



070 245 245

A watchful foretaste of Article 45 Annex VIII: things you will wish you knew before Verstegen G¹, Mostin M¹, Descamps A¹.

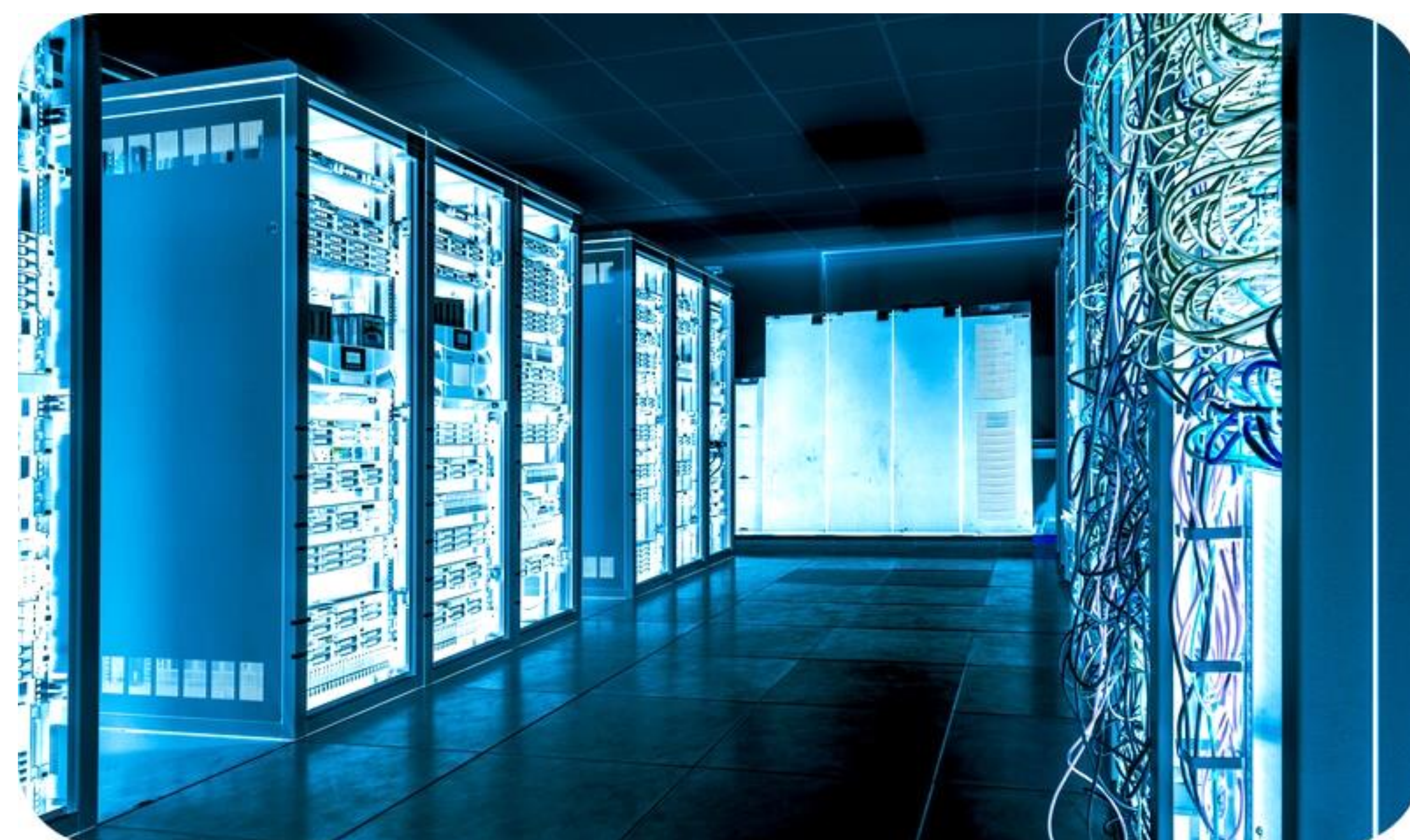
¹Belgian Poison Centre

Objective

Annex VIII to CLP will gradually take effect starting from January 1st of 2021. It is expected to sweeten the notification process through the benefits of a well-designed database and improvement in product identification through the unique formula identifier (UFI), reducing overtreatment of patients. Nevertheless, there are some risks that could make the process turn sour. We aim to sketch a broad picture of the possible implications for Poison Centres.

Methods

We picture our concerns and open questions we stumbled upon during our discussions in the frame of the EU stakeholder consultations.



Results

The number of submissions is expected to increase significantly resulting in a huge amount of data to be handled by ECHA. Subsequently, this will put a huge burden onto appointed bodies and/or Poison Centres that accept submissions in the form of administrative workload, IT-requirements and costs. Additionally, the sheer amount of notifications could make the searchable database, in-house or via the Poison Centre Notification (PCN)-portal, unworkable by slowing it down or by the inability to restrict the number of hits if there is no UFI available.

Moreover, for the appointed bodies that receive the submissions, handling the complex IUCLID format could be a hard nut to crack. If Poison Centres and appointed bodies aren't ready to accept submissions before the deadline, this could threaten the quality of the advice given by Poison Centres. Furthermore, security requirements imposed by ECHA, more stringent than those required for the CPNP-portal, are a major concern, especially for smaller entities. Availability of the PCN-portal could be another issue as Poison Centres that will consult the data online will entirely depend on it. Until now, the Belgian PC has good experiences with industry voluntary notifying non-dangerous mixtures.

The increasing complexity and burden of the PCN-portal could raise the threshold to voluntarily notify, creating the need to install a parallel simplified system, especially for smaller companies submitting voluntary notifications. Notwithstanding these concerns, the harmonized format and product categorisation system as such have generally been welcomed as a progress.

Conclusion

The harmonization of the notification through annex VIII has brought some blessings but also a lot of complexity. It will be a challenge to finetune the tools in time in order to have a system that is suitable for the purpose it has been created for.

Contact: geert.verstegen@poisoncentre.be