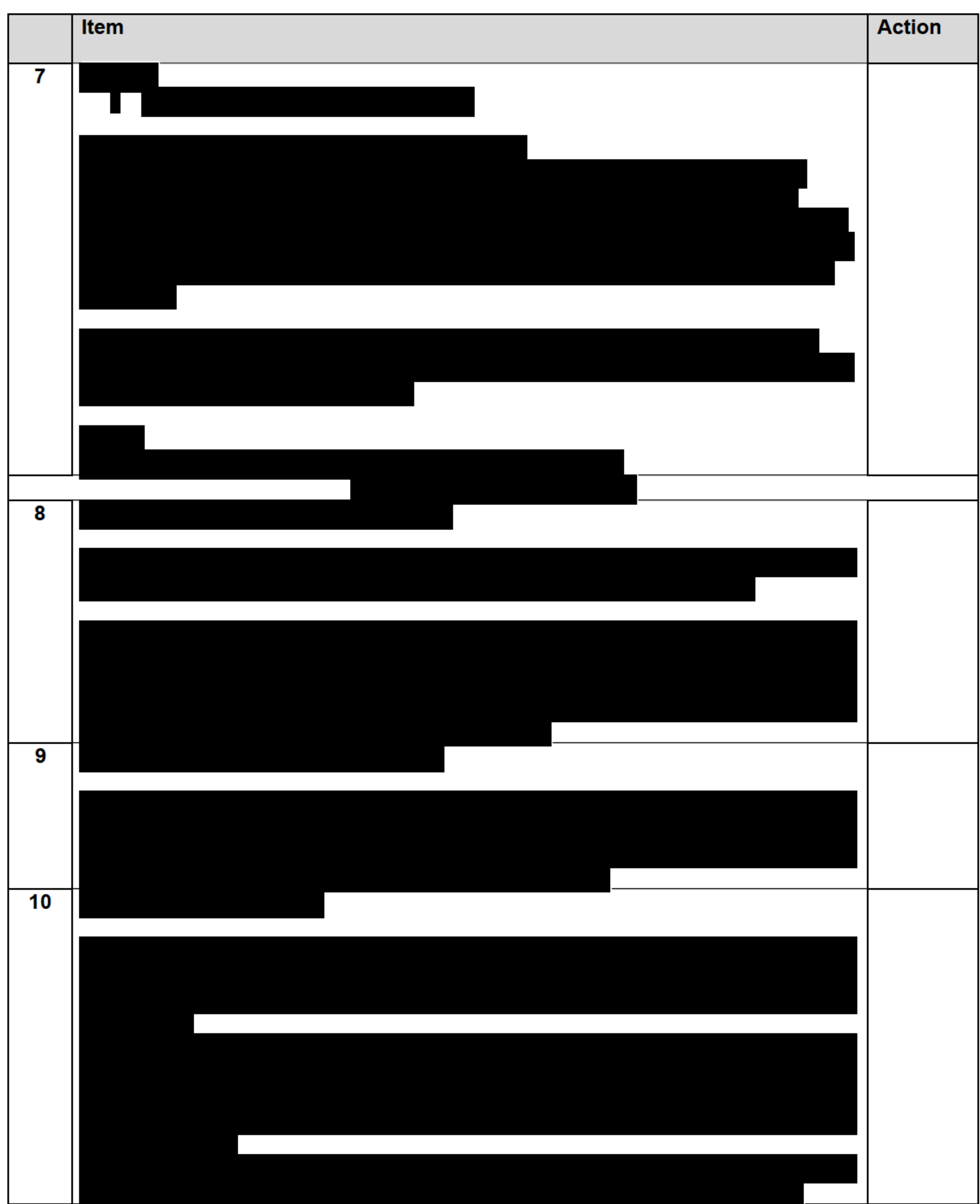
	Finance	



	Item	Action
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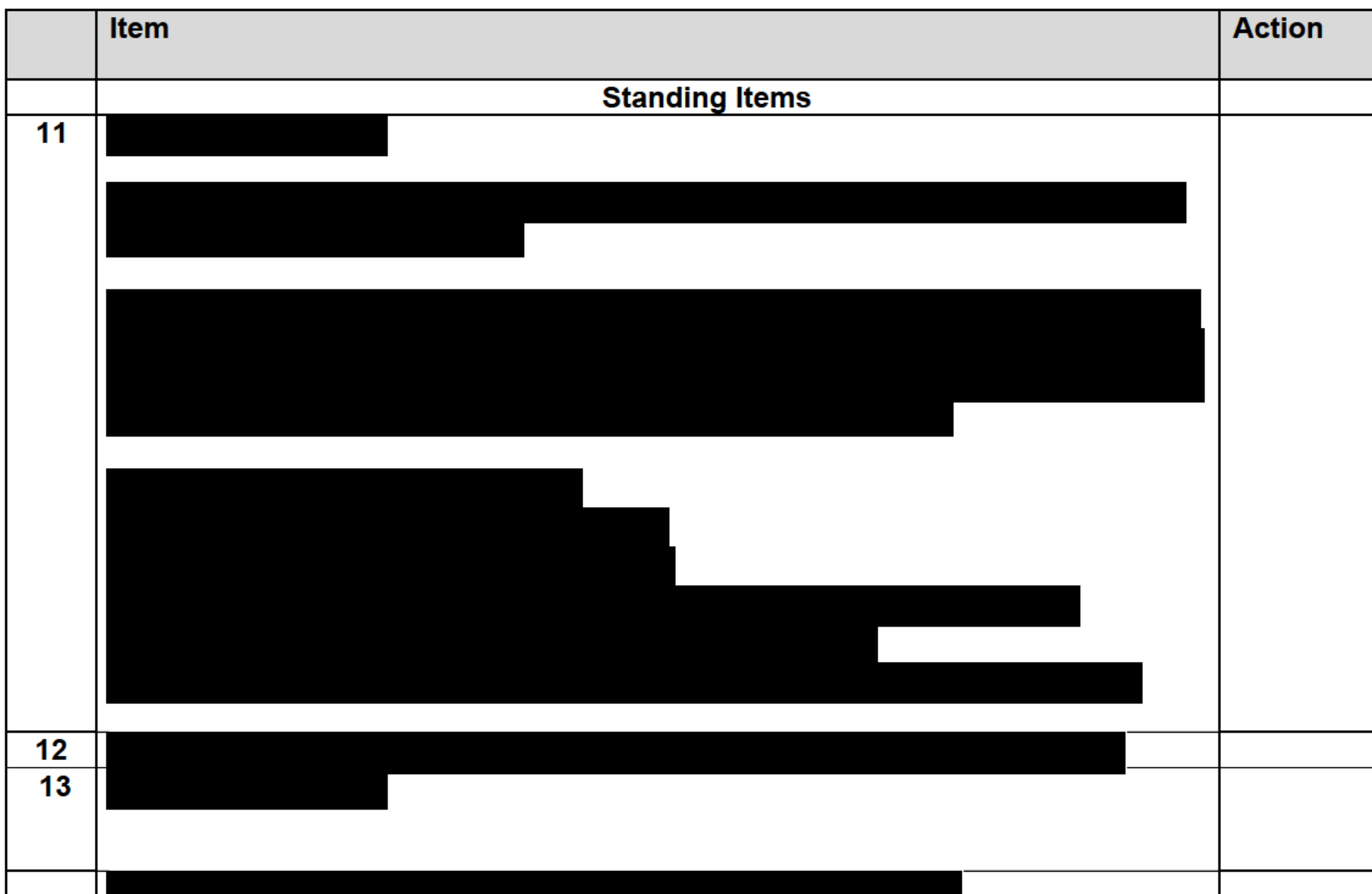

	Item	Action
	Standing Items	
11		
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Team Administrator
BNSSG ICB
December 2024

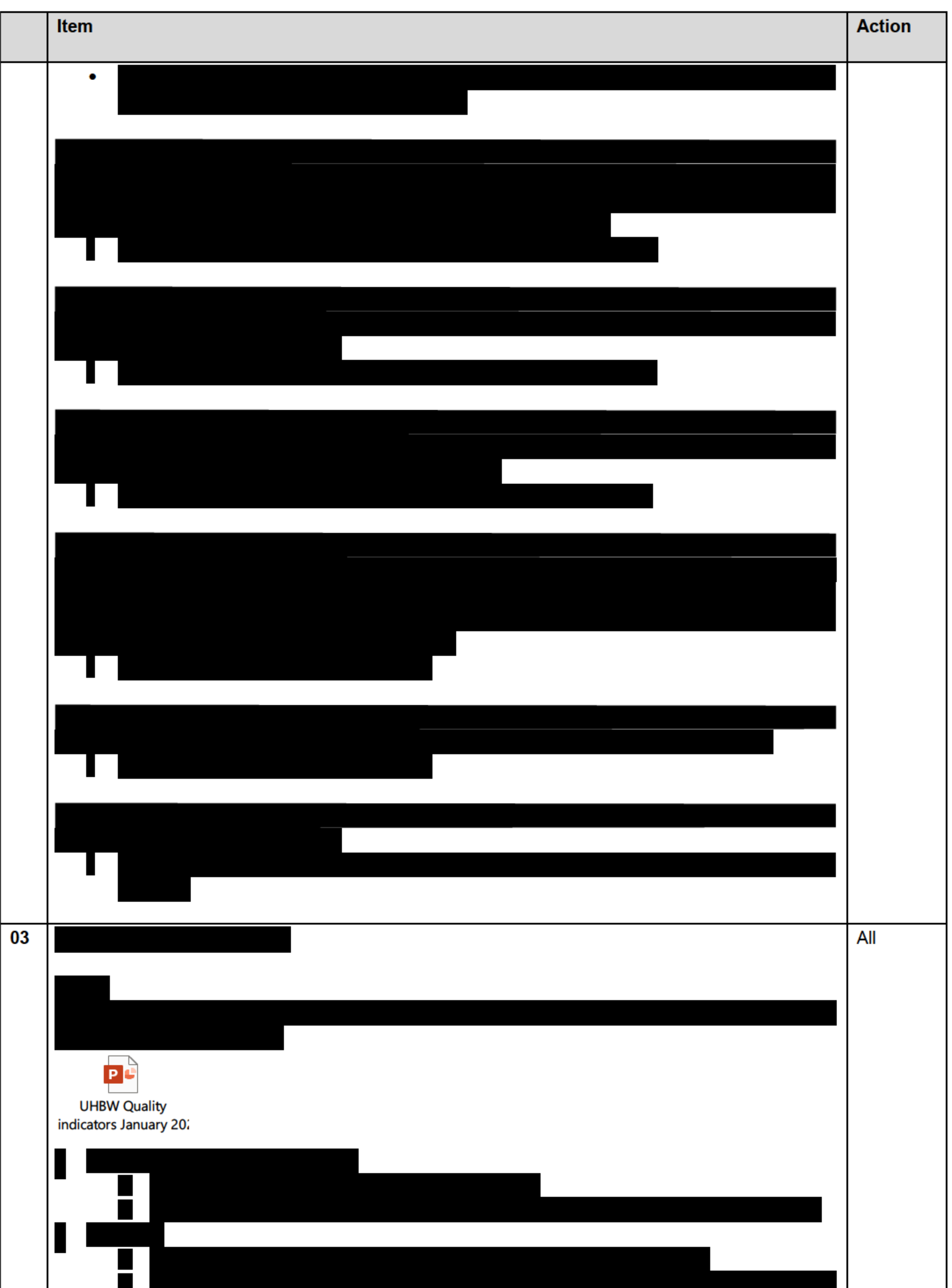
ICS Medicines Optimisation – Medicines Quality and Safety Group Meeting

Date of Meeting: Thursday 25th January 2024
Time: 13:00 – 15:00
Venue: Microsoft Teams

Minutes

Present		
	Deputy Chief Pharmacist BNSSG ICB	
	Team Administrator, Medicines Optimisation, BNSSG, ICB (Minute taker)	
	Medication Safety Officer & Clinical Governance Pharmacist, UHBW	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Senior Pharmacist, Medicines Optimisation, BNSSG, ICB (Antimicrobial stewardship lead ICB)	
	Head of Care, Children's Hospice Southwest	
	Head of Medicines Optimisation Sirona Care & Health	
	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Associate Chief Pharmacist – Clinical Pharmacy and Self-Pay Pathways, Practice Plus Group	
	Interim Medication Safety Officer, AWP	
Apologies		
	Deputy Director, Medicines Optimisation, BNSSG, ICB	
	Associate Director of Pharmacy, Medicines Governance and Safety, NBT	
	Clinical Pharmacy Manager, UHBW	
	Programme Manager, West of England AHSN	
	Chief Officer Avon LPC	
	Lead Clinical Pharmacist, Spire Bristol Hospital	

	Item	Action
01	**Welcome, Introductions, Apologies and Declarations of Interests** No declarations of interest were declared. The meeting today was **not** quorate.	
02		



	Item	Action
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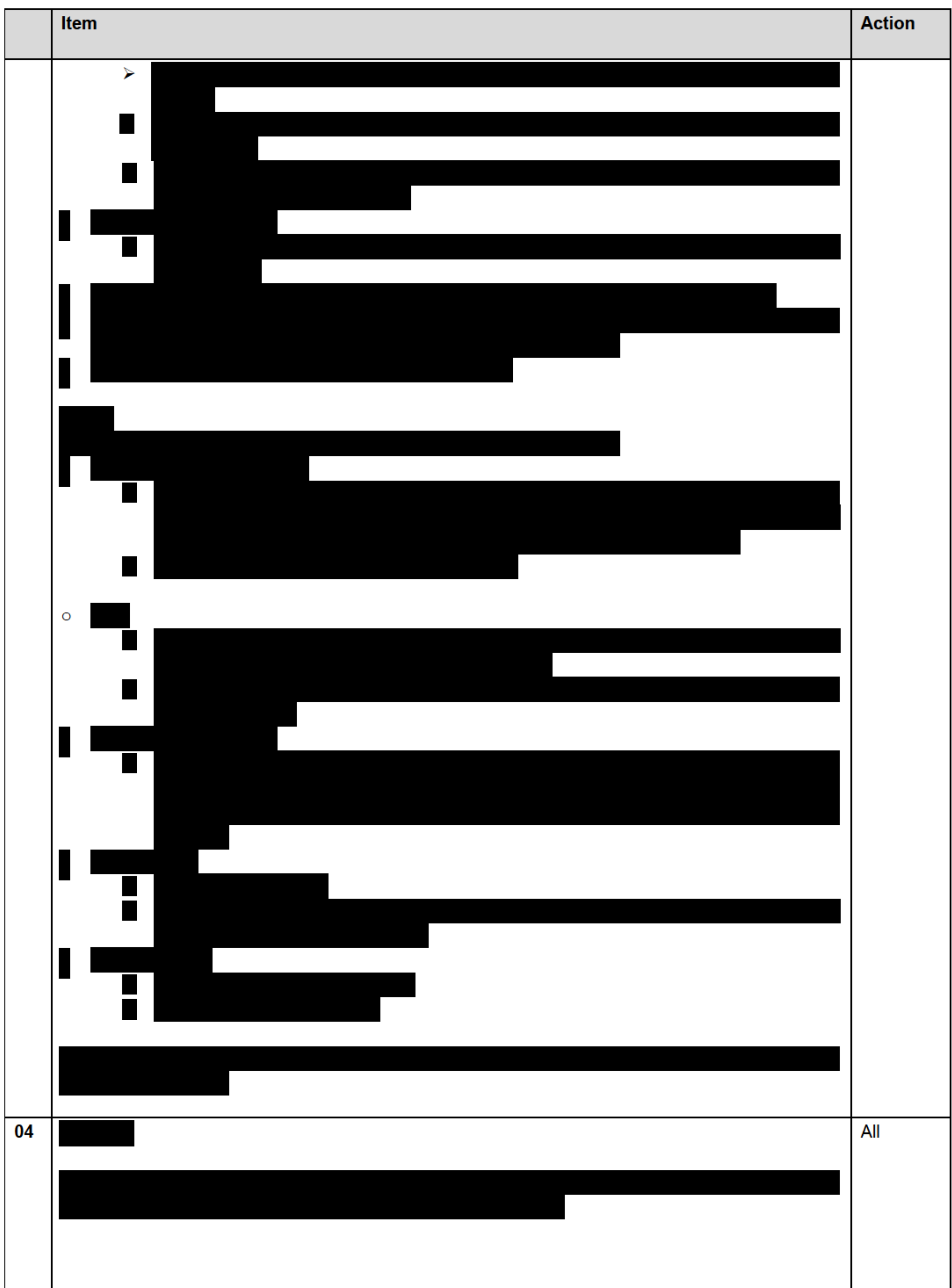
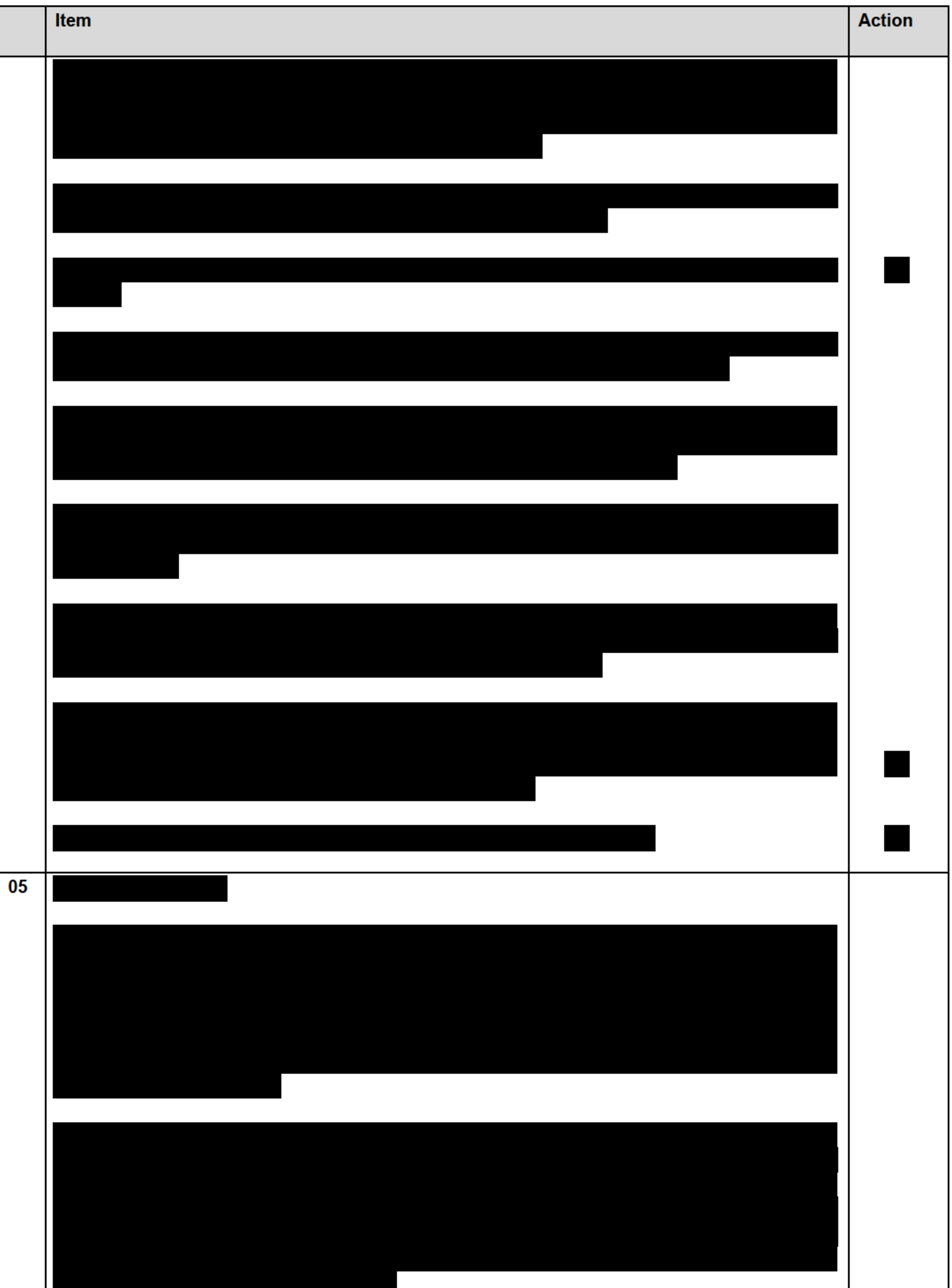
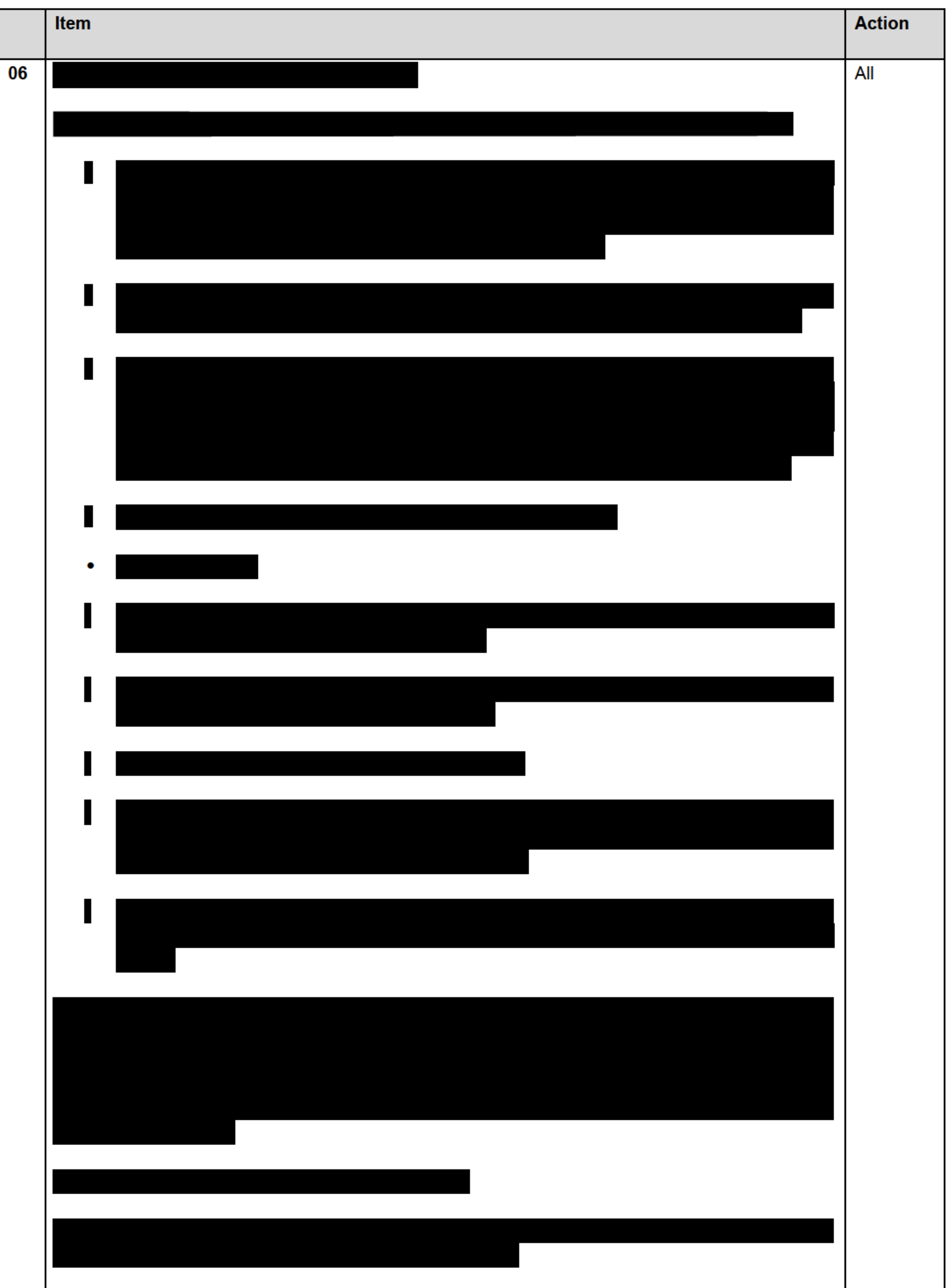
03	UHBW Quality indicators January 20:	All



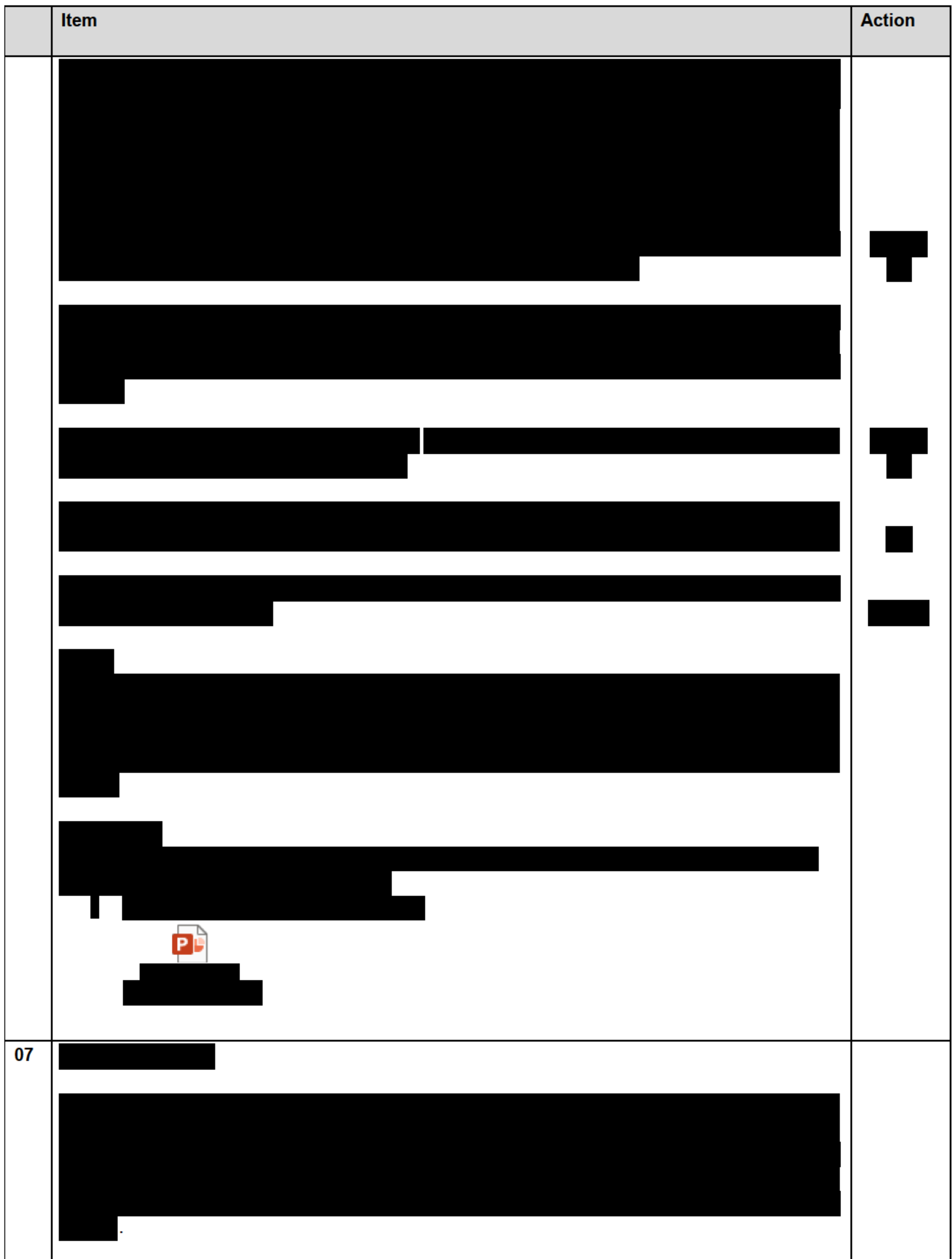
	Item	Action
04		All



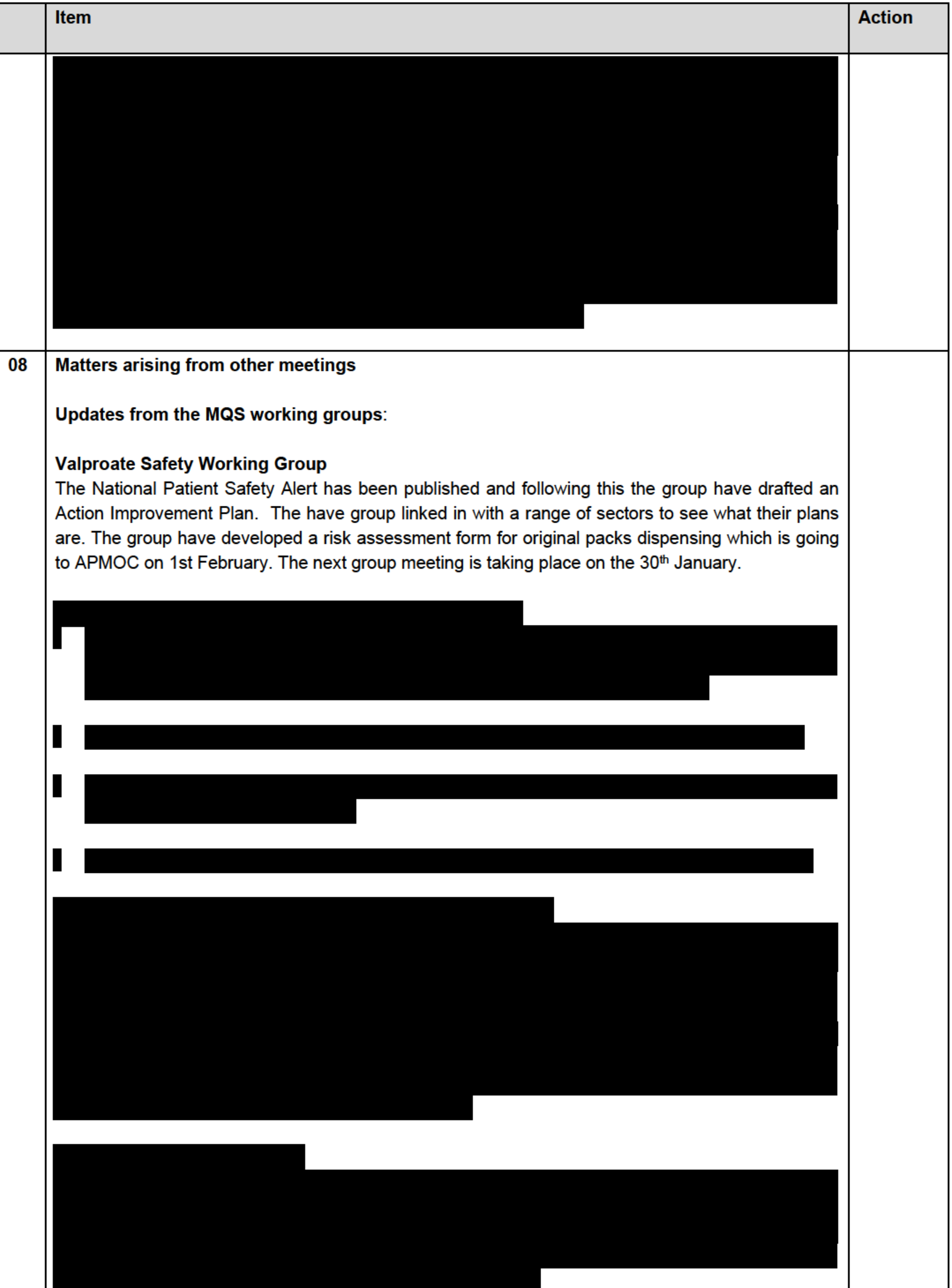
	Item	Action
05		



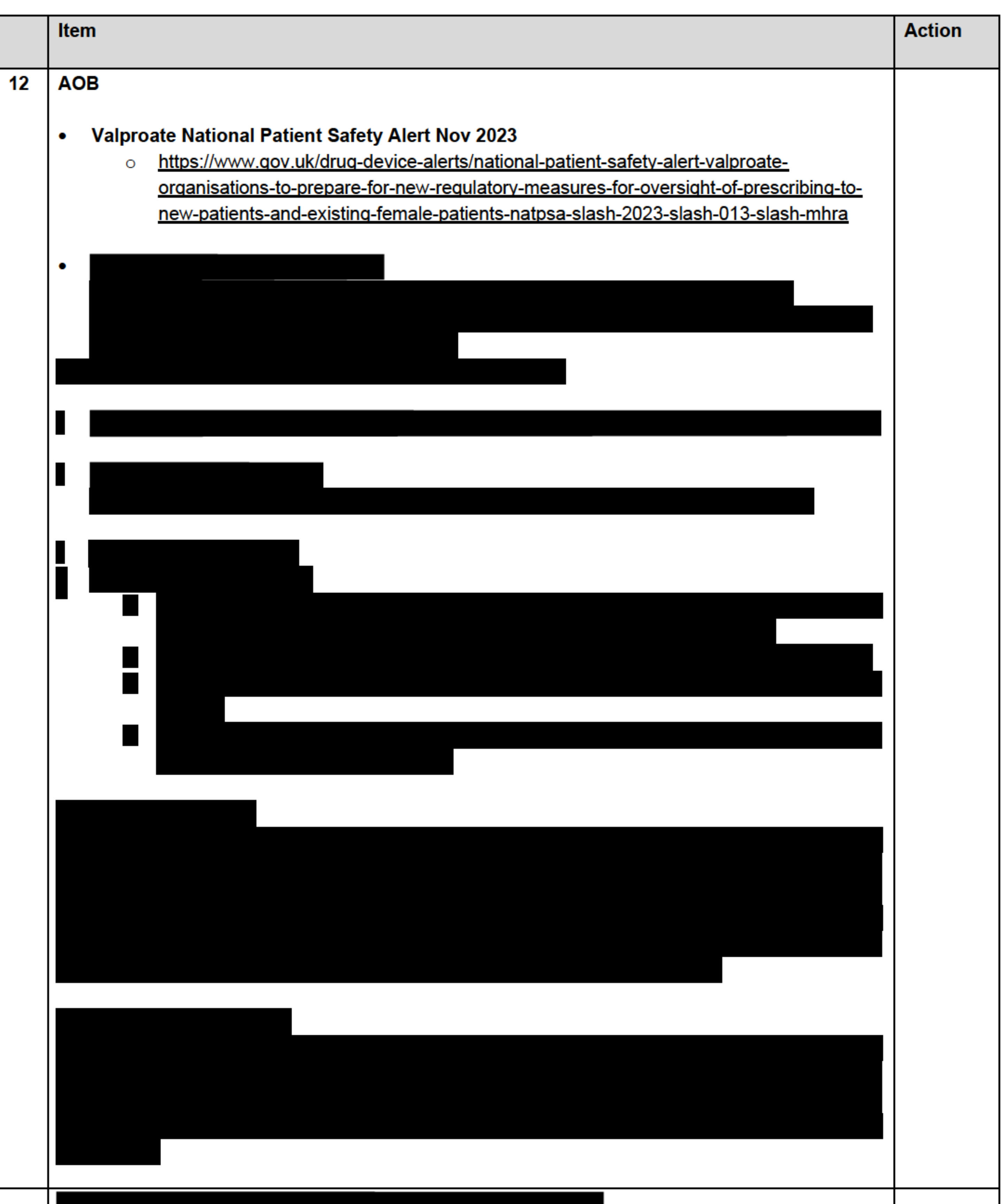
	Item	Action
06		All



	Item	Action
07		



	Item	Action
08	**Matters arising from other meetings** **Updates from the MQS working groups**: **Valproate Safety Working Group** The National Patient Safety Alert has been published and following this the group have drafted an Action Improvement Plan. The have group linked in with a range of sectors to see what their plans are. The group have developed a risk assessment form for original packs dispensing which is going to APMOC on 1st February. The next group meeting is taking place on the 30th January.	



	Item	Action
12	**AOB** • **Valproate National Patient Safety Alert Nov 2023** ○ https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-valproate-organisations-to-prepare-for-new-regulatory-measures-for-oversight-of-prescribing-to-new-patients-and-existing-female-patients-natpsa-slash-2023-slash-013-slash-mhra •	

- BNSSG ICB
January 2024

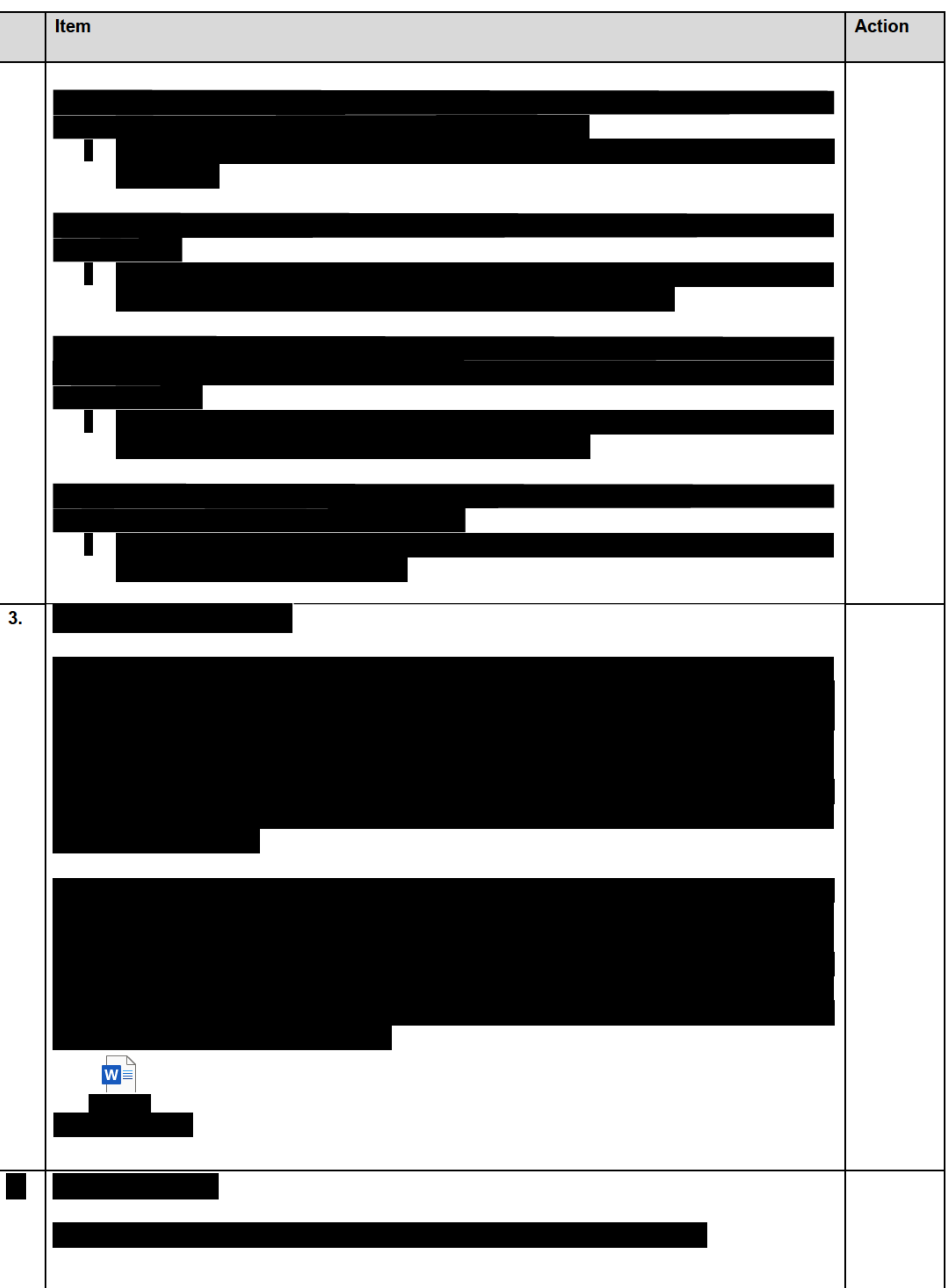
ICS Medicines Optimisation – Medicines Quality and Safety Group Meeting

Date of Meeting: Thursday 15th August 2024
Time: 13:00 – 15:00
Venue: Microsoft Teams

Minutes

Present		
	Deputy Chief Pharmacist BNSSG ICB	
	Team Administrator, Medicines Optimisation, BNSSG, ICB (Minute taker)	
	Principal Pharmacist, Medicines Optimisation, BNSSG ICB (Antimicrobial stewardship lead)	
	Senior Medicines Optimisation Pharmacist, BNSSG ICB	
	Associate Director of Pharmacy, Medicines Governance and Safety, NBT	
	Associate Chief Pharmacist and Pharmacy Manager in Emersons Green, Practice Plus Group	
	Prescribing Clinical Lead	
	Lead Pharmacist (Medicines Safety, Governance & R&D), AWP	
	BNSSG area Clinical Lead, AWP	
	Pharmacy Manager and Medicines Management Lead Nuffield Health Bristol Hospital	
	Associate Director of Pharmacy, UHBW	
Apologies		
	Chief Pharmacist, Medicines Optimisation, BNSSG, ICB	
	Principal Pharmacist Medicines Optimisation, Controlled Drugs Lead BNSSG ICB	
	Clinical Lead for Health Innovation Network, West of England	
	Senior Project Manager, Health Innovation Network West of England	
	Principal Pharmacist, Medicines Optimisation, BNSSG ICB	
	Senior Team Leader, Charlton Farm Childrens Hospice Southwest	
	Chief Officer, Community Pharmacy Avon	
	Deputy Chief Medical Officer Sirona Care & Health	
	Programme Manager, West of England AHSN	
	Lead Clinical Pharmacist, Spire Bristol Hospital	
	Head of Care, Children's Hospice Southwest	
	Head of Medicines Optimisation Sirona Care & Health	
In Attendance		
	Clinical Lead Pharmacist Secure & CAMHS and Lead Pharmacist for Education and Training, AWP	

	Item	Action
01	**Welcome, Introductions, Apologies and Declarations of Interests** No declarations of interest were declared. The meeting today was quorate.	
02		

	Item	Action
		
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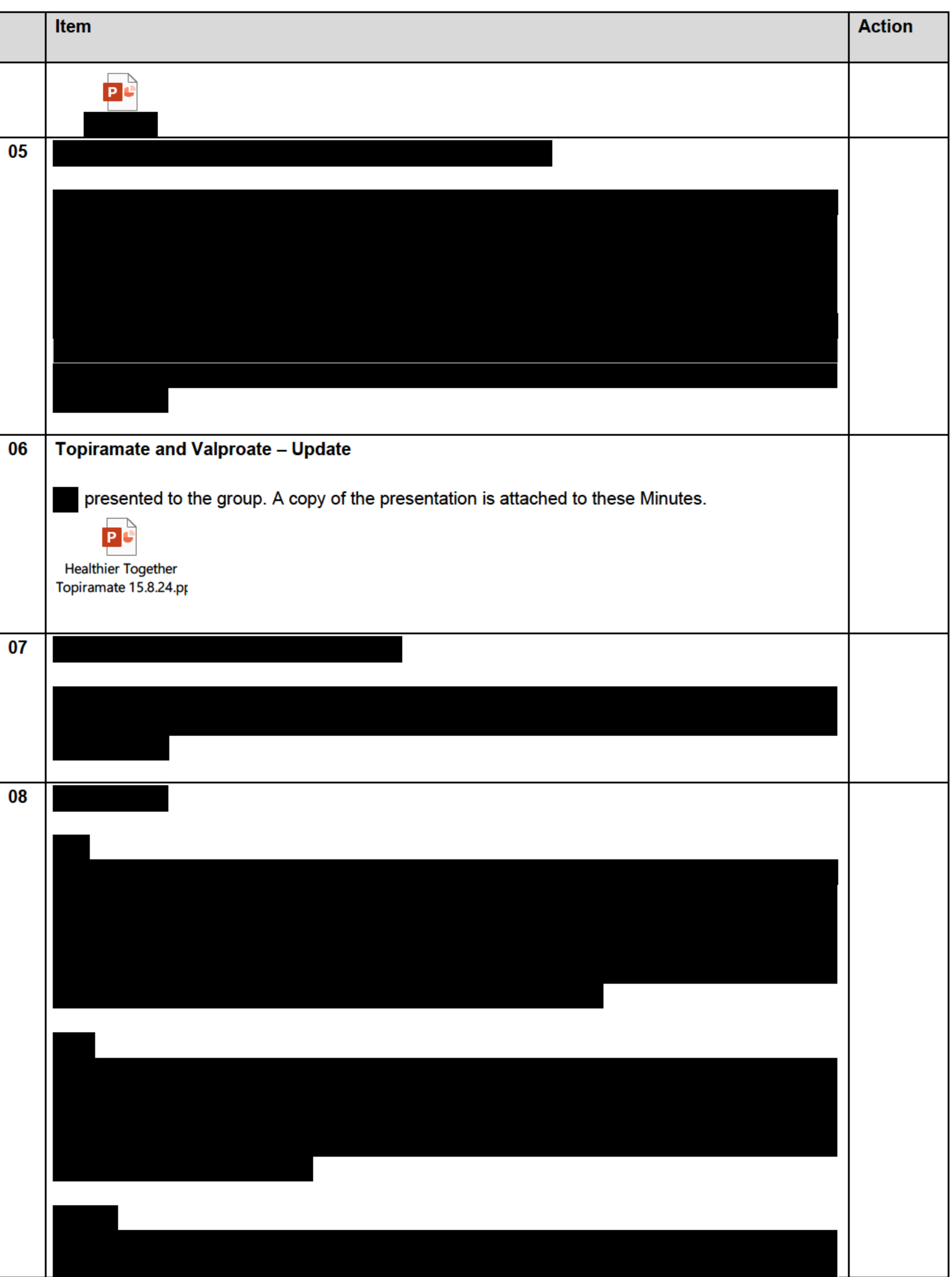
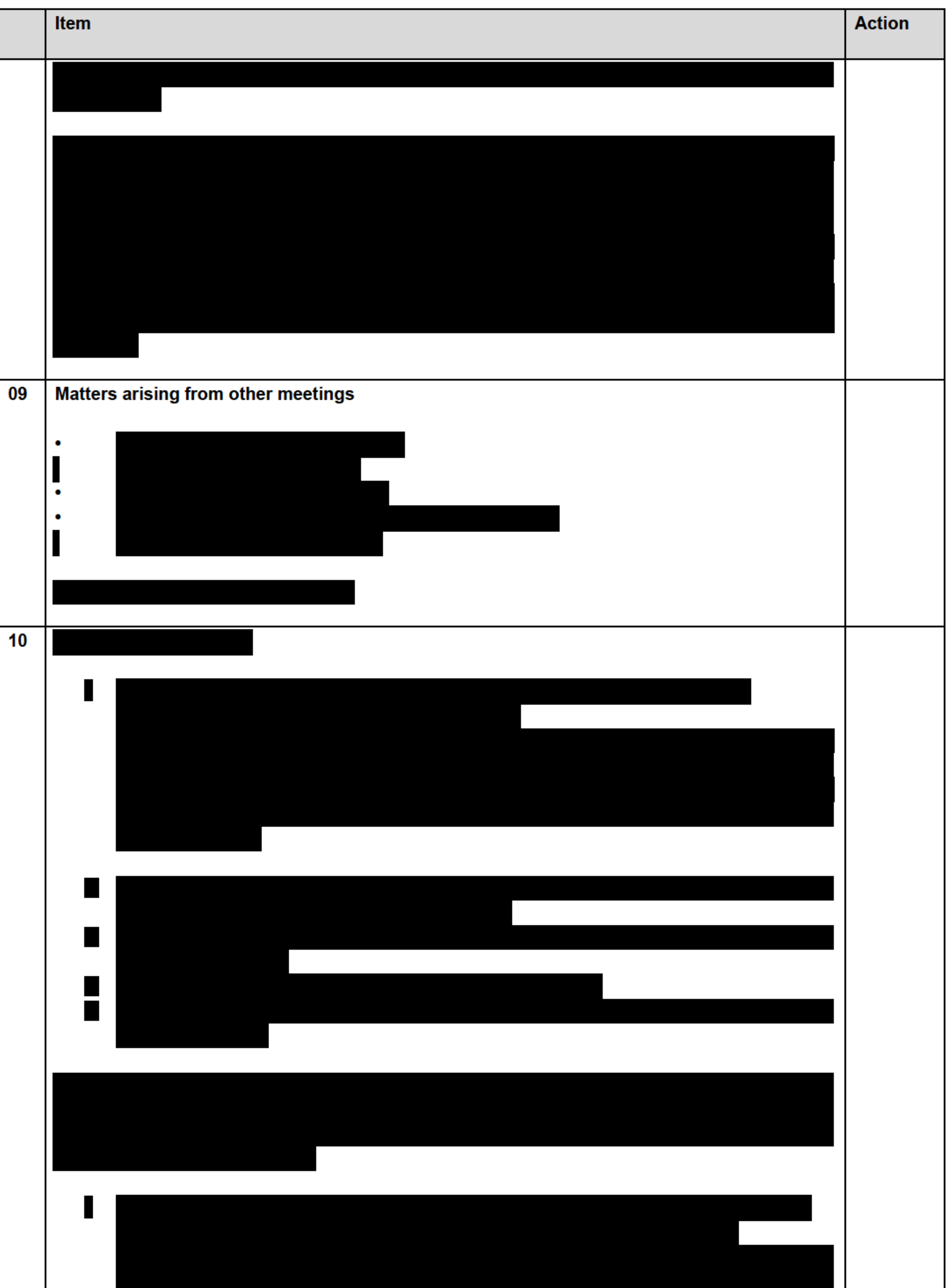
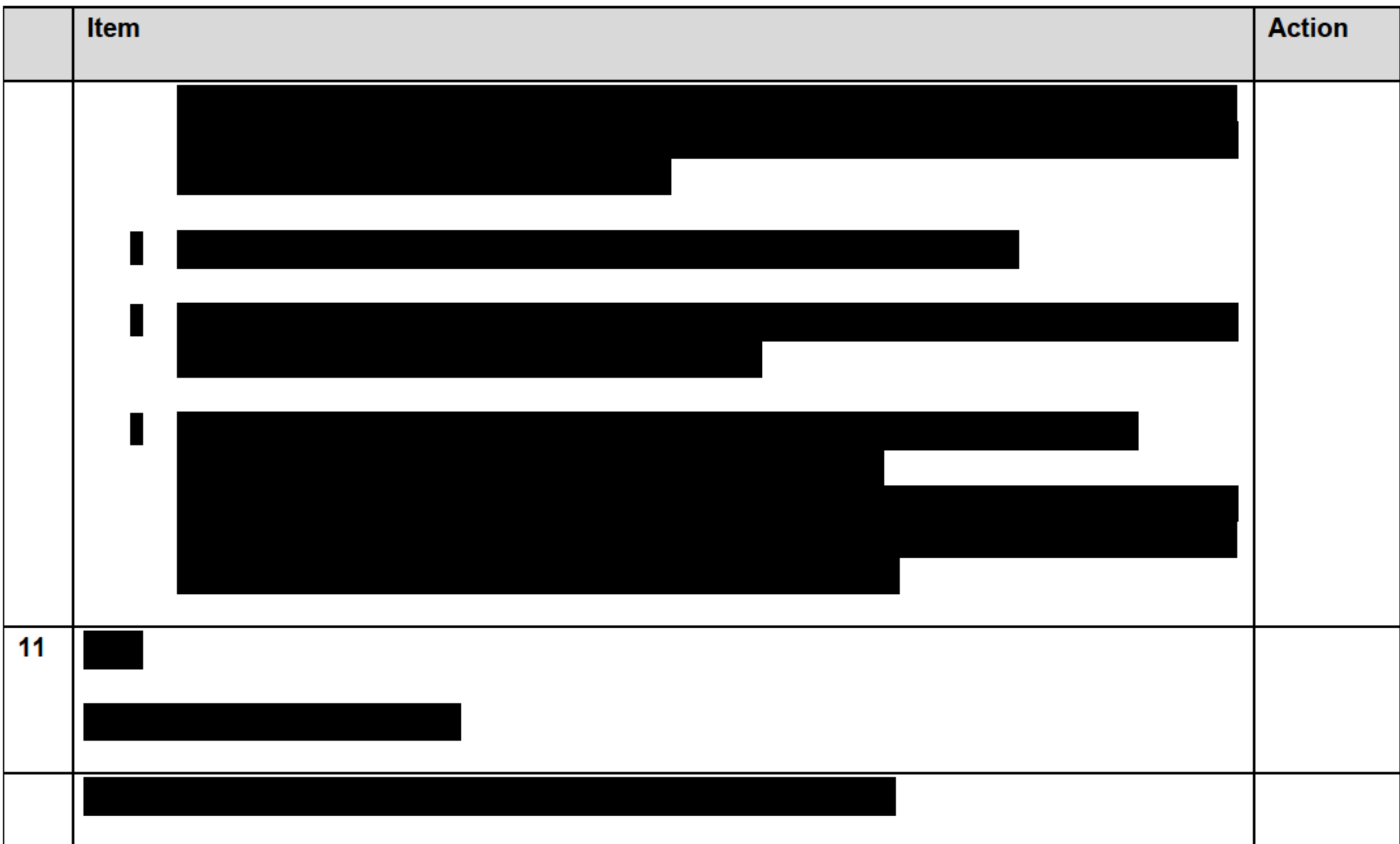


	Item	Action
05		
06	**Topiramate and Valproate – Update** presented to the group. A copy of the presentation is attached to these Minutes. Healthier Together Topiramate 15.8.24.pp	
07		
08		



	Item	Action
09	**Matters arising from other meetings**	
10		



	Item	Action
11		

- BNSSG ICB
August 2024