APAC Med
The voice of MedTech

Risk-based Regulatory Oversight of Research Use Only (RUO) Products

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CONTENTS

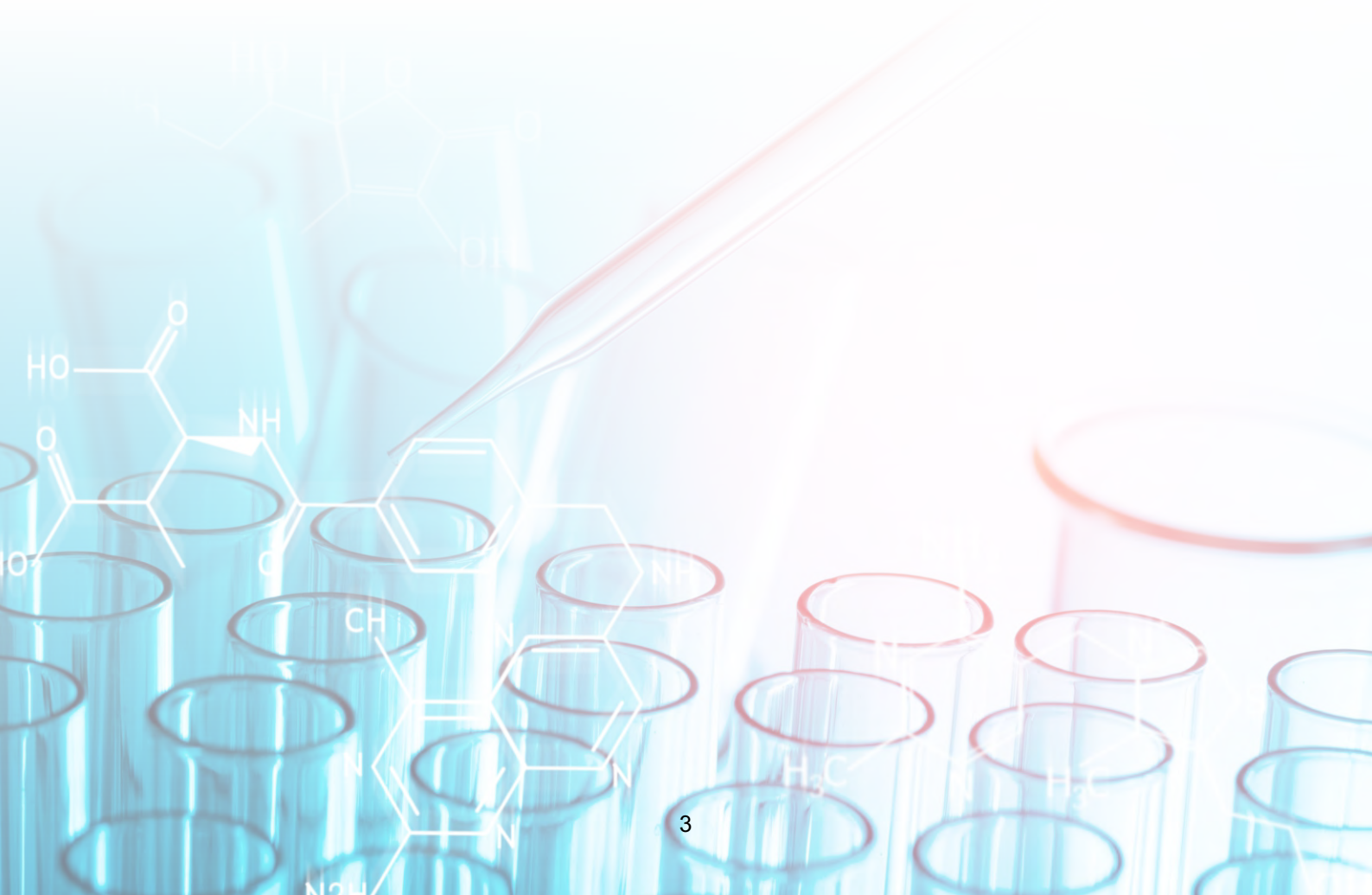
1 Introduction

The Asia-Pacific Medical Technology Association (APACMed) is the first and only regional MedTech trade association in Asia Pacific. In joint efforts with its members, APACMed works with governments and industry bodies in the markets to improve the standards of care for patients through innovative collaborations among stakeholders.

Many of APACMed members are manufacturers of In Vitro Diagnostics (IVDs) as well as manufacturers of Research Use Only Products (RUOs).

Some regulatory authorities, for various reasons, have created highly burdensome regulatory measures for RUO products that are disproportionate to the risks of such products, without addressing the root cause of key concerns such as off-label use with the appropriate stakeholders.

Therefore, APACMed members worked on this paper together to illustrate key stakeholder responsibilities throughout the RUO lifecycle, highlight RUO oversight divergences in key markets, as well as propose recommendations on a risk-based RUO oversight mechanism that is consistent with global good practices.



2 What is a Research Use Only Product (RUO)

There are various definitions for the Research Use Only Product (RUO) across the globe, but it can generally be described as below:

- It is intended for research and development purposes, and not for medical/clinical diagnostic use;
- It should be clearly labeled as "For Research Use Only (RUO)" and additionally be distributed/advertised/promoted in consistent with the labeling;
- It does not fall under the definition of devices (medical devices, IVDs, SaMD), and hence is NOT in scope for general controls for device products, such as registration of manufacturers, listing of devices, GMP compliance, reporting of adverse events, etc.

Research Use Only products (RUOs) can be used in various ways for research purposes. Below are some examples:

1) Fundamental Research

RUO products can be used for fundamental research in the laboratories to understand various aspects of the human body. They are used in discovering and developing medical knowledge related to human disease and conditions. This includes research for academic purposes.

2) Pharmaceutical Research

RUO products can be used in pharmaceutical research for verification of drug compound reactions in animals and humans.

3) Laboratory research for IVD development

During the development process for IVDs, the focus of manufacturer-initiated studies is typically to evaluate design, limited-scale performance, and issues such as usability of the test [8].

More examples of such RUOs include:

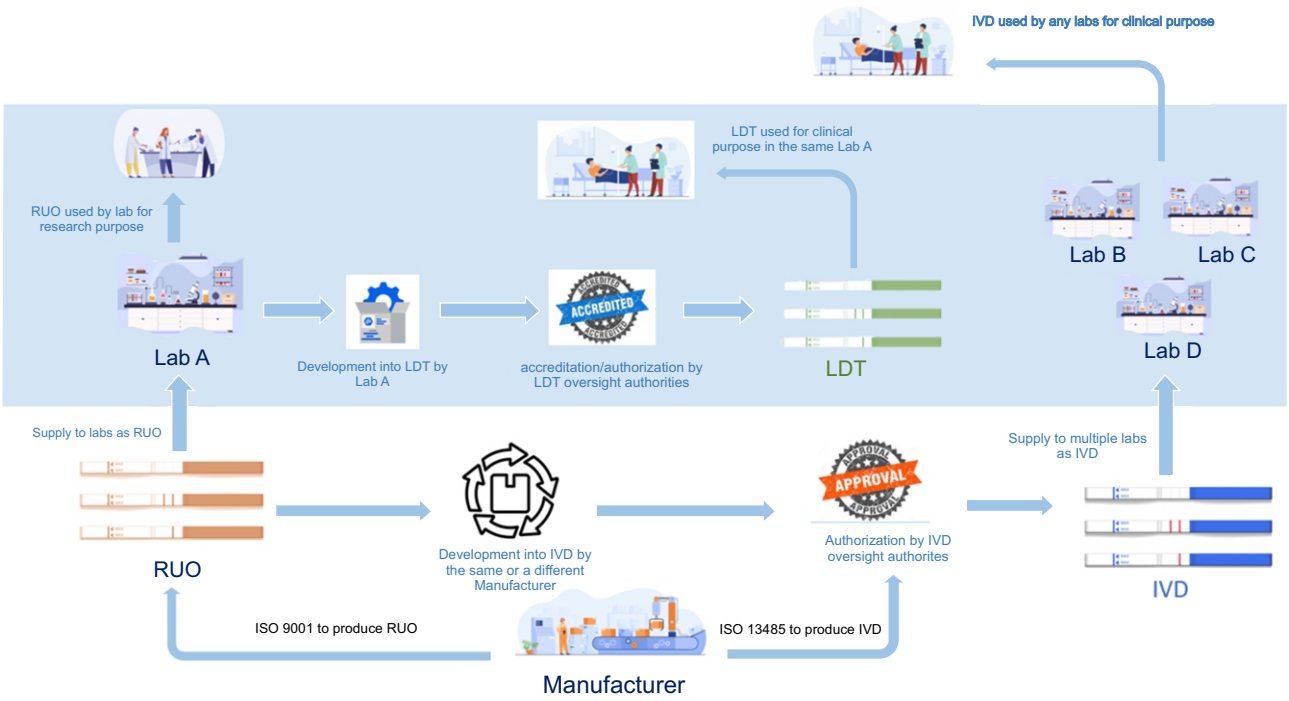
- Tests that are in development to identify test kit methodology, necessary components, and analytes to be measured;
- Instrumentation, software, or other electrical/mechanical components under development to determine correct settings, subcomponents, subassemblies, basic operational characteristics, and possible use methods;
- Reagents under development to determine production methods, purification levels, packaging needs, shelf life, storage conditions, etc.

As illustrated in **Figure 1** below, some commercially distributed RUOs maintain their RUO status indefinitely.

However, other RUOs might be purchased by a laboratory and used as components to be further assembled, modified, developed or validated into a Laboratory Developed Test (LDT); or similarly used by the same manufacturer or purchased by a different manufacturer, to be further developed into In Vitro Diagnostics (IVDs). In this case, it is important to note that LDTs and IVDs will be subjected to regulatory measures imposed by respective authorities, **before they can be claimed/used for clinical diagnostic purpose.**

Such regulatory measures should be covered by specific regulations for Laboratory Developed Tests (LDTs) and/or In Vitro Diagnostics (IVDs), hence it is not in scope for the discussion of this paper.

Figure 1: The Lifecycle of the Research Use Only product (RUO), the Laboratory Developed Test (LDT) and the In Vitro Diagnostic Medical Device (IVD)



3 Divergent practices on RUO oversight across the globe

From a global perspective, most countries are applying a risk-based approach for RUO oversight, by putting basic requirements in place for the RUO product that matches its risk benefit profile and intended purpose.

However, there are a few exceptions where countries are imposing overly challenging requirements for RUO products. Based on APACMed members' observation on the level of regulatory oversight, we have classified markets into three categories (as shown in **Table 2** below).

Table 2. RUO oversight comparison in key markets across the globe

Category 1: Markets exempting submissions for RUOs		**Category 2: Markets requiring simple submissions for RUOs**	**Category 3: Markets requiring complex or burdensome submissions for RUOs**
Australia	Russia	Regulated Middle East markets (e.g. Kingdom of Saudi Arabia, United Arab Emirates, Bahrain, Egypt)	Cambodia
Brazil	Singapore	Myanmar	India
Canada	Thailand	Korea	Indonesia
China	Taiwan		Philippines
EU	USA		
Japan	Vietnam		
Malaysia			

Note: Markets where the general medical device regulation is not enforced as of now, are excluded from this analysis.

Category 1: Markets exempting submissions for RUOs

In these markets, it is well understood that RUO products are not developed or used for diagnostic purposes, and thus should not be regulated as IVD medical devices. **No submission is required for importation or distribution of RUO products .**

Some basic requirements are in place on labeling and advertising of RUOs. For instance, RUO products must be clearly labelled as "For Research Use Only - Not for use in diagnostic procedures", or just the first half, or a similar disclaimer. Additionally, advertising and promotion of RUO products by the manufacturers/distributors must adhere to the same intended use as the labels.

Category 2: Markets requiring simple submission for RUOs

In these markets, in addition to the basic requirements as described for Category 1 markets, authorities are requesting some basic documents for importation or customs clearance.

Such documents may include:

- Product label, and/or
- A Declaration Letter by **the user** to claim that products imported will only be used for research purpose.

It is worth noting that some markets will require a new Declaration Letter prior to the importation for each batch of the same products.

Category 3: Markets requiring complex or burdensome submission for RUOs

Globally, only a small number of markets are requiring complex or burdensome submission for RUOs. Some requirements are either extremely difficult to fulfill, or the requested information is simply not available due to the nature of RUO products.

Notably many of these challenging requirements are only applicable for RUO importers but not for local developers, which may harm the fair business environment in the local market. Examples of such requirements are described below:

1) **Requesting Free Sale Certificates and technical documentation that are generally not available for RUO products**

In some markets, Free Sale Certificates (FSCs) or a similar document, as well as technical documentation, are required for RUO import.

However, it is extremely rare for government agencies to issue FSCs for RUO products that do not fall under therapeutic/diagnostic product scope.

Similarly, a lot of technical data that is available for **IVDs** are not available for **RUOs**, due to the nature in development of these two different types of products. Since RUO products are products that are still in the laboratory research phase of development (i.e. either basic research or the initial search for potential clinical utility), and not represented as an effective in vitro diagnostic product, it is nearly impossible for manufacturers to fulfill such requirements.

2) Requesting documents that are not required by any other countries

Some markets are requesting additional documents that are not required by any other countries, such as:

- Packaging photos from all angles of product packaging, including components inside the packaging;
- Product brochure and application form;
- Evaluation Test Protocol provided by users (to be submitted by manufacturer as post market requirement);
- Instructions for Use (IFU).

Since these documents, or a combination of these documents, are only required by a small number of authorities worldwide, it creates huge burden for manufacturers/distributors without tackling the root cause of the major concerns (i.e. off-label use) with the appropriate stakeholders.

3) Mismatch liabilities with stakeholders across the RUO product lifecycle

As illustrated in **Figure 1**, there are distinguished roles and liabilities for respective parties across the RUO product lifecycle. However, the situation is concerning in some markets where the authorities are mismatching the liabilities among key stakeholders.

For example, some markets are requesting declaration letter from manufactures/distributors to make a disclaimer on the usage of products, which should be solely the user's responsibility/liability instead.

Another example would be the Evaluation Test Protocol, which is owned by the research institutions and can be confidential in its nature. However, some authorities are requesting manufacturers/distributors to submit such information post RUO importation, which is very challenging to fulfil and also a mismatch in liabilities between manufacturers/distributors and users.

4 Impact of an overly burdensome RUO oversight mechanisms

There can be negative impacts on local regulatory resource efficiency, access to the variety of RUO products, the country's research and innovation endeavors and ultimately patient access to innovative medical products if markets have overly burdensome oversight mechanisms for RUO products.

Overly burdensome submission requirements for RUOs increase the workload for both the authority and the industry. A survey conducted among a sample of five APACMed member companies showed that out of these five sampled companies, the total estimated number of RUO products adds up to **7,226**. This could translate into a big volume of regulatory resources allocated for these very low-risk RUO products in such markets.

As these markets have much more burdensome requirements compared to the rest of the world, the importation and supply of various high quality RUOs into the market will be restricted or delayed, due to commercial considerations, challenges in obtaining certain documents, etc.

Consequently, due to the limited access to the variety of RUO products, this may hinder the non-clinical research and education activities of the academia and research institutions. This will then negatively impact local research and innovation capabilities, which is directly related to the scientific advancement and economic development of the market.

5 Case Study: Change of RUO regulatory practice in Thailand

In the past decade, the Thailand FDA spent significant regulatory resources on RUOs import control, requesting manufacturers to submit IFUs as well as a legalised statement letter issued by an overseas government agency.

Fulfilling such requirements was extremely challenging for the industry because only a limited number of health authorities globally will provide a declaration such that the product is for research use only. This has since hindered the import of RUOs into the Thailand market as well as the researches relying on such products.

After an arduous journey and joint efforts among **government agencies, academic hospitals/laboratories, and industry bodies**, a common understanding was reached that imposing registration requirements and import control on RUO products are not the appropriate or effective measures to minimize the misuse or off-label use of RUOs for patient safety.

It was also understood for scenarios where laboratories purchased RUO products as components to further develop into Laboratory Developed Tests (LDTs), it becomes the laboratory's responsibility to validate the product performance and safety according to specific requirements about LDTs, as well as go through the accreditation/authorization process with respective authorities, before it could be claimed or used for clinical diagnostic purpose.

The Thailand FDA and all key stakeholders (including **manufacturers, distributors, laboratories and doctors**) concluded that, registration and import control of RUO products may create huge barriers for scientific research in the country, hence RUO products should not be classified or regulated as IVD medical devices in Thailand.

On 7 May 2021, Thailand FDA announced *the Guidance for Industry and other authority on RUO products*, where it clearly states "the production, import or sale of RUO test kit products is not regulated under the *Medical Devices Act B.E. 2551 and the Amendment (No.2) B.E. 2019*". The guidance focused on the promotion, marketing, and distribution/sale of RUO products.

As Thailand just rolled out its new medical device regulation in accordance with the ASEAN Medical Device Directive (AMDD) in February 2021, the exemption of RUO products from this regulation was a timely enabler for Thailand authorities to optimize regulatory resource efficiency and to focus regulatory resources on products with higher risks and bigger impact on patient safety.

6 Key Recommendations

In summary, RUO products are for research use only and are not intended for clinical diagnostic purpose.

RUOs do not fall under the definition or regulation of devices (medical devices, IVDs, SaMD), hence are not in scope for general controls for device products, such as registration of manufacturers, listing of devices, GMP compliance, reporting of adverse events, etc.

Therefore, APACMed is recommending a globally harmonized and risk-based regulatory oversight for RUO products as summarized below.

Definition of RUOs

Respective Authorities are recommended to include the RUO definition into the local medical device regulation or relevant regulations, whereby the regulation clearly exempts **appropriately labeled and properly marketed RUO products** from registration requirements for import and/or distribution.

Labeling & Distribution of RUOs

RUO products should be appropriately labelled, bearing the statement as "For Research Use Only - Not for use in diagnostic procedures", or just the first clause, or a similar disclaimer. The RUO labeling is meant to serve as a warning, to prevent such products from being used in clinical diagnosis.

Respective authorities should look into general distribution practices (e.g. labelling, advertising and promotion), to ensure that verbal or written statement made by the manufacturer are consistent with the RUO labeling.

In general, RUOs should be exempted from regulation submission for the purpose of import and/distribution. But for countries that still require certain process/documentation for customs clearance, then a simple submission of Product Label and/or a Declaration letter from the user should be sufficient.

Roles and liabilities across the RUO lifecycle should be clearly and reasonably defined as well as understood by each of the relevant parties.

Laboratories Oversight

Laboratories are important stakeholders to consider and include in the discussion of regulatory oversight for RUO products. Notably, laboratories are regulated under a different regulatory system from manufacturers.

But because laboratories are the users of RUO products, it is critical to contemplate and consider their role in the appropriate use of RUO products.

We recommend, as a starting point, respective regulatory authorities collaborate with laboratory accreditation authorities to improve laboratory compliance and strengthen good laboratory practices. This collaboration can continuously improve the quality systems for laboratories and leverage best practices from other markets. Some examples of good practices include, but are not limited to, the Good Laboratory Practice, and laboratory accreditation programs. Appropriate laboratory regulation is imperative to ensure appropriate use of RUO products.

7 Conclusion

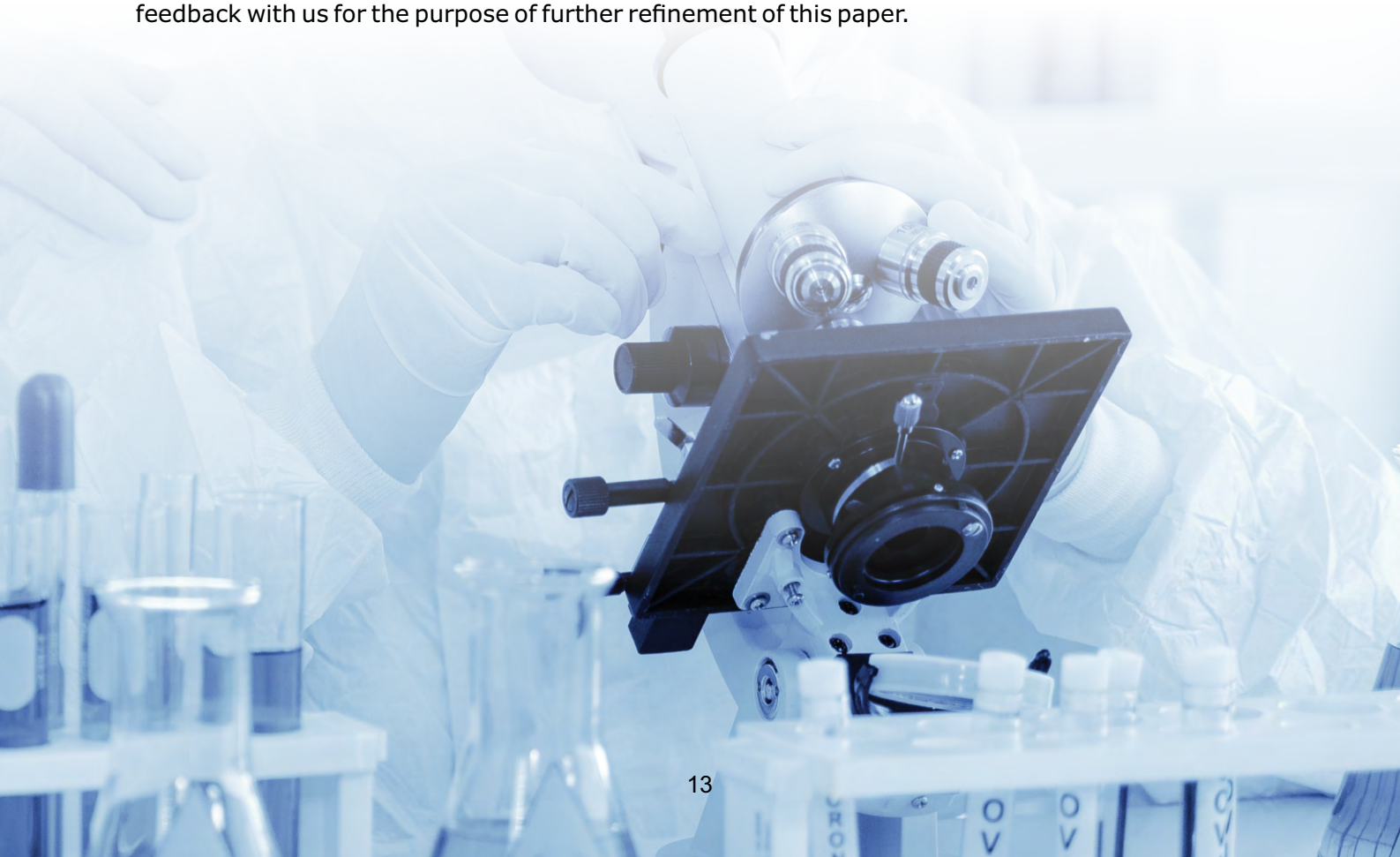
As a unified industry body, APACMed shares the concerns with authorities about the off-label use of RUO products, which may cause harm to patients, as these products have not been designed/manufactured/validated/verified for clinical diagnostic purposes.

Therefore, we are committed to collaborating with authorities and remaining compliant by fulfilling our responsibilities as RUO manufacturers in production, labeling and distribution of RUO products.

Meanwhile, our recommendation (as detailed above) for respective authorities is to evaluate the RUO oversight measures from a **risk-based and lifecycle perspective**, focusing on the root cause of the compliance issues, assigning the liabilities to the appropriate stakeholders, and increasing collaboration across relevant ministries to ensure proper access to RUO products that are vital for local innovation.

More importantly, we see the immense benefits for governments to increase investment in laboratory quality systems and promote good laboratory practices. This will help address the root causes of key concerns described in this paper.

Finally, this paper was based on the publicly available information and observations made by APACMed members. We understand the global landscape is changing rapidly and thus welcome policy makers, regulators, industry peers, researchers, and other experts to share comments and feedback with us for the purpose of further refinement of this paper.



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[8] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of In Vitro Diagnostic Device Evaluation and Safety, FDA (November 2013). Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only, Guidance for Industry and Food and Drug Administration Staff.
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9 Appendix: A list of RUO definition and level of oversight by country

Category 1: Markets exempting any submissions for RUOs
Category 2: Markets requiring simple submission for RUOs
Category 3: Markets requiring complex or burdensome submission for RUOs

Country	RUO definition	Level of RUO regulatory oversight
ASEAN	Research Use Only is where the device is made available to institutions/laboratories to be subject to studies intended for collation of data only. The product is not intended for any medical purpose or objective [1]. Given that RUO products are not intended for any medical purpose or objective, they are not subject to AMDD requirements. The intended use of an RUO product—research, not diagnosis—presumptively removes it from the definition of a medical device under the AMDD. As a practical matter an RUO is essentially unregulated under AMDD.	**Category 1**
Australia	While RUO, IUO, ASR products may be commercially supplied, they are not intended by the manufacturer to be used for an in vitro diagnostic purpose and will not be included on the Australian Register of Therapeutic Goods (ARTG) [2] . Representation for therapeutic use includes verbal or written statements made in relation to products as part of their labelling, advertising or promotion (regardless of the RUO label).	**Category 1**

Country	RUO definition	Level of RUO regulatory oversight
Brazil	Products intended for research use only, including those imported and labeled as RUO - Research Use Only [3].	**Category 1**
Cambodia	No official definition for RUO. RUO products are regulated as Medical Devices.	**Category 3** Free Sales Certificate (FSC), ISO certificate, Technical Documents are required.
Canada	IVDDs which are labelled "For Research Use Only" (and are not otherwise labelled or otherwise represented by a manufacturer for a specific diagnostic application, or labelled with specific performance characteristics, or a bibliography listing articles referring to the use of the marker for a specific application) are exempted from the Medical Devices Regulations [4]. Health Canada outline that The use of "For Research Use Only" labelling applies to a medical device in the laboratory research phase of development. It's not intended for a device represented for use in clinical trial or clinical diagnosis, screening or surveillance. A commercial medical device is not considered to be in the "research phase" of development and cannot be labelled "For Research Use Only" if it: • Has validated performance characteristics; • Has instructions-for-use documents citing performance claims or; • Is under review for regulatory approval by Health Canada (or another regulatory jurisdiction).	**Category 1**

Country	RUO definition	Level of RUO regulatory oversight
China	No specific RUO definition. RUOs are only allowed to be used for research and not for commercial purposes.	**Category 1**
EU	The IVDR clearly states that the regulation does not apply to products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.	**Category 1**
India	Products meant for ''Research Use Only'' to be used in academic research institutions and not meant for any diagnostic or therapeutic purpose.	**Category 3** RUOs are not regulated under the provisions of Drugs & Cosmetics Act and Medical Devices Rules there under. However, as per the CDSCO notification June 19th 2020, the applicant needs to submit an undertaking (per shipment) in this regard at the concerned port office of CDSCO stating that the imported products shall be used by the research institution for academic research purpose only and shall not be used for any in-vitro diagnostic/ therapeutic purpose in diagnostic labs/ hospitals. [5]
Indonesia	Research product (Research Use Only/RUO) is medical device and in-vitro medical device product that is in research development stage and has not been approved to be used for clinical purposes; or which is declared RUO by the authorized body in country of origin of the manufacturer.	**Category 3** 1. Application letter stating product name, list number and amount to be imported

Country	RUO definition	Level of RUO regulatory oversight
		2. Instructions For Use 3. Additional label state RUO on the products 4. Statement letter for using for local evaluation and or research only 5. Legalized statement letter from manufacturer 6. Evaluation Test Protocol from institution (this is for post-market reporting as in commitment letter submitted by license holder during pre-market application). *Adhoc requests from MOH for packaging photos (photos from all angles of product packaging, including components inside the packaging).
Japan	No official definition for RUO. A reagent distributed "with purpose to be used only" for (non-clinical or clinical) research use, and not for diagnostic nor treatment. Reagents labelled as IVDs in other countries are sometimes imported to be sold as RUO, with adding indication to restrict use in diagnostics. • To add a label declaring it to be an RUO. • To comply with local regulation in handling and storage (for the ones with substances hazardous, poisonous, flammable etc.) • To provide Safety Data Sheet in compliances to local substance regulation.	**Category 1**

Country	RUO definition	Level of RUO regulatory oversight
Korea	The Korean IVD Act does not define RUO but it is defined and regulated under the Chemicals Control Act, as well as Act on the Registration and Evaluation of Chemical Substances. According to local laws and regulations, RUO Reagent refers to a chemical of a specific purity used for detection or quantification of a substance by a chemical method.	**Category 2** A simple submission of documents is required for RUO import and customs clearance
Malaysia	No official definition for RUO.	**Category 1**
Myanmar	No official definition for RUO.	**Category 2** A submission of Declaration Letters from all relevant customer/ institutes claiming Research Use Only purpose is required for RUO import and customs clearance
Philippines	Medical devices strictly for research, clinical trial, exhibit, and/or donated brand new medical devices are exempted from Notification and Registration. However, the researcher, institution, and/ or user of such devices shall apply for a Certificate of Medical Device Listing (CMDL).	**Category 3** Free Sales Certificate and Letter of request from the users/institutions are required to apply for CMDL.
Russia	RUO is out of scope of IVD and chemical regulation is applied. RUO attestation letter is required only if an institution is involved in the local studies of the Diagnostics version of the device.	**Category 1**
Regulated Middle East markets (e.g. Kingdom of Saudi Arabia, United Arab Emirates, Bahrain, Egypt)	RUO devices must have no medical intended purpose and be labelled ''For Research Use Only'' to avoid their potential misuse by institutions or laboratories. Such devices are not considered Medical Devices.[6]	**Category 2** Label example clearly stating "educational or non-clinical research purposes" and declaration on letterhead is required to be submitted. A 90-day Medical Device Importation License (MDIL) will then be granted.

Country	RUO definition	Level of RUO regulatory oversight
Singapore	Products intended by the product owner for Research Use Only (RUO) and clearly labelled as RUO are not medical devices. They are generally intended for research and development purposes and not for human or clinical use. RUO kits are not intended for clinical use and do not fall under the official definition of medical devices, hence are not subjected to premarket registrations in Singapore. Analysers that are not manufactured, sold or represented by manufactures for use in IVD applications are not considered to be IVDs. This includes products sold for general laboratory applications and products that are labelled ”For Research Use Only” (RUO). [7]	**Category 1**
Taiwan	No official definition for RUO.	**Category 1**
Thailand	Thai FDA recently announced a new guidance on May 7 - Guidance for Industry and other authority on RUO products where they clearly state the production, import or sale of RUO test kit products is not regulated under the Medical Devices Act B.E. 2551 and the Amendment (No.2) B.E. 2019.	**Category 1**
USA	RUO products are IVD products in the laboratory research phase of development and not represented as effective IVDs (21 CFR 809.10(c)(2)(i)). RUO products are reagents, instruments, or systems under development and evaluated for their potential use as IVDs (for evaluation of design, performance, usability, etc.). RUO products are unregulated in the U.S but have to be labelled with the following statement: "For Research Use Only. Not for use in diagnostic	**Category 1**

Country	RUO definition	Level of RUO regulatory oversight
	procedures". Labelling a product as such permits it to be used by researchers, who can evaluate usefulness for a specific diagnostic purpose. Beyond the labelling statement, FDA regulations do not mandate any other restrictions or limitations on RUO products, and RUO manufacturers do not have to register or list their RUO products with FDA or comply with manufacturing standards. RUO products can be offered for sale without any FDA clearance or approval. RUO products can be also used in conducting nonclinical laboratory research with goals other than commercial IVD product development and are used in basic life science research and not intended for further clinical diagnostic use development. In this case, these RUOs are used to carry out research and are not, themselves, the object of the research. As good marketing practices, RUO products must never be represented as effective IVD products. And no specific disease, condition, or diagnostic performance claims can be made for RUO products. In the other side, an IVD product that is inappropriately labelled as RUO may be also considered misbranded or adulterated due to the lack of premarket notification (510(k)) or premarket approval (PMA) if distributed/or labelled for clinical diagnostic purpose. [8]	
Vietnam	RUO is used for life science research use only. It is not tested for use for diagnostics procedures. It is not regulated under the Medical Device Regulation. It falls under the Chemical Substance Law, but no submission is required for import.	**Category 1**

About APACMed

The voice of MedTech

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific, representing both multinational corporations as well as small and medium enterprises, together with several local industry associations across the region.

Headquartered in Singapore, APACMed's mission is patient-centric, and we strive to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific. We are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

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