Malta's comments on a Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance: Public Consultation on Legislative Proposals

Malta welcomes the proposed Strategy by the European Commission to rationalise and improve the EU pharmacovigilance system. These new and important changes which are being introduced in the pharmaceutical legislation across the EU are envisaged to improve the safe use of medicines across the EU.

On the basis of this Strategy, Malta would like to submit the following comments for consideration by the Commission.

Fast robust EU decision-making on safety issues by rationalising the existing EU referral procedures and reinforcing the committee structure

Under Section 3.2 of the Strategy, which deals with the legislative strategy and the key proposals for legislative change, the Commission notes the establishment of a new committee (to replace the existing Pharmacovigilance Working Party) within the European Medicines Agency (EMEA).

Malta believes that the setting up of such a committee, to specifically deal with pharmacovigilance issues across the EU, is a step in the right direction in order to harmonise safety signals across the EU.

Notwithstanding, Malta would like to refer to the recently established Committee for Advanced Therapies (CAT) which specifically deals with licensing and post-marketing issues (including pharmacovigilance and follow up of efficacy) of advanced therapy medicinal products as defined under Regulation (EC) 1394/2007 on advanced therapy medicinal products.

The rationale behind the setting up of this specific committee within the European Medicines Agency (EMEA) was based on the need to have the required expertise to assess such complex and specialised products. Therefore, Malta believes that a general pharmacovigilance committee will not have the relevant expertise to regulate pharmacovigilance issues for specialised products, such as advanced therapy medicinal products. It is thus suggested that for these products, the Committee for Medicinal Products for Human Use (CHMP) through the Committee for Advanced Therapy Medicinal Products (CAT) is consulted during the risk / benefit assessment.

Simplify informing the authorities about the company pharmacovigilance system and decreasing duplicate Adverse Drug Reaction (ADR) case reports

Malta welcomes the proposed initiative to reduce administrative burden with respect to ADR reporting. Malta also welcomes the proposal to decrease the current duplicate reporting system that exists across the EU for Individual Case Summary Reports via both paper and electronic copies across different Member States.

Malta believes that it would be useful to introduce a specific legal obligation to follow the requirements of the International Conference on Harmonisation (ICH)[1] for electronic submission.

Furthermore, it is important to point out that a lot of precious resources for pharmacovigilance at a National Competent Authority (NCA) level are used up acknowledging Individual Case Safety Reports (ICSRs) sent by companies.

Such a burden can be avoided by better utilising resources, for example, to set up registries or to carry out epidemiological studies which are extremely useful to study post-marketing safety of drug products.

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

The Commission's proposed strategy to introduce a new section for safe use of medicines is very important. It must be highlighted, however, that the current structure as per Article 11 of Directive 2001/83/EC on the Community Code relating to medicinal products for human use, which deals with the Summary of Product Characteristics (SmPC) is extremely rational.

Malta believes that the current structure, as is, is intended to achieve the safe and effective use of medicines authorised within the European Union. More importantly, Malta supports the Commission's proposed initiative to introduce a new section on Key Safety Elements of the Drug Product under Article 11 of the above Directive.

Malta is of the opinion that this new section should appear as a boxed warning, following Section 4.2 on posology.

Justification: A medicine is efficacious and safe if is given to the right person, at the right time and at the correct amount. The Summary of Product Characteristics (SmPC) is to be used by prescribers even at a clinical level. Thus, the correct information has to be presented quickly and easily to prescibers.

The first key questions that prescribers ask before a prescription is written are along the following lines:

To whom do I give the medicines to? And not, who can not take this medicine?

Currently this appears as section 4.1 in the Summary of Product Characteristics (SmPC).

One does not see the point of asking "who can not take this medicine?" if the patient cannot be prescribed the medicinal product, because it lacks a licensed indication.

Similarly, the next key question that needs to be addressed relates to the amount of drug (posology) that can be prescribed.

Following these key questions, the prescriber then needs to know the Key Safety Elements of the drug product.

Malta would also like to make reference to Annex I of the Commission Strategy which outlines detailed proposals for legislative change, particularly Article 101(h)(c) which states that:

[1] *International Conference on Harmonisation*, an international organization that attempts to standardizes globally the regulatory and scientific aspects of clinical research, drug development, and pharmaceutical product registration.

The following provisions shall apply to non-interventional post-authorisation safety studies that are initiated, managed or financed by the marketing authorisation holder and that involve the collection of data from patients or healthcare professionals and that do not fall within the scope of Directive 2001/20/EC:

c) A draft protocol shall be submitted to the national competent authority for studies to be conducted in only one Member State, and to the Committee on Pharmacovigilance referred to in Article 56(a)a of Regulation (EC) No 726/2004 for studies to be conducted in more than one Member State.

Malta supports the above proposed wording with respect to the draft protocol to be submitted to the national competent authority. However, Malta would like to reiterate that problems during scientific assessment of Clinical Trial Applications might ensue if the mandate of the Pharmacovigilance Committee might be expanded to interventional trials (this is not the case with the current text of the proposed Strategy, but might change during the co-decision procedure). It is also worth pointing out that specific expertise is required at committee level to be able to devise post-marketing follow-up studies on efficacy and their ethical implications. The Commision might want to take note of this point

*General:*Malta considers the proposed Commission Strategy to be extremely timely whilst introducing a number of eagerly awaited elements of revision that are required in order to rationalise the current EU pharmacovigilance system.

However, Malta notes that the proposed Strategy does not deal with any pharmacovigilance issues at a clinical trial level. As also highlighted during a recent conference on Clinical Trials in Europe held at the European Medicines Agency (EMEA), one of the key issues to be addressed is the disharmony on pharmacovigilance requirements across the EU for Clinical Trials. In this respect, an eagerly awaited revision might be warranted.