WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

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PHA Information Exchange Service

**ALERT No. 29**

**ARUMALON®: SUSPENSION OF MARKETING AUTHORIZATION**

**Germany.** The Federal Health Office has suspended, until 31 December 1992 in the first instance, the marketing authorization for a mixture of aqueous calf cartilage and bone marrow extract (Arumalon®: Robapharm), indicated for treatment by the intramuscular route of degenerative joint disease.

The Office has received reports of severe adverse reactions, possibly of immunopathogenetic origin, including glomerulonephritis, thrombocytopenia, leucopenia, polyneuropathy, pulmonary fibrosis and dermatomyositis, in patients receiving the preparation. However, causality has not yet been fully established and further investigations would be necessary to assess the immunological basis of these conditions.

In 1987, the Federal Health Office considered, on the basis of the labelling permitted at that time, that the risks associated with the product outweighed the potential benefits. The manufacturer subsequently extended the labelled contraindications for the product, excluding its use in conditions with altered immune responses such as systemic inflammatory and autoimmune diseases, atopy, allergy to medicines, asthma and infections.

In addition to the concerns relating to safety, this measure was based on lack of sufficient evidence regarding efficacy and pharmaceutical quality of the product.

*References:*

1) *Communication to the World Health Organization from the Federal Health Office, Berlin, dated 5 June 1992.*

2) *Bundesgesundheitsblatt 4/92, p.219, April 1992.*

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