

PHARMACOTHERAPY FOR SARCOIDOSIS AS AN EXAMPLE OF THE OFF-LABEL PROCEDURE

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Sarcoidosis is a granulomatous multiorgan diseases with an unknown etiology, with the predominant lung involvement. Immunosuppressive agents such as corticosteroids, methotrexate, azathioprinum, ciclosporinum A, chlorambucil, cyclophosphamide, hydroxychloroquinum, indomethacin, pentoxifyllinum, thalidomide, leflunomidum, and adalimumab, or infliximab have been used in its treatment. It should be emphasized that the Summary of Products Characteristics (SPC) of these drugs does not specifically recommend their use in the therapy for sarcoidosis. That makes the application of the drugs in sarcoidosis an off-label use, which is not formally accepted by the authorities but is supported by medical bibliography or recommendations given by scientific bodies. That stems from the fact that an indication for ?sarcoidosis treatment? may not be registered by the marketing authorization holders (pharmaceutical manufacturers) due to the lack of specific clinical trials with a given drug. A relatively small target population of people suffering from sarcoidosis may be the cause. Thus the off-label drugs raise legal, but also ethical and medical problems. The dosing regimen and the required duration of therapy for SA are missing. In effect the therapy usually follows the recommendations from the American and European Respiratory Societies (ATS/ERS), based on the long-term clinical trials. The American Food and Drug Administration recognizes the existence of the off-label use and allows for the information to prescribers, although forbids specific drug promotion. Private insurance may cover the off-label use. European, including Polish, legislations do not precisely specify the rules for the admissibility of the off-label use. The doctrine of law assumes that the off-label use constitutes a medical experiment. Therefore, the commencement of therapy with such drugs requires patients? informed consent, which must be kept along with other medical records. In Poland, the off-label drugs prescribed for sarcoidosis at outpatient clinics are not reimbursable. Thus, insufficient knowledge of the legal regulations may result in civil and professional liability of a physician supervising the therapy of a sarcoidosis patient, especially in case of adverse effects.