

Dr Catarina Andersson Forsman
Director General
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Dear Dr Andersson Forsman,

Paracetamol

The Association of the European Self-Medication Industry (AESGP) – which represents the manufacturers of non-prescription medicines in Europe – would like to share some considerations related to possible changes in the distribution system currently in place with regard to paracetamol-containing medicines in Sweden.

Apparently, the number of suicide attempts in Sweden linked to overdoses of paracetamol increased between 2000 and 2013. MPA seems to see a link between this increase and changes in the distribution structure.

Evidently we are sensitive concerning inappropriate use of any non-prescription medicine. Risk minimization measures include e.g. restrictions on pack size and age groups. While we do not question the need to implement risk mitigation measures in the given context, we think that further measures related to distribution channels need careful considerations. Patient safety must always be the guiding principle but decisions must also be proportionate and lead with high probability to the intended effect. The expected impact of the planned decision must be weighed against reduced availability for patients in a country like Sweden with a relatively low density of pharmacies.

From our understanding there has been no investigation on the causal link between the increased accessibility of these medicines and the number of overdoses. We were also informed that the Swedish Poisons Information Centre (Giftinformationscentralen) questions that a restriction of distribution channels would have an important impact on the number of overdoses.

From a European perspective, it is important that a sound decision making process is applied as it may have implications in other countries. The Swedish Medical Products Agency is widely seen as one of the leading regulatory authorities in the European Union and has the reputation to take well-founded and scientifically correct decisions. Consequently particular attention is paid from all over the world.

In light of the uncertainties in the given context, we were wondering if a detailed analysis of the impact of a possible restriction regarding retail channel related to the use of paracetamol-containing medicines could be carried out in the upcoming months. This would allow to draw conclusions based on further scientific evidence.

Yours sincerely,



Dr Hubertus Craz
Director General