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Co-Proxamol (Distalgesic) Procurement in Bahrain Policy Implications for Gulf Cooperation Council Countries

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Co-proxamol (Distalgesic), a prescription analgesic, is a combination of dextropropoxyphene (32.5 mg) and acetaminophen (325 mg). Dextropropoxyphene, a Schedule-IV controlled opioid, is licensed for treating mild to moderate pain. Mortality from co-proxamol overdose has been a cause for concern, and has received much adverse publicity worldwide [1–3]. Co-proxamol accounted for 18 and 41% of drug-related suicides in England and Wales (1997–1999) and Scotland (1995–1998), respectively [1, 4].

Using evidence-based data, the Committee on Safety of Medicines (CSM) [5] in the UK advised the withdrawal of co-proxamol from the market in January 2005. Consequently, the Medicine and Health products Regulatory Agency (MHRA) [6] announced a gradual withdrawal of the commonly prescribed co-proxamol from the market by the end of 2007. The license for all products containing co-proxamol is expected to be withdrawn, and the medications will no longer be available as UK licensed products. During the withdrawal phase, interim restrictions and warnings concerning the use of co-proxamol would be included in the product information. Prescribing unlicensed co-proxamol would thereafter be the responsibility of the prescriber.

Implementation of CSM advice by MHRA was based on the following: (1) poor efficacy of co-proxamol for mild to moderate pain; (2) risk of overdose toxicity, both accidental and deliberate; (3) fatality resulting from respiratory depression and cardiac arrhythmia that may occur with multiple therapeutic doses; (4) pharmacokinetic and pharmacodynamic interactions of co-proxamol with central nervous system depressants, notably ethanol, are hazardous and reduce the threshold for fatal toxicity.

We have audited co-proxamol procurement trends in Bahrain between 1997 and 2006. The analysis of annual purchases of co-proxamol by the Ministry of Health was based on data obtained from the Directorate of Material Management, Inventory Section. We found that over a 10-year period, estimated per capita co-

proxamol varied between 1.45 and 1.52 tablets (fig. 1). This fluctuation was characterized by a decline between 1997 and 2000, followed by a paradoxical increase between 2000 and 2006 (annual growth rate = 10.1%). During this period, attempts to restrict or withdraw co-proxamol have been made worldwide. Co-proxamol-related suicides in Scotland were attributed to the high rates of co-proxamol prescribing [4]. In 1998, based on the number of co-proxamol utilized and the population, the calculated per capita co-proxamol tablets in Scotland were 2.15. Although the per capita co-proxamol consumption in Scotland is somewhat higher, Bahrain's context of a small population and close-knit society, with an annual procurement growth rate of 10.1%, suggests that there is a potential risk of accidental or deliberate fatal toxicity due to the drug. Lack of routine postmortems and coroner's records in Bahrain may have obscured the adverse outcomes associated with co-proxamol overdose. We suggest that in view of the poor efficacy and safety concerns associated with the use of co-proxamol, health policy decision makers in Gulf Cooperation Council countries including Bahrain should enforce restrictive measures on its procurement and prescription. In particular, they should follow the worldwide example of Swiss, Swedish [3] and British [1, 5, 6] regulators, by doing a phased withdrawal of this drug from clinical use. Meanwhile, if doctors are to continue to prescribe co-proxamol, they must make every effort to inform the patient of safety concerns, obtain informed consent, preferably signed to reduce liability, and ensure that, as far as possible, the drug is used responsibly [7]. In particular, there will be a need to feel confident that alcohol is not consumed at the same time, that overdose is unlikely, and that the patient keeps the medication in a safe place so that it cannot be used by another person [8].

Fig. 1. Per capita co-proxamol ingestion between 1997–2006 in Bahrain.

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