Volume 2019, Nr. 1

January 2019

# Newsletter

## A word from the President

Dear Members,

Another year passed. Time is flying too fast and it seems to go faster every year. Our first wish for the year is that you find the time to enjoy what you are doing. In these times of change controls and risk management, it is important to focus on what is really important. As Socrates wrote a long time ago:

*The secret of change is to focus all of your energy*
*not on fighting the old, but on building the new.*

We wish you all the best for a healthy and prosperous 2019!

For UPIP-VAPI, 2018 was a "Premier Grand Cru Classé" with three memorable events:

- the General Assembly for our 65th anniversary
- the Social Event at the Moscow City Ballet
- the Seminar on the Falsified Medecines and Unique Barcode.

It will be a challenge for us to live up to these standards. Find out for yourself on March 14th with Healthcare Thinker and Futurist **Koen Kas** as keynote speaker on our General Assembly. Hope to meet you all there and on our other events.

Enjoy the reading.

Frank Peeters
President UPIP-VAPI

Events to remember:

**24th January 2019**
**GDP Certification Training**

Venue: Thomas Moore Mechelen

**19th February 2019**

**Curalia presentation of the insurance for pharmacists of the industry – QP – GDP RP**

Venue: Curalia Brussels

SAVE THE DATE !

**14th March 2019**
**General Assembly**

**"The pharmacist of the Industry 4.0"**

**Seminar on the upcoming technologies, and how they will affect healthcare and our role in the pharmaceutical industry**

Venue: CERPAN
Nivelles - Nijvel

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## General Assembly 2018

In 2018 UPIP-VAPI was celebrating its 65th anniversary. We thereby organize a Seminar on New and Emerging Regulations that was held on Tuesday 20 February 2018 at the Military Hospital Queen Astrid in Neder-Over-Heembeek. The following topics were presented by our excellent speakers:

- M. Xavier De Cuyper (AFMPS/FAGG) Role and view of the regulator
- Prof. Claude Farrugia (EIPG) Update and status of the Falsified Medicines Directive (FMD)
- M. Karel Verlinde (BeMedTech) Medical Technologies in Belgium: overview and challenges
- M. Philippe De Buck (AFMPS/FAGG) The new legislation on psychotropics and narcotics

For this occasion, HRH Princess Astrid honored us with her presence, which was very much appreciated by the audience as you can see in the pictures below. A very successful event that we will not forget in a very long time. We also introduced our new four board members: Alexia Rensonnet, Philippe Okusa, Gunther Pauwels and Erik Haghedooren.



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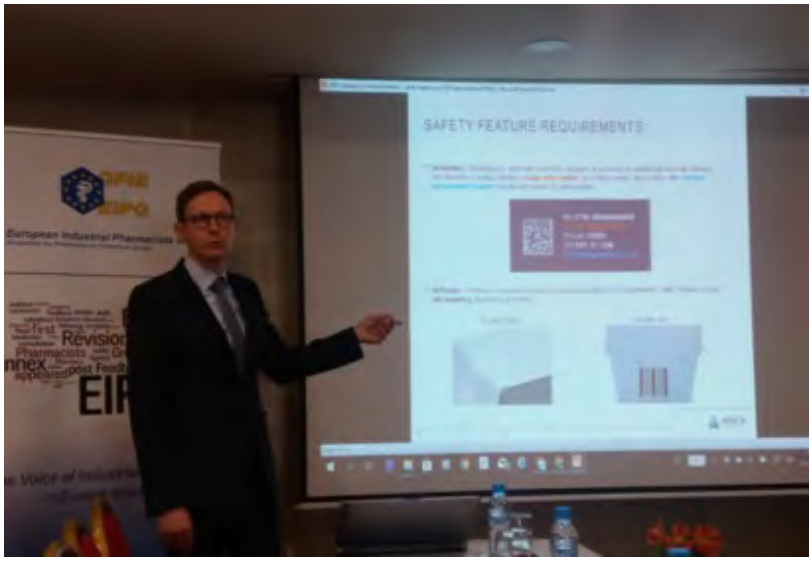
# Participation to the General Assembly of the European Industrial Pharmacists Group (EIPG).

The General Assembly (GA) of the European Industrial Pharmacists Group (EIPG) took place in Casablanca (Morocco) from 04 May to 06 May 2018. **Alexia Rensonnet** (board member) and **Thomas Lion** (board member and EIPG delegate) represented the Belgian Association. It was the first time that the annual event was organized outside Europe. Morocco (with its association: C.O.P.F.R: Conseil De L'Ordre Des Pharmaciens Fabricants Et Répartiteurs) being an observer member of the European association, it was a real honour and a joy for them to welcome their European colleagues as mentioned by **Fatima Lahmouddi**, the president of the association.

The GA started with a scientific symposium "Morocco's Pharmaceutical Industry: Player in healthcare access in Africa" in presence of the Moroccan authorities. In fact, Moroccan pharmaceutical industry is recognized as European zone by World Health Organization thanks to the quality of its products and its good manufacturing practices. Moreover, it can be an actor to fight against falsified medicines in Africa thanks to its presence and its local manufacturing.

During the GA, the Belgian Association UPIP-VAPI was mentioned several times and recognized for its very active and pertinent contribution to the work of EIPG, for instance for the review of the new Annex 1 (Manufacture of Sterile Medicinal Products) in the Eudralex or for the review of QP code of conduct. **Claude Farrugia**, president of EIPG, mentioned also that our GA in February 2018 in the presence of the Princess Astrid was a real success and that it is very positive that the association is now also open to people who are not pharmacists but working in the pharmaceutical industry. The work of the Belgian Association was applauded by all the participants. The national associations from the other countries were encouraged to contribute to the European association in a similar manner as it is the case for Belgium.

At the GA, two working groups were also organized. The first was entitled: "Safety Features and Qualified Person Responsibilities". It considered the responsibilities of Qualified Persons involved in serialisation. The structure of a guidance document was discussed.




The second was entitled: "Preparing for Brexit: the Impact on European industrial pharmacists". Commenting on the outcomes of the Working Groups, EIPG President **Claude Farrugia** noted that since the Falsified Medicines Directive deadline coincides with Brexit, this exacerbates the potential risk to the availability of medicines in United Kingdom.

The next GA will take place in Hungary in May 2019.

## GS1 Belgilux Healthcare Working Group on Traceability

This workgroup started in Oct 2017 with the objective to ensure traceability in the healthcare value chain, including "aggregation barcoding". The system with unique barcodes that will be implemented on Feb 9th is an end-to-end system with intermediate spot checks, but no full traceability of each phase of the chain. This is different from the "e-pedigree" system in the US, where full traceability is required over the complete supply chain. The latter is far more complex, and that is also what we see when discussing the 'intermediate traceability" in the GS1 workgroup sessions this year (March, September and November).

The aim of these workshops is to develop an Implementation Guidance for GS1 Standards to improve the traceability of medicines in the healthcare supply chain.

A 25-page document has been drafted, which is reviewed and discussed during the workshops with the stakeholders of the pharmaceutical industry, hospitals, pharmacies and the authorities. We are more than half way through the document, so we should be able to complete this Standard in the near future.

## GMP & GDP Training

Our yearly GMP Basic Training, given by Jacques Defrance, was hosted by Takeda Belgium in their new offices in Zaventem. Takeda moved there after closure of the manufacturing facility in Molenbeek. Since our GMP training always includes a visit of a manufacturing facility in the afternoon, we were welcomed by J.-P. Pirney, head of the Lab MCT of the Military Hospital Queen Astrid. We got an introduction on phage therapy to treat bacterial infections of severe burn patients. This is a very promising alternative to antibiotics which show more and more resistance. But we also learned about the difficulties to comply with the GMP regulations when the product is not a well-defined pharmaceutical substance but a living organism that has to change in time to adapt to its mutating target. The next GMP training is scheduled for late May or early June.

In 2018 we continued the GDP Certification Training session we started in 2017. The first session in January at the logistics center of Janssen Pharmaceutica in La Louvière was fully overbooked and with reason! After the theoretical sessions we were invited for a visit of the premises. Very impressive. We organized a second session in September at Eumedica in Manage. Because of the mixed audience of persons who were new in the field and experienced GDP RP's, we split the group in two. After a refresher course on the role and responsibilities of the GDP RP and a session on the Falsified Medicines Directive, we split the group in two. Ludwig Everaert presented the GDP regulation of 2013 and its relating quality system for the novice persons, while Frank Peeters hosted a workshop on Risk Management and FMEA techniques for the veteran GDP RP's. The training ended with a GDP quiz, and the attendants received a training certificate when they passed the test.

The next GDP Certification Training will take place at Thomas Moore in Mechelen on Thursday 24 January. This will be a training without company visit but composed of *two parallel sessions:* a basic and an advanced one. The topics will be presented in the form of workshops and peer discussions. The focus of this training is *Risk Management and Temperature Mapping*. A must for everybody seeking basic or a more in-depth knowledge on GDP issues.

## Social Event – Swan Lake by the Moscow City Ballet

Our 4th Social Event was a hit. We made a first reservation of 50 tickets but had to buy 20 more. We think this is due to the day: a Saturday evening instead of a weekday. More members came with the whole family, making it a real social event. However not all made it to the reception afterwards. The reason here was clear: the ballet started much too late and ended around 23:30. Far too late for the families with younger kids. We discussed this and decided to organize the reception before the event next time. In the past this was not possible because of the weekdays. It is not a good idea to ask people to come a reception at 18h in the center of Brussels, Antwerp or other big city. But very well possible in the weekend. All ideas welcome for our next event.

## Insurance for pharmacists working in the industry

Together with Curalia and Baloise we have been working on an insurance for pharmacists working in the pharmaceutical industry. The insurance will only be available via UPIP-VAPI and will cover responsibilities relating to the legal activities of our members (QP, GDP-RP…) but also general activities such as QA, validation etc… Depending on the situation, the insurance can cover the liability or provide legal support.

A selection of cases that were presented to Curalia to be covered are:

- A member needs to take a decision to approve or reject a batch of medicinal products. The person takes his decision with all the data available at that moment, but actually he took the wrong decision because of a personal mistake.
- A member works on the review of important IOPQ documentation of some equipment, and after his task completion, realizes that he/she has lost some critical documents. The company reclaims the investment that was performed for the IOPQ.
- A member agrees to perform an audit to challenge the internal quality system, but during the audit, the person leans against an expensive calibration equipment that falls on the ground and breaks. The company requests him to repay the expensive tool.
- A member got injured during working in a company and needs to be hospitalized. The was however caused by an unsafe work environment where he was forced to work.

We will host this on **19 February** to present this insurance to our members. More information will follow soon.

## Common event with A3P

UPIP-VAPI has organized a common event with A3P Belgique on 7th Jun at the Hotel Fonteinhof in Borgloon.

The subject of the day was Integrity Testing and Visual inspection. It was very interesting to share networking/expertise with another association. The program started with legislative points and continue with more technical aspects (for example pros and cons of different technologies) while passing through validation questions.

This event ended with a beautiful visit of Datwyler plant.

Thanks again to A3P Belgique for this joint organization.

## Column in the J. Pharmacie de Belgique – Farmaceutisch Tijdschrift België

In 2018, the “Journal de Pharmacie de Belgique” / “Farmaceutische Tijdschrift voor België” was celebrating it’s 100$^{th}$ year of existence and has publish thematic columns on the different activities and roles of the pharmacist professions. UPIP-VAPI has been asked to write the column on the history, evolution and future of the pharmacist in the Pharmaceutical Industry, which was published in the December issue of the journal.

# Seminar on Falsified Medicines – Unique Barcode

In the board meeting of September we had the idea to organize a seminar on serialization. When we sent out the first invite to speakers we got the feedback that this was rather late, and that most companies should be ready by now. Otherwise they would not be able to put their products on the market in February or deliver them to the patients. This is true for manufacturers of prescription drugs and for pharmacies, but what with the intermediate supply chain? We got a lot of question from our members relating to different issues such as: timelines, regulatory variations, financing, QP release, unit doses, verification by wholesalers, import/export, the situation of Luxembourg etc…

Some examples of questions are:

- What can happen when my 3PL for storage or distribution is not ready in time?
- Will the use of CNK-code completely disappear? If so, by when?
- Do I need a variation just for labelling?
- Do I need to pay BeMVO to put products on the market with 2D matrix for reimbursement only?
- Can a Release Pharmacist input the files in the EU HUB, or should this be done by the registered QP?
- Is mass decommissioning allowed and possible?
- Etc…

The event was organized at the OFF in Waver, and was split into 4 parts:

1) Presentations on the new regulation by:
   - FAGG/AFMPS: The view of the National Competent Authority including the Regulatory aspects (Variations) and possible flows of QP release.
   - Belgian Medicines Verification Organization (BeMVO) & Arvato: Current situation of the Medicines Verification System and the National Database, onboarding of end users and pending questions of the industry.
   - GS1: Presentation of the GS1 standards used for serialisation of the secondary packages of medicines, the structure of the GS1 identification keys and the main specifications of the GS1 DataMatrix. The use of GS1 standards in the process of *Aggregation Barcoding.*

2) A panel discussion & Q&A with the FAGG/AFMPS and BeMVO

3) Implementation testimonials by the CMO/CPO companies CRNA and W Pharma

4) Workshops organized by GS1, Arvato, Movilitas, Tracelink and Zetes presenting their solutions to comply with the FMD's. Fifteen different workshops were organized in 5 parallel sessions, each aimed at a different public : wholesalers & 3th party logistics, marketing authorization holders, contract manufacturing & (re)packaging and hospitals.

The questions asked by more than 100 attendants showed that not everybody is ready yet.

We are working on a Q&A document with new issues and solutions to be added to the FAQ list of BeMVO. In case you would have any urgent questions, it's a good point to start your research here: https://bemvo.be/nl/start/faq/

## Presence at promotion of KULeuven students in pharmaceutical sciences

UPIP-VAPI was present during the promotion of students in pharmaceutical sciences on 15 September 2018 at KuLeuven in Gasthuisberg. After subsequent academic speeches from professor Veerle Foulon, dean Paul Declerck and rector Luc Sels, the proclamation followed for the 'Masters Pharmaceutical Care', 'Masters Drug Development', 'Master of Hospital Pharmacy', 'Masters of Industrial Pharmacy' and 'Masters of Laboratory Medecine'. As you can see on the picture, it was a beautiful day and great to see the 142 students who received their degree, congratulations again!

## Collaboration with EIPG (European Industrial Pharmacists Group)

A part of our collaboration with the EIPG consists in giving feedback on EU legislation or WHO guidance documents in draft or under discussion. EIPG centralizes and combines comments from all their member countries into one review document. This generates a far stronger position to impact and influence the final version of the requirements or guidelines. UPIP-VAPI has recently given their comments on the QP code of conduct or Annex1.

During each EIPG GA, workshops are organized on hot topics, such as Brexit and Falsified Medicines directive. These outputs help the EIPG to define an official position, sometimes written down in a position paper.

If you are aware of future guideline or requirements that UPIP-VAPI could comment/influence via EIPG, don't hesitate to contact us. You are also always kindly invited to respond to the review requests of the EIPG that we forward to our members.

## Presence of UPIP-VAPI on social media: New Facebook page

Since last June, UPIP-VAPI is also present on Facebook. This presence is complementary to our website and has several goals: firstly, to have more interactive relationships with our members. In fact, we can announce our events, share some pictures of the life of the association or interesting information from partner associations,… Secondly, it is a better means for us to be connected with the younger generation and students.

Stay in touch with us! Like our page and follow it! And obviously, share it with your friends industrial pharmacists or working in the life sciences industry.

Facebook page: https://www.facebook.com/UPIPVAPI/

Our website: http://www.upip-vapi.be/

We are also on LinkedIn and Twitter!

LinkedIn: https://www.linkedin.com/company/upip-vapi/

Twitter: https://twitter.com/upip_vapi

If you have comments, do not hesitate to communicate them in order to improve our presence on social media.

## General Assembly 2019 – The Pharmacist of the Industry 4.0

Please already book the afternoon of **March 14th 2019** in your agenda for the next edition of our GA.

The subject of the afternoon will be the changes that lie ahead of us. The topics handle the possibilities to cure patients in the future such as genomics, nanotechnology, personalized medicine, iRNA etc… and how this will affect the role of the pharmacist and professionals of the industry.

A couple of days ago I attended a presentation on the new drugs of 2018. Some of these are drugs consisting of more than 20 nucleotides, each separated by a chiral linker. This results in ≥ 500 000 different conformations of the drug. The phage therapy mentioned above is another example of flexible solutions that must fit into “rigid” pharmaceutical laws. Think of the genomic revolution, wearables and implants, biomarkers, medical apps, avatars for everybody etc… We name the current situation “healthcare” but in fact it is still “sickcare”.

Healthcare Thinker and Futurist **Koen Kas** is the best speaker to talk about how healthcare will be transformed in the (near) future, and how our profession will look like in 10 or 20 years. Prof. Dr. Ir Marcel Van de Voorde also already confirmed to talk about nanoscience and nanotechnology.

More information will follow later.

## UPIP-VAPI Program 2019

| | |
|---|---|
| Jan 24 | GDP Advanced Certification Training (Thomas Moore - Mechelen) |
| Feb 19 | Insurance seminar (Curalia – Brussels) |
| Mar 14 | General Assembly (CERPAN – Nijvel - Nivelles) - The Pharmacist of the Industry 4.0 |
| May | General Assembly EIPG Hungary |
| May-June | GMP Basic Training – Introduction to Quality Management Systems |
| Jul 21 | Reception for Royal Associations (Ghent – Province House) |
| Sep | NSF Legislation Update |
| Sep-Oct | GDP Certification Training |
| Q4 | GMP Advanced Training on Qualification & Validation |
| Q4 | Social Event |

## Board Membership

Are you interested to join our Board? We have some vacancies that will be filled during the General Assembly in March. Please contact us if you would like to join the board or want to participate in a more informal way in organizing our activities.

You can always request to attend a board meeting to get a better feeling of the board work.

Hope to see you soon.

Frank Peeters
President