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| **Risk Assessment Title:** Original full pack dispensing of Valproate-containing medicines in Community Pharmacies | **Date of Risk Assessment:**  |
| **Date of next Review:**  |
| **Department / Ward / Area controlling the activity:**  | **Location of Activity:** Name of Community Pharmacy |
| **Responsible Manager Job Title:**  | **Print Name and Sign:** **(Assessment Completed Actions Outstanding)** |
| **Risk Assessor Job Title:**  | **Print Name and Sign:**  |
| **Responsible Manager Job Title:**  | **Print Name and Sign:****(Assessment and All Actions Completed)** | **Date:**  |
| **Task / Activity/ie~~s~~ Being Risk Assessed:** Original full pack dispensing of Valproate-containing medicines Valproate-containing medicines are dispensed for individual patients from Community Pharmacies within the NHS Grampian Health Board location. Medicines & Healthcare products Regulatory Agency (MHRA) guidance requires all valproate-containing medicines to be dispensed in the manufacturer’s original full pack as it contains specific warnings and pictogram which alert patients to the risks to unborn babies if valproate is used in pregnancy. At the point of dispensing valproate-containing medicines patients are also given the relevant valproate-containing medicine Patient Information Leaflet (PIL), the Patient Guide: What you need to know about valproate and the Valproate patient card (also known as risk reduction materials).For some patients full pack dispensing of medicines is not appropriate or safe and is of greater risk than the risk addressed by original full pack dispensing of Valproate-medicines. Certain groups of patients may be exempt from original full pack dispensing of valproate-containing medicines but processes within the Name of Community Pharmacy ensure that a “warning for women and girls” sticker is applied to the packaging of part pack valproate-containing medicines and the PIL and risk reduction materials are given to the patient.Groups exempt from original full pack dispensing of Valproate-containing medicines are:* People who use compliance aids
* People where there are concerns about compliance or their capacity or their ability to follow a medication regime (unintentional overdose) and require daily or weekly dispensing
* People who are at risk of intentional overdose

Others not captured in the groups identified above may also require a smaller supply of medicines, these people will have an individual assessment of risk undertaken and documented in their record. |

| Hazard | **Who** Might be Harmed & **How** might they be harmed (type of injury / ill-health) | Existing Control Measures | Initial Risk | Additional Control Measures(*if action required add within the control measure*) | Residual Risk | Any Actions Required |
| --- | --- | --- | --- | --- | --- | --- |
| Likelihood | Consequence | Risk Rating | Likelihood | Consequence | Risk Rating |
| Owner | Target Date | Completed Date and Initials |
| People in one of the groups above are dispensed original full pack valproate-containing medicines and take the wrong dose of valproate-containing medicine. | **People who use Community Pharmacy services.****Users of compliance aids:** may forget to take or take too much Valproate-containing medicine as it is separate from the other medicines in the compliance aid resulting in uncontrolled/ deterioration of their condition or overdose resulting in hospitalisation or a prolonged hospital stay. | People who are assessed as requiring a compliance aid, daily/weekly dispensing or small pack supplies of medicine for any reason automatically have valproate-containing medicines dispensed in the same way.An individual Assessment for Exception to Requirement to Dispense Sodium Valproate Containing Medicines in Original Packs is completed each time valproate containing products are dispensed not in their original full packs. | **U** | **M** | **M** |  | **U** | **M** | **M** |  |  |  |
|  | **Concerns over unintentional overdose:** may accidentally take too much Valproate-containing medicine resulting in major side effects or death due to toxicity. |  |  |  |  |  |  |  |  |  |  |  |
|  | **Risk of intentional overdose:** may intentionally take took much Valproate-containing medicine resulting in major side effects or death due to toxicity. |  |  |  |  |  |  |  |  |  |  |  |
|  | **Staff working in the Community Pharmacy:** increased workload and stress responding to deterioration in condition/side effects of patients/people who have taken too much or too little valproate-containing medicine.Moral injury of having supplied a larger supply of valproate-containing than is safe to at risk people. |  |  |  |  |  |  |  |  |  |  |  |
|  | **Organisation:** Reputational damage if reported in local media/news outlets. |  |  |  |  |  |  |  |  |  |  |  |
| People are not given the risk reduction materials at the point of dispensing Valproate-containing medicines.  | **Unborn babies of pregnant people:** may develop congenital malformations and neurodevelopmental disorders due to Valproate exposure.Exposure of an unborn baby to valproate during pregnancy is associated with a high risk of congenital malformations (11%) and neurodevelopmental disorders (30–40%), which may lead to permanent disability. MHRA Guidance Oct 2023. | People are dispensed valproate in original full packs unless assessed as unsuitable for original full pack dispensing.People requiring valproate-containing medicines in compliance aids or part packs of valproate-containing medicines have:* A “warning for women and girls” sticker applied to the packaging

And are given the following at the time of dispensing:* Relevant PIL
* Patient Guide
* Patient Card
 | **U** | **E** | **H** |  | **U** | **M** | **H** |  |  |  |
|  | **Pregnant people & their families:** psychological harm as a result of having a child born with congenital malformations and neurodevelopmental disorders due to Valproate exposure. |  |  |  |  |  |  |  |  |  |  |  |
|  | **Staff:** moral injury if a baby is born with congenital malformations and neurodevelopmental disorders due to Valproate exposure. |  |  |  |  |  |  |  |  |  |  |  |
|  | **Organisational:** reputational and financial harm if processes have not been followed and pregnant patients have been dispensed valproate-containing medicines by the Community Pharmacy without receiving risk reduction materials. |  |  |  |  |  |  |  |  |  |  |  |