FLEXmag

#15
July 2020

The Technoflex group news magazine

The AMA,
the African super regulator

Excellence in customer service

Stock shortages and drug prices under control

Editorial

Olivier Chesnoy
President & CEO

This 15th issue reaches you in a very particular context, that of the Covid-19 pandemic which has hit and continues to affect many areas of the world. It gives me the opportunity to emphasize the total commitment of our teams and their individual contributions to ensuring the continuity of our activities serving the health sector. While implementing all the safety measures required to protect our employees and partners, we have seamlessly continued to produce the innovative packaging that is essential for the injectable treatments of our clients in the pharmaceutical industry. Congratulations and thanks to the entire Technoflex team!

These events once again highlight the importance for each region of the world of putting in place the means to ensure the availability of care and treatment for the greatest number of people. This applies to two examples that we present in this issue: firstly, the efforts made by the African continent to improve control over the quality of the drugs at its disposal, and secondly, the implementation of innovative solutions to avoid the stock-outs that are a regular feature of the American market.

Finally, providing the best service to the customers who place their trust in us remains the mantra of our teams, and particularly of our Customer Service Department, which aims to obtain the highest level of customer satisfaction by anticipating their needs and providing support at all stages, from the order through to shipping. Read all about them in our "Business" section.

Happy reading to all !

Flexmag, a world of connections

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Flexmag

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Quick facts

New application for AI

Artificial Intelligence is expanding its scope of application. Already used in diagnosis, it is now stimulating research into new medicines. A French company has developed a technology that is able to simulate new molecules then evaluate them. This new technology is based on two algorithms containing millions of data points relating to chemical compounds and the physicochemical properties of molecules that have already been synthesized and tested. The first algorithm generates virtual molecules which are then analyzed by the second. In the United States also, AI is not being left behind. A new antibiotic drug has been discovered by researchers at MIT and Harvard University thanks to AI. The research algorithm predicts that the structure of the molecule will enable it to be more effective against many bacteria that are resistant to traditional antibiotics. A huge step forward which will allow a more rapid selection of drugs with high medical potential.

Free medicines in Argentina

Launched in 2000, the "Remediar" plan authorized the free distribution of medicines throughout the entire country at the time. It was abandoned when universal health cover was rolled out. As this has been judged ineffective in combating the steep increase in drug prices, the Argentine government has just reactivated "Remediar". So 15 million people will receive 50 essential medicines free of charge.

Agenda

2nd quarter 2020

Due to the Covid-19 pandemic, some events could be postponed or cancelled.
The updated agenda is available at www.technoflex.net

Healthcare Packaging Expo	November 8-11, 2020	McCormick Place Chicago – USA	Healthcare Packaging EXPO	**Booth LU-7018**	
CPhI India	November 25-27, 2020	India Expo Mart, Greater Noida Delhi – Indie	CPhI india	**Booth 3D21**	
ISBT	December 12-16, 2020	CCIB – Barcelone Spain	ISBT BARCELONA 2020	**Booth 1302**	

The AMA, the African super regulator

Drug regulatory agencies evaluate, monitor and guarantee the safety of medical products before and after they are placed on the market. Although present in the large majority of nations, they are absent in a number of regions around the world. This is the case with Africa. Hit hard by counterfeit drugs and the lack of pharmaceutical industries, the countries of the African Union have decided to take up the challenges represented by universal healthcare coverage and safety.

Sylvie Ponlot

Africa, which has 1.2 billion inhabitants, lists scarcely more than 350 drug manufacturers and a few producers that package medicines bought in bulk. This observation is unquestionable. By way of comparison, India and China each have 1.4 billion inhabitants and 5,000 and 10,500 drug manufacturers respectively. If we exclude the extreme northern and southern regions of the continent where industry is sufficiently developed to supply the local population, Africa is therefore largely dependent on the big pharmaceutical groups. Around 80% of patients are being treated using resources produced outside the continent, but these numerous imports bring serious consequences. The complexity of the supply chain and the multiplicity of middlemen inevitably entails a negative impact on product cost. An impact which, combined with the poverty and lack of healthcare coverage in most countries, encourages the population to turn towards parallel markets.

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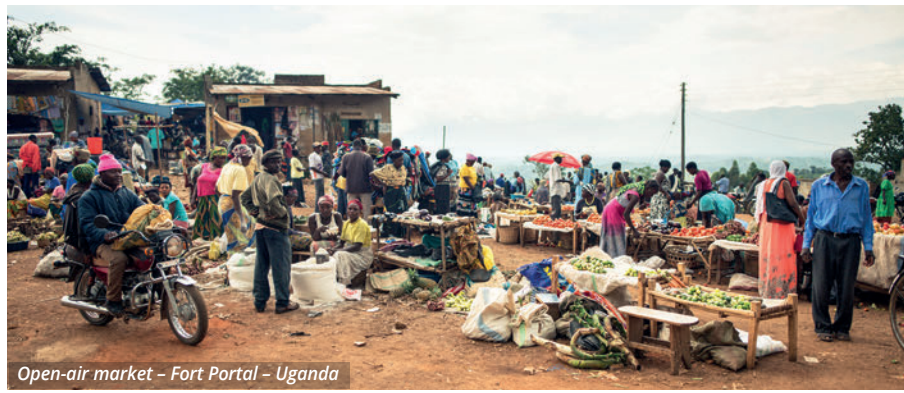

Open-air market – Fort Portal – Uganda

Small hospital in the district of Wakiso, in the Central Region of Uganda

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A new step to halt the trafficking

Antimalarials, analgesics, antibiotics, vaccines - there are a plethora of counterfeit medicines. Whether they are simply of inferior quality, or completely falsified, they flood the market and represent 50% of medical products on average. In addition to resale in open-air markets [1], they are also found in healthcare establishments. Last April, a falsified version of chloroquine was identified in several pharmacies and hospitals in Cameroon. The drug was completely devoid of the active ingredient!

Faced with terrifying mortality figures [2] caused by counterfeit products, the leaders of several African countries *(Congo, Gambia, Ghana, Niger, Senegal, Togo and Uganda)* decided to react strongly. In launching the opera-tion christened the " Lomé Initiative", ratified unanimously, the signatories undertook to fight the traffickers more effectively. Among the resolutions adopted were the pooling of efforts which will ensure better cooperation between government departments and the effective sharing of information. Other measures announced were the strengthening of current laws, ensuring that these are applied strictly, and above all the introduction of big criminal penalties to criminalize the trafficking of health-care products following the example of Togo. In 2015, the country revised its criminal code: trafficking is no longer considered a simple coun-terfeiting infraction as in most African countries, it is a criminal offence. Prison sentences were increased and associated with fines of several million CFA francs.

In parallel, another objective consisted in increa-

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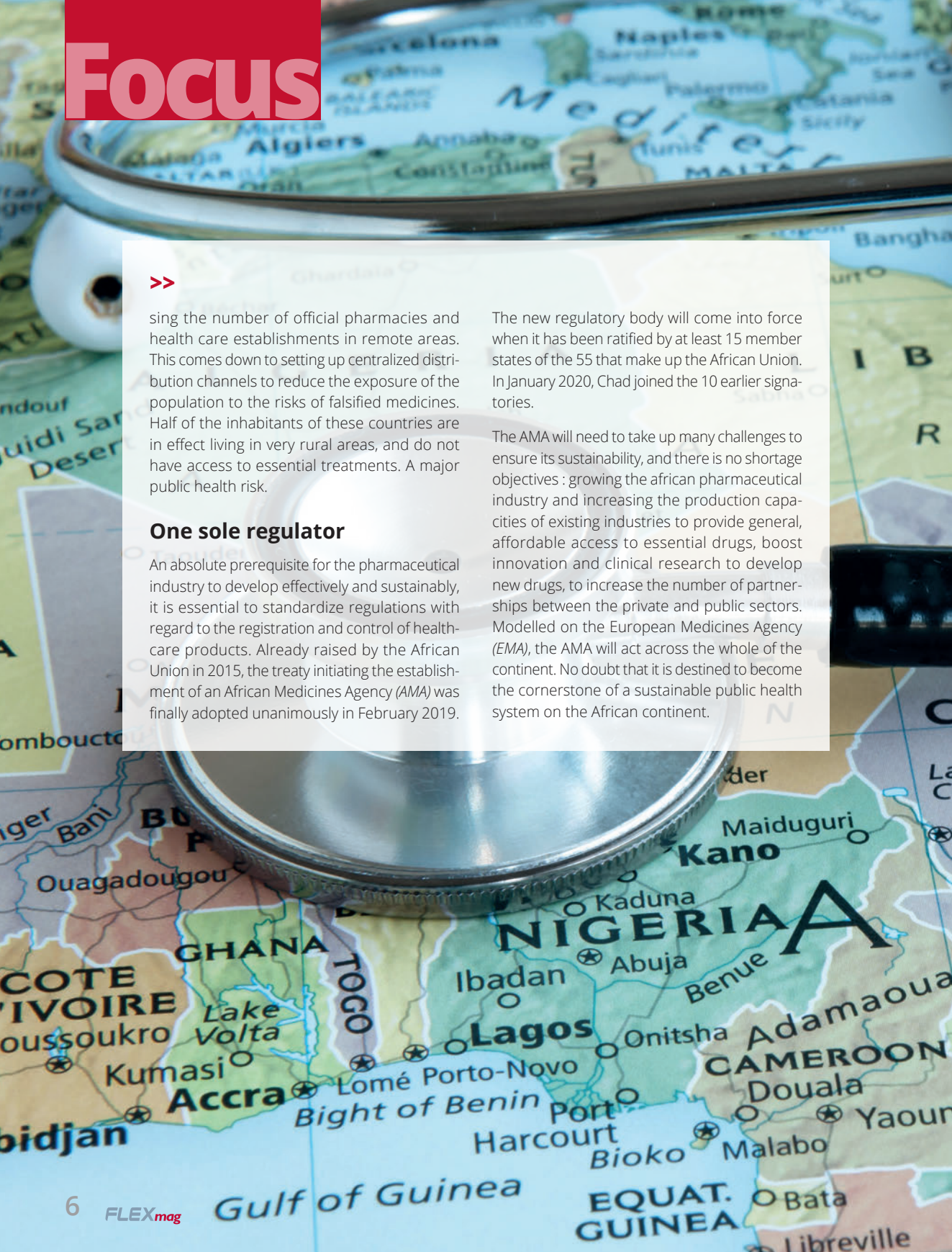
[1] Counterfeit treatments often carry prices that are half of those in pharmacies. The latter, subject to the regulations in force, are supplied via the legal channels of wholesale distributors and are inspected regularly.

[2] According to the WHO, fake medicines are directly involved in the death of almost 200,000 children every year.



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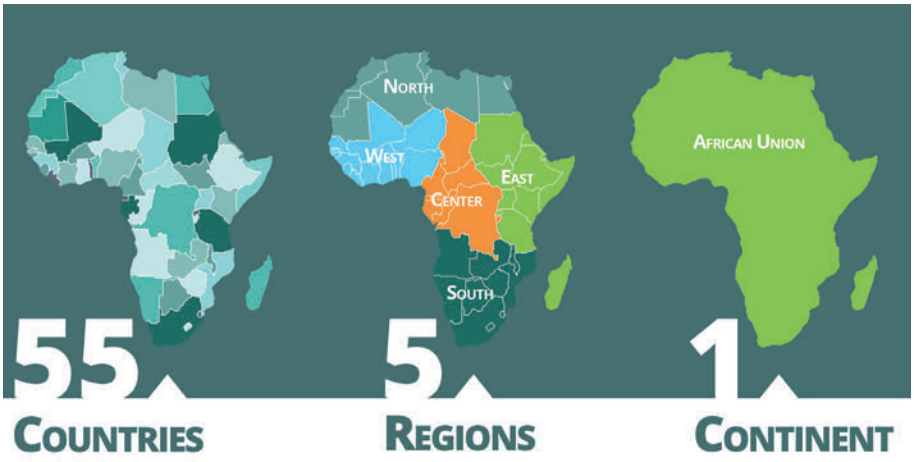
sing the number of official pharmacies and health care establishments in remote areas. This comes down to setting up centralized distribution channels to reduce the exposure of the population to the risks of falsified medicines. Half of the inhabitants of these countries are in effect living in very rural areas, and do not have access to essential treatments. A major public health risk.

One sole regulator

An absolute prerequisite for the pharmaceutical industry to develop effectively and sustainably, it is essential to standardize regulations with regard to the registration and control of healthcare products. Already raised by the African Union in 2015, the treaty initiating the establishment of an African Medicines Agency *(AMA)* was finally adopted unanimously in February 2019.

The new regulatory body will come into force when it has been ratified by at least 15 member states of the 55 that make up the African Union. In January 2020, Chad joined the 10 earlier signatories.

The AMA will need to take up many challenges to ensure its sustainability, and there is no shortage objectives : growing the african pharmaceutical industry and increasing the production capacities of existing industries to provide general, affordable access to essential drugs, boost innovation and clinical research to develop new drugs, to increase the number of partnerships between the private and public sectors. Modelled on the European Medicines Agency *(EMA)*, the AMA will act across the whole of the continent. No doubt that it is destined to become the cornerstone of a sustainable public health system on the African continent.



AU, strengh through unity

The Organization of African Unity *(OAU)* was created in 1963 and aspired to achieve the ideal of unity by making the peaceful resolution of conflicts and the struggle against racial discrimination its priority concerns. Its fight against apartheid would culminate in two great victories. The first was the release of Nelson Mandela, the second was when he was elected President of South Africa. The OAU outlined the contours of a united Africa and plotted the path to follow for the African Union *(AU)* which succeeded it in 2002. The AU intends to accelerate unification by federating the 55 countries that make up the African continent. It has set itself broad goals: an Africa completely at peace and democratic based on respect for human rights, an Africa strengthened by a common heritage and cultural richness, an Africa politically united, economically prosperous and present on the international stage. To guarantee a just distribution of power between large and small countries, governance of the African Union is ensured by a Chairperson appointed for a one-year period. Since February 2020, the African Union has been chaired by South Africa. The new Chair, Cyril Ramaphosa, has already indicated that security and the African Continental Free Trade Area would be the priorities for his term of office. The Democratic Republic of Congo will take over from South Africa in 2021.

Excellence in customer service

What was, for many companies in the past, a simple administrative service, "Sales Administration", has evolved significantly. Of crucial importance, Customer Service is today at the heart of the company . Direct point of contact with the customer, its major goal is to ensure customer satisfaction from the moment the order is placed. Headed at Technoflex by Marine Boninfante, it is responsible for management of customers' requests, manages order tracking, supports each customer at every step, provides them with information and above all meets their needs and anticipates their expectations.

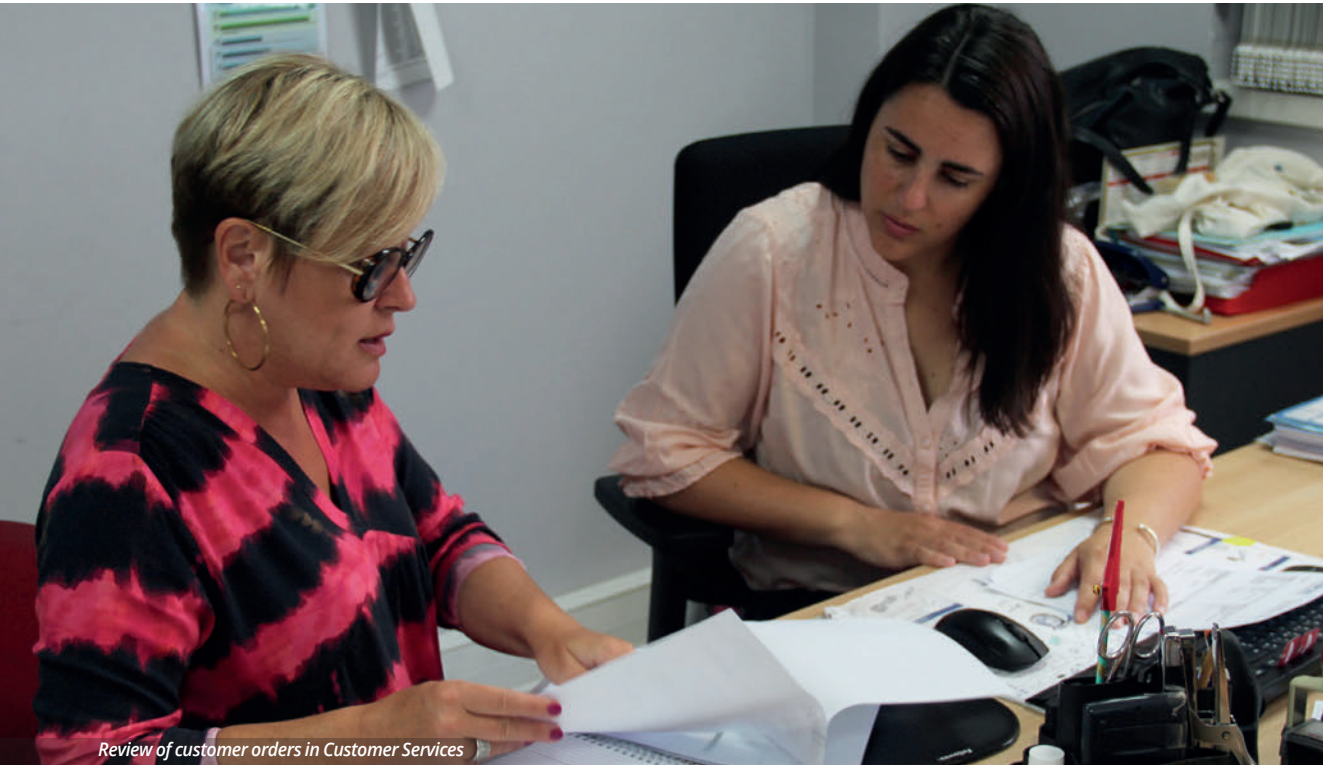
Sylvie Ponlot: You have been at the helm of Customer Services at Technoflex for 4 years. How does your department define its task?

Marine Boninfante : In our personal life we are all customers. We expect our suppliers to understand us, provide clear answers and act in a responsive manner. This is exactly what we put into practice with our customers. Being there when they need us and always doing as much as possible to support them. Our main objective can be summarized in a key phrase: "to satisfy our customers".

Knowing our customers well inevitably implies a more personalized human experience. So we are constantly at their disposal. Having a full understanding of their needs and constraints is essential! Depending on the mode of communication, our response time is always between 24 to 48 hours maximum from receipt of their request. We apply an approach of ongoing improvement, using indicators that are updated in real time. We make every effort to respond to our customers' requests as quickly as possible.

SP: The question of deadlines is often the subject of discussion. Could you enlighten us?

M B : Absolutely, shipping and delivery deadlines are very often confused with each other. Shipping delays correspond to the duration of internal processing from the order to the preparation of products for shipping. We manufacture primary packaging for injectable solutions which complies with very strict regulations. From this point, numerous variables which often require a set period of time have to be taken into account. By way of example, these include the tooling of industrial equipment and printing plates which change for each production, raw materials conformity tests, inspections during



Review of customer orders in Customer Services

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the manufacturing process, batch release tests ***(bioburden, endotoxin analysis, etc.)***. Finally, time for product sterilization must also be added when this is required. Each production batch is unique!

The delivery deadline, relates to the time necessary to transport the finished products from our production site to our customers. These may transit by land, sea or exceptionally by air. It therefore depends on external constraints as has been seen during the recent epidemic.

SP: Technoflex has large industrial facilities and demand management must require great rigor. How do you organize yourselves?

M B : Forming a veritable bridge between our department and production, "demand management" activity is assigned to Customer Services. In the first instance, we discuss the projected orders of our customers over a 12 month period. These projections are simply indicative, but they are vital for correct forward planning of the future deployment of our machines and to meet the needs of our customers in an optimal manner. Then, we organize regular telephone calls with our customers to track their current orders and monitor developments regarding their projected orders. This allows us to fine tune our production planning this time with firm orders. From time to time it happens that these projections are not communicated in time by our customers, which complicates our work. We then rely on their order history or on data sent by our sales department to be able nevertheless to anticipate their needs and to make sure that we can satisfy requests even if these are late. All information obtained is discussed with Supply Chain, so enabling us to make our customers' voices heard, and to find solutions to remove any obstacles.

Stock shortages and drug prices under control

Sylvie Ponlot

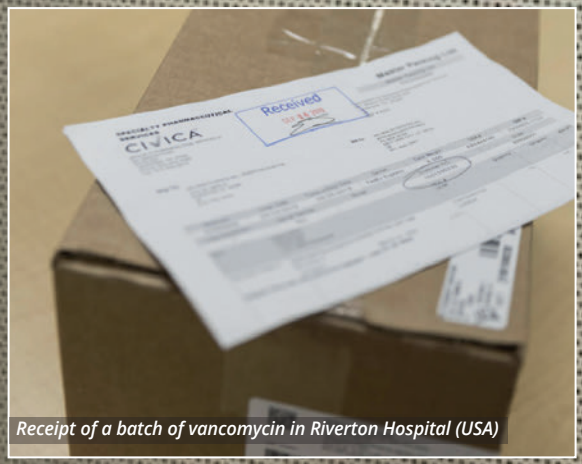
The Civica Rx [1] association was created in 2018 by three philanthropic foundations [2] and seven organizations [3] which alone represent 1,200 healthcare establishments in 46 of the 50 American states. It has a single objective in the crosshairs: to combat the recurrent problem of stock shortages in the United States. A real national crisis for hospitals and patients, the shortages affect a wide range of therapies: anti-cancer drugs, antibiotics, anesthetics and analgesics. As a non-profit association, the economic model of Civica Rx is unique: its members do not possess shares in the association, there are therefore no shareholders. In addition the legal articles of the Association are drafted so as to prevent any sale or modification of its main mission. Civica Rx was rapidly approved by the FDA as a drug manufacturer. Several months later, the first hospitals received the first batches of vancomycin, an antibiotic that is essential but in insufficient supply. Civica Rx, which always ensures that essential generic drugs are always available at an affordable price, today offers 20 generic drugs in injectable pharmaceutical form.

In early 2020, it was the turn of the Blue Cross Blue Shield Association *(BCBSA)* to point a finger at stock shortages and the staggering rise in the cost of medical products. According to the California Medical Association, expenses associated with treatments had reached $328.6 billion, and the price of some essential drugs were posting increases of between 10 and 100% in just one year! *"We think that everyone should have access to healthcare treatment, no matter where they are or where they live"*, said Scott P. Serota, CEO of the BCBSA. The Blue Cross Blue Shield Association and 18 of its affiliated companies therefore decided to come together to launch their own drug manufacturing operation concentrating on affordable generic drugs outside of the hospital setting. To succeed in their new mission, they will work in close collaboration with the Civica Rx association. *"Through this partnership we will achieve the vital objective of providing better access to essential drugs"* said Scott P. Serota. No less than $55 million will be invested, and the production of a dozen products for the treatment of multiple sclerosis, diabetes and some mental illnesses should be launched soon. The association expects to place future drugs on the market from 2022 onwards.

[1] *Flexmag 13*

[2] *Laura & John Arnold Foundation, The Peterson Center on Healthcare and the Gary and Mary West Foundation*

[3] *Catholic Health Initiatives, HCA Healthcare, Intermountain Healthcare, Mayo Clinic, Providence St Joseph Health, SSM Health and Trinity Health.*



Receipt of a batch of vancomycin in Riverton Hospital (USA)

Nurse inserting a vancomycin infusion line

Reconstitution and preparation of an antibiotic treatment for IV administration

Joëlle Poupeau,
Operational Quality Assurance Manager

Sylvie Ponlot

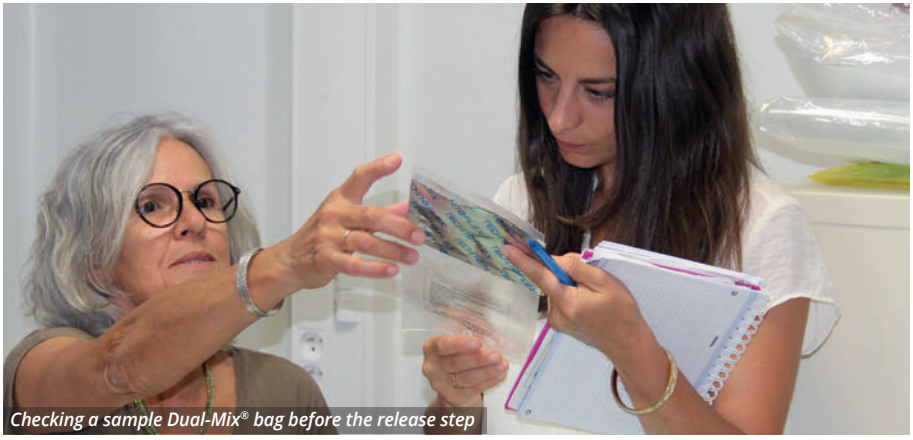

Joëlle Poupeau

With a Doctor in Pharmacy qualification from the Faculty of Bordeaux, Joëlle Poupeau headed for the industrial sector from the outset. Her decided liking for analytical chemistry *(setting up data analysis and evaluation methods)* then led her to a Masters in Quality Control - Validation Methods - Quality Assurance. This course finished with an end-of-studies internship with Pierre Fabre Laboratories, where she became Deputy to the Quality Control Manager. This experience gave her the desire to find out more about Quality Assurance, and drove her to join the SPI Pharma laboratory as Quality Assurance Deputy Qualified Person.

Joëlle then expanded her area of expertise to include primary packaging of drugs by joining the Technoflex team. For almost two years she has been managing the Operational Quality Assurance Department *(OQA)*, where, from launching new projects to the release of finished products, she brings all her pharmacist's expertise. *"The activity of Technoflex is closely linked to health. An environment where the quality culture is constantly evolving, without forgetting the competent authorities such as the FDA or the EMA which are increasingly demanding with respect to the traceability of manufacturing data. Coming from the pharmaceutical industry, my experience allows me to explain the ever growing requirements of our customers and to give meaning to each of these"* said Joëlle Poupeau.

She considers OQA to be of vital importance at all stages of the manufacturing process, whether or not these are critical. This implies a solid knowledge of current standards, Good Manufacturing Practices as well as proper coordination to secure all phases affected in advance. *"All changes must imperatively be mastered in order to define the potential risks which may impact product quality and therefore patient safety. So I have introduced a new management system for change control requests. Together with the Validation Committee which brings together all experts from each core activity, we can define with precision the action plan(s) to be implemented to control all the risks identified"* she said. *"In addition the world in which we operate is governed by the precautionary principle. OQA therefore operates in many departments: Production, Maintenance, and Supply Chain. By training teams in all good practices, we are helping to empower every employee"*.

A true field and investigative activity, Operational Quality Assurance is built, according to Joëlle, with method, rigour and the participation of all. It allows Technoflex to supply high quality, safe products for caregivers and patients.


Checking a sample Dual-Mix® bag before the release step

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