Labelling of small packagings containing reference standards for laboratory testing or analysis

Transmitted by the Council of Europe
The European Directorate for the Quality of Medicines & HealthCare (EDQM) in the Council of Europe welcomes the globally harmonised system for classification, labelling and packing of dangerous chemicals.

The EDQM supplies about 2500 reference standards to the control laboratories around the world for the testing of components used in medicinal products, notably pharmaceuticals. The EDQM supplies some of these reference standards on behalf of the United Nations World Health Organization. Because the EDQM considers the protection of the occupational health and the environment essential in addition to the human and animal health, we classify the hazards of our reference standards, provide material safety data sheets and are in process of GHS classifying them. We control the risk also through restricting the quantities supplied in addition to the protection provided by laws, standards and good practises applicable to laboratories and marketing authorisations granted by the competent authorities.

We are in favour of implementing the GHS extensively, but are unsure how to incorporate the requirements of the chapter 1.4, particularly the labelling procedures 1.4.10, to the immediate containers of our reference standards, illustrated in the attachment. We are aware that 1.4.10.5.4.4 (d) allows competent authorities to make derogations to the labelling of small packagings.

Taking into consideration that the reference standards are moving in international trade, we refer to the section 1.1.3.2.1 (a) and (b) of GHS. We propose that the section 1.4.10.5.4.4 labelling of small packings, point (c), would exempt elements from the immediate labelling, if the container is too small and the material is provided as a reference standard for laboratory testing or analysis with the material safety data sheet.