EFPIA/EBE response to public consultation on measures for improving the recognition of medical prescriptions issued in another Member States

H. Comments

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In its response, EFPIA/EBE wishes to address questions C, E and G which are of more direct relevance to research-based pharmaceutical companies which research, develop and manufacture the medicines that are prescribed throughout Europe. In preparing its response, EFPIA/EBE liaised with PGEU, the organization representing community pharmacists in Europe. On issues of common concern the EFPIA/EBE response is much in line with PGEU, save one difference of emphasis on prescribers' recommendation regarding generic substitution. EFPIA/EBE considers it would greatly support cross-border prescriptions to have a box to tick clarifying the physician recommendation as it would remove any potential misinterpretations based on differences of language inherent to cross-border prescriptions. At the very least EFPIA/EBE could consider a blank field in the prescription were prescriber can write a note to a pharmacist making a recommendation to dispense specific brand, as recommended by PGEU.

C1. Identification of medicinal products

EFPIA/EBE consider that all elements proposed are important to identify a medicinal product, and that when INN are used, they should always be accompanied by the brand name of the product, or the name of the manufacturer, to ensure that products are delivered in accordance with the patients' specific medical needs. EFPIA/EBE would therefore be opposed to a policy of mandatory INN prescribing without reference to the brand name of a medicinal product or the name of the manufacturer. In the case of biotech derived medicinal product for example, two biological medicinal products or similar biological medicinal products (i.e. products that are similar but not identical to their reference product) that have similar active ingredient, based on the same amino acid sequence, will often share the same INN but if they are produced using different materials or manufacturing processes, this may be reflected in a changed side effect or efficacy profile. Without clear product identification, pharmacovigilance follow-up would be significantly compromised. For some condition such as epilepsy for example, it is also recommended that patients be always maintained on the same brand, because of safety concerns. Some patients are also particularly accustomed to a specific brand. This is often the case for example for elderly patients or patients taking combination products. An additional tool that would support the identification of medicinal products cross-border would also be to rely on national databases that provide information on all medicinal products approved and in use in EU countries listed by brand name and active ingredient. We understand from our members that such databases already exist in a number of EU countries.

E1. Better patient understanding of prescription

EFPIA/EBE considers that patient understanding of treatments is essential to ensure adherence and better patient outcomes. Appropriate patient information is essential to ensure patient understanding and some easy tools such as print prescriptions rather than manuscript prescriptions can support better patient understanding of prescriptions and treatments. However we understand that in many countries prescriptions are retained by the dispenser and that patient information therefore cannot rely on the prescription. Healthcare professionals, in particular prescribers and dispensers, are key in providing this information, and industry also plays an important role in providing unbiased information on their products based on reviewed and approved documents such as the patient information leaflet. For example the UK "Medicines Information Partnership" and the Swedish "FASS" system (including a trusted website with 4 million visitors per month) are successful models, which should be considered in the debate on how to improve the legal framework on information to patients across Europe.

G1. Other information

EFPIA/EBE considers that all items put forward in the public consultation are important. Regarding generic substitution, we would like to underline that this practice is not always possible. As stated above, two biological medicinal products or similar biological medicinal products will often share the same INN but if they are produced using different materials or manufacturing processes, this may be reflected in a changed side effect or efficacy profile and a patient stabilized on one product may react differently to another product. It is therefore important to ensure that the substitution of a biological medicinal product by a biosimilar only takes place with the knowledge of the prescribing physician. Also for small molecule generics there may be reasons why generic substitution is not warranted, such as with products with a narrow therapeutic index; in psychiatric conditions or where the choice of the device is important for handling and patient adherence. Therefore EFPIA/EBE considers it important to leave the option to the prescriber to indicate whether he/she considers, based on the patients' medical condition, that generic substitution is secure.

In order to address any potential concerns regarding limits to the dispensers' ability to dispense available products according to local rules, EFPIA/EBE would suggest clarifying that the box in no way consists of an obligation but remains merely an indicative recommendation that is easily readable across countries. This could, for example, be addressed by adding the following clarification to the Commission's suggested wording "generic substitution: yes/no (without prejudice to local generic substitution rules)". At the very least EFPIA/EBE could consider a blank field in the prescription were prescriber can write a note to a pharmacist making a recommendation to dispense specific brand, as recommended by PGEU.

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