

3. The accession of Antibiotice to the Romanian Association of the Producers of Non-Prescription Medicines, Food Supplements and Medical Devices (RASCI)

One of the trends observed in the Romanian pharmaceutical market in recent years is the increase in share of non-prescription products (OTC medicines, food supplements and medical devices). Medicines delivered without a prescription (OTC drugs, food supplements and medical devices recorded in Cegedim) recorded a steady increase in sales in the recent years, reaching over 20% of the total market in 2016, with an average annual growth rate of 14.2% in the period 2014-2016.

At the same time, it is noticed that the legislation relating to the authorization of non-prescription drugs (OTC medicines) and their advertising is *rigorously applied* by the National Agency of Medicines and Medical Devices (NAMMD), this category of products reaching the consumers only after obtaining **the Marketing Authorization**.

Other products for preventing diseases or increasing the quality of life, which may be released without medical prescription in pharmacies or other consumption channels (drugstores, organic stores, public nutrition stores, supermarkets) such as dietary supplements, get to the consumer after a notification (given by the Ministry of Health or the Institute of Food Bioresources). The consumer's access to them is also possible through online sale.

Under these conditions, there is a need for campaigns to properly inform the population about the non-prescription products in the category of food supplements/medical devices and also for collaborations among manufacturers and regulatory authorities for this market segment, to support a fair competition environment in the non-prescription drug industry.

The Romanian Association of the Producers of Non-Prescription Medicines, Food Supplements and Medical Devices is a non-governmental, non-profit, apolitical and independent association, founded through the free association of its members, constituted and governed in accordance with the legislation in force, GO no. 26/2000 on associations and foundations.

RASCI's mission is to support the cooperation among the manufacturers of non-prescription medicines, food supplements, medical devices in order to keep and improve integrity of the non-prescription medicine industry and promote common legitimate interests that bring benefits of our company.

RASCI's purposes are similar and consistent with the purposes of Antibiotice (in detail in the Appendix):

- to promote the industry of non-prescription medicines/ food supplements/ medical devices as an efficient and positive solution for the Romanians' health;
- to properly inform the public on these categories of products through the advertising made according to law in force;
- to carry out public awareness campaigns on the responsible use of these types of products;
- to promote a fair competitive environment;
- to represent the industry of non-prescription medicines/ food supplements/ medical devices in front of the government, legislative and regulatory bodies.

RASCI's specific objectives are:

- to promote the compliance with the Romanian and community law on the industry of non-prescription medicines/ food supplements/ medical devices;
- to promote adopting and implementing the legislative framework applicable to the RASCI members;
- to protect the mutual interests of the RASCI members by participating in public debates on drafts of normative acts and by representing the RASCI members' interests in front of any authority, body or organization, whether public or private;

- to support the RASCI members from a logistic, technical and legal viewpoint.

RASCI members' rights (in detail in the Appendix):

- to participate in the GMS of RASCI and vote
- to benefit from data received by RASCI.

RASCI members' obligations:

- to observe the terms of the Constitutive Act, Article of Incorporation, Code of Ethics of RASCI
- to inform RASCI about any measure or initiative that could have a negative impact on the industry of non-prescription medicines/ food supplements/ medical devices.

The founding members of RASCI, established in 2016, are Bayer, GlaxoSmithKline Consumer Healthcare, Johnson&Johnson, Sanofi, Reckit Benckiser, Pfizer, Prisma International Trading. Other current members are: Fildas, Terapia, Secom, Unicoms. RASCI collaborates with RAC (Romanian Advertising Council) - an association with attributions in the field of advertising of non-prescription products, AEGSP (Association of the European Medication Industry), CEGEDIM.

The annual membership fee is EUR 5,000 and will be paid in proportion to the duration of the membership.

Considering the following:

- The consumption trend of self-medication products is upward, driven by the increase of the population's interest in the health condition and of the special attention given to prevention.
- Through its portfolio, Antibiotice ranks the 15th in the top of the companies activating on the OTC market in Romania (out of a total of 213 companies), uphill with 3 positions compared to 2015. The average annual growth rate recorded in the period

2014-2016 is 19.7%, above the overall market rate (according to Cegedim 2016).

- The share of OTC medicines in our company's turnover grew up to 16 % in 2016 (13% in 2014), the successful products being the foods supplements Fluxiv[®], Silithor[®], Equilibra[®], Soriso[®], precum si OTC-urile Rompirin[®]E, Ibufen[®], Clafen[®] gel 5% si Cicatrol[®].
- Our company's interest is to further develop this product segment (OTC medicines, medical devices, food supplements), to respond to the need of consumers for accessing the products for preventing and maintaining or increasing the quality of life (Fluxiv[®] - ranks third in the relevant consumer market with a 12% market share in the first year after launch, Equilibra[®] - ranks fourth in the consumption, with a 9% market share, Silithor[®] - ranks ninth in the consumption, with a 3% market share in the second year of sale, Soriso[®] - ranks second in the consumption, with a 17% market share in the first year of sale);
- The legislation framework is not still consolidated for the food supplements, medical devices as well as the advertising for this type of products;
- The need to promote the legitimate interests of Antibiotice as a manufacturer of OTC medicines, food supplements and medical devices, to improve the legislative framework and contribute through fair campaigns to informing the consumers on the benefits of the responsible self-medication.

We strongly support our accession to RASCI (Romanian Association of the Producers of Non-Prescription Medicines, Food Supplements and Medical Devices)

CEO

Ec. Ioan Nani

MEDICAL DIRECTOR

Physician Mihaela Mosnegutu

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