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Apotex to halt drugs shipping to EU

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The agency has also recommended withdrawal of the siteâ??s good manufacturing practice (GMP) certificate.

Medicines & Healthcare products Regulatory Agency

Medicine and Healthcare products Regulatory Agency (MHRA) in UK has banned Apotex Research Pvt Ltd from shipping drugs made at its plant in Bengaluru to the EU after inspectors raised concerns about the potential for cross contamination.

The inspection last month identified failures in the cross contamination controls applied by the manufacturer resulting in a risk of cross contamination above Permitted Daily Exposure (PDE) from some products.

The agency has also recommended withdrawal of the site's good manufacturing practice (GMP) certificate. MHRA has advised member states to contact the site to determine the level of risk associated with specific products related to market.

The only products not covered by the ban are those likely to be in short supply. Apotex will be able to continue supply if the marketing authorization holder gains written approval from MHRA in the intended market.