POLISH HERBAL COMMITTEE ul. Libelta 27, 61-707 Poznań. Poland

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Polish Herbal Committee is an association representing herbal business related enterprises, supporting scientific research and technical progress in herbal industry.

Poland is one of the biggest herbal manufacturers in Europe and a wide range of herbal products (herbal substances – standardized herbs, as well as herbal preparations – dry or liquid extracts etc.) are defined as active substances for medicinal products for human use.

We would like to comment the Draft Guidelines on the Principles of Good Distribution Practices of Active Substances for Medicinal Products for Human Use (SANCO/D/6/SF/mg/ddg1.d.6(2013)179367).
We find **article 18 "Active substances should be normally stored apart from other goods"** difficult to implement, based on the following argumentation:

- herbal substances or herbal preparations are used not only as active substances in herbal medicinal products but also as components of food supplements, food or cosmetic products
- that is why active substances of herbal origin are very often stored in the whole supply chain together with food supplements and other components
- we see no quality risks resulting from storing active substances of herbal origin together with food supplements, bulk medicinal products or even food products of herbal origin; very often these are the same products as far as composition and physical-chemical properties are concerned
- warehouse management systems and products identification systems allow to properly manage deliveries to customers and prevent mix-up of products of different status.

We see no necessity to dedicate separate storage area (which could be understood by authorities as separate rooms) for active substances, especially of herbal origin.
In our opinion similar argumentation refers to vitamins, minerals and many other active substances widely used in "non-medicinal" products.

We suggest the following content of article 18:
" Active substances should be stored under conditions specified by the manufactures (e.g. controlled temperature and humidity when necessary). These conditions should be monitored periodically and records maintained. The records should be reviewed regularly by the person responsible for the quality system".

Yours sincerely,

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President of Board

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