Volume 2018, Nr. 1

January 2018

Newsletter

A word from the President

Dear Members,

First of all we wish you all the best for a prosperous and healthy 2018.

The UPIP-VAPI board is pleased to present you the first newsletter of this year, giving an overview of our activities in 2017 and inform you of our planned events.

Last year's agenda was quite busy as you will find out. UPIP-VAPI is connecting more and more with our European mother association EIPG, other national associations and the competent authorities. We also responded positively to several requests from the EIPG to represent the European pharmacists at the European Commission.

We start this year with a bang. Two events on January 25th (EU GMP Annex 1 Workgroup and GDP certification training), and on February 20th we celebrate the 65th anniversary of our association in the presence of her Royal Highness Princess Astrid. We start the afternoon seminar -on the new and upcoming regulations- with a presentation by Mr. X. De Cuyper. Hope to see you all there!

Enjoy the reading

Frank Peeters,
President UPIP-VAPI

Dates to remember:

25th January 2018 (new date!)
GMP Annex 1 Working Group

Venue: Bone Therapeutics Gosselies

25th January 2018
GDP Certification Training

Venue: Janssen Pharmaceutica Distribution Center La Louvière

SAVE THE DATE !

20 February 2018
General Assembly - 65 Years Anniversary UPIP-VAPI

Seminar on the new and upcoming regulations

Venue: Royal Military Hospital Queen Astrid
Neder-over-Heembeek

In this issue:

Newsletter Volume 2018, Nr 1

General Assembly 2017

The first activity we organized for our members in 2017 was the general assembly with a seminar on the KB78/AR78, the new legal framework for healthcare professionals in Belgium. With our minister of Health Maggi De Block as speaker we couldn't have anyone better to kick off the event. We got a very good overview of the scope and implication of this new decree by:

- Prof. Em. Herman Nys on the preparation of the reform and it's legal aspects
- Thomas De Rijdt on the opportunities for hospital pharmacists
- Johan Van Calster on the impact for the pharmacists in life sciences industries
- JanDepoorter on the te view of the community pharmacist and the patient.

We learned that the structural reforms caused by the new decree will have a big impact on the life science industry. The healthcare will become more:

- patient-centered to deliver the best quality at the lowest possible cost
- evidence-based, with a huge role for diagnostics and prevention
- interdisciplinary between the different stakeholders.

The 500,000 healthcare professionals in our country should be prepared…

EIPG General Assembly

UPIP-VAPI is one of the most active associations of the EIPG, our mother association at EU level. Mounir Rizovsky (Vice-President) and Thomas Lion (Board member and EIPG delegate) have represented UPIP-VAPI at the EIPG General Assembly in Malta on 20 and 21th May 2017. There was a symposium on Precision Medicines held on Friday 19th as pre-opening meeting. Two days of general assembly followed this scientific meeting. Some keys points of this GA are:

- Creation of working group on the Brexit
- EIPG VP Election: Anni Svala from Finland has been re-elected as VP Education and Giorgos Panoutsopoulos (Greek delegate) has been elected as VP Communication
- Many debates about hot topics such as drugs shortages, serialization, falsified medicines, new regulations...

The Next GA will not be held in the EU but in Morocco (Casablanca).

GS1 Belgilux Healthcare Working Group on Traceability

VAPI-UPIP received an invitation to become member of a working group around traceability in the healthcare value chain. This took place on Oct 3th at the premises of GS1 Belgium.

The objective of this working group is simple in its starting point, complex in its end-result: ensure traceability in the healthcare value chain. Traceability of medicines will be a legal requirement in 2019, but only end-to-end. Will this be sufficient to cope with all regulations, or do we need a better traceability at the intermediate level (i.e. group labels). This working group aims to establish a consensus between all stakeholders to ensure traceability.

GS1 gave a presentation of their standards, and started a discussion on the legal requirements forthcoming from the GDP's and Falsified Medicines directive. The drivers for implementation will be the legislation and possible returns on investments. Not an easy exercise with so many stakeholders involved. We will keep you informed of the progress in this workgroup.

FAGG session on Auto control of Medical Devices

There is a new legal regulation (AR/KB) in Belgium concerning the notification of the materio-vigilance contact point and registration of distributors and suppliers of Medical Devices, including manufacturers and authorized representatives. Implementation is due within 6 months after publication of the AR/KB foreseen by the end of 2017.

The main intention of this new regulation is that storage, transport and distribution of Medical Devices is properly performed, assuring optimal safety for the patients. The AFMPS/FAGG has created a computer template which will have to be used by all concerned companies and persons to implement all necessary information. A specialized team of Inspectors will follow-up this new regulation as soon as the AR/KB is released.

Newsletter Volume 2018, Nr 1

Royal Association

On July 21st UPIP-VAPI was invited at the reception in the province house of Ghent to receive the official predicate as Royal Association. Our president and vice-president were present and received the document from the governor of East Flanders, in the presence of the mayor of Ninove where the seat of our association is located (in Meerbeke). As new Royal Association we are invited the upcoming 5 years. If you also want to attend, just join our board ;-)

Newsletter Volume 2018, Nr 1

GDP & GMP Training

Our yearly GMP Basic Training, given by Jacques Defrance, took place at Purna Pharmaceutical in Puurs, with a tour of the non-sterile liquids and semi-solids facility. We added the subtitle “Quality system introduction” because this reflects the content of the training. The board has been discussing the possibility to organize an in depth GMP training, and plan a session on Qualification and Validation in 2018. Any other topics are welcome, just contact us to discuss.

New is 2017 was that we also started a yearly GDP training. Section 2.4 Training of the GDP regulations states that “All personnel involved in wholesale distribution activities should be trained on the requirements of GDP”. And the responsible person should also maintain his/her competence in GDP through regular training. We organized our **1st yearly GDP certification training** at Archemin in Mechelen. covering the GDP guidelines for finished products (2013/C 343/01) and for API’s (2015/C 95/01).

The program included an overview by Frank Peeters of the roles and responsibilities of the GDP RP. Using this overview as a checklist, the compilation of a job description for this functions is now a straightforward task. The practical implementation of the Guidelines of 2013 on Good Distribution Practice of Medicinal Products for Human Use was then reviewed by Ludwig Everaert. It is hereby obvious that the implementation of the Delegated Regulation (EU) 2016/161 on falsified medicines will have a considerable impact on the standard quality manual for Good Distribution Practice. Not only will job descriptions of several members of the warehouse personnel have to be amended but it can be expected that several procedures such as those describing the receipt of medicinal products, storage and inventory protection, the preparation of shipments, batch recalls and the handling of returned product will have to be revised.

The training ended with a GDP quiz, and the attendants received a training certificate when they passed the test. Everybody passed, maybe we must make it a bit more difficult next time ;-)

As the title indicates, this will be a repeating event that we will organize at least once per year, each time with a different focus on the GDP’s. Note that we can also provide these half day GDP sessions on request at your company.

Since we had a full house in the September session, some persons ended up on the waiting list. Therefore we already organize a new training on January 25th 2018, this time at the Janssen Pharmaceutica Distribution Center in La Louvière. The training is not only intended for GDP RP’s, but also for warehouse and distribution personnel handling pharmaceutical products. GDP’s for Active Pharmaceutical Ingredients and medical devises are also discussed. A good occasion to start the year fully trained on the GDP’s.

Social Event – Cirque du Soleil TOTEM

The social event that we organized for the 3th time was a great success. For the second time in these 3 years we selected a spectacle by Cirque du Soleil: the show "Totem". UPIP-VAPI booked 50 seats for their members, relatives and collaborators. The concept is that our members get together with family and friends, not just networking with colleagues. Some members also took the occasion to invite their employees as this is a great occasion for team building.

The UPIP-VAPI event was sold out and everyone enjoyed the magical spectacle offered by the Cirque du Soleil's team. We escaped our world during the evening and went through the magical world of Cirque du Soleil. The spectacle was one giant machine with a lot of sound and light effects and with fast set changes to keep things moving in an artistic blur. The performance of the artists just blows your mind. A wonderful 2-hour show to remember.

Afterwards, we enjoyed a nice evening at the "Taverne du Heyzel" where a room was scheduled with drinks and snacks. This was the time to share our impression of the spectacle and the latest news, professional and other. The party ended late, the last ones closed the event around midnight.

Thanks to all for this very great moment.

New bylaws

We have drafted a proposal for new bylaws (statuts - statuten). The current ones do not reflect the changing environment we are facing, e.g. the legal possibility of non-pharmacists to become QP or GDP RP. Currently these persons cannot become a member although they share the same activities and have the same problems as we have. Our training sessions are also followed more and more by non-pharmacists working in the life sciences.

The new bylaws will clarify what we are: a group of pharmacists working in all possible domains of the life science industry, and who want to share their experience with the professionals of these industries.

Later this month the new bylaws will be sent to our members for review and comments, so that the General Assembly can approve them in February.

Qualified Person /QP responsibility and QP insurance

Together with Curalia we are working on an insurance for members working as Qualified Person or GDP RP. This insurance, only available via UPIP-VAPI, will cover the following legal responsibilities:

- QP responsibility at pharmaceutical companies: QP contract with the company in relation to “Liability Insurance”, “Responsibility Civil” and “Job Responsibility- legal assistance”
- In case of physical damage of distributed medical products there is necessity to have as QP a legal assistance and eventual insurance. This should also be incorporated in the company contract as employee but certainly also as external independent responsible QP.

More information on this during our General Assembly in February.

Green book

Choosing a career path is an important decision. It is a choice that all of us have to make at some point and that will determine a big part of our lives.

At UPIP-VAPI, we noticed that students are usually not aware of all the career possibilities offered to pharmacists. This is why we took the initiative to write a guide to help them having a broader picture and investigating their options.

This guide, called “Green Book”, is the result of a team work across the Board but not only. It requested the collaboration of many colleagues active in various areas, we thank them for their help. The Book is especially oriented to students but it can also be helpful for professionals willing to give their career another direction.

If you are interested, please visit our website to download the Green Book or contact info@upip-vapi.be to receive a paper copy. The UPIP-VAPI team would be happy to answer any question you would have and to receive any feedback on this guide.

Annex 1 working group

It was said that the future draft Annex 1 should be available before the New Year and we received it as a Christmass gift, maybe not the type of gift we are generally expecting. The rationale for EU GMP and Annex 1 revision is to tide up with current sterile manufacturing processes, reinforce the need for the manufacturer to keep up with current technologies and innovative technologies. Clarify regulatory requirement for disposable systems, singe use closed systems and remove some ambiguities.

The UPIP-VAPI first workshop on the EU GMP Annex 1 "Manufacture of Sterile Medicinal Products, " was held the 19 October 2016. 20 persons subscribed to the workshop. 95% of the participants were from the sterile pharmaceutical industry, while, 5% were from the hospital sector. The sterile pharmaceutical industry was represented by 77% of manufacturer and 18 % of consultants.

During the session, Walid El Azab shared to the working group the different revision that would be proposed in the future EU GMP Annex 1. Based on the various information shared, the working group discussed their current and future strategy to pro-actively implement actions to reach compliance level, while being competitive in the market. Finally, good practices and lessons learned among the different manufacturers were shared.

The goal of this working group is to comment the future draft Annex 1, share best practices and lessons learn and create a Belgium aseptic community.

It is expected that the future draft Annex 1 should contain more than 70 pages. The structure will change and should include the following sections:

1. Scope
2. Principles
3. Pharmaceutical Quality System (PQS): additional requirements from the EU GMP chapter 1 should be added.
4. Personnel
5. Premises
6. Equipment
7. Utilities
8. Production and specific technologies
9. Viable and non-viable environmental monitoring and process monitoring
10. Quality control
11. Glossary

The UPIP-VAPI working group Annex 1 is currently planning several rounds of workshop to review and comment the draft Annex 1. The next workshop will take place on **January 25th 2018 at Bone Therapeutics in Gosselies**. Come prepared as the comments needs to be handed out to the EMA before March 20th 2018!

NOTE: the initial date of January 17th had to be cancelled, that's why we move this event to the week after.

Various Activities

Other training/workshop sessions we organized this year were:

- Stress Management, by trainers from EPSA
- Audit – Regulations and Best Practices, held at CVO in Waterloo.

UPIP-VAPI represented the pharmacists of the industry at a lot of events, such as AFMPS meetings , the EPSA GA at the European Commission, Curalia sessions for graduated pharmacy students, the VFSO career day, "speed dates" for pharmacy students (UA), as jury member for bachelor posters and the career evening (UGent) etc…

The Journal de Pharmacie de Belgique is celebrating it's 100th year of existence and will publish thematic columns on the different activities and roles of the pharmacist professions. Hereby UPIP-VAPI has been asked to write the column on the history, evolution and future of the pharmacist in the Pharmaceutical Industry, to be published in Dec 2018.

General Assembly 2018

In 2017 we were honored by the presence of our Minister of Health at our GA, but this year we even go a step further.

UPIP-VAPI was founded in 1953. This is therefore our 65th anniversary, and the first as a Royal Association. We had the idea to invite her Royal Highness Prinsess Astrid, and she has accepted our invitation to be present at our GA on February 20th 2018.

Maybe not many of you know that the Princess is colonel in the medical service of the Belgian army. We contacted the medical component of the army and immediately got a positive response to hold our GA at the Military Hospital Queen Astrid in Neder-over-Heembeek.

The focus of the afternoon seminar will be on the new regulations, such as the falsified medicines delegated regulation 2016/161, the autocontrol initiative of the FAMPH and new ISO on medical devices, and the new decree on psychotropics and narcotics.

Mr. Xavier De Cuyper, Administrator-General of the FAMHP, has accepted to introduce these topics and provide the view from the FAMHP, followed by knowledgeable speakers from the field.

Please already book the afternoon of **February 20th 2018** in your agenda for this memorable edition of our GA. More information will follow soon.

Newsletter Volume 2018, Nr 1

UPIP-VAPI Program 2018

Jan 25	GDP Certification Training (Janssen Pharmaceutica - La Louvière)
	EU GMP Annex 1 Workgroup (Bone Therapeutics - Charleroi)
Feb 20	General Assembly 65 years Anniversary Edition (MHKA-HMRA - Neder-over-Heembeek)
Mar	Lecture by UPIP-VAPI on the VFSO congress (jobbeurs) for pharmacy students
	Curalia QP insurance meeting
Apr	GMP basic training – Introduction to Quality Management Systems
May 20	General Assembly EIPG in Casablanca, Morocco - Friday 19th pre-opening on precision medicine
Jun	NSF legislation update
Jul	Reception for Royal Associations (Ghent – Province House)
Sep	GDP Certification Training
Oct-Nov	Social Event
Nov-Dec	GMP advanced training on Qualification & Validation

TBD Q2 or Q4: joint event with A3P

Working groups,

- Annex 1 Follow-up meeting
- Destruction of medicinal products

Any other suggestion….