



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL  
TAXATION AND CUSTOMS UNION  
Customs  
Protection of citizens and enforcement of IPR

## Report on the COM/EFPIA meeting Brussels (J 79-2/02), 09/12/2019

### 1. LIST OF PARTICIPANTS

#### COM participants

- TAXUD : [redacted] A.5), [redacted] A.5),  
[redacted]
- SANTE : [redacted]
- GROW : [redacted] F.3), [redacted]
- TRADE : [redacted]

#### External participants

- [redacted] : [redacted], EFPIA Secretariat  
[@efpia.eu](mailto:[redacted]@efpia.eu)
- [redacted] Servier [@servier.com](mailto:[redacted]@servier.com)
- [redacted] [redacted], Pfizer  
[@pfizer.com](mailto:[redacted]@pfizer.com)
- [redacted] Boehringer Ingelheim  
[@boehringer-ingelheim.com](mailto:[redacted]@boehringer-ingelheim.com)
- [redacted] Novartis  
[@novartis.com](mailto:[redacted]@novartis.com)
- [redacted] Pharmaceutical Security Institute  
[@psi-inc.org](mailto:[redacted]@psi-inc.org)
- [redacted] GSK  
[@gsk.com](mailto:[redacted]@gsk.com)
- [redacted] [@pfizer.com](mailto:[redacted]@pfizer.com)
- [redacted] [bayer.com](mailto:[redacted]@bayer.com)

## 2. ISSUES DISCUSSED

- the increase of counterfeit medicines;
- the decrease of customs seizures of medicines;
- the health risks counterfeit medicines can pose and the opportunity to deal with it as an EU political priority;
- the scope and application of Regulation 608/2013 (customs enforcement of IPR at the EU borders) and of Directive 2001/83 (medicinal products for human use) as amended by Directive 2011/62 (Falsified Medicines);
- the lack of information from customs to pharma right holders (RHs) – in case of Reg. 608/2013 – and from national medical authorities to pharma right holders (RHs) – in case of Directive 2001/83 and Directive 2011/62;
- the lack of full implementation of article 52 b) of Directive 2011/62 – action by customs in transit;
- the lack of request from RHs that customs use the small consignment procedure and the lack of use of the same procedure by customs when a RH has requested it;
- the opportunity to create a Pharma Working Group;
- the opportunity to create a memorandum of understanding (MoU) with TAXUD.

## 3. COM COMMENTS


### TAXUD

- acknowledged the conflicting trends (increase of counterfeit and decrease of customs detentions) and agreed on the importance to protect IPR as it is essential and beneficial to businesses and to the health of the EU citizens;
- showed its availability to raise the points of concerns at technical level within the framework of the Customs Expert Group, IPR section meetings regarding Regulation 608/2018 and in the PARCS meeting (group gathering TAXUD and customs experts from MS on customs controls on prohibition and restrictions) to discuss the difficulties MS customs may encounter when implementing the Directive 2001/83 and the Directive 2011/62;
- recalled that under Regulation 608/2013 the RHs should receive information from customs and asked the Pharma representative to name the national customs that do not do so: Pharma companies replied that actually they do not receive information from customs because they do not act under Regulation 608/2013 but prefer instead to act under Directive 2001/83 under which there is no requirement to inform right holders;
- pointed out that customs face constraints in terms of resources especially due to the increase of volumes of small consignment shipments and recalled that there is under Regulation 608/2013 a simplified procedure for small consignments that apparently is not so used by the pharma companies

[REDACTED]

nevertheless, in the daily practice, Pharma companies confirmed that indeed they would prefer customs to use the standard procedure under Reg. 608/2013 rather than Directive 2001/83 (because under the

latter there is no requirement for customs or medicines authorities to inform them; national medicines authorities have also declined to inform them due to data protection constraints); in practise customs authorities may have been using more the tools offered by Directive 2001/83;

- asked EFPIA about what they would like to use the information from customs/national medical authorities for; EFPIA explained that those information would be very important to create intelligence, to raise awareness and to share information with enforcement authorities in third countries;
-  EFPIA stated that the French association LEEM was in the process of making a report on the implementation of article 52 b) of Directive 2011/62 and promised to share the report once available;
- showed its availability to discuss with MS the points of concerns above mentioned during the support visits to be carried out under the current Action Plan;
- does not see the opportunity nor the need to establish a Pharma Working Group as there is already an annual joint meeting customs/private sector where customs implementation of Regulation 608/2013 could be raised; in addition ad hoc meetings like the one organised today could be a more effective way to address specific questions from Pharma industries;
- regarding the proposal of MoU it is not a TAXUD practice to enter in such memorandums.

## **SANTE**

- explained that Directive 2011/62 is aimed at protecting the legal supply chain from falsified medicines, including an end-to end verification system;
- recalled that the Directive does not cover IP infringements;
- explained that only authorised pharmacies may sell medicines online to patients and offers of sales on platforms (Facebook, Ebay etc) are illegal;
- offered to raise the issue of cooperation between medicines authorities, customs and the pharmaceutical industry at their next Expert Group on safety features to better understand what MS are doing to prevent falsified medicines from entering the EU territory from third countries.

## **GROW**

- explained the main on-going workstreams on IPR enforcement, in particular the [MoU on the sale of counterfeit goods via the internet](#) and the [MoU on online advertising and IPR](#)), and invited EFPIA to (re) assess the opportunity to join these industry-led initiatives;
- detailed the work carried out in the EUIPO Observatory's Expert Group 'Cooperation with Intermediaries';
- offered to check if the issue of counterfeit medicines could be further discussed in meetings gathering various law enforcement authorities, such as EUIPO meetings on Joint Efforts against IP Crime and EUIPO Enforcement Working Group meetings, instead of creating a new forum (as requested by EFPIA).

## **TRADE**

- TRADE informed EFPIA about the upcoming Counterfeiting and Piracy Watch List and invited EFPIA to contribute to its preparation.
- TRADE informed EFPIA about the negotiations on an African Continental Free Trade Area and invited EFPIA to send information on the pharmaceutical industries' priorities.

## **4. CONCLUSIONS**

COM committed to investigate the points of concerns discussed with the MS, namely about the implementation of Regulation 608/2013 (TAXUD) and Directives 2001/83 and 2011/62 (SANTE) and to inform EFPIA accordingly.

EFPIA will investigate the opportunity to join the MoUs currently in force as presented by GROW.

EFPIA will share the report of LEEM on implementation of article 52 b) of Directive 2011/62.

Other ad hoc meeting like this meeting could be replicated once a year (in the same format, or bilaterally with specific DGs).

Report done by [REDACTED] (TAXUD), [REDACTED] (TAXUD) with contributions from [REDACTED] (SANTE), [REDACTED] (GROW) and [REDACTED] (TRADE).