

ANNEX – 2

Acknowledgement of Risk Information Form - Treatment with valproate for female patients

A. Checklist for Prescribers

Name of Patient /carer

I confirm that the above named patient does not respond adequately or tolerate other treatments or medical treatments and requires valproate

☐

I have discussed with the above named Patient/carers:

The overall risks of an approximately 10% chance of birth defects and up to 30-40% chance of a wide range of early developmental problems that can lead to significant learning difficulties in children exposed to treatment with valproate during pregnancy.

☐

Individual risk can be minimised by use of the lowest possible effective dose

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The need for contraception (if child bearing age)

☐

The need for regular review of the need for treatment

☐

The need for urgent review if the patient is planning a pregnancy

☐

I have given the patient/carers a copy of the patient information booklet

☐

Name of Prescriber

Signature

Date

B. Patient /Carer Checklist

I, the undersigned, understand

Why treatment with valproate rather than another medicine is considered necessary for me

☐

The risks of an approximately 10% chance of birth defects and up to 30-40% chance of a wide range of early developmental problems that can lead to significant learning difficulties in children exposed to treatment with valproate during pregnancy.

☐

That I am advised to use contraception if not planning a pregnancy

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That my treatment should be reviewed regularly

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That I should request an urgent review if planning a pregnancy PRIOR to attempting to conceive

☐

Name of Patient/ Carer

Signature

Date