Pharmacovigilance (PhV) Division

Special Situations & Medication Errors Reporting Form

Please answer the questions as completely and accurately as possible. Your answers will help us to better understand the type of errors that are happening, where and why they are happening, and how to keep patients safe by reducing errors to the lowest possible rate and avoid any harm.
The following events are **considered Special Situations** for safety reporting **even in the absence of a potential side effects.**

Report Date*

Special Situations / Medication Error Type

1) Use of UTOPIA Product during **Pregnancy** ☐
*(Where **Embryo** or **Fetus** may have been exposed to UTOPIA Product, either through maternal exposure or transmission of a medicine via semen following paternal exposure).*

2) Use of UTOPIA Product during **Breastfeeding** ☐
*(Where **Infants** following exposure to UTOPIA Product from breast milk).*

3) Paediatric (<18) ☐	**4) Geriatric (>65)** ☐
5) Overdose ☐	**6) Abuse** ☐
7) Off-label use ☐	**8) Misuse** ☐

9) Drug-Drug Interactions ☐ (.....with.....)	**10) Drug- Food** Interactions ☐ (.....with.....)	**11) Drug-Food Supplement** Interactions ☐ (.....with.....)

12) Medication Error ☐
Error in Diagnosing ☐ Wrong Patient ☐ Wrong Medicine ☐ Wrong Dosage Form ☐ Wrong Dose, Strength or Frequency ☐
Wrong Time of Dose Administration ☐ Wrong route of administration ☐ Dose Omitted or Delayed ☐
Wrong Quantity ☐ Wrong Duration ☐ Wrong Rate (too fast/too slow) ☐ Expired Medicine ☐
Other (please specify):

13) Lack of Therapeutic Efficacy ☐
(Specially in critical conditions or for the treatment of life-threatening diseases, vaccines, contraceptives, a life-threatening infection where the lack of therapeutic efficacy appears to be due to the development of a newly resistant strain of a bacterium previously regarded as susceptible)

14) Occupational Exposure ☐
(Where an exposure to a medicinal product as a result of one's professional or non-professional occupation. It does not include the exposure to one of the ingredients during the manufacturing process before the release as finished product.)

Other (*please describe***)**

Patient Information

1) Patient Name/Initials	2) Country	3) Date of Birth

4) Gender (Male ☐ / Female ☐)

Reporter Details (*The Person who reports the Event***)**

1) Name		2) Specialty (*If Physician*)
3) Telephone/Mobile	4) Address	5) e-mail
6) Is it acceptable to contact you if we have more questions about this report?	Yes ☐	No ☐

Patient Outcome

1) No Harm ☐	2) Fatal ☐	3) Potentially Fatal ☐	4) Severe (*permanent harm*) ☐	5) Potentially Severe (*permanent harm*) ☐
6) Moderate Harm (*requiring active treatment*) ☐			7) Potentially moderate Harm (*requiring active treatment*) ☐	
8) Mild Harm (*requiring monitoring*) ☐			9) Potentially mild Harm (*requiring monitoring*) ☐	

Suspected Drug (s) Information

Product Name (Trade or Generic Name / Concentration)	Daily Dose and Route	Used For	Start Date	Stop Date	Batch No.

Concomitant Drug (s) Information
(*Please list the medications you have taken within the last Month***)**

Product Name (Trade or Generic Name / Concentration)	Daily Dose and Route	Used For	Start Date	Stop Date

Utopia Medical Representative Details

1) Name	2) Telephone	3) Scientific office

UTOPIA Head Office
4-Hassan Maamoun Tower-Nasr City-Cairo-Egypt.

PhV e-mail: utopiapharma.pv@gmail.com	**PhV Telephone No.:** 01110202227
UTOPIA website: www.utopiapharma.com	**UTOPIA Telephone No.:** (+2) 02/23498142 - 23498143 – 23498144