**Distinguishing criteria pharmaceutical drugs vs. food supplements**

| | **Pharmaceutical Drugs** | **Supplements** |
|---|---|---|
| Determination of purpose | disease-related effect: prevention, alleviation, cure of diseases | health-promoting effect: Supplement to normal diet (food!), maintenance of normal body functions |
| Consumer | Patients | Healthy consumers |
| Legal basis | Directive 2001/83/EC and in Regulation (EC) No 726/2004 | EU Regulation 1925/2006, Directive 2002/46/EC, Directive 2006/37/EC, Regulation 1161/2011, Regulation 953/2009, Regulation 307/2012, etc. |
| Prerequisites for marketing | after official approval procedure, in the course of which quality, efficacy and safety have been tested after official registration | official controls only on suspicion, manufacturer is responsible for safety |
| Information on the packaging | actual dosage of the active ingredients may deviate by no more than 5% | actual quantity in the product may deviate by 50% or more |
| Manufacturing | defined manufacturing process that ensures standardised, consistent quality | manufacturer is responsible for safety |
| Minimum and maximum levels | No maximum levels set for ingredients (except for technological additives) | Dosages of all ingredients are tested and precisely defined as part of the approval process |
| Safety | Classical clinical trials, starting with dosage-finding, pharmocokinetics, pharmacodynamics, etc. safety (phase I) | manufacturer is responsible for safety , upper limits to be adhered to |
| Efficacy | Clinical trials phase II to IV | clinical trial according to standard scientific criteria, GCP, before being allowed to make any claims |
| Advertisement | Disease-related statements permissible | Disease-related statements not permissible |