BPI Bundesverband der Pharmazeutischen Industrie e.V.

BPI's Position on EASAC's Publication on Homeopathic Products and Practices from September 20, 2017[1]

A working group of 11 scientists acting in an individual capacity prepared the Statement "*Homeopathic products and practices: assessing the evidence and ensuring consistency in regulating medical claims in the EU"*. This statement was published by the European Academies Science Advisory Council ("EASAC").

About EASAC

The participating scientists acted in an individual capacity (cf. page 10 of the statement) and published their statement through the EASAC, an organization formed by the national science academies. The EASAC is neither an institution of the European Union ("EU") nor a body tasked by the EU or by any EU Member State.

Conclusions of the Statement

The declared purpose of EASAC's statement which covers homeopathic products for human and veterinary use is to "*reinforce criticism of the health and scientific claims made against homeopathic products*".

BPI's Position

- EASAC's initial hint (page 4) that a lot of patients demand access to homeopathic medicinal products is correct. This is confirmed by a survey of the Allensbach Institute in 2009[2] and a very recent survey of the Forsa Institute of May 2017[3].
- EASAC's reasoning directed against the current EU legislation on homeopathic medicinal products in Directive 2001/83/EC contains nothing new. Already in 1990 the EU Commission addressed the high demand of patients, emphasized that it "*is not for the Commission to take sides for or against a particular style of medical practice*" and focused on harmonized high quality standards[4]. In 1992 the EU legislator stressed that "*patients should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the said products*" and that it is necessary "*to provide users of these medicinal products with a very clear indication of their homeopathic character*"[5].

  As a recently published comprehensive legal review6 shows current EU legislation fully ensures quality and safety of homeopathic medicinal products based on the same standards as for all other medicinal products. Differently from the approach taken in the US fulfillment of these standards is checked by competent authorities of EU Member States prior to distribution of the products in registration/marketing authorization procedures. On the labelling and in the package leaflet the homeopathic nature of the product is clearly indicated. Finally the

[1] http://www.easac.eu/fileadmin/PDF_s/reports_statements/EASAC_Homeopathy_Statement.jpg
[2] http://www.ifd-allensbach.de/uploads/tx_reportsndocs/prd_0914.pdf
[3] http://www.bpi.de/home/nachrichten/nachrichten/patienten-vertrauen-homoeopathischen-arzneimitteln/
[4] EU Commission, COM(90) 72 final of 22.03.1990, Explanatory Memorandum and Report to the Council.
[5] Preamble to Council Directive 92/73/EEC of 22.09.1992 on homeopathic medicinal products
[6] Prof. Dr. Wolgang Voit, Anforderungen an die Verkehrsfähigkeit homöopathischer Arzneimittel, Pharmarecht 2017, 369 ff.

manufacture of homeopathic medicinal products is also subject to the same standards and the same monitoring by inspection authorities as for all other medicinal products. The Federal Institute of Drugs and Medical Devices' (German "BfArM") summary available on BfArM's website7 provides a good example how EU law is implemented in the Member States.

- EASAC's approach to explain the successful practical use of homeopathic medicinal products simply with the placebo effect and the achieved results in clinical trials simply with *"poor study design … or publication bias"* falls short.

  In particular the therapeutic results achieved in the treatment of animals of different species (e. g. also cattle and pigs) with homeopathic medicinal products cannot that easily be put down with a simple reference to a placebo effect. Additionally EASAC has not thoroughly investigated the studies summarized in the statement (page 5/6). For example, the Australian National Health and Medical Research Council's ("NHMRC") 2015 review is currently under scrutiny of the Commonwealth Ombudsman due to irregularities in the way it was conducted[8]. Finally it is inappropriate to attribute all studies performed with homeopathic medicinal products to poor study design or other deficiencies[9].

- EASAC's position related to the use of homeopathic medicinal products for veterinary use by organic farmers requires a look into the relevant articles. According to Art. 24 (2) and (3) Commission Regulation (EC) No. 889/2009 on organic products *"phytotherapeutic, homeopathic products, trace elements … shall be used in preference to chemically-synthesized allopathic veterinary treatment or* ***antibiotics****"; however, "if the use … is not effective and if treatment is essential to avoid suffering or distress of the animal, chemically synthesized allopathic veterinary medicinal products or antibiotics may be used"*.

  This treatment sequence follows the objectives of organic production[10], is a suitable measure in combatting further increase of antibiotic resistances and ensures animal welfare by allowing conventional treatment to the extent necessary.

To sum it up the statement which was prepared by 11 scientists in their individual capacity, repeats the known argumentation of critics of homeopathy which is the declared purpose of this statement. Since all these aspects have already been duly taken into account in the current EU legislation there is no need for any legislative action. Instead patients' access to safe and high-quality medicinal products of their choice needs to be maintained.

[7] http://www.bfarm.de/DE/Service/Presse/Themendossiers/Hom%C3%B6opathie/_node.html
[8] https://www.hri-research.org/resources/homeopathy-the-debate/the-australian-report-on-homeopathy/
[9] https://www.hri-research.org/resources/research-databases/
[10] Preamble of Council Regulation (EU) No. 834/2007 which is the basis for Commission Regulation (EU) No. 889/2009.

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About BPI

As an industry association with 65 years of experience in drug research, development, authorisation, manufacturing and marketing, BPI is the only national trade association which represents the pharmaceutical industry with all its variety. Our membership consists of over 250 companies that cover classic pharmaceutical companies, businesses from biotechnology, phytopharmacy and homeopathy as well as companies with a small generic portfolio. The majority of our membership is family owned businesses as well as small and medium sized enterprises that represent more than 11 percent of the pharmaceutical industry workforce in Europe. As an association representing the whole section of the pharmaceutical industry BPI´s goal is to ensure that patients receive the care and medicines they need.

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