1. Claims related to either first or second medical uses of a product are not accepted, since they are considered to indirectly refer to therapeutic methods of treatment. However, first non-medical uses of a new product might be accepted.

2. In those cases where the structure of a product is not known, products in product claims may be defined by the physical, physical-chemical and/or biological properties that unambiguously define said product. Parameters such as the molecular weight together with the IR or NMR spectra are considered to clearly define a product. However other parameters such as the melting point, crystalline form, viscosity or solubility are not considered to define a product accurately enough.

3. Product-by-process claims are only allowed when it is not possible to define the product by its structure and/or physical chemical or biological parameters, and when the process leads unambiguously to the claimed product.

4. Compounds existing in the nature that have been isolated (i.e. a plant extract), are not patentable. However, the process for their obtaining may be patentable provided it is new and inventive. Regarding compositions containing a non-patentable product - such as a plant extract -, a simple dilution will not be patentable, unless the solvent helps the active ingredient to be in a suitable administrable form according to the purpose of the invention.

5. Compounds included within a Markush formula shall be allowed provided that they are a reasonable generalization of the examples duly identified and their activity proved in the specification. The reasonable generalization will be examined based on the structural and isosteric similarity between the claimed compounds and the examples described in the specification.

6. General composition claims comprising a new compound and "pharmaceutical acceptable excipients" may be accepted. However, general claims referred to compositions comprising a known compound are not accepted. These claims must also include other qualitative and/or quantitative technical characteristic that allow to distinguish the claimed composition from the prior art.

7. Combination claims characterized by an administration method or a dosage regime are not patentable, since they are considered to indirectly refer to therapeutic methods of treatment. Combination claims of known compounds might be rejected due to lack of novelty and/or inventive step when comparing each of the components of the combination separately with the prior art.

8. Even though a restrictive position regarding the patentability of polymorphs can be deduced from the guidelines, it is specifically stated that a new process for the obtaining of a polymorph can be patentable, provided said process is inventive.

9. Manufacturing or pharmaceutical processes for known compounds are accepted provided it is sufficiently disclosed in the description and comply with the requirements of novelty, inventiveness and industrial applicability. A process is considered to be novel if it consists of a new combination of steps, chemical reactions and/or reaction conditions, even if those are known separately.

Although a restrictive analysis of the inventive step may be expected from the DNPI, the new guidelines explicitly state that claims referred to new compounds included in a Markush formula, or to isomers, polymorphs, salts, compositions, combinations, prodrugs and active metabolites of known compounds are considered as "complex subject matter" that should be analyzed individually and their allowance, regarding the compliance with the novelty and inventive step requirements, will depend both on the context of the specification and the relevant prior art.