WHITE PAPER: PROTECTIVE CLOTHING IN PHARMACY
THE NEW PPE REGULATION AND ITS SIGNIFICANCE FOR THE HANDLING OF CMR DRUGS AND POTENTIALLY INFECTIOUS MATERIALS

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For 20 years, users of certified personal protective equipment (PPE) can be sure that their products meet basic health and safety requirements. Since 1989 the PPE Directive 89/686/EEC [1] created the conditions necessary for a uniform level of design and testing throughout Europe. This has contributed significantly to the reliability of individual protective measures. However, over the years, ambiguous formulations as well as changed requirements for market and product monitoring necessitated a revision of this legislation. Therefore, the PPE Directive lost its validity after the last transition period which expired in April 2019. Two years earlier, the new PPE Regulation (EU) 2016/425 [2] had already come into force. Since then it has regulated the design, provision and free movement of PPE within the European Union in a more detailed, precise and binding manner than its predecessor. The following article shows the significance of the new regulations for personal occupational safety when handling CMR drugs and infectious materials.

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Avoiding contact - occupational safety in medical care

The occupational handling of medical drugs classed as carcinogenic, mutagenic or toxic to reproduction (CMR substances category 1A and 1B) are regarded as an activity within the sense of the German Ordinance on Hazardous Substances [3]. This applies especially to facilities for human and veterinary medical care, such as pharmacies, oncological practices, wards or nursing homes [4]. Comparable protection requirements apply to the handling of potentially infectious materials (e.g. body fluids) in health care facilities [5, 6]. Which measures are to be taken are determined by the risk assessment that each employer must carry out individually for any professional activity involving exposure to physical, chemical or biological hazards. The basic aim is to "eliminate hazards at their source" [7]. However, eliminating or substituting special chemical or biological substances is usually just as impossible in pharmacy operations as it is when working on patients or handling microbiological samples. Appropriate technical, administrative and personal protective measures must, therefore, be taken, to ensure that there is no contact with toxic or infectious agents. Even if personal measures are of secondary importance due to their individual character, they play an important role in pharmaceutical, medical or microbiological activities. Only by using protective gloves, gowns and coveralls as well as additional components for particular high risk activities (e.g. removal of spills) exposure can be prevented during manual work (Figure 1). The employer must ensure that the PPE provided by him offers adequate protection against all relevant hazards without impairing the user's health by itself. In particular, it must comply with the German Ordinance on the Use of Personal Protective Equipment [8]. One important consequence of this law is that the basic design and performance of PPE must follow the requirements of the new PPE regulation. This must be taken into account not

Figure 1: Use of PPE in the disposal of CMR drug spills

only by economic operators, but also by the respective employer. In short: Only PPE whose conformity with the requirements of the PPE Regulation has been confirmed may be used at the workplace. However, the path to a declaration of conformity is complex and not every product is able to pass the extensive tests.

Risk categories – The right level of protection for each hazard

The old PPE Directive already provided for a categorisation of protective equipment. As a result, conformity assessment procedures with an adapted degree of complexity had to be carried out. However, the classification related to the PPE itself ranged from simple design PPE for protection against minor risks (Category I) to complex design PPE for protection against "mortal danger or against dangers that may seriously and irreversibly harm the health" (Category III). According to these criteria, PPE used as a barrier against CMR substances fell into the highest category and had to satisfy a comprehensive catalogue of requirements even before the new regulation was introduced. This has not changed in the current regulation. However, it is no longer the PPE itself that is categorised, but the risk against which it is to be used as a protective measure. In Annex 1 of the regulation, certain risks are now explicitly assigned to the respective categories I and III. The list of complex PPE takes into account hazards caused by chemical agents (now referred to as a risk from "substances and mixtures which are hazardous to health"), but also those caused by "harmful biological agents". The resulting conformity assessment measures are extensive but necessary to ensure the required degree of protection. They are used to secure that test samples of the PPE in question comply with the relevant normative specifications (EC type examination) and to monitor that the final product is strictly conform to the type test samples described in the EC type examination certificate (control of product samples from the production process or control of the quality assurance system, Figure 2).

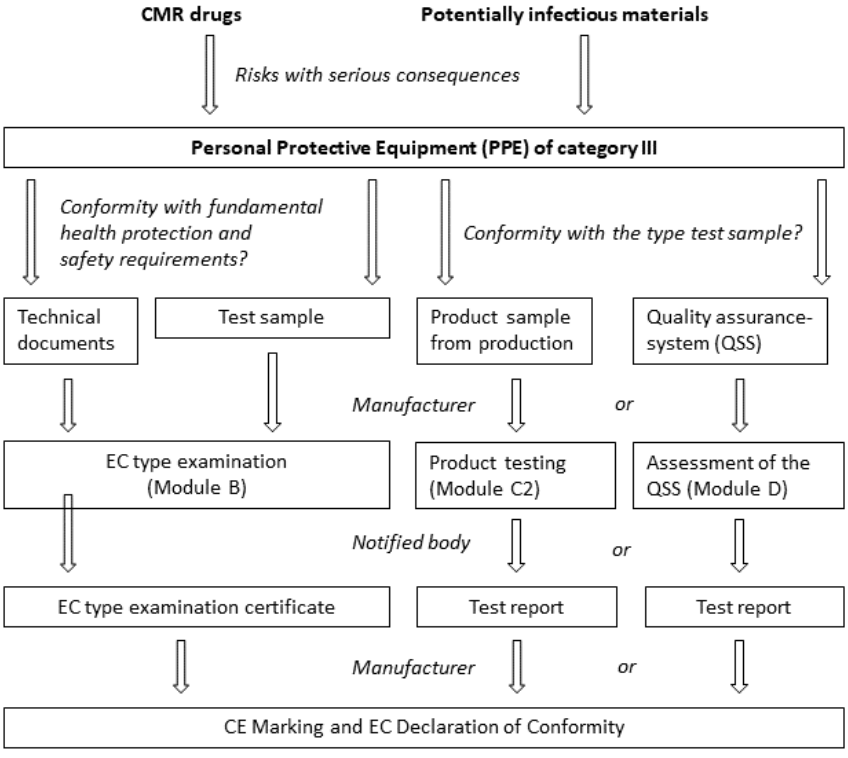

Figure 2: Diagram of the conformity assessment procedure for category III PPE

EU type examination - the first major hurdle

Economic operators who wish to place category III PPE on the market must prove that it meets all the applicable requirements given by the PPE Regulation. However, they are not allowed to carry out this work without the assistance of an "independent third party". This means, inter alia, that a representative PPE prototype as well as the associated technical documentation must be checked regarding conformity by an accredited organisation. This “notified body” is usually a suitably equipped testing institute that is designated and monitored by a higher authority. The EU type-examination process (according to Module B of the PPE Regulation) is based on relevant harmonised standards or equivalent technical specifications. A type is thus deemed to conform with the regulation if it meets the criteria specified in the relevant standards. For this purpose, extensive technical tests must be passed. The depth of testing becomes clear when one takes a look at the essential performance requirements that have to be met by the PPE core components used in pharmaceutical and microbiological laboratories:

For protective gloves against hazardous chemicals, tests based on the DIN EN 374 family of standards are an essential part of the examiantion procedure. Important criteria here are resistance to penetration through defective areas (penetration according to DIN EN ISO 374-1 [9], DIN EN 374-2 [10], Figure 3) and the barrier performance of the uninjured material against selected test chemicals (permeation according to DIN EN ISO 374-1 [9], DIN EN 16523-1 [11], Figure 3). A possible harmful change in the protective material (degradation) must also be determined for each test chemical (DIN EN ISO 374-1 [9], DIN EN 374-4 [12]). The user should make sure that chemicals frequently handled by him were taken into account in the test. So-called "cytostatic gloves" should therefore explicitly be tested against cytostatic drugs, even if an all-encompassing evaluation is not possible due to the large number of corresponding drugs.

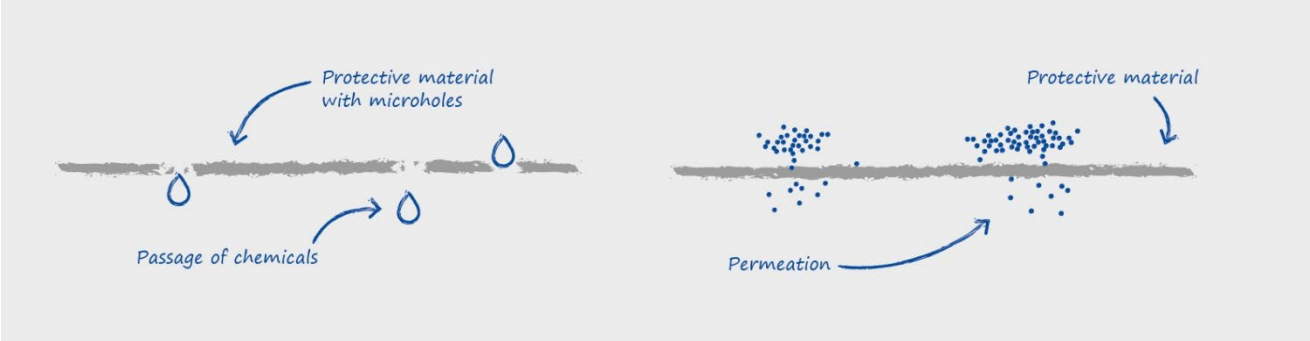

Figure 3: Penetration (left) - The movement of a chemical through materials, seams, pinholes or other defects at the non-molecular level. Permeation (right) - The movement of a chemical through the protective material on a molecular level. The process includes absorption, diffusion and desorption.

Just as with protective gloves, the retention potential of protective clothing is the most important performance criterion. Since seams are usually present, their impermeability must also be tested. As a comprehensive standard, DIN EN 14325 [13] specifies corresponding test procedures and a performance classification for materials as well as for seams, joints and composites. Mechanical properties (abrasion, bending crack, tensile and puncture resistance) must also be taken into account in the evaluation procedure. How to perform these tests and the subsequent classification is described in subordinate standards. Testing for penetration and permeation (DIN EN ISO 6530 [14] and ISO 6529 [15], Figure 4) are particularly important for handling liquid chemicals. Before evaluating the penetration of entire garments or parts of them, it must be specified whether they should be liquid-tight, spray-tight or only partially liquid-tight (Type 3 or PB [3], Type 4 or PB [4] or Type 6 or PB [6]). In the corresponding test procedures, the samples are exposed to a jet of liquid (jet test according to DIN EN 14605 [16], EN ISO 17491-3 [17]) or a spray of varying intensity (spray test according to DIN EN 14605 [16] or DIN EN 13034 [18], DIN EN ISO 17491-4 [19]). If the risk of infection is to be minimized by the protective clothing, not only the tightness against chemicals but also against infectious agents must be evaluated (DIN EN 14126 [20]).

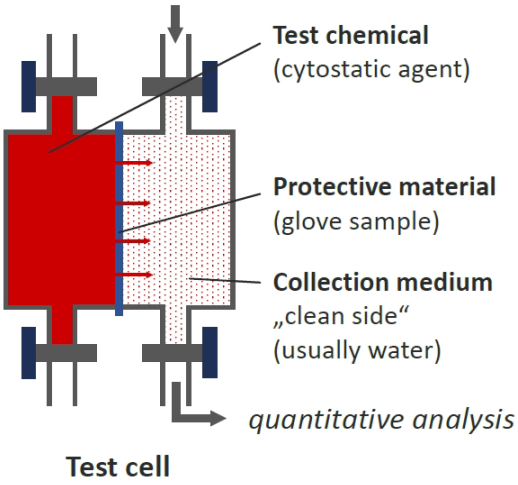

Figure 4: Test cell for determining permeation

In addition to standardised tests, the notified body carries out additional checks to clarify whether the requirements of the PPE regulation are met. Particular attention is paid to the quality of the technical documents and also to the extent to which the information given there haven been taken into consideration during manufacturing of the tested type. If the assessment shows that the tested prototype meets the applicable basic health and safety regulations, the notified body issues an EU type examination certificate to the manufacturer (Figure 5). In contrast to the PPE directive, the new PPE regulation limits its validity to 5 years. The manufacturer must therefore apply for a new type examination before this period expires. A review of the certificate is also necessary if modifications are made to the approved prototype that may affect the confirmity sample or if the state of technology changes.

Conformity to type - control during the running process

The conformity assessment procedure is not completed with the successful assessment of individual test prototypes. In order to ensure that the products from the ongoing manufacturing process are in conformity with the type described in the EU type-examination certificate, the PPE regulation stipulates various procedures which must also be implemented or monitored by the notified body on behalf of the manufacturer. Two procedures are provided for category III PPE, which can be used alternatively. The manufacturer is free to have conformity type assessed on the basis of an internal production control plus supervised product checks (module C2 of the PPE Regulation) or on the basis of a quality assurance system for the production process (module D) (see Fig. 2).

Under the former procedure, the notified body carries out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate. If the manufacturer opts for the second procedure, his quality assurance system for production, final product inspection and testing of the PPE will be assesed. The notified body carries out audits to check whether it can ensure the conformity of manufactured PPE with the tested type and with the requirements of the PPE regulation.

The necessary checks and audits, respectively, are carried out at least once a year at irregular intervals. If the assessment process shows that the production conditions or the performance of the quality system meet all demands of the PPE Regulation, the manufacturer has fulfilled the last essential requirement for to draw up an EU Declaration of Conformity for his PPE model. As an external sign of the successful completion of the conformity assessment procedure, the CE marking is affixed to each individual product together with the four-digit identification number of the notified body (Figure 6). This combination makes it easily recognisable that the minimum requirements for free internal EU trade and safe use are met.

bsi.

By Royal Charter

EU Type Examination Certificate

This is to certify that:

Berner International GmbH
Werner-von-Siemens-Str. 19
Elmshorn
Schleswig-Holstein
25337
Germany

Holds Certificate Number: CE 715808

In respect of:

Model Cleo® saphir and Codan Chemoprotect® Protective Clothing range of gowns, oversleeves and overshoes
To EN 14126:2003 and EN 14605:2005+A1:2009

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 0086):

Chris Lewis - Certification Director, Product Certification

First Issued: 2019-07-29
Latest Issue: 2019-07-29

Effective Date: 2019-07-29
Expiry Date: 2024-07-29

Page: 1 of 3

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Figure 5: Example of a type examination certificate for chemical protective clothing

PPE conforming to the regulation - safety for employers and employees

The new Regulation (EU) 2016/425 provides guidance not only for economic operators but also for all those who are involved in the selection and use of suitable PPE. In particular this means those who are concerned with the handling of toxic or (potentially) infectious agents. As these are activities with considerable health risks, good and safe PPE products are essential. The implementation of the new PPE Regulation ensures a guaranteed level of protection by having category III PPE assessed on the basis of internationally recognised procedures before and during its placing on the market. The assessment must be carried out by an independent, monitored institution. This increases the validity of the testing results and ensures a reliable monitoring process.

Figure 6: Example of CE mark with the four-digit identification number of the notified body

The successful completion of the conformity assessment procedure is an essential criterion for the selection of suitable PPE. In addition to the individual risk assessment, the employer is obliged to provide only those products that comply with the PPE Regulation. The new regulation, therefore, affects significantly the conditions under which CMR drugs and infectious materials have to be handled. PPE, which is planned, tested and manufactured in accordance with the new regulation, thus not only improves occupational safety and health, but also minimises liability risks.

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