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To the European Commission 31st January 2008

Dear Dr Arlett,

Re : Strategy to better protect public health by strengthening and rationalising EU Pharmacovigilance
Reckitt Benckiser Comments on the Proposed Revision of European Legislation

Reckitt Benckiser welcomes the overall strategy proposed by the EMEA regarding changes to the current pharmacovigilance legal framework, as it would reduce the current administrative burdens on the industry and authorities, but also it would strengthen the PV EU system.

Reckitt Benckiser is very pleased to be offered the opportunity to review this proposal. Please find below Reckitt Benckiser (RB) comments related to the Section 3 of the proposal.

3.2.3. Simplify informing the authorities about the company pharmacovigilance system

RB agrees that a "detailed description of the pharmacovigilance system" should not be submitted as part of the dossier because any minor change in the MAH pharmacovigilance system necessitates variations to marketing authorisations in the Member States.

3.2.4. Rationalise risk management planning

RB recommends that there should be no requirement for Risk Management Plan (RMP) for old established products such as Over-the-Counter (OTC) medicines. The safety profile for these medicines is well known. In actual fact, by the very nature that these products are available over the counter, it implies that these products are very safe for public health.

3.2.6. Simplify and make proportional reporting of single serious adverse drug reaction (ADR) case reports

RB strongly agrees with the fact that the current ICSR reporting rules are very complex and lead to heavy costs on industry and regulators. To reduce burden and free up resource, the EMEA proposes the reporting of all EU domestic reports go only to Eudravigilance and thereby to the Member State where they occurred.
RB strongly agrees to only report ICSR to one place, namely to Eudravigilance.
However, RB recommends reporting only the medically confirmed, serious & unexpected EU ICSRs, as it is currently with most Member States. The reporting of all EU ICSRs would increase the MAH reporting workload without any benefit for patient safety.

RB would recommend the EMEA to clarify whether the reporting is based on the active ingredient or the licensed product.

RB agrees that the definition of adverse drug reaction regarding medication errors should be clarified and the reporting rules should make clear that medication errors which result in an adverse reaction should be reported to the competent authorities.

RB strongly agrees with the fact that the EMEA should screen the scientific literature and enter case reports from the literature on Eudravigilance. This would avoid the duplication currently conducted by the MAHs to screen and report the same literature cases to the EMEA.

3.2.7 Simplify and make proportional to risk periodic safety update report submission by industry (PSURs)

RB strongly agrees that for old established products, such as Over-the-Counter medicines, there should be no requirement for routine PSUR from MAHs. MAHs will, however, maintain database of adverse events which can be made available to authorities when required.

RB agrees that the EMEA should provide the legal basis for the existing Member State PSUR assessment work-sharing.

RB recommends that regarding renewals within the EU, renewal dates should follow the harmonised birthdates rather than the national birthdates. This would reduce workload for the MAHs as the MAH will not have to produce a number of additional PSUR/addendum report/bridging reports to various Member States within small period of times.

RB also recommends that the reference Member State is not only responsible for the PSUR assessment work-sharing but also for the assessment of the renewals.

3.2.9 Clearer safety warnings in product information to improve the safe use of medicines

RB agrees to introduce a new section in the Summary of Product Characteristics and Patient Information Leaflet on ‘key safety information' with a transitional phase of 5-years
However, RB recommends that clear guidelines on what information should go in are published.

Yours sincerely,

Dr Phil BERRY

EU PV Qualified Person
Global Medical Director