Malaria RDTs are in vitro diagnostic medical devices (IVDs): the Latin term “in vitro” means “in glass”, referring to the use of IVD outside the human body. In regulatory practice, IVDs are considered a subset of the large family of medical devices (MD), some of which make contact or are used inside the human body (from tongue depressors to pacemakers)[15]. Of note, in regulatory terms “labeling” refers to labels (for instance on the IVD packaging) as well as to instructions for use.

The International Medical Device Regulators Forum (IMDRF) (http://www.imdrf.org/) - previously the Global Harmonization Task Force (GHTF) – brings together medical device regulators from Australia, Brazil, Canada, the European Union, Japan, the United States of America, China and the Russian Federation. The World Health Organization is an official observer. IMDRF aims to accelerate international medical device (and therefore IVD) regulatory harmonization and convergence through the development of non-binding guidance documents for regulatory implementation. The guidance documents are open-access and have no restrictions on reproduction and diffusion. Relevant to this project is the guidance document “Label and Instructions for Use for Medical Devices” (GHTF/SG1/N70:2011)[15].

The International Organization for Standardization (ISO) (http://www.iso.org/iso/home.html) is a worldwide federation of national standard bodies preparing standards in liaison with international governmental and non-governmental organizations. ISO 18113 “In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)” provides detailed information about labeling of IVD including terms, definitions, general requirements and labelling[18]. ISO 15223 “Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied” lists symbols that convey information to the safe and effective use of the IVD [20]. ISO documents are copyrighted and should be purchased from the ISO website.

In the European Union (EU), the regulatory framework for IVDs is provided by the “In Vitro Diagnostic Medical Device Directive (IVDD 98/79/EC)”[21], operational since 2000 and currently under revision. The European Committee for Standardization (known by its French acronym CEN) further elaborated IVDD 98/79/EC: with regard to labeling, there is the European Standard EN 980 “Symbols for Use in the Labeling of Medical Devices”. CEN Standards are adopted (i.e. translated in national legislation) by each of the EU member countries. Of note, ISO and CEN have close interaction: more than 30% of European Standards adopted by CEN are ISO standards and in 2013, EN980 has been replaced by the adopted EN ISO 15223 standard[20]. In addition to CEN standards, there are guidelines (“MEDDEVs”) produced by experts from manufacturers and organizations involved in conformity assessment procedures. Although they are not legally binding they provide useful information; for labeling, there is the MEDDEV.2.14/3 rev.1 “IVD GUIDANCES: Supply of Instructions for Use (IFU) and other information for In-vitro Diagnostic (IVD) Medical Devices”[22].

The USA Food and Drug Administration (FDA) (http://www.fda.gov/) regulations relating to labeling of IVDs are documented in document Title 21 of the Code of Federal Regulations, Part 809 (21 CFR 809.10)[24]. Requirements are in line with those described in IMDRF guidelines and ISO/CEN standards.

A future evolution is the globally harmonized “Unique Device Identification” (UDI) of Medical Devices” - IMDRF and FDA recently published guidance documents [17,43]. The UDI consists of numeric and/or alphanumeric unambiguous identification and tracking of a specific medical device on the market. It includes a device as well as a production identifier and is linked to a UDI Database. The UDI carrier can be presented by readable characters and/or captured by bar codes, smart cards or other technologies. The marking of the UDI to the device or its package and to all higher levels of package is proposed to be an additional requirement for labeling.