STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGTHENING AND RATIONALISING EU PHARMACOVIGILANCE.

RESPONSE TO PUBLIC CONSULTATION ON LEGISLATIVE PROPOSALS
by
GALPHARM INTERNATIONAL LIMITED (A PERRIGO COMPANY).

Galpharm International Limited (Galpharm) are a UK based pharmaceutical supplier, operating within the generic non-prescription medicines sector. Galpharm hold a number of marketing authorisations for products containing well-established active ingredients which are distributed to patients, mainly in the UK although with an expanding EU business, via various grocery and pharmacy retail outlets usually as 'store-brands' or 'own-label medicines'. Galpharm do not currently operate in the prescription medicines sector and also do not currently work with products containing new chemical entities (NCE's) or biological active ingredients.

Galpharm are providing these comments in response to the public consultation on the legislative proposals as a pharmaceutical industry stakeholder and welcome this opportunity to provide our own views on the strategy.

In general, Galpharm broadly support the legislative aims and strategies outlined in the consultation document, which we view as proposing further clarification and simplification of existing legislation through measures including centralisation, greater collaboration across the EU, more use of technical advances in communication and, most importantly, taking a much more risk-based approach to pharmacovigilance activities within the EU. The planned changes to the legislation appear to be measured and proportionate and should ensure that medicinal products are approved for placing on the EU market with a clearly positive risk/benefit profile and that continued marketing of such medicinal products is based only on this positive risk/benefit profile being continually maintained. We also support moves within the legislative proposal to make the risk/benefit profile of pharmaceutical products the only criteria upon which regulatory decisions about those products should be made. Furthermore, Galpharm strongly believe that the proposed changes will ensure that the levels of pharmacovigilance monitoring and control required (and therefore the resources needed for such systems) for products with different risks are tailored to the individual products and are no longer based on the 'one size fits all' approach which tends to be the current situation arising from the existing legislation.

Notwithstanding our broad support for the legislative aims and strategy outlined in the consultation Galpharm do believe there are still some areas in which further clarification of the intention of the revised legislation would be useful particularly in ensuring a that small companies or those companies working with lower-risk products such as those containing well established ingredients or those intended for short term non-prescription use are not significantly disadvantaged by the proposals compared to much larger companies and those working with higher-risk products (such as prescription medicines intended for long term use, NCE's or biological active ingredients).

For example, under the proposed article 101e(1) it is a proposed requirement that marketing authorisation holders submit adverse event reports 'electronically' to 'Eudravigilance' yet the specific requirements of electronic reporting are not stated or discussed within the proposed article and thus, this could result in a requirement for costly new IT systems.

Under the proposed article 101e(5), with regards to literature searching, it is unclear if the agency monitoring of literature reports removes completely the need for marketing authorisation holders to perform additional literature searches and further clarification on this is needed.

Despite the proposed changes to article 8(3)(ia) which will reduce the regulatory burden it remains a requirement for marketing authorisation applicants to provide, with each application, details of the Qualified Person for Pharmacovigilance (QPPV). Galpharm would suggest that this information is required only in the Pharmacovigilance System Master File and thus, should a marketing authorisation holder be required to change their QPPV, this would not result in a need to vary each marketing authorisation they hold significantly reducing potential burdens and cost.

Under the proposed changes to article 59(1) there appears a new requirement for the addition of a new section of 'key safety information' to the patient information leaflet. Galpharm's concern with this proposal is that all UK patient information leaflets are currently being amended to take account of earlier changes to directive 2001/83/EEC (for example those required by article the existing articles 59(1) and 59(3)) thus requiring further changes to the content of patient information leaflets will involve further costs and be time consuming.

Galpharm also believe that all of the proposed changes to this legislation must be underpinned by harmonised EU guidance, which itself acknowledges the significant differences in the risk/benefit profiles of different types of pharmaceutical products.

In summary, Galpharm do believe that moving to a more risk-based approach to pharmacovigilance within the EU as proposed by this consultation and the revisions to the legislation is the fairest and most equitable method ensuring that an appropriate level of control is applied to products which have different levels of patient risk and thus ensuring that the health of all EU citizens is protected and enhanced.

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