Introduction

Origin Packaging Ltd are a Pharmaceutical Packaging Manufacturer with our head office Melton House, Wyke Way, Melton, East Yorkshire, UK, HU14 3HJ.

We have a passion for child safe packaging and have been a pioneer in this area for many years. We work very closely with the Child Safe Packaging Group (Group, 2003) who represent the greater part of the supply industry for re-closable child resistant packaging in the UK. In addition to this, we also sponsor the Child Accident Prevention Trust (Trust, n.d.) Who raise awareness of the risks of child accidents and how they can be prevented.

We would like to raise concerns and make recommendations in relation to the shake and vape “short-fill” loophole and the integrity of some primary packaging being used in the industry.

Short-fill Products

Short fill products are sold in larger capacity bottles offering consumers a cost-effective approach to vaping, hence their popularity. At point of sale they do not contain nicotine, the practice being to add the nicotine to whatever desired strength the user chooses from a separate bottle purchased for this purpose. The short fill zero nicotine package is partially filled (hence the term short fill) to allow the addition of liquid nicotine.

The Tobacco Products Directive (COUNCIL, 2014) rightly states that ‘Electronic cigarettes and refill containers could create a health risk when in the hands of children. Therefore, it is necessary to ensure that such products are child and tamperproof, including by means of child-proof labelling, fastenings and opening mechanisms. As explained above, at point of sale of short-fill bottles they do not contain nicotine and therefore can be argued that they do not require a child resistant closure. Under the 2005 Consumer goods act. (Regulations, 2005)

Although some companies choose to use child safe packaging for short fills, some do not, and this substantially increases the risk of harm to a child once the nicotine content has been added to these bottles. Please see below image of a selection of Non- child resistant short fill bottles currently available on the market.

The short-fill products in the image below show a lack of awareness of safety for children in the domestic environment when it has been infused with nicotine (harmful/ toxic substance).
Even where a child resistant closure is used on a short fill bottle, the additional process of removing the tip from the short-fill bottle and introducing the nicotine shot greatly increases the opportunity for nicotine leakage on the container and/or surrounding surfaces. This further enhances the risk of ingestion and the possibility of unintentional dermal exposure to a child and in fact to the user themselves.

A further issue from a child safety standpoint in relation to short-fills is the way that they are marketed. The below image is an example of packaging that is highly attractive to young children, portraying it as a sweet/food product. This further increases the risk of an ingestion from an inquisitive child.

Nicotine poisoning in children is already a major concern as the number of children under 6 poisoned by nicotine in e-cigarettes in the US alone rose by nearly 1,500% between 2013 and 2015. According to an analysis of calls to the National Poison Data System (Pediatrics., 2016)

More than 90% of the children swallowed the e-liquid and nearly half of the exposed children were under the age of 2. From January 2012 through April 2015, the National Poison Data System received 29,141 calls for nicotine and tobacco product exposures among children younger than 6 years, averaging 729 child exposures per month. Cigarettes accounted for 60.1% of exposures, followed by other tobacco products (16.4%) and e-cigarettes (14.2%). The monthly number of exposures associated with e-cigarettes increased by 1492.9% during the study period. Children <2 years old accounted for 44.1% of e-cigarette exposures, 91.6% of cigarette exposures, and 75.4% of other tobacco exposures. Children exposed to e-cigarettes had 5.2 times higher odds of a health care facility admission and 2.6 times higher odds of having a severe outcome than children exposed to cigarettes.

There is further extensive evidence relating to this in The ‘Study on the identification of potential risks to public health associated with the use of refillable electronic cigarettes and development of technical specifications for refill mechanisms’ ([ENSP], 2016)
Page 57 states that the EU has seen a similar rising trend as outlined below.

**Time trends:** The increase in the number of e-cigarette poisonings/incidents in the EU (Figure 1) indicate a sharp increase in the number of incidents between 2012-2013, a similar pattern was noted in the UK which indicated a jump in e-cigarette related incidents between 2012/2013 and 2013/2014 reporting years. Events related to e-cigarette product exposure reported to the American Association of Poison Control Centres increased 42% from 2011 (n=256) to 2012 (n=438), while after the beginning of 2013 a dramatic increase in the number of exposures to ecigarettes and their refills was seen in the US, which peaked in April 2014 and comprised 35% of all nicotine-related single exposure calls [1-3].

See below extract from ANNEX B. Report on the risks of ecigarettes and refillable e-cigarettes in particular
A death has already occurred in association with a nicotine liquid exposure and clearly shows how leaving the short-fill market ineffectively and insufficiently regulated is a tragedy waiting to happen. Not only for an innocent child but also for the industry itself. It could take years for it to recover from a fatality due to a child ingestion from an unregulated “short-fill” product.

It is imperative that the “short-fill” bottles are regulated urgently. We understand that MHRA are suggesting it should be regulated through the General Product Safety Regulations 2005 (Regulations, 2005) Will this not result in the same content of the TPD needing to be re-written to ensure that “products” being sold are truly “safe” as outlined in the regulations?

An alternative solution to regulating by GPSR is to mirror what the Netherlands have done in amendment to the Dutch Tobacco and Smoking Products Act (Act, 2014)

As extension to this and to prevent or limit the risks highlighted by the RIVM’s research, the government has:

- extended current rules on nicotine-containing e-cigarettes to e-cigarettes that do not contain nicotine (sometimes known as shisha pens);

By ministerial regulation, to protect public health or to implement the tobacco products directive, requirements are imposed on the design of an electronic cigarette and an electronic cigarette without nicotine and on a refill pack, refill pack without nicotine, pattern without nicotine and the ingredients of nicotine-containing and non-nicotine-containing liquid

This seems to be a simple and effective way to close the loop-hole and effectively manage the situation without having to rewrite the TPD under a different name.

---

A Table Provided That Compares Exposures Related to E-Cigarettes Recorded in European and United States (US) Poison Centres.
We ask that as a minimum the short-fill market is regulated in line with the below statement, also taken from The ‘Study on the identification of potential risks to public health associated with the use of refillable electronic cigarettes and development of technical specifications for refill mechanisms’

“The refill liquid vial must as a minimum conform to ISO 8317:2004 for a re-closable pack and EN 862:2005 for a non-reclosable pack to mitigate the potential risk of ingestion, especially among children”

The longer it is left unregulated, the longer our children are at risk and the more paediatric poisonings there will be!

March 2018
References


