

Guidance on Adverse Event Reporting

Why to report?

- Detection of unknown safety issues associated with medicines
- Detection of increases in frequency of known safety issues associated with medicines
- Identification of risk factors
- Quantifying risks associated with medicines
- Preventing patients from being adversely affected unnecessarily after medicine intake
- Patient safety
- Compliance/Regulatory Requirements.

When to report?

Within 24 hours of noticing any safety issue/product complaint

Who can report?

Any health care professionals (such as physicians, pharmacists, nurses) and consumers (such as patients, family members)

How to report?

For adverse events or product feedback/complaints, please fill adverse event form and email to drugsafety@cipla.com or directly call on Country Wise Help Line Numbers.

What to report?

If you get to know that an adverse event has occurred; collect the below minimum information:

- Details of the patient: Characterised by initials, patient identification number, date of birth, age or gender
- Details of the reporter: Characterised by qualification (e.g., physician, pharmacist, other healthcare professional, lawyer, consumer or other nonhealthcare professional) name, initials, or address
- A Cipla suspect drug: One or more suspected substance/medicinal product
- Adverse Event (AE): One or more suspected adverse event (may or may not be related to Cipla's product)

Confidentiality of the events reported

The patient's and reporter's identity are handled with strict confidentiality. Company shall not disclose the reporter's or patient's identity in response to a request from the public.

Country Wise Help Line Numbers

Country Name	Contact number
Austria	+43 (0) 800292572
Australia	1800-569-074
Belgium	0800-711-05
Bulgaria	008001104961
Croatia	+385 800 989 061
Czech	+420 800 022 832
Denmark	+45 80253706
Germany	8001807015
Spain	800654770
Hungary	+36 800 80 377
Iceland	354-800 4252
India	18002677779
Colombia	57-1-6964627
Ireland	353 1800903622
Italy	+39 800790786
Kenya	+25 4728478653
Other Countries (Except US and EU)	+91 821-6643551
Latvia	+371 80 005 618
Luxembourg	+352 (0) 800 268 02
Malta	80062894
Netherlands	00318000225584
Norway	80026539
Poland	00 800 112 5152
Portugal	+351 (0) 800 819 317
Romania	+40 800890183
Slovak Republic	+421 800 008 153
Sweden	+46 200430415
Switzerland	800559135
Brazil	0-800-725-0444
Malaysia	+603 79562677, +6037956 2676
South Africa (SA HO)	+27 21 943 4200
United Kingdom	+44 (0) 8000 472 144
USA	866-604-3268
Uganda	+256755 823 356