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Limit's groups – reimbursement reflections

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The idea of limit's groups utilized by the Act of 12 May 2011 on the reimbursement of medicinal products, special purpose dietary supplements and medical devices is not an unique concept related only to the field of reimbursed products used for medical purposes.

It results from the natural human need of reality rearrangement. This need manifests in grouping different things and ideas having common properties, usefulness and characteristics. Through the common criteria we can replace each subject belonging to the same group. The grouping is a very frequently observed form of human activity. It begins in childhood (e.g. grouping toys according to their colors, shapes, etc.) and is still present in adulthood (e.g. grouping food/meals according to their main constituent: proteins, carbohydrates, fats). Both childhood and adulthood experiences with grouping help identify things with a similar application. The same concerns medicinal products in the reimbursement system.

The need for seeking methods to avoid an excessive payment for pharmacotherapy available at a lower cost is justified by the fact the prices of so called "original drugs" are greatly overpriced even after the patent expiry. This is a worldwide phenomena and some available comparisons of Active Pharmaceutical Ingredients (API's) and ready to use product prices are very impressive. According to some examples given by the United States Department of Commerce, the price of one "original" tablet containing 10 mg of amlodipine can be even 134,000% more than the price of 10 mg of the API and the price of one "original" capsule containing 20 mg of omeprazole can be 69,000% more expensive than the same amount of API. Hopefully, there are available generic pharmaceutical products (generics) which offer the same efficacy and safety at a price much lower than branded products. The reimbursed costs/prices of generics decrease along with the increase of the number of available products on the market as a result of commonly known trade rule. This loads to the multiplication of reimbursed units of generics for the same amount of money comparing to the number of soled and reimbursed branded products. It is clearly seen in the number of published reports inclusive of the IMS Health report by Sheppard et al.

Additionally to the price pressure put by generics onto originators who make the costs of medicines more realistic, it is also

another way for positive (from the payer's point of view) price regulation of reimbursed drugs. The fact remains that not all drugs containing different (considering the chemical aspect) active substances differ in terms of their mechanism of effect, and consequently indications, safety and clinical efficacy/usefulness. There is a number of very homogeneous groups of drugs in terms of pharmacological properties and the place of therapy despite the fact that they contain different active substances (so called "congeners" or "me-too" drugs). These "new" drugs in contrast to genuinely innovative compounds having new mechanisms of effect or affecting previously unknown points of activity, carry no significant progress into the therapy but benefit from patent protection. They do not undergo competition of generics unless their patent protection expires, and finally generate excessive (unnecessary) reimbursement costs. But we should know (and remember) that the therapeutic effects of the previously mentioned excessively priced drugs, can be obtained by significantly cheaper generics of originators whose patent protection expired.

Thus, the need for establishing limit groups appears obvious - it is dictated by rationalization and economy reasons.

The criteria allowing the qualification of different drugs into the same limit group are defined by the Act of 12 May 2011 on the reimbursement of medicinal products, special purpose dietary supplements and medical devices. They cover the same or different INN but the same therapeutic effect and a similar mechanism of effect. In the process of grouping and establishing limit groups different sources of data and opinions are used including the opinions created by Agency for Health Technology Assessment (AHTA/OTM), members of Economic Commission, ATC classification system, foreign reimbursement decisions/regulations, other sources. The ATC classification deserves special attention - it is a clear, logical, constantly updated survey of active substances grouped according to criteria which can support majority of decisions on replacement of many drugs with other ones.

The limit lists established under the Reimbursement Act clearly illustrate similarities and possible interchangeability of drugs grouped under the same heading. The best examples are highly homogeneous groups named "Drugs affecting lipid metabolism – reductase HMG-CoA inhibitors", "Anticancer and immunomodulatory drugs – enzyme inhibitors – oral aromatase inhibitors", "ACE inhibitors – single and fixed dose products", "Corticosteroids for inhalation", etc.

The results of establishing limit groups as a barrier for uncontrolled reimbursement and excessive outflow of public money have a positive outcome. This tool of reimbursement regulation guarantees the access to all important drugs for the majority of patients furthermore protects the national economy against wasteful loss of funds. We observe that this opinion is shared by a number of independent bodies not associated or related to the Ministry of Health and the National Health Fund (NHF). This summarizes our opinion that the work of the Economic Committee under on the Act of 12 May 2011 on the reimbursement of medicinal products, special purpose dietary supplements and medical devices has significant share in the process of the improvement of the Polish reimbursement system.

To recapitulate, the idea of the limit groups and their implementation is a very useful and relatively simple tool for creation of positive changes on the market of the reimbursed drugs. It serves the purpose of the optimization of public expenditures for drugs, protects patients against excessive co-payment, and finally, stimulates prescribers to make choices of more cost-effective therapies offering the same clinical efficacy as more expensive therapies. ■