MEDICINES VERSUS DIETARY SUPPLEMENTS: WHO IS WHO AND WHO SHOULD DO WHAT?

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Dietary supplements are health products liberalized with major impact, and the European market is a reflection of this adherence. Despite its physiological and complementary effect, the qualitative profile, the scientific and regulatory features are poorly known, corroborating several indicators described in literature. Meantime, the medicines as health technologies presents an assured quality, proven safety and efficacy, and strict evaluation tests, that make them references in the pursuit of patient safety. In this sense, we intend to evaluate the regulatory processes, clinical development and quality assurance of supplements, and determine the homologous and non-homologous vectors between supplements and medicines.

SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis on dietary supplements, through a cross study between EU legislation (supplements and medicines) and scientific/financial/statistical studies of retrospective nature.

Of the EU countries, 23 allow direct mutual recognition for marketing of supplements, 21 evaluate case by case the introduction of new bioactive substances in supplements and only 14 of them places this matter on the authority of the Ministry of Health. Compared with medicines, we verify absence and irregularities regarding the health information presented to the public, technical essays and evidence of effectiveness. The SWOT analysis determined that 100% of the opportunities and 60% of strengths inherent to supplements derived from the economic and market context, and that 87.5% of the weak points and 81.8% of the threats arising from vulnerabilities of Public Health, that should be a priority in the risk/benefit assessment.