Medication error is the third largest contributor in case of death after Heart diseases and cancer. The magnitude may be clear with a data that about 7.7 million patients hurt every year globally. It involves economic consequences like extended hospital stays, additional treatment. Medication errors may occur due to Prescription Errors, Administration error, Transcription error and Dispensing error.

There are several causes of medication errors like illegible hand written prescription, wrong dose especially in case of child below 15 years and elder above 65 years. Sometimes half of the adult dose prescribed for children inspite of calculating dose on the basis of microgram or mg per Kg body weight leading to over dosage. Other examples are use of wrong abbreviations (confusion between microgram and mg), not using zero before decimal etc. Look-alike and sound-alike drugs are also a common cause of confusion leading to medication error.

Besides all stakeholders pharmacists can play an important role in reducing medication error in case of Storage, Dispensing, Compounding, Patient counseling and they are doing it efficiently specially in institutional setup but high patient load per pharmacists is a deterrent here.

In our country a major portion of the drugs are being dispensed from retail medicine outlets on prescription of registered medical practitioners or as self medication, where the role of Pharmacists are immense to reduce medication error. Therefore pharmacists should update themselves, serious in dispensing and be present in the community pharmacy as long as selling activities is continuing.

Finally I would request all health care professionals and patients be careful about this issue as “Patient safety is everyone’s responsibility” on the eve of World Patient Safety Day on 17th September 2022.
MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)

NOTIFICATION
New Delhi, the 10th August, 2022

S.O. 3757(E).— In exercise of the powers conferred by section 6 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 8 of the Drugs Rules, 1945, and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare number S.O. 2662(E), dated the 31st October, 2012 published in Gazette of India, Extraordinary, Part II, section 3, sub-section (ii), except as respects things done or omitted to be done before such supersession, the Central Government hereby authorises Dr. Soroj Kumar Ghosh, Director In-charge of Central Drugs Laboratory, Kolkata to sign statutory certificates of test or analysis on the samples of drugs and cosmetics sent by the Courts of Law under sub-section (4) of section 25 of the said Act or in Form I of the Drugs Rules, 1945, as the Director In-charge of the Central Drugs Laboratory, Kolkata, for the whole of India with effect from the date of publication of this notification in the Official Gazette till the regularly appointed person takes charge of the post or until further orders, whichever is earlier, in respect of all classes of drugs, except the classes of drugs mentioned below, namely:—

1. Sera
2. Solution of Serum Proteins intended for injection
3. Vaccines
4. Toxins
5. Antigens
6. Anti-toxins
7. Sterilised surgical ligature and sterilised suture
8. Bacteriophages

9. Anti-Sera for Veterinary use
10. Vaccines for Veterinary use
11. Toxoids for Veterinary use
12. Diagnostic Antigens for Veterinary use
13. VDRL Antigen
14. Intra-Uterine Devices and Fallope Rings
15. Human Blood and Human Blood Products
16. Blood Grouping reagents and diagnostics kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus
17. Condoms.

[F. No. X.11014/4/2022-DR]

Dr. MANDEEP K. BHANDARI, Jr. Secy.
New Drugs: Onasemnogene abeparvovec for spinal muscular atrophy

Approved indication: spinal muscular atrophy
Zolgensma (Novartis)
vials containing $2 \times 10^{13}$ vector genomes/mL

Spinal muscular atrophy is an autosomal recessive genetic disorder. Mutations in the survival motor neuron (SMN) 1 gene lead to a deficiency of SMN protein. This results in the loss of motor neurons and therefore reduced muscle function. The severity of the disease depends on how much SMN protein can be produced by another gene (SMN2). In the most severe form of the disease, spinal muscular atrophy type 1 (SMA1), the infant is unable to sit upright and usually requires ventilation before the age of two years.

As there is no effective treatment for spinal muscular atrophy there has been research into gene therapy to correct the underlying disorder. Infusing a copy of the gene could increase concentrations of SMN protein. A phase I study tried gene therapy in 15 infants with SMA1. Following a single infusion of genetic material at 3–6 months of age, the infants’ motor function improved. They were all still alive at 20 months of age and did not require ventilation before the age of two years.

Onasemnogene abeparvovec is a genetically engineered copy of the human SMN gene delivered by an adeno-associated viral vector. The dose is determined by the weight of the child and is given by intravenous infusion over one hour. The vector spreads through the body and is shed in saliva, urine and the faeces. Most of it is cleared within one month and the virus is not expected to cause infections.

An open-label phase III trial in the USA enrolled 22 babies (mean age 3.7 months) with SMA1. They had bi-allelic mutations of the SMN1 gene with one or two copies of the SMN2 gene. After a single infusion of onasemnogene abeparvovec, they were followed up until they were 18 months old. By this age, 59% (13/22) were able to sit for at least 30 seconds and 82% (18/22) did not require ventilation. One infant died during the trial.\(^1\)

A similar trial in Europe treated 33 patients (mean age 4.1 months). By 18 months 44% (14/32) had been able to sit for at least 10 seconds and 97% (31/32) did not require ventilation. One infant died.\(^3\)

Another open-label trial investigated giving onasemnogene abeparvovec to babies who were expected to develop spinal muscular atrophy. These presymptomatic babies had bi-allelic mutations with two or three copies of SMN2. They were treated before they were six weeks old. All of the 14 children with two copies of SMN2 were able to sit independently for at least 30 seconds by the age of 18 months.\(^5\) The 15 children with three copies of SMN2 were all able to stand for at least three seconds at the age of two years and 14 were able to walk.\(^4,5\)

Adverse reactions to onasemnogene abeparvovec are common. A review of safety data from several trials identified hepatotoxicity, thrombocytopenia, and cardiac adverse events as potential problems.\(^6\) Liver function tests, platelet counts and troponin concentrations therefore require monitoring. To reduce the effect on liver function, prednisolone is recommended for 30 days, starting before the infusion. Patients are also at risk of immune reactions and thrombotic microangiopathy. Approximately half of the patients will develop a fever after treatment. While the quantity of long-term data is limited by the rarity of the disease, the children from the phase I trial have now been followed up for five years. The 10 who received the therapeutic dose of onasemnogene abeparvovec all survived and did not require permanent ventilation.\(^2\)

Although the outcomes for children given onasemnogene abeparvovec appear better than the historical outcomes in SMA1\(^2,3\) there is still substantial motor impairment. Patients who have already had irreversible damage to their motor neurons may be less likely to benefit from therapy. Experience in Australia with onasemnogene abeparvovec supports early treatment.\(^8\) The Australian indication includes presymptomatic cases and the approval is restricted to infants under nine months old.

References


Source: Australian Prescriber.

**Status in India:** Industry source reveals that the estimated cost of Onasemnogene abeparvovec is around 16 Crores. But there are some patient support programme extended by Roche, which made the drug at a lower price. Patients have to wait till generic versions are available in India.

**Medication safety conference:**

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