Government of the People's Republic of Bangladesh

Directorate General of Drug Administration (DGDA)
Pharmacovigilance Department
Aushadh Bhaban, Mohakhali, Dhaka

RMP Evaluation report of Typhocon Vaccine

Product Name: **Typhocon**
Active Ingredient(s): Purified Vi Capsular Polysaccharide of S. typhi conjugated to Diphtheria Toxoid
Dosage Form: Solution
Product Category: Vaccine
Marketing Authorization Holder (MAH): Incepta Pharmaceuticals Ltd. (Vaccine Division)

Comments of Pharmacovigilance Department:

1) Section-I (Product Overview in Bangladesh)

   Observation: Name of product and active ingredients is not specified.
   Recommendation: Brand name (**Typhocon**) should be mentioned in the product name part and name of active ingredient(s) should be in accordance with the PIL i.e *"Purified Vi Capsular Polysaccharide of S. typhi conjugated to Diphtheria Toxoid"*

2) **Section-IV (Safety Specification: Summary of Safety Concerns)**

   Observation: There are more important identified risk, potential risk & missing information has been found through our study according to different international references such as WHO, EMA, CDC etc.

   Recommendation: MAH is recommended to update information the above issues as per following table.

SL No	Submitted information	Remarks/ Recommendation
1)	**Important identified risk:** 1. Fever 2. Headache 3. Diarrhea 4. Vomiting	**Other Important identified risk:** 1. Injection site reactions [2] 2. Systemic Reaction (Headache & Fatigue) [2]
2)	Important potential risk: 1. Pain at injection site 2. Tenderness, Swelling at the injection site 3. Hypersensitivity to constituent of the vaccine	**Important potential risk:** 1. Hypersensitivity 1 2. Respiratory tract infection (nasopharyngitis, cough, pneumonia)3 3. Febrile Convulsion4 4. Gastroenteritis 4
3)	**Missing information:** 1. Safety in pregnancy 2. Safety in lactation 3. Fertility	**Missing Information:** 1. Safety in special populations (Like- elderly, children, pregnant women) 2. Interaction with other vaccine 3. Genetic variability impact

3) **Section-VI (Risk Minimization Plan)**

Observation: Risk Minimization Plan was made according to previous safety concerns.

Recommendation: Though there are some new identified and potential risk mentioned in the previous table, so Risk Minimization Plan have to updated with new safety concerns.

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Mahbub Hossain
Assistant Director
&
Member secretary of ADRM Cell
Directorate General of Drug Administration
Email: mhossainbmb@gmail.com

Reference:

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2. CDC - "Typhoid Vaccine Information Statement" (2021) https://www.cdc.gov/vaccines/hcp/vis/vis-statements/typhoid.html
3. Kumar Rai G, Saluja T, Chaudhary S, Tamrakar D, Kanodia P, Giri BR, Shrestha R, Uranw S, Kim DR, Yang JS, Park IY, Kyung SE, Vemula S, Reddy E J, Kim B, Gupta BP, Jo SK, Ryu JH, Park HK, Shin JH, Lee Y, Kim H, Kim JH, Mojares ZR, Wartel TA, Sahastrabuddhe S. Safety and immunogenicity of the Vi-DT typhoid conjugate vaccine in healthy volunteers in Nepal: an observer-blind, active-controlled, randomised, non-inferiority, phase 3 trial. Lancet Infect Dis. 2022 Apr;22(4):529-540. doi: 10.1016/S1473-3099(21)00455-2. Epub 2021 Dec 20. PMID: 34942090; PMCID: PMC8942857. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8942857/
4. Qadri, Firdausi et al. 2021, **Protection by vaccination of children against typhoid fever with a Vi-tetanus toxoid conjugate vaccine in urban Bangladesh: a cluster-randomised trial,** The Lancet, Volume 398, Issue 10301, 675 – 684, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01124-7/fulltext