Joint Statement on transparency and data integrity - International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO)

ICMRA* and WHO call on the pharmaceutical industry to provide wide access to clinical data for all new medicines and vaccines (whether full or conditional approval, under emergency use, or rejected). Clinical trial reports should be published without redaction of confidential information for reasons of overriding public health interest.

The COVID-19 pandemic has brought into sharp focus the need for information and data to support academics, researchers and industry in developing vaccines and therapeutics; to support regulators and health authorities in their decision-making; to support healthcare professionals in their treatment decisions; and to support public confidence in the vaccines and therapeutics being deployed.

While some initiatives have met with stakeholder support (e.g. WHO International Clinical Trials Registry Platform, US NIH ClinicalTrials.gov database, Health Canada Clinical Information Portal, EMA Clinical Trials Register and Japan Registry of Clinical Trials), not all past efforts have been successful. Often this was because they were unsustainable due to reliance on goodwill or lack of appropriate resourcing**.

The common aim of these initiatives is to ensure that results of research are accessible to all those involved in health care decision-making. The priority should be for new innovative medicines and

vaccines. This improves transparency and strengthens the validity and value of the scientific evidence base. To succeed, initiatives need multi-stakeholder engagement aimed at finding solutions that deliver benefits for public health.

Regulators continue to spend considerable resources negotiating transparency with sponsors. Both positive and negative clinically relevant data should be made available, while only personal data and individual patient data should be redacted. In any case, aggregated data are unlikely to lead to re-identification of personal data and techniques of anonymisation can be used.

The first benefit is public trust. Regulators are opening their decisions to public scrutiny demonstrating confidence in their work.

Another benefit is the possible check of data integrity, a scientific necessity and an ethical must. Data must be robust, exhaustive and verifiable, through peer-review. Data integrity is priceless. Wrong regulatory decisions, made on selected or unreliable data, will affect the patients who receive that medicine.

Lack of public access to negative trials has been identified as a source of bias, which weakens the conclusions of systematic reviews and provides a false sense of reassurance on the safety or efficacy of the medicine.

Publication of data allows science to advance faster, by avoiding repetition of unnecessary trials and waste of resources (human and financial). This also brings benefits by improving the efficiency of development programmes and reducing both development costs and time. Publication of data also allows secondary analyses (and meta-analysis) which have a different or complementary focus.

Many public bodies have made open access a requirement as data are a common good. Providing access to data is also owed to trial participants who contributed physically and took the potential research risks.

Not all data are of high quality, and increased public scrutiny should eventually improve the overall quality of data. Resources however are needed for data sharing, and systems for such access need to be established. Standardisation of data will allow better analyses but is not a requirement.

While there may be a small risk of misuse of data (piracy or data mining for unfair commercial purpose) and misinterpretation, trial data can be put in context when published with the regulatory review of such data.

Data must be published at the time of finalisation of the regulatory review. It cannot be justified to keep confidential efficacy and safety data of a medicine available on the market, or which has been refused access to the market. Some regulators regularly publish the data that support positive approvals, but fewer do this for rejections, while this should avoid false expectations, misuse (accidental or not) and safety issues. Many completed trials on publication platforms only disclose protocols while results remain partial, outdated or unpublished.

ICMRA and WHO are conscious of concerns that some stakeholders may have as regulators move to greater levels of transparency, but we remain confident of the overwhelming positive public health benefits of doing so.

Providing systematic public access to data supporting approvals and rejections of medicines reviewed by regulators, is long overdue despite existing initiatives, such as those from the European Medicines Agency and Health Canada. The COVID-19 pandemic has revealed how essential to public trust access to data is. ICMRA and WHO call on the pharmaceutical industry to commit, within short timelines, and without waiting for legal changes, to provide voluntary unrestricted access to trial results data for the benefit of public health.