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Gambian children's deaths due to contaminated cough syrups are a mutual responsibility

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Dear Editor,

The WHO estimates that ~66 children in The Gambia passed away after ingesting a cough syrup that was possibly connected with acute kidney damage due to toxic chemical contamination[1]. All children who had taken these medicines (cough and cold syrup) suffered from the inability to pass urine. The WHO stepped in when The Gambia's medical officials noticed a rise in acute kidney damage cases among children under the age of 5 in late July 2022[1,2]. The culprit four products viz., *Promethazine Oral Solution, Kofexmalin Baby Cough Syrup*, *Makoff Baby Cough Syrup,* and *Magrip N Cold Syrup* were produced by Maiden Pharmaceuticals Limited, an Indian company, located in Haryana state, which has not offered assurances regarding its safety till now[1]. The WHO has issued a medical product alert and started investigations related to these four contaminated cough syrups[2,3].

Since then, the Gambian government of The Gambia has prohibited the consumption of all paracetamol or promethazine syrups and advised citizens to take pills instead, which resulted in a check on the number of deaths by late September 2022, and as of 15 October 2022, the total deaths due to contaminated cough syrup has been limited to 70[4]. In addition, the government has directed importers and retailers to halt sales of all varieties of paracetamol syrup. Moreover, the medication has been recalled from all pharmacies and homes by implementing an urgent door-to-door campaign. Unfortunately, The Gambia lacks a laboratory that can determine if they are safe; therefore, it had to ship medicines abroad for testing. A few of the syrup samples sent for testing to Senegal, Ghana, France, and Switzerland revealed contamination. On 5 October 2022, WHO declared the laboratory analysis revealing that the samples of the products contained unacceptable amounts of diethylene glycol and ethylene glycol as toxic chemical contaminants[3]. Diethylene glycol and ethylene glycol are able to induce acute kidney injury which may lead to death. The USA had passed a stringent legislation in 1938 immediately after a public health crisis that took place wherein 105 people died from diethylene glycol poisoning. The Gambia health services director Mustapha Bittay declared that traces had also been found of *Escherichia coli* in the product samples. President Barrow said the outbreak is now under control, with only two cases reported in the last 2 weeks.

Disappointedly, the Indian company has only clarified that it has not marketed these products in India[5]. In addition, Dr. YK Gupta, Standing National Committee member, said that the license for this medicine was solely for export and Indian cough syrups don't have this possibility. Vivek Goyal, the company's director, said that the government authorities in India visited the Maiden factory four times in early October 2022 and the samples were drawn by the Central Drugs Standard Control Organisation (CDSCO) along with all pertinent documents[6]. The Haryana health minister, Anil Vij, told the news agency ANI that after inspection of Maiden's factory, 12 violations were found and the company's production would be shut down[2]. The quality of Maiden Pharmaceuticals medicines has long been questioned, data published by India's Food and Drug Administration revealed that six medicines manufactured by this company have been deemed substandard and flagged by the states of Kerala and Gujarat[2,5]. Bihar and Vietnam placed them on a 'blacklist' in 2011 and 2014, respectively. Its products failed Kerala's quality checks five times as recently as 2021–2022[5]. More recently, an article published in *The Lancet Journal* on 22 October 2022, mentioned that cough syrup deaths expose lax drug regulation in India[7], hence stringent and strict regulations need to be adopted for adequate quality control checks of drugs and medicines before exporting, marketing and their use by the public for safeguarding health issues as well as the importing country should also test the medicinal products for quality before sanctioning their usage.

Now fears exist about distributing these medicines through informal markets to other countries or regions[3]. Therefore, all batches of these items should be regarded as unsafe till they can be examined by the pertinent National Regulatory Authorities. Currently, Gambia is in need for establishing adequate laboratory facilities to check imported drugs for better quality control over these contaminated medicines. There are endeavors for the creation of a quality control national laboratory for drugs and food safety in the Gambia, through discussions with the World Bank to get funding. For ensuring that such occurrences might be regulated and prevented, the country's drug-related regulations should be revised and updated.

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The data in this correspondence article is not sensitive in nature and is accessible in the public domain. The data is therefore available and not of a confidential nature.

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