FMD serialisation generates high and disproportionate costs for pharmaceutical SMEs and potentially reduces availability of medicines – time to adjust

The Falsified Medicines Directives is without a doubt a key step forward in combatting medicine falsification and further guaranteeing patients' health. AMLIS and EUROPHARM SMC however have concerns with regard to the unintended consequences the implementation of this Directive has, impacting on the competitiveness of SMEs in the global pharmaceutical industry and more importantly the risk of medicine shortage for patients.

Notably the costs related to the FMD serialisation system are exorbitant and disproportionate for SMEs. At the dawn of the entry into force of the new system, AMLIS and EUROPHARM SMC call upon the EU Commission to adjust the system to help pharmaceutical SMEs to deal with their challenges and to help overcome the societal challenge of medicine scarcity that looms around the corner.

In 2011, the EU adopted the Falsified Medicines Directive (FMD). The Directive provides for a number of delegated and implementing acts, one of them requiring the setting out of the safety features, including how medicine authenticity should be verified and by whom. Although this seemingly gives sufficient time to the market to prepare, the delegated act was only adopted in 2016 *(Delegated Regulation 2016/161)* after lengthy discussions. The transposition of the Directive into national law in the EU Member states occurred in 2017-2018 and the NMVOs only started to gear up for 'onboarding' in 2018. So only towards the end of 2018 the negative effect of this regulation has become clear.

The so-called 'serialisation' system sets up the European Medicines Verification Organisation (EMVO) as well as National Medicines Verification Organisations (NMVO) to manage the system. Its article 31.5 explicitly foresees that the costs related to serialisation are to be taken on by the marketing authorisation holder (MAH) without stipulating the financing modalities.

These modalities became clear in the context of the Expert group meetings the Commission held with Member state representatives in the course of 2016-2018. During the 29th June 2016 Expert group meeting, the EMVO indicated to the EU Commission that a flat-fee model per Marketing Authorisation Holder (MAH) was preferred for reasons of '*practicality, predictability, transparency, fairness, up-front payment'*. It should be noted that manufacturers however, tend to pass these costs onto marketing authorisation holders, most often SMEs. The latter are confronted to high costs and big investments which they have difficulty in taking on board.

The option of a waiver from the flat-fee model for SMEs was raised by several EU Member states and the Commission referred the matter to EMVO. The latter has proven not receptive to these comments. During an Expert Group meeting on 10th April 2018, it was only emphasised that '*every effort should be made to ensure that the fee model takes into account the specific situation of SMEs*.'

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AMLIS, EUROPHARM SMC and their members are extremely preoccupied with the repercussions the current fee system and all implementation and maintenance costs will have in terms of competitiveness for SMEs in the global pharmaceutical market, and on the access to medicine and patients' health.

EUROPHARM SMC is the official European Association representing Small and Medium Sized pharmaceutical companies from 15 countries in EU. We support and defend the interests of our members, in order to establish a legal and political framework compatible with the interest of SMEs in the global pharmaceutical industry. In this capacity, we take part as a stakeholder in the different meetings within the European Commission and (www.europharmsmc.org).

AMLIS is a national association representing French SMEs and a member of Europharm (www.amlis.fr)

Costs for SMEs - 5 times higher than assessed – impact on product availability

Each NMVO determines the exact model of flat fees; some NMVOs opt for a one time entrance fee, others opt for turnover and/ or volume based fees. It should be noted that due to Brexit the NMVO costs are expected to increase further.

Depending on the countries and the turnover of the company, the annual fee structure can range between 1,000€ and 60,000€.

Although these amounts may appear low for large pharmaceutical companies producing high volumes, they are very high for SMEs with a much more limited turn-over and often much smaller production volumes.

NMVO fees, are evidently not the only costs related to the new serialisation system: implementation costs related to adaptations of the packaging and packaging lines, costs related to generating, exchanging and managing the serial numbers, maintenance and running project costs, also need to be added.

CapGemini's 2017 study on the impact of the FMD serialisation system for the generic market in the Netherlands, shows that the cost is an average 0.17€ per box of packaging (http://bogin.nl/files/FMD%20Cost%20evaluation%20Bogin%20def.%20report%20(eng)%2014112017.pdf).

At AMLIS and at EUROPHARM SMC we have each done our own survey and the findings go in a similar direction, with a **cost per pack between 0.05 and 0.15 €**, as opposed to 0.005 to 0.03 € in the 2015 EU Commission impact assessment. This represents 100.000€ per year for each 1mio units of serialized packs.

For some SMEs the break-even point of their investments is threatened obliging them to reflect on taking products off the market.

Key findings from AMLIS and Europharm's surveys (based on 64 companies)

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Average implementation costs per company (15% of the turnover of the serialized	**815 962 €**
Software service provider:	53 700 €
Validation /performance qualification costs (internal or external):	33 281 €
Onboarding to the EMVO:	6 553 €
Onboarding to the NMVOs (depending of the number of MA and turnover):	33 539 €
Manufacturing Investment (Only for CMOs for an average of 2 packaging lines)	688 889 €
Average yearly costs per company (2,2% of turnover of the serialized products)	**123 077 €**
Annual fee 2019 service provider:	30 393 €
Annual fee to be paid to NMVOs for 2019:	36 113 €
Costs of human resources (regulatory and technical):	56 571 €

Key finding Europharm survey

- *37% of the responding companies will drop products form the market: an average of 2 per company*

Risk management based on preventing counterfeiting and boosted action to tackle non-controlled circuits

Preventing counterfeiting can only be welcomed. **Questions however arise as to how proportionate the measures are in relation to risk and number of counterfeited products**.

- The CapGemini study clearly indicates that the **effects** of the FMD measures to prevent counterfeiting are **focusing on the controlled distribution chain for prescription medicines which already has in place** numerous quality checks and Good Distribution Procedures under supervision of the authorities.

- The genuine risk is related to the illegal **internet sales** which escapes the controlled distribution chain and which is therefore not really addressed by the FMD. Tackling this issue requires specifically adapted measures.

- The Commission is well aware of the products that pose a greater risk. Medicinal products with **low prices, marketed in low volume markets** have a very **low risk of falsification and therefore should have been kept out of the regulation or be considered for a later stage of implementation.**

Imposing a complex and costly system on a high number of products at the same time is in our view not the proper approach and the EU Commission should opt for a phased approach based on risks of counterfeiting, type of medicines and SME dimension.

The system also refrains from taking into account the situation of **specific categories of medicines, notably life-saving and niche medicines**. The flat fee system is from an economical point of view e.g. not in line with the essence of Regulation 141/2000 on orphan medicines and even annihilates the meaning of this Regulation.

As the above was not taken into account during the impact assessment, we call upon the Commission to **perform a new risk management study with regard to priority setting**.

Un-preparedness of hospitals/pharmacies and consequent impact on product availability

AMLIS and EUROPHARM SMC are also concerned about the **un-preparedness** of hospitals and pharmacies to adequately integrate requirements of the new system. This will create extra burden on the distributor and/or marketing authorisation holder with regard to decommissioning or handling of consolidated codes. Many hospitals have no budget available for the required investments and additional resources.

Out of the approx. 2,000 companies concerned by serialisation, at the end of December 2018 only 1,093 OBPs were connected to the EMVO Portal.(IQVIA public information) How should this be interpreted? Have companies taken a delay in preparing for the FMD obligations? Are SMEs unprepared for serialisation? In AMLIS and EUROPHARM SMC's view other considerations must be taken into account.

A number of SMEs - confronted to costs related to serialisation - has **strategically decided to take certain products off the market or to transfer marketing authorisation to larger companies**. This means that for some medicines, **competition will be reduced, which will lead to increased prices and a risk of medicine shortages** in the short and medium term. A number of micro or small companies that are not members of the local national industry associations, also **lack guidance and/or are unaware on how to proceed** with the implementation of the system.

EU Commission can and should adjust the implementation of the FMD

We strongly believe that the Commission can and should take measures to guarantee unhindered access to medicines for patients and to remedy the high costs and reduced competitiveness for SMEs.

- because Article 54§3 of the FMD provides that the EU Commission '***shall take due account of … (d) the cost-effectiveness of the measures***'. This disposition gives the EU Commission a clear mandate to instruct and guide the serialisation system and its governing bodies in this sense.

- because the EU Commission must make sure that the implementation of the FMD **adheres to the objectives of the FMD**, i.e. *guaranteeing the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified*

medicinal products. For reasons explained above, and notably the definition of the fee model per NMVO and the risk of reduced availability of medicines, these objectives are genuinely hampered.

- because **Better Regulation** requires Commission services to live up to key principles of good governance: proportionality, taking on board Member states comments/queries, performing an SME test and proper impact assessments.

Whilst fully supporting the objectives of the FMD, but due to risk of medicines availability and unintended detrimental impact of its implementation on SMEs, EUROPHARM SMC and AMLIS request that the EU Commission adopt adequate adjustment measures.

1. Perform an adequate **risk management study** differentiating between types of medicines, types of marketing authorisation holders and the degree of risk for counterfeiting. AMLIS and EUROPHARM SMC are available to contribute with the data they dispose of.

2. Provide **recommendations to EMVO and directly to NMVOs** to establish or adapt their **fee system to guarantee proportionality** in terms of turn-over whilst providing technical and/or financial support to SMEs.

3. Draft and adopt **guidance that interprets the serialisation system and especially** specific guidance with regard to the possibility to give **consolidated codes** allowing the simultaneous verification of several identifiers.