

# NEWSLETTER

January 2018

A DIARY OF ACHIEVEMENTS SEPTEMBER TO DECEMBER 2017



## September

Johanna Engel joins GIRP as the new intern, is briefed on ASOP EU activities and her support is welcomed. Initial discussions and briefing on the biocides vs licensed medicines issue relating to patient safety begins. Attendance at EUIPO Observatory meeting - Alicante - EAASM speaker and panelist on "The Internet: a safe and transparent place for patients and consumers to buy medicines?"

## October

Attendance at Annual MHRA lecture at Francis Crick Institute. Speaker and panelist at the World Customs Organisation Working group on E-Commerce (WGEC) in Brussels, on subject of "Diffusion Challenges – Safety, Security and Control Perspectives" Contributor to the Fight the Fakes Partnership meeting, Brussels with the International Federation of Pharmaceutical Wholesalers (IFPW).

## November

Attendance at the PACT Patient Access Partnership workstream meeting and subsequent input in to partnership survey on the future direction for PACT and its objectives. Attendance as speaker at the SECURIKETT inauguration of new headquarters in Munchendorf (Vienna) Austria. Attendance and intervention made at the 10th European Antibiotic Awareness Day (EAAD), a European health initiative for national campaigns on the prudent use of antibiotics.

European Medical Association (EMA) Annual General assembly, London official signing of ASOP EU & EAASM Membership. GIRP annual European Parliament lunch reception dedicated to "Partnerships for Timely and Sustainable Access to Medicines".

Speaker at IQPC Conference entitled "8th Annual Serialisation & Traceability 2017 pharmaceutical conference". Meeting with SECURIKETT on future collaboration including using ASOP EU/EAASM educational website links from SECURIKETT website. EUIPO Observatory meeting - Brussels, attendance at Common Session and raising public awareness and law enforcement working groups to contribute to 2018 work plans.

ASOP EU Google Educational AdWord grant renewed, enabling the 5 country campaign to be continued.

## December

European Patients Forum (EPF) meeting on Cross-Border Healthcare Roundtable, Brussels. Input to working group. Attendance at EUROPOL/EURID meeting entitled "Cross-Border Collaboration in Fighting Cybercrime" best practices workshop organised by EURid in Brussels.



## Chair of EAASM

### 2017 Reflections

*Cathalijne Van Doorne*

Yet again we have had a year of tumult across the world, both in political terms as well as natural disasters, all of which have affected populations and caused great humanitarian suffering with subsequent appalling health and patient safety issues.

Listening to an interview just after Christmas by Prince Harry with ex-US President Obama, it was clear that here was a President deeply committed to do good in the world. His Obamacare bill, which enabled some 20 million people to access healthcare, was a shining example of this. His initiative to encourage youth leadership is also to be welcomed. Prince Harry is also championing this goal. The Invictus Games in which wounded, injured or sick armed services personnel and their associated veterans also help to highlight the need for social and health reforms across the world.

In this context of better health for all, it is important to remember the breakthrough made possible by Sir Alexander Fleming and his discovery of Penicillin G in 1928. This revolutionised medicine and has saved millions of lives. However, in 2017 the world population is in grave danger of losing these innovative medicines due to anti-microbial resistance (AMR).

Criminals who falsify antibiotics and enable the consumer to buy them illegally online are potentially contributing to AMR.

To highlight and take action on this important issue, the 10th European Antibiotic Awareness Day (EAAD), took place. This European health initiative provides a

platform and support for national campaigns on the prudent use of antibiotics. In addition on November 15th 2017, the European Center for Disease Prevention and Control (ECDC), in cooperation with the European Commission, hosted an EU-level event entitled 'Keeping Antibiotics Working' in Brussels.

Mike Isles, Executive Director EAASM, met the European Commissioner for Health and Food Safety, Dr Vytenis Andriukaitis, who gave the keynote address. Mike importantly took the opportunity to make an intervention at the meeting (the content can be read on page 11) and to inform the Commissioner that consumers and patients are buying antibiotics online from illegally operating pharmacy websites so potentially contributing to AMR. This will undoubtedly have helped to raise awareness about the Internet being a contributor to AMR.

I was delighted to receive the news that Google had renewed the educational AdWord grant which is of tremendous importance as it enables the EAASM with ASOP EU to run campaigns to inform the public about falsified medicines. Currently there are national campaigns running in France, Germany, Italy, Spain and the UK (the "reach" statistics make for encouraging reading and can be found on page 8). The fact that the Falsified Medicines Directive under Article 85d legally obliges all Member States (MS) and the Commission to publicise the meaning of the Common Logo and a falsified medicine, is clearly good news. What is less good, is the current lack of engagement on this obligation by many MSs.

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# Chair of EAASM

## 2017 Reflections

*Cathalijne Van Doorne*

However, the close cooperation and trust that the EAASM has built up with MS personnel, who are responsible for implementing Article 85d, is very encouraging. The subsequent authoritative report (see page 7) will help to catalyse further collaboration and concerted action by all stakeholders and in 2018 we should see further good progress here.

The EAASM was again very active on the topic of Off Label Usage (OLU) and whilst the objective of creating pan-EU guidelines was not realised, the whole profile of OLU has been raised significantly. And I am sure that the well constructed and convincing letter from the EAASM to the Health Commissioner arguing strongly for the need for OLU guidelines will have helped greatly. Work on this will continue in 2018. The area of licensed medicines being substituted for unlicensed ones also poses patient safety issues and we will continue to follow and contribute to this debate and activity in 2018.

I would like to welcome two new Members to the EAASM, firstly the European Medical Association (EMA) whose reach to many thousands of doctors

across Europe gives the EAASM a unique opportunity. An icon representing falsified medicines is planned to appear on the EMA website; which will route through to the educational website, which is available in 5 languages.

Secondly, please also welcome Becton Dickinson, a company that provides innovative solutions on many fronts and whose technology will help healthcare organisations address the new European Falsified Medicines Directive.

It just remains for me to wish all of you a most successful 2018 and the EAASM looks forward to contributing to patient safety through the various activities which are highlighted on page 5 of this newsletter.

Finally, it goes without saying that only by enhanced collaboration and cooperation between all stakeholders can we continue the good progress being made in our mutual fields of patient safety.



## Director of ASOP EU

### 2017 Reflections

*Klaus Gritschneider*

If I were to summarise the achievements of ASOP EU during 2017 in a sentence, then I would have to focus on the 5 highly effective educational campaigns currently running across Europe on falsified medicines. I do not know of any other organisation that is doing this so comprehensively and whilst some individual Member States are indeed running public awareness campaigns, it is questionable if they are making the same impact.

We were therefore all greatly encouraged to receive the good news that the Google AdWord educational grant had been renewed. This means we have funding to continue the campaigns up to December 2018.

With a phenomenal reach of over 35,000 first page impressions per day – this is where the ASOP advertisement appears on a first Google search page result – and with over 1000 people clicking on the advertisement, this has to be recognised as a most worthwhile civil society initiative. This opinion can be backed up by over 1500 completed website survey responses which is yielding rich data about visitor motivations.

Most importantly we have discovered that over 70% of visitors armed with new information about the risks of buying online will in fact change their behaviour, with half of these saying that they will search for a genuine safe website whilst the other half will revert to their local retail pharmacy.

ASOP has so far arranged 5 meetings with Member State personnel involved in the implementation of the Common logo. The last meeting had input from 17 Member States and three European Economic Area Member States. I am sure that the next meeting

planned for March 9th 2018 at the MHRA London offices will continue the successful collaboration and further enhance sharing of best practices.

The ASOP EU & EAASM (see page 7) report provides a good snapshot of Member State activity in raising public awareness. It is, however, disappointing that many MSs have not even embarked on any significant activity. Hopefully this report, to which the Health Commissioner Dr Vytenis Andriukaitis has contributed some words of encouragement along with a foreword by Lynda Scammell of the MHRA Enforcement Group, will catalyse further cooperation and galvanise all stakeholders to embark on educating their public.

We should remember that the implementation of the safety features of the Falsified Medicines Directive takes place in February 2019. It was somewhat disconcerting to attend a recent meeting in Lithuania on this subject, with all interested parties, to be informed that not all pharmaceutical manufacturers were ready to serialize their prescription packs as well as add tamper evidence features. However certainly much good preparation has been completed. We will continue to monitor this and encourage all parties to maximise their engagement.

Finally the MEDICRIME Convention has now been ratified by 12 countries around the world and ASOP EU was privileged to be approached to consider becoming part of the Committee of the Parties – for sure we welcome this invitation and look forward to contributing our expertise. On page 6 you can find an infogram which summarises nicely the extent of the ambition of ASOP EU in 2018 and we would welcome any support that you are able to give.

# EAASM PLANNED MILESTONES FOR 2018



- 1 Continue EAASM's work to protect patients within the online environment by closer cooperation with Health Care Professionals and Patient Groups (PGs).

- 2 Continue the campaign for the creation of guidelines on off-label/unlicensed medicines usage. Keep in close contact with DG Sante and support the introduction of the GOLUP (Good Off-label Use Practices) declaration.

**PROMOTING GOOD PRACTICE  
FOR THE OFF-LABEL  
USE OF MEDICINES:**

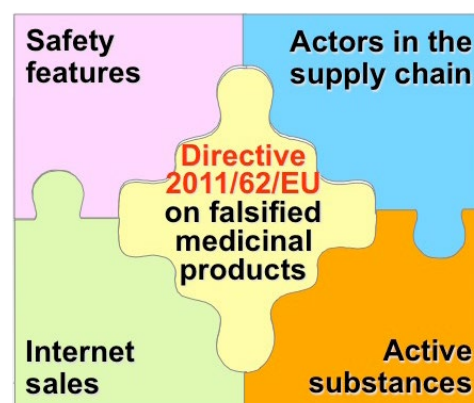
A harmonised European approach to prioritise patient safety

[▶ DOWNLOAD THE DECLARATION](#)



- 3 Support the European Parliament "Call for Action" entitled "Protecting European Citizens using the most suitable skin antiseptics before Medical Treatments" which is challenging the norms and has the objective of harmonising the approach to the classification of preoperative disinfectant products. Currently there is a key issue surrounding the use of unlicensed products vs licensed products which leads to patient harm and increased healthcare costs due to delayed discharges from prolonged treatment.

- 4 Support the introduction of the safety features of the Falsified Medicines Directive as well as the ongoing implementation of the Common Logo by further development of educational websites.



- 5 Explore the issue of compounding within hospitals which can give rise to unsafe medical practices.

# ASOP EU PLANNED MILESTONES FOR 2018



Develop AdWord campaigns to target vulnerable groups



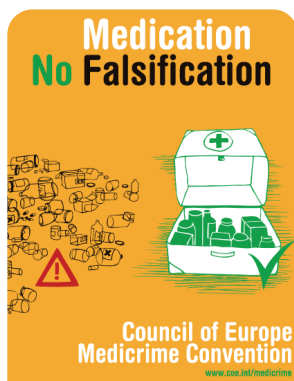
- 1 Develop public-facing campaigns by analysis of Google tools and analytics to determine strategies to better target vulnerable groups. Share findings through best practice meetings with Member States involved in the Common Logo implementation.

- 2 Publication of report on Member State public awareness campaigns and disseminate to Council of Europe, EU Parliament, DG Sante, and to all stakeholders.

- 3 Contribute to the Internet Society and partners' commitment to the next generation of Internet leaders through the Youth IGF Programmes.



- 4 Engagement by stakeholders to enable Principles of Participation which is a voluntary code of practice for Internet intermediaries namely: Advertising Service Providers, Registries/Registrars, Shipping Companies, Payment System Operators.

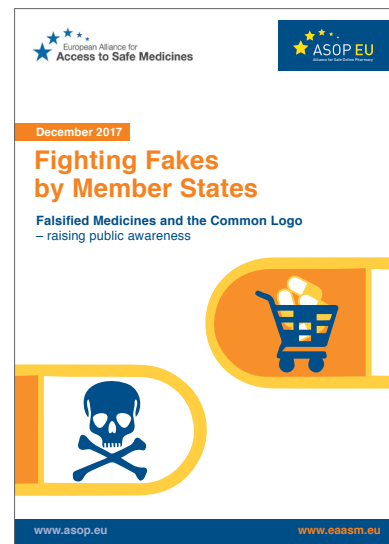


- 5 Potential participation in the MEDICRIME Convention Committee of the Parties.

- 6 Become active in ICANN policy discussions on several issues including the EU's General Data Protection Regulation (GDPR) and WHOIS transparency, implementation of new generic Top-Level Domains and the development and release of new gTLDs in the next several years.



- 7 Continuation of the ASOP EU combined newsletters.

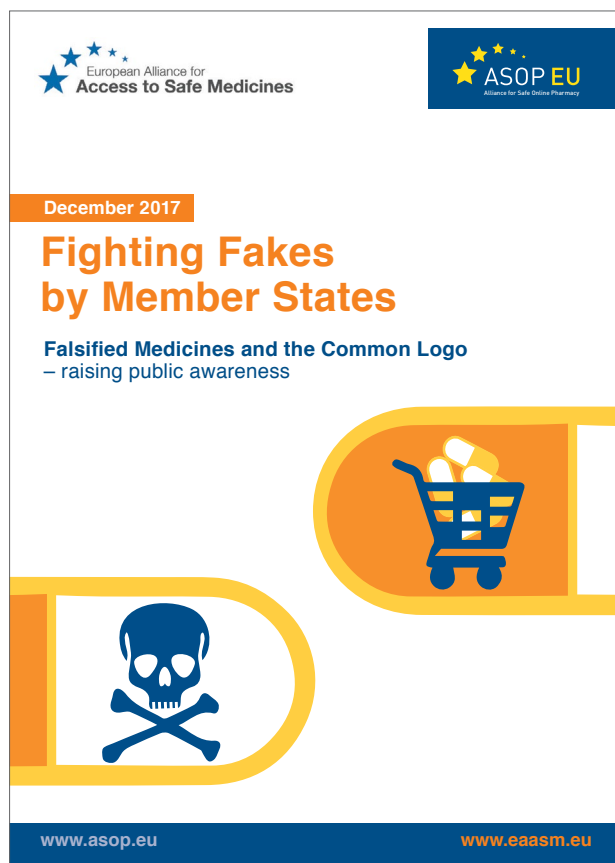


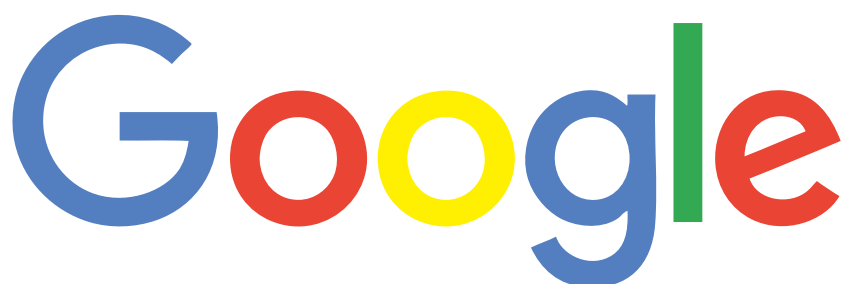
# FIGHTING FAKES BY MEMBER STATES AND NGOS - A MAJOR NEW REPORT ON STATUS OF RAISING PUBLIC AWARENESS

Following a series of sharing best practice workshops which brought together Member States and Civil Society not for profit organisations, a report is about to be released entitled “FIGHTING FAKES BY MEMBER STATES – Falsified medicines and the Common Logo – raising public awareness”. This is a snapshot of the progress being made to educate the public about how to buy medicines online safely and to understand the risks of buying medicines from the Internet.

Mike Isles, Executive Director of ASOP EU, speaks positively about the progress so far and underlines the concluding statement of the report “We welcome the words of encouragement by the Health Commissioner Dr Vytenis Andriukaitis and would call upon Member States, the Commission, the Parliament and all interested parties to continue to build on the many initiatives that raise public awareness which in turn will help to combat this growing threat to public health.”

Libby Baney, Director of the Global arm of ASOP says “falsification of medicines is a worldwide phenomenon and it is good that within Europe, the Falsified Medicines Directive is being implemented, which includes a section that supports patient protection through a Member State requirement to register all legally operating pharmacies who wish to sell medicines online. These websites must add a common logo on each page of the website, that links back to a genuine registry. This is a step forward but we know that criminals will cut and paste the logo hence the real need to educate the public on how and where to buy safely from the Internet. I welcome this report, as it brings together the various organisations in the fight against this criminal and harmful activity. However, it is clear that more activity by Member States with their own campaigns is a critical success factor if we are to educate the largely unwitting public”





## AdWord campaign now extended to end 2018 and live in 5 major European countries

We are delighted to announce that Google has extended the educational AdWord, grant for another year. This means the current campaigns running in France, Germany, Italy, Spain and the UK will continue throughout 2018.

The current combined “impression rate” – this is the number of times per day that the Google advertisement is appearing on page one of a research results page having used a key word such as “pharmacy Online” this is giving over 35,000 impressions per day with over 1000 visitors per day clicking on the advertisement to obtain more information about the subject. The voluntary survey is also yielding rich results on motivations of those searching to buy medicines online as well as indicating that behaviours can be changed once the visitor is made aware of the dangers and risks involved.

If you would like to visit the websites please [click here](#) and it will take you through to country landing pages.



# EUROPEAN MEDICAL ASSOCIATION JOINS ASOP EU AND EAASM



Mike Isles and Dr Vincenzo Costigliola

## The official membership signing took place during the First European Medical Association Annual Conference.

Mike Isles was invited to attend the EMA General Assembly by the President, Vincenzo Costigliola. Mike was also given the opportunity to present the aims and objectives of ASOP EU and the EAASM to the audience present.

The EMA General Assembly took place within the prestigious Acute and General Medicine Congress at the London Excel Congress centre.

The European Medical Association was created in 1990 by doctors from 12 member states, and was established as an “international foundation pursuing a scientific aim” according to the Belgian law dating 25/10/1919. It is a unique, independent non-profit organisation, which offers every European community doctor the opportunity to: join a European network of doctors, add a European dimension to their professional and social life and actively influence the development of European healthcare.

In terms of collaboration with ASOP EU and the EAASM, plans are well under way.

As an example, an educational leaflet for patients informing them about the dangers associated with falsified medicines is being progressed. This has the potential to be effective in raising awareness across the EMA network and thus enhance patient safety greatly.

In addition, EMA website visitors will soon be able to click on a falsified medicines icon which routes through to an educational website in 5 languages. This website mirrors those that are currently part of the extensive Google AdWord campaigns running in France, Germany, Italy, Spain and the UK.

Commenting on the new Membership Dr Vincenzo Costigliola stated “We are very pleased to be joining ASOP EU and the EAASM. These organisations, like the EMA, strive to achieve practical and tangible goals and so the awareness-raising plans on which we can work together, will be of great benefit to doctors and patients alike.”

# EUROPOL AND .EU ACADEMY HOLD CROSS-BORDER COLLABORATION TALKS IN FIGHTING CYBERCRIME - BEST PRACTICES



L to R: Geo Van Langenhove, EURid, Margarita Louca EC3 EUROPOL, Juan de Dios Toledo Martinez, EUROPOL Internet, Erik Planken, Council of Europe, Cathrin Bauer-Bulst, EC DG Home, Peter Van Roste, CENTR, Bertrand de la Chapelle - Internet and Jurisdiction

**ASOP attended this important collaborative meeting which brought together key players and stakeholders to discuss best practice and analyse the current challenges and issues.**

The positive vetting work that was being carried out by EURID, which is responsible for the .EU country top level domain name, was covered by Geo Van Langenhove - Legal Manager EURID. He demonstrated how internal systems (called Quality Verification software which looks for patterns) was proving 95% accurate in discovering areas for further investigation. This was enabling better governance of those entities wanting to use the .EU country domain and was providing a collaborative tool to the Belgian customs work to fight against abuse situations.

The address by Bertrand de la Chapelle, Executive Director of the Secretariat of the Internet & Jurisdiction Policy Network presented the strong case for better transnational coordination and collaboration on 3 key cross-border issues: criminal investigations, objectionable content and Domain Name System (DNS) related abuses. He highlighted the dire need for transnational policy standards and cooperation

frameworks in that regard and highlighted the second [Global Internet and Jurisdiction Conference](#) that will take place in Ottawa on 26-28th February 2018.

This conference will enable important collaborative discussion among all stakeholders to further the goal of a more harmonised approach to jurisdictional issues on the internet.

Erik Planken, Chair of Cybercrime Convention, Council of Europe discussed procedural tools such as expedited preservations and disclosure of preserved traffic and stated that new powers were needed to enhance mutual legal assistance.

Margarita Louca, EC3, Europol presented the Avalanche Operation as an example of Law Enforcement coordination with different judicial authorities, the public and private sector. Margarita highlighted the need to further discuss the legal challenges posed by carrying out cross-border investigations with the aim of disrupting criminal ecosystems and striving for crime attribution across multiple legislations.

# ASOP VOICES SERIOUS PATIENT SAFETY CONCERNS AT THE 10TH EUROPEAN ANTIBIOTIC AWARENESS DAY



Dr Vytenis Andriukaitis and Mike Isles

ASOP attended the 10th European Antibiotic Awareness Day organised by the European Centre for Disease Prevention and Control (ECDC). The European Commissioner for Health, Dr. Vytenis Andriukaitis, gave the keynote address, and Mike Isles took the opportunity to inform him that consumers/patients who were buying antibiotics from illegally operating websites were potentially contributing to antimicrobial resistance (AMR).

Organisations were invited to say how they were contributing to the collaborative effort to combat AMR.

Based on a [recent report](#) from the National Association of Boards of Pharmacy (NABP) about AMR being potentially exacerbated by people buying antibiotics from the Internet, Mike Isles stated “The ASOP EU and its partner ASOP Global are making the public aware of illegally operating online pharmacy websites. Purchasing antibiotics from these websites means

consumers are taking these powerful medications without oversight from a licensed healthcare provider and potentially contributing to antibiotic resistance. This is of major public health concern and highlights the need to educate patients and caregivers about how the overuse of antibiotics from illegal online pharmacies is leading to antibiotic resistance.”

ASOP has a number of initiatives to raise awareness, namely:

- A Google educational AdWord grant to raise public awareness in 5 major countries in the EU.
- Encouraging Member States and the Commission to share best practice on the implementation of the [Common Logo](#) which is a key part of the Falsified Medicines Directive.
- [ASOP Global](#) also has several public awareness-raising initiatives as well as being highly active in policy discussions with United States Congressional staff and the White House on Canadian online pharmacies and importation.
- Publication of the [largest consumer survey/report](#) to date to understand consumer perception and behavior around online pharmacies.
- Active engagement with US Government offices on issues relating to buying medicines via the Internet.
- [A full programme](#) to support Internet medicines governance issues around the world, including the Asia-Pacific region providing a supply chain tool and various specific activities in India and China.



# *Important Patient safety meetings*

## **ASOP “All Hands” meeting Thursday 8th March 2018**

Please save this date for an “All Hands” ASOP meeting to be held in the heart of London at the Fagre Baker Daniels LLP offices, 7 Pilgrim Street, London EC4V 6LB. Here ASOP Members and Observers will have the opportunity to build and contribute to the 2018 patient safety activities to help make the Internet a safer place to buy medicines. Further details will follow shortly.

## **Member States “Sharing Best Practice” meeting Friday 9th March 2018**

This meeting, to be held at the MHRA offices, 151 Buckingham Palace Rd, Belgravia, London SW1W 9SZ will be the 6th “Sharing Best Practice” meeting between Member State colleagues and like-minded stakeholders who are involved in the implementation of the Common Logo and the publicisation of this important Falsified Medicines Directive initiative. Invitees will be Member State personnel as well as not for profit patient safety organisations. More information on the event will follow shortly.

## **ASOP GLOBAL RECOGNISED FOR NEW PHARMACY E-COMMERCE AWARD**

ASOP Global’s 2017 Internet Pharmacy E-Commerce Award – issued to Rightside and Realtime Register – was acknowledged as part of the U.S. Trade Representative’s (USTR) “2017 Out-of-Cycle Review of Notorious Markets” report. Winners were chosen on the basis of “corporate policies and practices; responsiveness to illegal online drug sellers; prevention of illegal use of domain names for illegal online sales; cross industry collaboration; and public consumer awareness efforts.” USTR also provided an update on a 2016 suggestion, Nanjing Imperiosus, and included two additional organisations as suggested by ASOP Global in the 2017 report – IndiaMart and Rebel.

[More](#)



**ASOP GLOBAL** | ALLIANCE FOR SAFE  
ONLINE PHARMACIES



OFFICE of the UNITED STATES TRADE REPRESENTATIVE  
EXECUTIVE OFFICE OF THE PRESIDENT

## **2017 Out-of-Cycle Review of Notorious Markets**

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