



PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

Activities Report

March 2014

Table of Contents

1.	NEWS FROM THE SECRETARIAT	4
	PGEU met the EC on e-pharmacies logo and awareness campaigns	4
	EU Parliament Workshop	4
	PGEU attended European Diabetes Leadership Forum	4
	PGEU met EDQM in Paris	4
	PGEU attended the eHealth Governance Initiative	4
	PGEU at EFPIA Workshop on Product Information	4
	PGEU attended the Pharmaceutical Care Network Europe (PCNE) Symposium	4
	PGEU attended EC conference "Health in Europe - Making it Fairer"	5
	PGEU met EuropaBio	5
	PGEU attended eHGI Patient Access to Medical Records meeting	5
	PGEU attended European Patients' Forum Campaign Exhibition at the European Parliament	5
	PGEU attended Stakeholder Meeting on Equity of Access and Sustainable Approaches to Financing of Pharmaceuticals	5
	PGEU met with Merck's Chief Medical Officer	5
	PGEU attended European Innovation Partnership (EIP) on Active and Healthy Aging (AHA), Action Group	5
	PGEU met EFPIA/AEGATE	5
	PGEU attended Patient Safety and Quality of Care Medicines Reconciliation Webinar	6
	PGEU attends EU Professional Card Focus Group	6
	PGEU in Stockholm	6
	PGEU attended EAHP Congress in Barcelona	6
2.	NEWS FROM THE EU	7
	EMA publishes its work programme for 2014	7
	EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommends restricting use of domperidone	7
	EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommends updates to the product information of zolpidem	7
	CMDh endorses recommendations to restrict the use of diacerein-containing medicines	7
	EMA publishes first summary of a risk-management plan for a medicine	8
	eHealth in the EU: what's the diagnosis?	8
	EU Commission Health Expert Panel adopts first three opinions	9
	EU Commission publishes study on medicines reimbursement	9
	EU Health Award offers €10,000 euro for multi-country health projects and initiatives	9
	Italy: Pharma groups fined €180 million	9
3.	ONGOING DOSSIERS OF INTEREST TO PGEU	11
	Tobacco Products: new Directive approved in Council	11
	Troika helped to avoid the worst, but flawed structure harmed recovery	11
	Falsification: Internet Drug Outlet Fraudulently Claiming NABP Accreditation	11
	Medicines shortages: EAHP launch 2014 survey in Europe	12

Data Protection: MEPs tighten up rules to protect personal data in the digital era	12
EU Transparency Register: New measures to encourage lobbyists to sign it	12
4. NEWS FROM MEMBER STATES and beyond	13
Belgium: New remuneration for magistral preparation enters into force	13
Belgian study reveals 15% of prescriptions are problematic	13
Bulgaria: Parliament overturns presidential veto on parallel export restrictions	14
Czech Republic: the only EU country against compulsory e-prescription	14
France: Prime Minister Service publishes recommendations for the pharmacy sector	14
Greece: OECD identifies hundreds of competition-distorting rules and provisions	15
Hungary: Number of emigrating pharmacists up	15
Italy: Antitrust fines illegal internet pharmacies selling POMs € 500 thousand	15
UK RPS says no to sale of e-cigarettes	15
UK: Boots to pilot automated dispensing hub	16
UK: New Medicine Service to continue into 2014/15	16
UK: Illegal online sales of prescription medicines on the rise, survey finds	16
UK: NHS launches consultation to shape the future of community pharmacy	16
UK: Independent pharmacies perceived to be poorly designed but more credible than others in terms of offering advice	17
Northern Ireland backs expansion of pharmacists' role	17
5. PGEU Legislative Observatory	18
6. DOCUMENTS PRODUCED BY THE SECRETARIAT	18
7. FORTHCOMING MEETINGS & EVENTS	19
PGEU Meetings	19
EUROPEAN INSTITUTIONS AGENDA	19
OTHER MEETINGS AND CONFERENCES	19

1. NEWS FROM THE SECRETARIAT

PGEU met the EC on e-pharmacies logo and awareness campaigns

On the 3rd March PGEU met the Commission official dealing with the common logo and the Internet awareness campaigns. The official confirmed that the Pharmaceutical Committee will look into the Commission proposal on the common logo, and that publication of the implementing legislation would probably be in May. She also outlined the Commission's approach to designing the awareness campaigns that will inform members of the public about the risks of purchasing falsified medicines in the Internet.

EU Parliament Workshop

PGEU attended a workshop on Prevention and Healthy Life on 4th March in the European Parliament. DG Health and Consumers presented an evaluation of the Health Programme 2008-2013. Following presentations touched prevention of specific risk factors, healthy lifestyle and healthy workplace.

PGEU attended European Diabetes Leadership Forum

On 4th March the PGEU attended the European Diabetes Leadership Forum in Brussels where a number of speakers presented on various initiatives on tackling this chronic disease. Of particular note was the forward thinking Danish initiative to combat this disease by the Steno Diabetes Centre and the significant advantages provided by a strong e-prescription system in the country.

PGEU met EDQM in Paris

On the 6th March PGEU together with the other ESM stakeholders met EDQM to further discuss possible collaboration on medicines authentication.

PGEU attended the eHealth Governance Initiative

On 11th-12th March the PGEU attended the eHealth Governance Initiative (eHGI) eprescription and electronic Identification (eID) workshops in Brussels where we argues for appropriate adherence to / interpretation to the Cross Border Health Directive i.e. to keep to national dispensing rules (for example on substitution and reimbursement) as the working group forms the guidelines on potential cross boarder eprescriptions.

PGEU at EFPIA Workshop on Product Information

On the 14th March attended a workshop on product information hosted by EFPIA. EFPIA demonstrated their plans to develop 'paperless' product information through web based information access through bar codes.

PGEU attended the Pharmaceutical Care Network Europe (PCNE) Symposium

On the 14th to the 15th of March PGEU attended the Pharmaceutical Care Network Europe (PCNE) working Symposium on 'Progress in Drug Related Problems (DRPs), Medication Review and Pharmaceutical Care (PhC) Guidelines' in Sliema, Malta. This particular event had three main themes: Drug related problems, Medication review and Pharmaceutical care standards and guidelines.

PGEU attended EC conference "Health in Europe - Making it Fairer"

On 18th March PGEU attended one day conference from the European Commission (DG Health and Consumers) "Health in Europe - Making it Fairer". Several speakers addressed issues such as discrimination in health, health inequalities and access to healthcare. During the workshop on "Equity in addressing chronic diseases" several needs for improvement were discussed such as importance of partnerships and multi-sectorial approach, need of involving new stake-holders such as insurers, employers and trading unions and also investment in promotion of prevention.

PGEU met EuropaBio

On 18th March PGEU attended a EuropaBio hosted workshop on the biosimilars market in Europe and attitudes toward biosimilars among health professionals.

PGEU attended eHGI Patient Access to Medical Records meeting

On 19th March the PGEU participated in an online eHGI Patient Access to Medical Records meeting where participants shared their experiences of patient access to their medical records and the potential impacts and advantages of such an initiative. Access by healthcare professionals such as pharmacist was also discussed positively.

PGEU attended European Patients' Forum Campaign Exhibition at the European Parliament

On 19th March the PGEU attended an exhibition in Europe organised around the of the patients manifesto adopted by the European Patients Forum ahead of the European Parliamentary elections. PGEU signed a petition in support of the manifesto.

PGEU attended Stakeholder Meeting on Equity of Access and Sustainable Approaches to Financing of Pharmaceuticals

On 19th March PGEU attended a meeting together with stakeholders from the health and pharmaceutical sectors to address the issue of equal access to medicines.

PGEU met with Merck's Chief Medical Officer

On March 20th PGEU met with Mike Rosenblatt, the Chief Medical Office of Merck, together with patients and physician's representatives, to discuss health literacy.

PGEU attended European Innovation Partnership (EIP) on Active and Healthy Aging (AHA), Action Group

On 20th March the PGEU attended the European Innovation Partnership (EIP) on Active and Healthy Aging (AHA), Action Group A1, Prescription and Adherence to Medical Plans, Polypharmacy sub-group. During this meeting several presentations on the topic were delivered by the European Commission and the sub-group's work-plan over the next year was decided. The PGEU will be contributing to the Polypharmacy sub-group.

PGEU met EFPIA/AEGATE

On 21st March the PGEU together with other ESM stakeholders met Aegate to discuss their approach to implementation of medicines authentication.

PGEU attended Patient Safety and Quality of Care Medicines Reconciliation Webinar

On 21st March the PGEU participated and contributed to the Patient Safety and Quality of Care Medicines Reconciliation Webinar hosted by the European Federation of Nurses (EFN). During this Webinar a number of presenters discussed Medicines Reconciliation and their experiences / successes in delivering this service.

PGEU attends EU Professional Card Focus Group

On the 25th March PGEU attended the second focus group on the European Professional Card. This group was composed by member states representatives and the representatives of health professionals' organisations. During the meeting the Commission presented a detailed proposal on the functioning of the European Professional Card and discussed with the audience some technical concerns as regards the functioning of the Card, such as how to organise the EPC fees and the documentation to be included in the EPC.

PGEU in Stockholm

On the 25th March PGEU gave a presentation on current trends in European pharmacy to the Swedish Pharmacy Market Days meeting in Stockholm.

PGEU attended EAHP Congress in Barcelona

On 26-28 March PGEU attended the Congress of the European Association of Hospital Pharmacists. The theme of this years' congress was innovation.

2. NEWS FROM THE EU

EMA publishes its work programme for 2014¹

The European Medicines Agency has published its work programme for 2014. Legislative developments remain one of the main drivers of the Agency's priorities this year. The European pharmacovigilance legislation brought one of the biggest changes to the legal framework for human medicines since the creation of the Agency. Among the priority activities in this area in 2014 are the further development of methods for collecting best evidence, enhancement of functionalities of EudraVigilance, the European database on adverse drug reactions, the development of a repository for periodic safety update reports (PSURs) as well as a system for monitoring the scientific literature for signal detection.

The Agency will also continue the implementation of the falsified medicines directive will closely monitor and contribute to the debate on new legislative proposals on the conduct of clinical trials and on veterinary medicines. This year the Agency will also maintain its emphasis on support to the early stages of medicines development. It will also support the development of new approaches and innovative medicines through the developing specific guidelines.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommends restricting use of domperidone²

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) at its March 2014 meeting has concluded an in-depth review of domperidone-containing medicines, carried out over concerns about the medicines' effects on the heart. The Committee has recommended changes to their use throughout the European Union, including using these medicines only to relieve symptoms of nausea and vomiting, restricting the dose and adjusting doses carefully by weight where it is licensed in children.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommends updates to the product information of zolpidem³

The European Medicines Agency's PRAC at its March 2014 meeting has recommended changes to the product information of zolpidem-containing medicines. These changes are aimed at further minimising the known risks of next-morning impaired driving ability and mental alertness (including somnambulism) with these medicines.

CMDh endorses recommendations to restrict the use of diacerein-containing medicines⁴

On 19 March 2014, the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)¹ endorsed recommendations to restrict the use of diacerein-containing medicines in order to manage the risks of severe diarrhoea and effects on the liver. Due to the risks associated with severe diarrhoea, diacerein is no longer recommended in patients aged 65 years and above. It is also advised that patients start treatment on half the normal dose (i.e. 50 mg daily instead of 100 mg) and should stop taking diacerein if diarrhoea occurs. In addition, diacerein-containing medicines must now not be used in any

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http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002045.jsp&mid=WC0b01ac058004d5c1

2

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002039.jsp&mid=WC0b01ac058004d5c1

3

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002037.jsp&mid=WC0b01ac058004d5c1

4

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002049.jsp&mid=WC0b01ac058004d5c1

patient with liver disease or a history of liver disease, and doctors should be monitoring their patients for early signs of liver problems.

These recommendations are based on the review of the benefits and risks of diacerein conducted by the EMA's PRAC and follow concerns raised by the French medicines agency (ANSM) about diacerein's gastrointestinal and liver effects. As the CMDh position on diacerein was adopted by majority vote, it will now be sent to the European Commission for a final legally binding decision valid throughout the European Union.

EMA publishes first summary of a risk-management plan for a medicine⁵

The European Medicines Agency has published the first summary for the public of the risk-management plan (RMP) of a newly authorised medicine. This RMP summary, which concerns the medicine Neuraceg, describes what is known and not known about the medicine's safety and states what measures will be taken to prevent or minimise its risks.

The Agency will pilot the publishing of RMP summaries for all newly centrally authorised medicines during 2014 and at a later stage will start producing RMP summaries for previously authorised medicines.

This new type of publication is a further step towards increased transparency and public access to relevant information on medicines and is one of the requirements of the new European pharmacovigilance legislation. The RMP summaries complement the public-friendly information already available in the Agency's summaries of the European public assessment report (also known as EPAR summaries).

eHealth in the EU: what's the diagnosis?⁶

According to two surveys in acute care hospitals and among General Practitioners (GPs) in Europe, the use of eHealth is starting to take off, with 60% of GPs using eHealth tools in 2013, up 50% since 2007. But much more needs to be done. The main findings of the surveys include:

- Top performing countries for *eHealth uptake* in hospitals are Denmark (66%), Estonia (63%), Sweden and Finland (both 62%). Full country profiles are available [here](#).
- eHealth services are still mostly used for traditional recording and reporting rather than for clinical purposes, such as holding consultations online (only 10% of GPs hold online consultations)
- When it comes to *digitising patient health records*, the Netherlands take the gold with 83.2% digitisation; with silver medal for Denmark (80.6%) and the UK taking home bronze (80.5%);
- However, *only 9% of hospitals in Europe allow patients to access online their own medical records*, and most of those only give partial access;
- When adopting e-health, *hospitals and GPs experience many barriers* ranging from lack of interoperability to lack of regulatory framework and resources.

When asked why GPs were not using eHealth services more, their reasons were a lack of remuneration (79%); insufficient knowledge of IT skills (72%); the lack of interoperability of systems (73%); and a lack of a regulatory framework on confidentiality and privacy for email doctor-patient communication (71%).

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http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500163610&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002041.jsp&mid=WC0b01ac058004d5c1

⁶ [Benchmarking deployment of e-Health services in Hospitals \(2012–2013\)](#); [Benchmarking Deployment of eHealth among General Practitioners \(2013\)](#); http://europa.eu/rapid/press-release_IP-14-302_en.htm

EU Commission Health Expert Panel adopts first three opinions⁷

The independent Expert Panel which advises the Commission on matters related to “effective ways of investing in health” has adopted its first three opinions.

The first opinion on a **frame of reference in relation to primary care with a special emphasis on financing systems and referral systems** is of particular interest to EU countries that are making efforts to improve the functioning and sustainability of their health systems. The opinion provides a core definition of primary care, underlines its importance, and recommends its strengthening in terms of infrastructures, organisation, access, and financing. A public consultation on this opinion will be launched soon.

The second opinion on **Criteria to identify priority areas when assessing the performance of health systems** has a practical aim. The Expert Panel has elaborated guidance on elements to be considered when developing such criteria.

The third opinion is an **assessment of the study “Evaluation of public-private partnerships in health care delivery across the EU”**. The opinion provides a critical peer review of a much debated topic. It examines the strength of the evidence and assesses the conclusions of the study.

These opinions, as all advice given by the Expert Panel on effective ways of investing in Health, are non-binding. To read the opinions: http://ec.europa.eu/health/expert_panel/opinions/index_en.htm.

EU Commission publishes study on medicines reimbursement⁸

The European Commission has published a study on **The policy mix for the reimbursement of medicinal products**. The study authors conducted a systematic literature review of relevant policy measures related to pharmaceutical reimbursement in the European countries, and a survey of relevant identified stakeholders for their views and perspectives. In terms of reaching conclusions about ‘ideal’ policy mix on medicines reimbursement, the authors concluded that such mix is likely not to include high co-payments, arrangements such as discounts, rebates, price negotiations or clawbacks, tendering applied in the out-patient sector, and external price referencing.

EU Health Award offers €10,000 euro for multi-country health projects and initiatives⁹

The European Health Forum Gastein is seeking applications to a ‘European Health Award’ to recognize achievements in the field of health care delivery across more than one European country. With a deadline for submissions of 30 May, the winner will be selected in September, and awarded the prize in October.

The European Health Forum is a platform that brings together decision-makers in various fields of public health & health care with the aim of advising and developing European health policy. The award is a key part of the annual Forum event in October, and is judged by a wide ranging jury including members of the European Parliament, European Commission, national health ministries and academics.

Italy: Pharma groups fined €180 million

Pharmaceutical giants Roche and Novartis have been fined on the 5th March 180 million euros by the Italian Antitrust Authority for a cartel aimed at blocking the sale of an eye treatment 10 times cheaper than the one on the market. The two pharma companies were found of having excluded a drug called

⁷ http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=1464

⁸ http://ec.europa.eu/health/healthcare/docs/policymix_reimbursement_medicinal_products_en.pdf

⁹ <http://www.ehfg.org/healthaward.html>

Avastin from the market and channelled the demand toward a similar and more expensive drug called Lucentis. Both medicines can be used in the treatment of serious eye problems.

In a letter to the European Commission in November last year, BEUC called for an EU-wide investigation taking into account that the two products are sold in many EU Member States.

3. ONGOING DOSSIERS OF INTEREST TO PGEU

Tobacco Products: new Directive approved in Council¹⁰

On the 14th March in the Transport Council, Ministers approved the revised Directive on tobacco products, which was formally endorsed by the European Parliament on 26 February 2014. Amongst the rules that will be transposed in the next few years are large mandatory picture warnings on both sides of packets of cigarettes and roll-your-own tobacco, a ban on products with characterising flavours and on slim “lipstick” style packs, a minimum of 20 cigarettes per pack and quality and safety requirements for electronic cigarettes. The new legislation ensures that tobacco products look and taste like tobacco so as to discourage young people from starting to smoke and improves the functioning of the internal market of tobacco and related products. The next steps for this Directive are its signature by the Presidents of both the Council and Parliament, and publication in the Official Journal of the EU in April/May 2014.

Troika helped to avoid the worst, but flawed structure harmed recovery¹¹

The EU/ECB/IMF "Troika" helped four EU countries through the crisis and prevented it from getting worse. But its flawed structure and working methods hindered national "ownership" and compromised transparency and accountability, says a resolution on the EP inquiry findings. A second resolution deplors the widespread negative impacts that Troika-inspired reforms had on employment and advocates revising the measures put in place.

Both resolutions were voted during the plenary session in March. The one on the Economic and Monetary Affairs Committee's inquiry into the workings of the Troika, drafted by Othmar Karas (EPP, AT) and Liem Hoang-Ngoc (S&D, FR), was approved by 448 votes to 140, with 27 abstentions. The Employment and Social Affairs Committee's resolution, authored by Alejandro Cercas (S&D, ES) was approved by 408 votes to 135, with 63 abstentions.

The “inquiry resolution” acknowledges that the immediate aim of avoiding disorderly defaults was achieved and that the challenges that the Troika was set up to tackle were "immense". It also deplors the fact that EU institutions were made a scapegoat for the adverse effects of reforms, even though it is finance ministers who should bear political responsibility for them. The Troika system is also criticised for taking a "one-size fits all" approach from which it was often reluctant to depart. The conditions imposed in return for the financial assistance have jeopardised the EU's social objectives, notably because little time was allowed to implement the measures and there was no proper assessment of their likely impact on various social groups, says the Employment Committee text.

The second resolution calls on the Commission and the Council to give the same attention to social imbalances as to macroeconomic ones. Member states and the EU should put in place a job recovery plan once the worst of the financial crisis has passed, taking particular account of the need to create favourable conditions for small firms, for instance by repairing the credit system. The Commission, the ECB and the Eurogroup (Eurozone finance ministers) should review and revise the measures put in place as soon as possible and the EU should support, with sufficient financial resources, the restoration of social protection standards, MEPs add.

Falsification: Internet Drug Outlet Fraudulently Claiming NABP Accreditation

Internet drug outlet, WellnessFitnessNutrition, LLP (WFN) offering to sell, without a prescription, prescription drugs such as antibiotics, anabolic steroids, and growth hormones, was fraudulently claiming to hold certain NABP certifications. Along with text claiming that the site was NABP certified, WFN posted a letter on its website that falsely claimed that WFN and its affiliate, “Dr Hector R. Rodriguez,” were certified

¹⁰ http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lisa/141527.pdf

¹¹ <http://www.europarl.europa.eu/news/en/news-room/content/20140307IPR38419/html/As-many-Commissioners-as-possible-should-be-chosen-among-MEPs-says-Parliament>

to practice pharmacy pursuant to the NABP “Foreign and National [sic] Pharmacy Graduate Examination Committee” certification program. The fraudulent claims on the WFN website illustrate the importance of NABP’s efforts to implement the .pharmacy domain, which will provide a safe place on the Internet for consumers seeking to purchase medications from legitimate online pharmacies. As the registry operator, NABP will require that registrars approved to sell .pharmacy domain names notify Internet pharmacy registrants that they must comply with all applicable laws and provide proof that they are licensed to operate and practice pharmacy. NABP has been deemed eligible to enter contract negotiations with the Internet Corporation for Assigned Names and Numbers to own and operate the .pharmacy domain suffix.

Medicines shortages: EAHP launch 2014 survey in Europe¹²

The European Association of Hospital Pharmacists (EAHP) has launched its **2014 survey on medicines shortages in Europe**. It will be open for 7 weeks, closing on 7th May 2014. Covering issues such as the prevalence of shortages, types of shortages, and length of shortages, the survey also investigates the impact that shortages have on patient care and the operation of hospital pharmacy services.

Data Protection: MEPs tighten up rules to protect personal data in the digital era¹³

MEPs inserted stronger safeguards for EU citizens’ personal data that gets transferred to non-EU countries in a major overhaul of the EU’s data protection laws voted in the plenary session on the 12th March. The new rules aim both to give people more control over their personal data and to make it easier for firms to work across borders, by ensuring that the same rules apply in all EU member states. MEPs also increased the fines to be imposed on firms that break the rules, to up to €100 million or 5% of global turnover.

To better protect EU citizens against surveillance activities like those unveiled since June 2013, MEPs amended the rules to require any firm (e.g. a search engine, social network or cloud storage service provider) to seek the prior authorisation of a national data protection authority in the EU before disclosing any EU citizen’s personal data to a third country. The firm would also have to inform the person concerned of the request.

The new rules should also better protect data on the internet. They include a right to have personal data erased, new limits to “profiling” (attempts to analyse or predict a person’s performance at work, economic situation, location, etc.), a requirement to use clear and plain language to explain privacy policies. Any internet service provider wishing to process personal data would first have to obtain the freely given, well-informed and explicit consent of the person concerned.

The European Parliament voted on its first reading of the draft legislation, in order to consolidate the work done so far and hand it over to the next Parliament. This ensures that the MEPs newly elected in May can decide not to start from scratch, but instead build on work done during the current term.

The draft regulation was approved by 621 votes to 10, with 22 abstentions. The draft directive was approved by 371 votes to 276, with 30 abstentions.

EU Transparency Register: New measures to encourage lobbyists to sign it¹⁴

Measures to encourage lobbyists working with the EU to sign the EU’s public “Transparency Register” were backed by the Constitutional Affairs Committee. MEPs reiterated their demand that the register be made

¹² Council recommendation on a Quality Framework for Traineeships:

http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lsa/141424.pdf (original version - EN)

¹³ <http://www.europarl.europa.eu/news/en/news-room/content/20140307IPR38204/html/MEPs-tighten-up-rules-to-protect-personal-data-in-the-digital-era>

¹⁴ <http://www.europarl.europa.eu/news/en/news-room/content/20140317IPR39132/html/New-measures-to-encourage-lobbyists-to-sign-the-EU-Transparency-Register>

compulsory and meanwhile approved new provisions to push interest groups to make their relations with the EU more transparent. The committee backed the introduction of incentive measures that would link the registration to:

- further facilitation of access to Parliament's premises and help in contacting MEPs,
- easier authorisation to organise or co-host events on its premises,
- facilitated transmission of information, including through specific mailing lists,
- participation as speakers in committee hearings,
- better chances of getting patronage by the institution for events,

The committee also encouraged the Commission to adopt similar measures. MEPs also asked for an evaluation of the Register before the end of 2017.

4. NEWS FROM MEMBER STATES and beyond

Belgium: New remuneration for magistral preparation enters into force¹⁵

As from the 1st April the reform on magistral preparations will enter into force. The reform concerns new public prices and a new pharmacy remuneration for reimbursed preparations only. Pharmacists will be remunerated with an "all in" formula: type of preparation, time consumed, material, accessories. A complementary remuneration is foreseen only for enteric covering of capsules. The quantity (20 or 60 pills) does not change the abovementioned remuneration. All galenic preparations have been classified in 3 different categories, to which corresponds a different remuneration calculated according to the time used for the preparations:

1. Simple preparations (capsules, solutions...), 20 minutes: 12,93 €
2. Dermatological preparations (cremes, lotions...), 32,5 minutes: 21,03 €
3. Difficult preparations (suppositories, ovules...), 50 minutes : 32,35 €

Belgian study reveals 15% of prescriptions are problematic

A new study involving 500 pharmacies throughout Belgium and their daily workload during 5 days, aimed at analyzing the frequency and the nature of the problems met by pharmacists when delivering a prescription and then the frequency and the nature of their intervention to solve the individualized problems. Here the main results:

- 64,962 prescriptions have been analyzed;
- 9,869 (15%) presented problems related to the prescribed medicines (from now on **PLM: *problems liés aux médicaments***);
- Given that each prescription could present more than one problem, overall 15,952 problems related to the prescribed medicines (PLM) were found;
- 2,597 (16%) of the registered problems were detected during a "a posteriori" control;
- 19,269 causes of PLM have been identified: 57% of technical origin, 37% of clinical origin and 6% of other kind;
- Involved pharmacists were able to solve almost 3 out of 4 detected PLM;
- In 1 PLM out of 2, the patients have been informed orally or in writing;
- Pharmacists have intervened in 44% of PLM discovered "a posteriori".

¹⁵ Source: Annales 15 mars 2014 pag 7

Bulgaria: Parliament overturns presidential veto on parallel export restrictions

The majority of MPs in the Bulgarian parliament have voted to overturn the president's veto on amendments to the Medicinal Products in Human Medicine Act passed by the National Assembly. These are designed to ensure that the country has sufficient amounts of medicines to meet domestic demand by limiting parallel exports. As a result, marketing authorisation holders (MAHs) will have to obtain approval for parallel exports from the Bulgarian Drug Agency. The requirement pertains to exports of drugs on the Positive Drugs List. MAHs have to submit an application for each individual export shipment, and the agency will have up to 30 days to give or withhold its approval. The BDA will reject applications for exports of drugs which are found to be in short supply in the country.

Czech Republic: the only EU country against compulsory e-prescription¹⁶

The Czech Republic may remain the only country in the Central Europe which does not bring in the compulsory e-prescription. At present, e-prescriptions can be issued in the Czech Republic on a voluntary basis, but a significant majority of medical professionals still fill them out on paper.

Other countries are in the process of implementing this e-health solution, or at least plan to do so, and perceive digitization of the healthcare system as a necessity.

Bulgaria plans to replace paper-based prescriptions with the e-prescription by end 2014, according to an agreement between the Bulgarian National Health Insurance Fund (NHIF) and the Bulgarian Pharmaceutical Union (BPhU) on the introduction of e-prescriptions in the country.

The Hungarian Ministry of Human Resources claims that the e-prescription system is being prepared, and the country will most probably not see the implementation of the e-prescription in 2014. The construction of the IT infrastructure for such a system is likely to cost as much as HUF 1bn (€3.4m), but this could be covered by an EU subsidy obtained for a National Health Insurance Fund (OEP) IT development project.

In Poland the e-prescription is scheduled to replace traditional paper prescriptions from 1 August 2016. The only exceptions will be so-called pro auctore and pro familiae prescriptions for reimbursed medicines, crossborder prescriptions, as well as prescriptions for persons with an unknown identity or those without access to the online platform. The deadline for the complete switch to electronic orders is 1 March 2017 and to digital patient records 1 August 2017.

The Slovak Ministry of Health plans to complete its eHealth programme in 2016, to include the e-prescription and electronic patient records. The Ministry claims that the eHealth programme will contribute to the reduction of mortality and morbidity among patients and will ensure more efficient use of healthcare resources.

Finally, in Romania all prescriptions have been issued electronically since 2013.

France: Prime Minister Service publishes recommendations for the pharmacy sector

A paper analyzing the French health sector and setting out a number of recommendations directly involving pharmacists was published this month by the CSFF. In detail, the paper advises the government to strengthen the advisory mission of pharmacists when dispensing medicines to patients. Moreover, it recommends better access of pharmacists to patients' health records, and better exchange of information between healthcare professionals. The CSPF takes as example of best practice the multidisciplinary primary care system established in the Netherlands, involving doctors and pharmacists, where doctors communicate information about their prescribing practices and pharmacists participate in the discussions to further change the therapy. The document recommends involving pharmacists in the preparation of

¹⁶ Central Europe Pharma News – Issue No. 5 (116) Wednesday, 5 March 2014

administered doses (PDA) and encourages dispensing units. The CSPF supports the adoption of a new remuneration system for pharmacists, including "extending the current projects on the establishment of a specific remuneration package for therapeutic patient education (FTE)". CSPF considers it necessary to improve information on the packaging, presentations and package leaflets. Finally, to ensure better compliance, seniors with loss of autonomy could be helped by the use of an electronic pillbox distributing medication at scheduled times, prepared by the pharmacist.

Greece: OECD identifies hundreds of competition-distorting rules and provisions¹⁷

An 11-month investigation by the OECD in cooperation with the Greek authorities has identified a wide range of regulations and legal provisions that undermine competition. In its report into Greece's food processing, retail trade, building materials and tourism sectors, the OECD identified 555 regulatory restrictions which it says, if lifted, would have major benefits for the Greek economy, not least through lower prices. The main findings include:

- Barriers to entry (such as the definition of "fresh" milk which sets the maximum shelf-life at five days, exclusive distribution of over-the-counter medicines (OTCs) by pharmacies, minimum requirements for touristic infrastructures and activities);
- Price distortions (such as regulated prices of OTCs, requirements to submit prices to trade associations and various forms of price notification and approvals);
- Rules that constrain the operation of businesses and their commercial practices (such as the regulation of promotions and sales, restrictions on the establishment and ownership of pharmacies);
- Third-party levies (such as the levy on cement, on the wholesale price of medicines and on flour);
- Obsolete legislation (such as various provisions in the Code of Foodstuffs and Beverages, including restrictions on bottling apple vinegar or importing certain types of peppers).

Hungary: Number of emigrating pharmacists up¹⁸

While the number of physicians planning to emigrate was down in 2013 compared to the previous year, numbers of pharmacists, dentists and nurses planning to leave Hungary all rose, according to the data of the Office of Health Authorisation and Administrative Procedures. In all, 1,950 health workers submitted a request for the certificate needed for foreign employment, 111 fewer than in 2012. Pharmacists made a total of 77 requests, 20% more than a year earlier. Among physicians planning to emigrate, GPs, internists and anaesthetists were the three most frequent groups. The most popular destination is Germany, with the UK and Sweden in second and third place.

Italy: Antitrust fines illegal internet pharmacies selling POMs € 500 thousand¹⁹

Hexpress Ltd British internet pharmacies 121doc.net, it.121doc.net and 121doc.it, and Italian websites www.anagen.net, and www.webpharmacy.biz, illegally advertising and selling POMs in Italy have been closed down and fined by the Italian Competition Authority after complaints initiated several months ago from national pharmacy associations Federfarma and Fofi.

UK RPS says no to sale of e-cigarettes

The UK's Royal Pharmaceutical Society (RPS) has put itself on course for a clash with some of its members by calling for pharmacists not to sell electronic cigarettes in their pharmacies. Noting that supplying and promoting e-cigarettes posed "an ethical dilemma for pharmacists", the RPS pointed out that it was seeking "consensus on how the profession and pharmacy owners" approached the issue. The RPS's stance

¹⁷ <http://www.oecd.org/newsroom/greece-oecd-identifies-hundreds-of-competition-distorting-rules-and-provisions.htm>

¹⁸ Central Europe Pharma News – Issue No. 5 (116) Wednesday, 5 March 2014

¹⁹ <http://www.federfarma.it/Edicola/Filodiretto/VediNotizia.aspx?id=6769>

puts it into direct conflict with the UK's two biggest pharmacy chain - Boots and Lloydspharmacy - both of which recently started stocking e-cigarettes. Lloydspharmacy announced in January that it had begun selling British American Tobacco's Vype brand of e-cigarettes. A month later Boots said it would start stocking Imperial Tobacco's Puritane brand.

UK: Boots to pilot automated dispensing hub²⁰

Boots has unveiled plans to trial a dispensing hub in a bid to cut the time pharmacists spend on repeat prescriptions. A dispensing support pharmacy would open in Preston in early summer to dispense medicines to 50 Boots branches.

Staff at the hub will pick stock, apply labels, perform accuracy checks and bag medicines with the help of automation, although Boots did not reveal how much of the process would be automated. The medicines will then be delivered to the branches, where they will be dispensed to patients.

The pilot project came in response to the shift in funding towards pharmacy services, Boots said, which meant pharmacists needed to be freed from "some of the volume of predictable work". The multiple said it would "explore" the option of providing additional clinical services in the pilot stores.

The multiple stressed that the pilot system would in no way compromise patient safety, which it said had been at the heart of the project. Boots said pharmacists would be able to spend "more quality time" with patients as a result of the reduced dispensing workload. Lloydspharmacy trialed a hub and spoke dispensing model in 2008, but has not announced any plans to extend it on a wider scale.

UK: New Medicine Service to continue into 2014/15

Funding for the new medicine service, which was due to run out on 31 March 2014 after three extensions, will be extended, but this time with no definite timeline. NHS England said it will "run throughout 2014/15", subject to the outcome of the evaluation of the service, which is expected to be published before May.

UK: Illegal online sales of prescription medicines on the rise, survey finds²¹

Nearly half of pharmacists have seen a rise in the number of patients buying prescription medicines through illicit websites, a survey by the Royal Pharmaceutical Society (RPS) has revealed. 41% of 2,500 pharmacists that took part in the survey, run with ITV's Daybreak programme, had seen an increase in the number of patients obtaining POMs from illegal websites over the past few years and 80 per cent said they were seeing examples of patients self-diagnosing and self-treating via the internet, the RPS said. 52% said they had suspected a patient of being addicted to a POM they were taking without their GP's knowledge. 60% of pharmacists thought the overall number of patients addicted to these medicines had increased in recent years.

UK: NHS launches consultation to shape the future of community pharmacy²²

Pharmacists and the wider healthcare sector were asked their views by NHS England on how community pharmacy can improve the primary care sector. The review was seen by some pharmacy organisations as an opportunity to reshape pharmacy services significantly and to stimulate debate in local communities, to shape local strategies for community pharmacy and to inform NHS England's strategic framework for commissioning community pharmacy.

²⁰ http://www.chemistanddruggist.co.uk/news-content/-/article_display_list/17521950/boots-to-pilot-automated-dis

²¹ http://www.chemistanddruggist.co.uk/news-content/-/article_display_list/17689692/illegal-online-sales-of-prescription-medicines-on-the-rise-survey-finds

²² <http://www.england.nhs.uk/ourwork/qual-clin-lead/calltoaction/pharm-cta/>

PGEU representative Sid Dajani commented: "We have had countless consultations, white papers and other publications which have promised to change or improve our future but this is a very important one because the NHS is reaching breaking point. GPs and other HCPs are struggling and don't want to take on new roles. The NHS is facing huge financial challenges, increasing demand (ageing society, rise of LTCs, increasing expectations), supply of NHS (increasing costs of providing care, limited productivity gains, constrained public resources), current ways of working are unsustainable and the government need radical changes to achieve £20bn cost savings.

The risk is that the NHS earmarks pharmacy as an area in which savings could be made. So we must convince the NHS of this value and convince it that we can do more. If health service finance departments see pharmacy as simply a cost, they will do all they can to cut that.

Given our expertise and knowledge, it is not such a big jump to imagine all patients with minor conditions being diverted from GP surgeries and sent to pharmacies instead or for patients with long-term conditions to have their reviews, medication and general health managed by pharmacies, only referring back to GPs if conditions seriously deteriorate".

The NHS will analyze the answers to the call and a strategic outline will be produced in 2014.

UK: Independent pharmacies perceived to be poorly designed but more credible than others in terms of offering advice²³

Customers of independent pharmacies believe that independents have more credibility offering advice and information services than large chains and supermarket pharmacies, according to research commissioned by the Independent Pharmacy Federation. However, they were also thought to be more expensive and poorly designed. The findings suggest patients trust the advice given by their local independent community pharmacist who they view as accessible and quick to respond. Pharmacists working in supermarket and multiple pharmacies, on the other hand, were seen as inaccessible.

The research was based on results from an online survey of 906 UK pharmacy customers — 600 who used an independent pharmacy once a month and 306 who used a multiple or supermarket pharmacy and did not use an independent more than once every three months.

Independents were also valued over multiple or supermarket pharmacies because of their location near to GP surgeries and because they had successful relationships with their customers. Customers also believed they were supporting their community by using their local pharmacy whereas supermarket and multiple pharmacies were perceived by some as "greedy, faceless organisations". Pharmacy layout was seen as better in supermarkets and multiples than in independents, which some customers thought were poorly designed and "chaotic". Independents were also perceived to be more expensive than supermarket or multiple pharmacies, offering a smaller range of products. Parking at independents could also be a problem for customers who had a disability, the study indicated.

Northern Ireland backs expansion of pharmacists' role²⁴

The Northern Ireland government has committed to increasing the use of pharmacists' clinical skills and promoting a version of the hub-and-spoke model, in a new five-year strategy for the sector.

²³ http://www.pjonline.com/news/independent_pharmacies_perceived_to_be_more_credible_in_terms_of_offering_advice

²⁴ http://www.chemistanddruggist.co.uk/news-content/-/article_display_list/17706300/northern-ireland-backs-expansion-of-pharmacists-role

The document, developed by a steering group from the Department of Health, Social Services and Public Safety, advised that pharmacists could support further change in the health system if they had access to electronic patient records and were able to deliver services as part of a hub-and-spoke model.

The document also sets out plans for pharmacy to have a "refreshed focus" on routinely advising patients about how to take their medicines correctly, as well as promoting self-care.

5. PGEU Legislative Observatory

None.

6. DOCUMENTS PRODUCED BY THE SECRETARIAT

- PGEU Response to Patient Safety and Quality of Care Consultation
- PGEU joint letter with CPM and CED on Data Protection
- PGEU Annual Report 2013

7. FORTHCOMING MEETINGS & EVENTS

PGEU Meetings

7 April 2014	Economics WG, Brussels
8 April 2014	Advisory WG, Brussels
12 May 2014	Professional Issues WG, Brussels
13 May 2014	Advisory WG, Brussels
13 May 2014	Executive Committee, Brussels
16 June 2014	Annual Symposium, Bratislava
17 June 2014	GA, Bratislava
18 June 2014	Social Programme, Bratislava

EUROPEAN INSTITUTIONS AGENDA

2-3 April 2014	EU Parliament Mini Plenary, Brussels
14-16 April 2014	EU Parliament Plenary, Strasbourg
22-25 May 2014	European Elections
19-20 June 2014	COREPER Health & Consumers Affairs
26-27 June 2014	European Council
1 July 2014	Italian Presidency of the EU Council for the next six months

OTHER MEETINGS AND CONFERENCES

31 March-01 April 2014	EuroPLX 54
01-04 April 2014	World Generic Medicines Congress Europe 2014, London
03-04 April 2014	Chronic Diseases Summit
03-04 April 2014	EGA International Biosimilar Medicines Conference, London
28-29 April 2014	Informal Meeting of Health Ministers, Greece
6-8 May 2014	mHealth Summit, Berlin
10-12 May 2014	eHealth Forum 2014 in Athens
03-05 June 2014	AESGP Annual Meeting, London
05-06 June 2014	EFPIA Annual Meeting, Lyon, France
25-27 June 2014	EGA Annual Conference, Madrid

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