



## Annual Report 2020

QUAMED

QUALITY MEDICINES FOR ALL

17 RUE ROUCAYROL 81100 CASTRES FRANCE

[www.quamed.org](http://www.quamed.org)





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## 1 President's report

I am pleased to introduce this QUAMED Annual Report, which is the result of our determination for more dynamic communication and development of our association, which we want to be more present to our members and partners but also to the outside world.



The year 2020 was marked by several changes within QUAMED and its structure. It was also a year with multiple and important challenges and achievements.

In May 2020, Olivier DeSanti left the organisation after having built it up again from a low point in early 2017 and have thus made it possible to keep it afloat. We would like to thank him once again for all his efforts.

At the same time, we would like to thank Ed Vreeke, who proposed to take over temporarily with the aim of guiding QUAMED through the Covid-19 pandemic and towards a financially viable future, and who since May 2020 is guiding QUAMED with a masterful hand!

The main challenge was posed by the Covid-19 pandemic which came with travel restrictions and much uncertainty in terms of planning of field activities. This has had a significant effect on our activities.

Despite a financially fragile starting situation and extra handicapped by the pandemic and the departure of former CEO, there have been important achievements. This has been made possible thanks to my colleagues in the board of directors who have supported the operational team where possible in determining the way forward. On a very practical level, individual members such as Laura Laughlin, Corinne Pouget, Sandrine Cloëz, Jason Bower, Kashi Carasso and others have invested significant time in working on strategic, organisational and operational issues that have all contributed to making the organisation more robust. We also would like to thank them wholeheartedly for their constant commitment.

We lastly would like to thank all our organisational members and the subscribers to our database for their patience and for having stuck with us despite our incapacity to go to the field this year.

One of the highlights of 2020 for me has been the opportunity to welcome new organisational and individual members. This has made us stronger and every new member brings us closer to achieving our vision of increasing access to quality assured medicines.

Daniel Vandenberg,  
Brussels, 28 January 2021

## 2 Executive Director's report

The board of directors allowed me to take over temporarily from Olivier DeSanti with as objective to guide QUAMED through the Covid-19 pandemic and steer it towards a financial sustainable future. Initially for 6 months, which has been extended until July 2021.



The year 2020 was quiet from an activity point of view. Where in 2019 we visited more than 60 suppliers in 12 countries, we visited none in 2020. Our income generating activities were limited to two MQAS audits, one full training course for ACAME, and two webinars (on quality assurance of medical devices and of personal protective equipment) also for ACAME. Fortunately, we maintained income from the subscribers to our database and we had some income through the membership fees. This has kept us financially afloat.

The operational team has worked hand in hand with QUAMED individual members on strengthening our internal organisation, reviewing and updating our standard operation procedures and our communication with our members and other stakeholders, in preparing the Quality Certification Programme (QCP) through working group discussions and the development of a member-only webinar series. We created a planning and reporting structure that will see regular annual plans and reports (like this one) shared with the members and we will be able to present our members with a 3-year strategic plan in the next general assembly.

We were also able to renew or increase our time investment in relationships with former, current, and new partners at multi-lateral and bi-lateral level. Since mid-year we adopted a communication strategy with as aim to improve the communication with our members and other partners using a variety of communication channels.

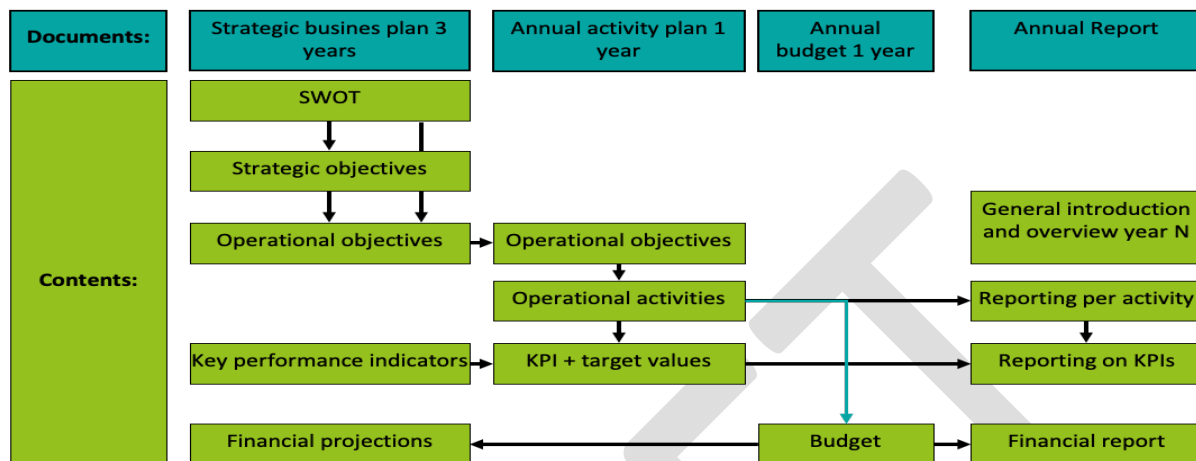
Some of our highlights also include having successfully passed our first ever internal audit and having been submitted for the first time to external audits (2) with positive results, applying for Non-State-Actor status with the WHO and signing a framework agreement with UNHCR. We also count as a highlight the preparation for an ISO 9001 certification by developing a quality management system manual and improving the standard operating procedures. The final highlight for me was the efficient collaboration with our technical coordinator and having been able to add an administrative and finance officer to the operational team.

We think that despite the challenges, all activities together have contributed to reinforcing QUAMED's position as one of the leading not-for-profit organisations in the field of pharmaceutical quality assurance.

## 3 Introduction planning and reporting cycle

This annual report is the first one using a new format. It is not yet associated with objectives, planned activities and key performance indicators. These will be introduced in the 2021 plan

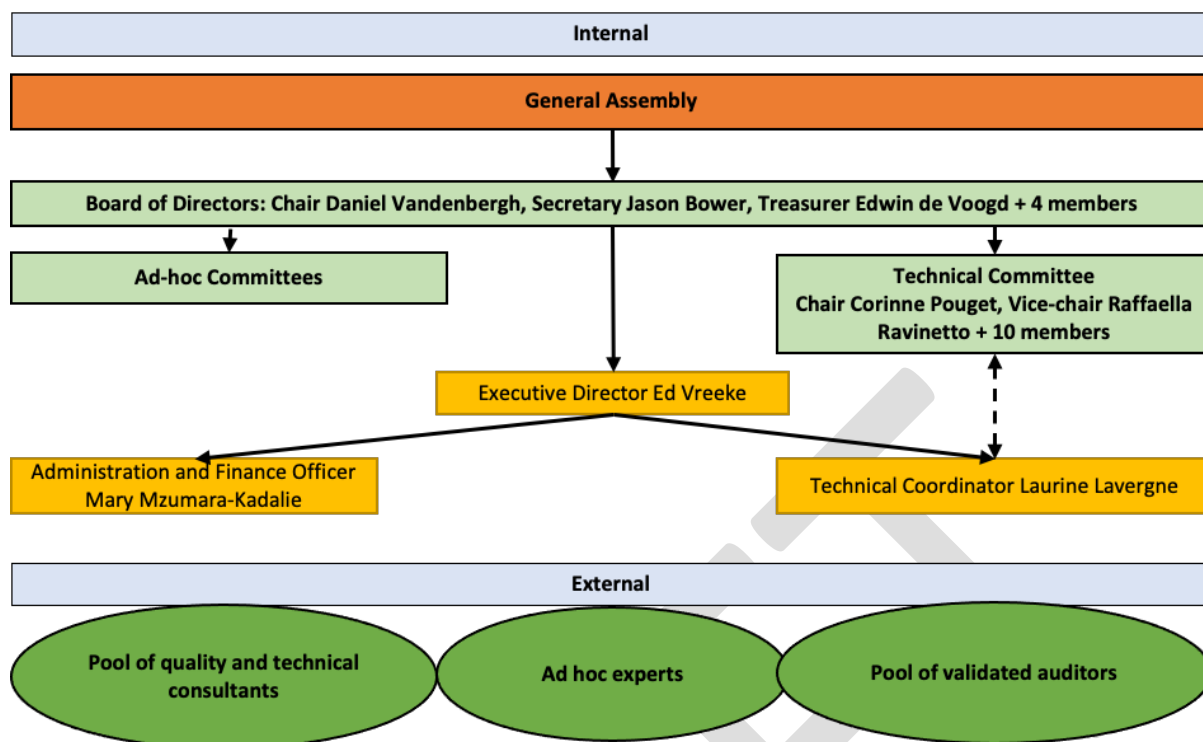
and budget. The figure below shows the planning and reporting documents and their linkages. They will be the ones that will be presented to the membership in the coming years. We trust that this approach will allow for a transparent monitoring of the executive team by the board of directors and the General Assembly.



#### 4 QUAMED's organisation

QUAMED (Quality Medicines for All) was formed in 2010 under the auspices of the Institute of Tropical Medicine in Antwerp. In 2016, QUAMED became an independent, France-based, not-for-profit association (governed by the law of 1901). QUAMED is registered at 17 rue Roucaÿrol, 81100, Castres, FRANCE.

We are a global membership organization. International Non-Governmental Organizations (NGOs), national pharmaceutical procurement centers and engaged individuals constitute most of our members. At the end of 2020 we had 42 members: 26 organizations and 16 individuals. The governance and organizational structure are composed of the General Assembly, the Board of Directors, a Technical Committee, and the Operational Team.



## 5 QUAMED’s General Assembly

The Ordinary General Annual Meeting of QUAMED was held on 09 June 2020. The meeting was held by videoconference (Zoom) due to the restrictions on travel related to the Covid-19 pandemic. It was a good opportunity to have many members participate without having to incur travel related costs. There were 13 organisational members present and 9 individual members. In addition, 20 invited guests participated. The narrative and financial reports were accepted without changes. One new organisational member and six new individual members were welcomed.

The board of directors were elected for a mandate of 2 years (until the GA of 2022). The current members are: M. Daniel Vandenberg, M. Daniel Berman, M. Ed Vreeke, Mme Corinne Pouget, M. Edwin de Voogd, M. Hugo Randé and M. Jason Bower.

The board decided that M. Vandenberg would remain the president. M. Bower has taken up the role of secretary and M. de Voogd the position of treasurer.

## 6 QUAMED’s Board of Directors and its committees

The Board of Directors (BoD) had 4 regular meetings in 2020. Several additional meetings were organised around specific topics such as the strategic business plan, the annual plan and the bylaws. The signed minutes of each meeting are available.

The BoD has one standing committee: the technical committee. Two of its members resigned for personal reasons. The technical committee did not have formal meetings in 2020 but its chair, vice-chair and its individual members met regularly around different technical issues in different configurations. As such the technical committee contributed significantly to the finalisation of the technical standard operating procedures. It also continues to be a support for the technical coordinator.

## 7 QUAMED staff

The end of May 2020 the employment contract of M. Olivier De Santi ended. He was replaced by M. Ed Vreeke who took the position for a period of 6 months to guide the organisation throughout the Covid-19 pandemic. His tenure was extended by the Board of Directors in their December meeting, until the 30<sup>th</sup> of June 2021. Ms. Laurine Lavergne is the technical coordinator since February 2020. Since early October, Ms. Mary Kadalie-Mzumara joined QUAMED as the administrative and finance officer.

## 8 QUAMED activities

### 8.1 GDP technical visits, GDP, MQAS and GMP audits

Two MQAS remote audits were still ongoing at the end of the year. They were done on behalf of MDM France, Action Damien and Light for the World.

One local market assessment (LMA) with 10 GDP technical visit had been planned for the Ukraine but had to be postponed to early 2021 because of Covid-19 related travel restrictions.

A pre-LMA survey was done for one pharmaceutical trader and two pharmaceutical suppliers based in France but with supply lines to Libya.

### 8.2 Training

We were contracted by ACAME to conduct a training on the principles of quality assurance. This training consists of 10 modules. We took the opportunity to update all the modules.

In addition, we commissioned consultants to develop 2 webinars:

- Quality assurance of personal protective equipment (PPE), Covid-19 related
- Quality assurance of medical devices

Both webinars have been presented to ACAME.

Late in 2020, it was decided to develop a member-only webinar series to increase the value of a QUAMED membership. A small committee consisting of 2 members and the technical coordinator have started designing the program. The intention is to have one webinar every



6 weeks. The first member-only webinar was the PPE webinar which was organised in both French and English.

### 8.3 Technical assistance

We developed and submitted three proposals for technical assistance activities:

1. In May we developed a proposal for the **“Quality Assurance Strategy shaping”** for the Global Fund, Bid Reference: TGF-20-029. The proposal was developed together with her. The GF never informed us of the result but we assume that it was awarded to another bidder.
2. In November we submitted a proposal to ACAME for the **“Recrutement de 2 experts internationaux en AQ pharmaceutique pour la réalisation des audits qualité finaux de 5 CNA membres de l’ACAME, bénéficiaires du projet PERFAPPRO”**. AO n° ACAME/2020/PERFAPPRO/01. We were informed that we will be notified of the result by mid-January 2021
3. In December we submitted a proposal to the RCE-VIHSCM in Kigali, Rwanda for the **“Development of the master’s degree Programme in Pharmaceutical Quality Assurance and Quality Control”**. We initiated the development of a consortium with the ITM, MEDS Kenya, the University of Western Cape and Action Medeor as members. QUAMED is leading the consortium. We will be notified of the result in the first quarter of 2021.

### 8.4 Research

We collaborated with the ITM on an **“Evaluation of quality systems of medical product procurement centres and distributors: challenges and opportunities of remote GDP technical visits and sourcing assessments in low- and middle-income countries hard-to reach during current COVID-19 pandemic”**. Our technical coordinator is a co-investigator. The study took successfully place in Afghanistan with the involvement of Medair and Relief International. An abstract will be presented early 2021 and a publication is scheduled for later in 2021.

### 8.5 Other activities and achievements

QUAMED formally applied to become a “non-state actor in official relations with the WHO”. This was done to create a formal framework in which to discuss further the roll-out of the quality certification program (QCP).

The “Guiding Principles for Donors Regarding Quality Assurance of Essential Medicines and other Health Care commodities” issued by the Inter-Agency group for Supply Chain Management included a reference to the QUAMED audits and standards.

QUAMED was invited to make a presentation to a USAID organised meeting on the role of private pharmaceutical suppliers in low- and middle-income countries. The presentation that was given was based on the three articles developed by ITM/QUAMED and that were published in the BMJ.

QUAMED initiated contacts with a variety of bi- and multi-lateral organisations to start a process of recognition of future QCP certificates.

## 9 QUAMED internal organisation

The quality of our organisation is determined by a combination of the quality of our tools, the quality of our standard operation procedures (SOPs) and the quality of the people employing the tools and the procedures.

In 2020, our technical coordinator, with the support of two of QUAMED's founding members, has updated our technical visit and audit tools, our technical SOPs and our expert and auditor database. We have organised one internal audit that resulted in a detailed report with a CAPA. The CAPA was implemented by the technical coordinator. The technical SOPs (SOP-Q-XXX-) were audited by 2 of our member organisations and did not give rise to major comments.

We have updated, developed, and implemented administrative, financial, human resources and governance SOPs in preparation of an ISO9001 certification audit in 2021.

Bylaws were developed and adopted by the Board of Directors for presentation to the General Assembly in the 2021 meeting.

A planning and reporting procedure was conceived and a strategic business plan 2021 -2023 and an annual plan 2021 were written. These plans were discussed and adopted by the board of directors in their December 2020 meeting.

## 10 QUAMED membership

We started the year with 19 organisational members and 11 individual members. Throughout the year, we had the opportunity to welcome an additional 7 organisations and 5 individuals. Their membership was accepted by the General Assembly or by the Board of Directors.<sup>1</sup>

At the end of the year, we therefore have 26 organisational members and 16 individual members. Of the 26 organisational members, there are 25 associative members (with right to vote) and 1 adherent member (without the right to vote). All individual members are associative members.

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<sup>1</sup> The board of directors gives tentative approval for memberships while the General Assembly has to confirm the membership.

We are continuing to actively approach eligible organisations with the aim to convince them to become a member. We are specifically targeting organisations based in the Global South to strengthen the global character of our organisation.

## 11 QUAMED database

At the end of 2020, we had 24 subscribers to our database. Because of the low level of technical visits and audit activities little new information was added. We have started working and discussing with other organisations that do pharmaceutical audits to see if and how we can include their audit reports in our database. We are also preparing a more regular upload of WHO PQ reports and other publicly available audit reports that may be interesting for our subscribers.

## 12 QUAMED policies

### 12.1 QUAMED Quality Certification Programme (QCP)

A market survey was done among pharmaceutical wholesalers, manufacturers, and other stakeholders such as regulatory projects, pharmaceutical associations, and others. Overall, the conclusion that we have been able to draw is that there is interest in the QCP from a suppliers' side on the condition that the QCP will be recognised by a significant number of buyers and funders.

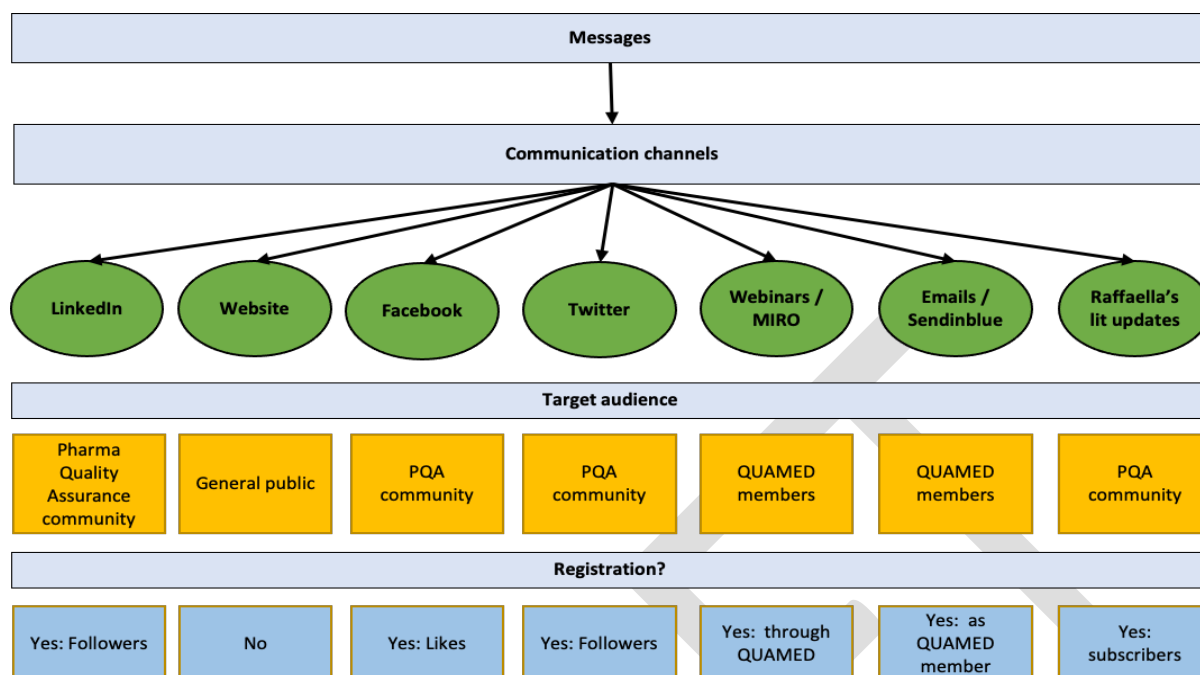
On that basis we have decided to move ahead. The final steps before launching the QCP are (i) to develop SOP specifically describing the QCP related processes and (ii) to seek legal advice on the legal and regulatory risks associated with a certification programme.

The groundwork is done and once the last two steps are completed the QCP will be launched.

### 12.2 QUAMED communication policy

To increase our name recognition, we developed a communication policy. The policy is based on regular and consistent communication using different channels and projecting as much as possible similar messages related to pharmaceutical quality assurance, access to medicines and organisational developments. In the ideal scenario a message is broadcasted through (i) our website in French and English), (ii) Twitter in English, (iii) LinkedIn and (iv) Facebook. In addition, we have continued with the regular literature updates edited by Raffaella Ravinetto and we approach our members specifically through targeted emails and through our webinar program.

The different communication channels target slightly different audiences as shown in the figure below.



### 13 QUAMED financial report

The income for the year 2020 consisted mainly of the membership fees, the subscription fees and payments for activities that had started in 2019 and were finalised before March 2020. The costs were relatively modest as we had less activities (lower cost of sales) and we had significant voluntary (non-remunerated) contributions from QUAMED’s individual members. The running costs for 2017 and 2018 have been included in the costs of sales for 2017 and 2018.

QUAMED 2020 - Summary financial report				
	Actual 2017	Actual 2018	Actual 2019	Actual 2020
<b>Sales</b>				
Annual Income	105,152	173,748	318,963	113,798
Exceptional Income	164,731	6,115	0	0
<b>A Total Sales</b>	<b>269,883</b>	<b>179,863</b>	<b>318,963</b>	<b>113,798</b>
<b>Cost of Sales</b>				
Direct Costs	268,243	145,807	159,785	46,931
Others				
<b>B Total Cost of Sales</b>	<b>268,243</b>	<b>145,807</b>	<b>159,785</b>	<b>46,931</b>
<b>Expenditure for Running Costs</b>				
Administration Costs			18,415	16,319
Personnel Costs			134,117	72,007
<b>C Total Running Costs (RC)</b>	<b>0</b>	<b>0</b>	<b>152,532</b>	<b>88,326</b>
<b>Total expenditure (B+C)</b>	<b>268,243</b>	<b>145,807</b>	<b>312,317</b>	<b>135,257</b>
<b>Operating result (A-(B+C))</b>	<b>1,640</b>	<b>34,056</b>	<b>6,646</b>	<b>-21,459</b>