SIP response to the EHDS templates consultation

The Societal Impact of Pain (SIP) Platform, a multi-stakeholder platform led by the European Pain Federation EFIC and Pain Alliance Europe, welcomes common templates for the secondary use of health data and asks that they take account of the ongoing move to the International Classification of Diseases, 11th Revision (ICD-11), in Europe.

SIP welcomed the inclusion in Annex I of the European Health Data Space Regulation of an international classification coding for current, resolved, closed or inactive problems in the patient summary. This is an important step. We encourage the Commission to support Member States in the national roll-out of ICD-11, which came into effect on 1 January 2022.

WHY ICD-11 SHOULD BE ROLLED OUT IN EUROPE

ICD is the international standard for diagnosis, epidemiology, health management and the reporting of diseases and health conditions. ICD-11 provides greater detail, integrates terminology and classification into a single structure, and ensures consistency across languages and cultures. It allows mortality and morbidity data to be recorded, analysed and compared across countries and over time. It also supports semantic interoperability, so that recorded data can be re-used for clinical decision-making, resource allocation, reimbursement and the development of guidelines.

The case is especially strong for chronic pain, the most prevalent health condition in Europe and one of the leading causes of disability worldwide. It affects around 20% of adults in Europe and can limit people's independence, their ability to work and their participation in family and community life. ICD-11 is the first classification to include a systematic representation of chronic pain. Under code MG30, it sets out seven categories, such as chronic primary pain and chronic neuropathic pain, so that chronic pain can be recorded as a condition in its own right and not only as a symptom.

For patients, this recognition helps to validate their experience and reduce stigma, and more accurate diagnosis can support tailored treatment and better access to specialised care. For researchers, standardised coding makes data more comparable. For policymakers, it gives more precise information on the costs, treatment and societal impact of pain.

WHAT THIS MEANS FOR THE TEMPLATES

The draft templates give diagnosis as an example of a selection criterion and include a field for statistical breakdowns and classifications, but do not refer to the classification behind a diagnosis. As Member States are at different stages of moving to ICD-11, the same diagnosis may be coded differently across datasets. We therefore ask that:

- the instructions invite applicants, where relevant, to indicate the classification and version used for a diagnosis criterion or statistical breakdown (for example ICD-11 or ICD-10), reusing catalogue information where available;
- any non-binding practical guidance on the templates include ICD-11 examples, such as the chronic pain categories.

These changes would add little administrative burden for applicants or Health Data Access Bodies, and would apply to every health condition, not only chronic pain. They would make data easier to compare and reduce the risk of misleading comparisons between countries.

SIP would be glad to discuss these points further with the Commission.