WHO response to Ipca’s voluntary suspension of shipments from the company’s active pharmaceutical ingredients (APIs) manufacturing facility situated at Ratlam (Madhya Pradesh, India) for the US markets

A recent Good Manufacturing Practice (GMP) inspection carried out by the United States Food and Drug Administration (US FDA), has identified deficiencies — listed in a US FDA Form 483 — regarding the level of GMP adherence at Ipca’s Ratlam manufacturing facility.

The company has voluntarily suspended shipments to the US market of active pharmaceutical ingredient (API) manufactured at this facility, while this issue is being addressed.

Voluntary stoppage of supply to manufacturers who are producing prequalified products has not yet been proposed by Ipca.

WHO action and advice

WHO has prequalified a number of medicinal products, the production of which may incorporate APIs manufactured by the Ipca Ratlam facility. WHO has also prequalified four APIs manufactured at this site (amodiaquine hydrochloride — WHOAPI-030; lumefantrine — WHOAPI-042; artesunate — WHOAPI-081; artemether — WHOAPI-163). The prequalification status of the medicinal products and of these APIs remains current.

WHO has contacted Ipca to obtain its risk mitigation strategy for WHO-prequalified products that have already been distributed to the market; and its strategy for ensuring the ongoing quality of API manufactured at this site. This will help WHO assess the extent to which the deficiencies identified by the US FDA apply to the prequalified products. Manufacturers of prequalified products that have been registered as using Ipca API have also been contacted and requested to take supplementary measures to help ensure that all batches of medicinal product that are distributed to the market, are of adequate quality.

Until further notice, procurement agencies may continue to procure the following products that contain API produced at Ipca’s Ratlam site, as issues that directly impact their quality have not been reported:

- **MA001 Amodiaquine (hydrochloride) + Artesunate 3+3 or 6+6 or 12+12 tablets, 153 mg + 50 mg (Ipca Corp.)**
- **MA038 Artesunate tablet 50 mg (Ipca Corp.)**

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1 The full address of the Ipca Ratlam manufacturing facility is: Ipca Laboratories Ltd, Sejavta, Ratlam, Madhya Pradesh, 457 002, India.
• MA052 Artemether / lumefantrine tablet 20 mg/120 mg (Ajanta Corp.)
• MA062 Artemether / lumefantrine tablet 20 mg/120 mg (Ipca Corp.)
• MA080 Amodiaquine hydrochloride / artesunate tablet 67.5 mg / 25 mg (Ipca Corp.)
• MA081 Amodiaquine hydrochloride / artesunate tablet 135 mg / 50 mg (Ipca Corp.)
• MA082 Amodiaquine hydrochloride / artesunate tablet 270 mg/100 mg (Ipca Corp.)
• MA092 Artemether / lumefantrine dispersible tablet 20 mg/120 mg (Ajanta Corp.)

Procurement agencies are nevertheless advised to request the manufacturers of the aforementioned products to respond to the questions below:

• Was the API from this source fully tested before use in the procured FPP?
• If this is not the case, on what basis does the manufacturer consider the API to be of adequate quality?
• What strategy has the manufacturer implemented to ensure the ongoing quality of API received from Ipca Ratlam?

All finished pharmaceutical product (FPP) manufacturers are reminded that they are responsible for ensuring the quality of the APIs that they use in FPP production. The suitability of these APIs should be confirmed on a batch-to-batch basis.

Further information:

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