International Association for Soaps, Detergents and Maintenance Products

A.I.S.E. POSITION ON TRIS NOTIFICATION 2019/601/D (GERMANY)

State Ordinance on infection prevention in medical facilities (Medical Infection Prevention Ordinance - MedIpVO

Summary:

1. The revision of the Medical Infection Prevention Ordinance (MedIpVO) of the Federal State of Schleswig-Holstein (Germany) constitutes a considerable trade barrier for the free movement of disinfectants in the EU, as it provides for additional requirements for the use of disinfectants, which particularly discriminates against marketers from other EU countries.
2. The EU BPR Regulation (EU) No. 528/2012 harmonizes conclusively and sufficiently the regulations for the marketability and use of disinfectants in the EU.
3. The requirements of the BPR for proof of the efficacy of disinfectants are fully sufficient to achieve the purpose of the amendment of the MedIpVO described in the notification. The intended requirements, however, are inappropriate and unsuitable for achieving this purpose.
4. The requirements are identical with those of a German association constituted under private law, the Verbund für angewandte Hygiene e.V. (VAH), which commercially offers a private certification system for disinfectants. The regulation is aimed at strengthening the legal and economic position of this association, as its certification system has been subject to professional criticism for years with regard to the BPR.
5. In the EU there is no alternative provider to the VAH that meets the requirements of the MedIpVO.
6. 6. The MedIpVO is a regulation at the level of the federal states which is therefore not even valid throughout Germany. Since there exist several other certification systems for disinfectants in Germany, this could lead to different regulations in all 16 German federal states and beyond. This clearly contradicts the harmonisation purpose of the BPR.

The notification submitted by the German Federal Ministry for Economic Affairs and Energy amending the State Ordinance of the Ministry of Social Affairs, Health, Youth, Family and Seniors of the German Federal State of Schleswig-Holstein on infection prevention in medical facilities (Medical Infection Prevention Ordinance - MedIpVO) is unacceptable as it restricts the free movement of goods in the EU and undermines the harmonization of the internal market by Regulation (EU) No. 528/2012 (Biocidal Products Regulation – BPR).

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The new version of § 2 section 8 of the MedIpVO (hereinafter: "Regulation") provides that, in the future, for the disinfection of surfaces in all rooms of hospitals intended for diagnostics and therapy, facilities for outpatient surgery, preventive or rehabilitation facilities, in which medical care comparable to that of hospitals, dialysis facilities and day clinics where contamination can be expected, only disinfectants may be used, whose efficacy, in addition to their authorization as a biocidal product, has been separately proven. For the corresponding proof, at least two independent surveys with the related test reports should be submitted in the future, whereby the tests must be carried out by test laboratories independent of the manufacturer. In addition, the test reports and surveys must be confirmed by independent experts in a scientifically justified assessment. The respective test laboratories must also have accreditation in accordance with DIN ISO EN 17025: 2018-03 from March 2018 or a comparable certificate of competence. The respective test method must be validated by ring trials or a similar method, to consider the statistical variability that may occur when at least two test repetitions are required.

The Regulation constitutes a significant trade barrier for the free movement of disinfectants in the EU, since it places additional, significant requirements on the use of disinfectants, which are particularly disadvantageous for marketers from other EU countries.

Disinfectants are goods according to Art. 28 II TFEU as well as products according to Art. 1 section 1 a) of the Regulation (EU) 2015/1535.

§ 2 section 8 MedIpVO is a sub-statutory regulation and therefore a state measure.

The Regulation is suitable to, directly or indirectly, actually or potentially, hinder the free movement of goods, since certain uses of surface disinfectants are prohibited, unless the manufacturer has additional evidence of efficacy. This deviates from the Europe-wide harmonized requirements for the marketability and use of corresponding products (cf.: Dassonville formula, ECJ judgment C-8/74).

It is also not solely a sales modality in the sense of the Keck formula (ECJ judgment C-267/91 and C-268/91). This interference with the free movement of goods is also not justified from the point of view of health protection, since the Regulation is neither necessary nor appropriate to achieve the purpose.

Regulation (EU) No. 528/2012 (BPR) harmonizes the regulations for the marketability and use of disinfectants in the EU appropriately and conclusively.

Contrary to the justification of the Regulation (point 9 – “brief statement of grounds” of the notification), the BPR does not primarily aim at avoiding unnecessary environmental and health risks for the users of biocidal products, while ensuring the protection of patients against infection is covered by the scope of the BPR. In particular, the requirements of the BPR for the proof of the efficacy of surface disinfectants are suitable and appropriate to ensure the protection of patients in medical facilities against infectious diseases.

According to Art. 17 section 1 BPR, biocidal products may only be made available and used on the EU market if they have been approved for the specific application (area of application, operation site, target organism - e.g. surface disinfection in hospitals to combat mycobacteria). According to Art. 19 section 1 b) i) BPR, the approval of a biocidal product requires especially

that the product is sufficiently effective against the advertised target organisms, while taking into account the expected application parameters.

The efficacy must be demonstrated in accordance with the requirements of the relevant guideline[1] of the European Chemicals Agency (ECHA). For disinfectants, the guideline for evaluating efficacy contains specific information on the test methods to be applied. According to point 5.4.0.4.2 *"Standard Test Methods"* of the guideline, CEN standards are to be used primarily for efficacy testing. If European standards are not available or cannot be used and an adaptation of such a standard according to the regulations of EN 14885 (chemical disinfectants and antiseptics - application of European standards for chemical disinfectants and antiseptics) is not possible, OECD test methods may be applied.

Only in cases where CEN standards and OECD test methods cannot be applied, are not available or cannot be used for a specific product or application, other test methods and guidelines may be used.

The relevant standards for the evaluation of disinfectants are listed in Appendix 2 of the guideline for evaluating efficacy. Table 28 contains the European CEN standards, while table 29 lists the other test methods and guidelines, including the OECD test methods. As a last point, the test methods of the German Association for Applied Hygiene (VAH) are also listed there.

Regarding the reproducibility of the data, the EN 14885 standard must be observed in accordance with the guideline, which requires revision tests to be carried out by independent second and third laboratories. Accordingly, as part of the authorization process according to the BPR, independent test reports from various laboratories are regularly drawn up with corresponding assessments.

Regarding the precision of the data supplied, it should be noted that in the authorization process it can be referred to the data of the approvals of the relevant active substances contained in the product to cross-check the submitted data. This represents a clear advantage over the Regulation, which does not provide or enable such verifiability of the precision of the efficacy tests.

The submitted documents are assessed by the experts of the competent national authorities. In the case of products that are authorized in several Member States, the results of the evaluating authority are checked by the experts of the competent authorities of the Member States concerned. In the case of a Union Authorization, a separate review is also carried out by ECHA's experts. As a rule, the requirements of the BPR also substantially go beyond the requirements of the Regulation on this point.

When selecting suitable laboratories, the guideline clarifies that studies and tests should be carried out in accordance with Good Laboratory Practice (GLP) or similar quality assurance systems, such as ISO 17025. Regarding the ensuring of the competence of the executing laboratories, reference is made in particular to the certification according to ISO 17025.

[1] Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C) (Leitlinie zur Wirksamkeit), Version 3.0, April 2018, ECHA-18-G-02-EN, IBAN: 978-92-9020-502-9, https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468.

The requirements of the BPR on the proof of the efficacy of disinfectants are absolutely suitable and appropriate for achieving the purpose of the change in the MedIpVO described in the notification. The intended requirements according to § 2 section 8 MedIpVO do not offer any necessary added value compared to the requirements of the BPR, which could justify an intervention in a harmonized legal field across Europe.

The main aim of the BPR is, according to Art. 1 section 1 BPR, the harmonization of the EU internal market regarding the rules on the placing on the market and the use of biocidal products. This aim would be ruined with the amendment of § 2 section 8 MedIpVO.