

APPLICATION FOR INCLUSION OF SODIUM VALPROATE FOR CHILDHOOD EPILEPSY IN THE WHO ESSENTIAL DRUG LIST

Sodium valproate is a widely used anticonvulsant for the management of chronic epilepsy in children. The current essential medicines list includes phenobarbital for the treatment of epilepsy in children. While it is true that phenobarbital is effective in the treatment of many of epilepsy syndromes in children as indicated in the application, its side-effect profile means that it is no longer recommended as first line therapy in many developed countries. Alternatives to phenobarbital are needed for the appropriate management of childhood epilepsy.

There are randomized controlled studies supporting the use of sodium valproate in children. The application identifies the widespread belief that sodium valproate is a more effective first choice antiepileptic than carbamazepine. This is because sodium valproate treats some generalized seizure disorders that may be exacerbated by carbamazepine. It should be noted that a formulation of sodium valproate, suitable for the treatment of adults, is currently listed on the essential medicines list.

(1) Have all important studies that you are aware of been included?

Yes No

(2) Is there adequate evidence of efficacy for the proposed use?

Yes No

If "No", suggest what is needed.

(3) Is there evidence of efficacy in diverse settings and/or populations?

Yes No

If "No", suggest what is needed.

(4) Are there adverse effects of concern?

Yes No

These are well described in the application. The main concern is the severe liver failure that occurs in young children (< 3 y.o.), especially those with a history of liver disease. The application recommends the monitoring of liver function during the initiation of therapy.

(5) Are there special requirements or training needed for safe/effective use?

Yes No

(6) Is this product needed to meet the majority health needs of the population?

Yes No

(7) Is the proposed dosage form registered by a stringent regulatory authority?

Yes No

(8) What action do you propose for the Committee to take?

I propose that the committee approve the addition of sodium valproate for children. The actual approved formulations are to be decided.

(9) Additional comment, if any.

Sodium valproate does not require routine therapeutic drug monitoring in the majority of clinical settings.