

PRODUCT STEWARDSHIP PROGRAMME FOR LIQUID LAUNDRY DETERGENT CAPSULES Status Update - March 2019

7/10/2019

Executive Summary

Relative to their market presence, the number of accidental exposures involving Liquid Laundry Detergent Capsules, as reported to Poison Control Centres of five EU countries, has decreased substantially over a period of five years until 2017, but over the past 1-2 years, no further prominent incident rate reduction can be observed. To create new momentum to reduce accidental exposures, additional voluntary measures (i.e. improved closures and an advertising code of conduct) have reached the market place in the course of 2018, the “Keep caps from kids” education campaign has been revamped in Fall 2017, and local consumer education campaigns are ongoing. In addition, the voluntary on-pack warning “patch” has been re-designed with a more attention-grabbing visual, and will appear in the market shortly.

The A.I.S.E. Product Stewardship Programme (PSP) for Liquid Laundry Detergent Capsules (LLDC), a voluntary industry initiative, was launched end 2012 to reduce accidental exposures to these products - in particular involving small children. This is achieved through product safety requirements and the promotion of safe use and storage. Communication efforts have been significantly reinforced as of April 2014, with child-safety messaging included on all LLDC brand communication and advertising. In parallel there was the industry campaign “Keep Caps From Kids”. In June 2017 an enhancement of this PSP was provided. This includes a further improvement and quantitative testing of child-impeding closures, as well as an advertising code of conduct. Both have reached the market in the course of 2018, and currently, additional improvements of the PSP artwork aspects are being explored. A re-vamp of the “Keep Caps From Kids” website was launched in September 2017, including a new video. Finally, based on consumer research in 2019, the voluntary on-pack warning “patch” has been re-designed with a photographic image to convey the message “keep out of reach of children”. This will be more effective at attracting consumers’ attention and will have a stronger emotional effect, which aims to lead to a stronger behavioural impact.

The reduction of the incident frequency (expressed as number of reported exposures per million capsules sold on the market) during the first five years of the PSP has been consistent and substantial, ranging from 43% up to 76% depending on the country. More recently (2018), no notable further decrease can be observed. Ongoing monitoring will allow to assess the effect of the implementation of the enhanced PSP (e.g. improved child impeding closures), which has been introduced to the market in 2018 and is anticipated to re-create downward momentum over 2019.

For more information on the A.I.S.E. Product Stewardship Programmes for Liquid Detergent Capsules and for previous progress reports, please visit www.aise.eu in the section “Our Activities” → “Product Stewardship Programmes” → “Liquid Detergent Capsules” → “Key activities of the Detergent Industry”.



Background - A.I.S.E. Product Stewardship Programme (PSP)

The A.I.S.E. Product Stewardship Programme for Liquid Laundry Detergent Capsules was first launched at the end of 2012. This was extended to cover all liquid containing detergent capsules in 2015. The PSP entails commitments regarding product/packaging, information and communication (both on-pack and consumer communication), as well as engagement with Poison Control Centres (PCCs).

The large majority of the LLDC market is covered by the six companies that signed up to the 2012 PSP. Today, essentially all products on the shelf comply with its requirements. This is also due to the CLP 'Soluble Packaging' Regulation (EU) No.1297/2014 that requires similar as well as additional measures for the product film, outer packaging and on-pack labelling, for all LLDC products placed on the market as of June 2015 (with official phase-out of non-compliant products by end 2015).

On June 12 2017, the formal agreement for additional safety measures in form of a new PSP has been opened by A.I.S.E., and to date 4 companies have signed up. Jointly these companies represent over 85% of the Liquid Laundry Detergent Capsules market across the EU (Euromonitor data, 2016). This PSP-2017 introduces the requirement for superior child impeding properties of the packaging, to be confirmed by means of quantitative testing according to a new A.I.S.E. protocol. Within maximum 18 months from their individual date of commitment, i.e. by early 2019, these companies shall have started the production of packaging that fulfils the new criteria. Phase-out of all non-compliant packs is committed within the subsequent 12 months. The PSP-2017 also introduces an advertising code of conduct. Participating companies commit to not advertising hazardous LLDC in any media channels that are primarily targeted to children below 5 years old, and to not promoting hazardous LLDC targeted to children of this age group. This was implemented for every new advertising / promotion contract established as of January 2018.

A revision of the existing PSP artwork commitment was introduced mid 2019, based on consumer research. A consumer-preferred and more engaging graphical image will replace the current icon to convey the message 'keep out of reach of children'. The "do not ingest" icon has also been improved. In addition, product-specific information how to open and re-close the pack can now be used instead of the generic icons. The revised "yellow patches" will start to appear in the market shortly.



Communication efforts have been significantly reinforced as of April 2014, with child-safety messaging included on all LLDC brand communication and advertising. In parallel to the PSP, in 2014 the "Keeps Caps From Kids" (www.keepcapsfromkids.eu) educational campaign was launched, and an entirely reworked web site was launched mid-September 2017. Additional education at the national level is currently being executed in some EU countries. Consumer education campaigns in collaboration with paediatricians have been implemented in 2018 in Germany and in France, and are ongoing. In Ireland, in collaboration with the Health Service Executive, shortly, all standard scheduled district nurse visits to children of age 6-9 months will cover education on capsules.



Incident Statistics - Reported Exposures to PCCs

Methodology

Exposure statistics.

The numbers of exposures reported to PCCs, on a monthly basis, are available until August 2017 for Ireland (IE) and until September 2017 for the Netherlands (NL), the Czech Republic (CZ), Italy-Milan (IT) and Spain (ES). These data were kindly provided by respectively the Dublin PCC, the Utrecht PCC (NVIC), the Prague PCC, the Milan Niguarda PCC, and the Madrid PCC.

These statistics represent the number of accidental exposures that have led to PCC enquiries - and are further referred to as 'reported exposures'.

Please note that reported exposure statistics are not always comparable between different countries:

- In some countries (e.g. the Netherlands), only medical professionals have access to the PCC. In most other countries the general public can also enquire directly, which may lead to a higher number of calls.
- Local cultural aspects may determine the proportion of accidental exposures for which the PCC is contacted. This may be especially relevant for cases with no or minor symptoms.
- Cultural aspects may also determine the number of enquiries not related to a clinical case (e.g. enquiries without an actual exposure). Note that such enquiries are in principle excluded from the statistics.
- Finally, not all PCCs cover the entire territory of a country (e.g. the Milan PCC covers approximately 70% of Italy). This impacts the normalisation of exposure numbers per million units sold across the country (see below), and makes this normalised rate not directly comparable to other countries.

Market volume data.

Monthly estimates of the total liquid laundry detergent capsules market size for each country are acquired from third party data suppliers by several detergent companies. These are not the individual sales volumes for single producers or brands, but are estimates of the total market (covering all producers, all brands) based on actual sales data in combination with coverage extrapolation factors. For all countries within scope, market size estimates were available from two or more detergent companies. For use in this report these estimated market size values were averaged between the different data sources.

Note that different companies use different extrapolation methods and different data providers to develop these market estimates. Consequently, the estimates may vary substantially between companies. For confidentiality reasons, it cannot be mentioned in this report which companies have provided data, nor how many companies have provided data for each specific country.

Market size normalisation.

To assess the trend and the effectiveness of risk reduction measures, a normalisation of the incident count to the market size is essential. The normalisation addresses the proportion of LLDCs on the market that have been involved in an accidental exposure.

For each individual month, as well as for the entire 12-month periods being assessed (i.e. baseline year, past 12 months, past 12-24 months, and past full calendar years), the number of reported exposures is normalised to the market size. This results in the number of reported exposures per million units sold - both on a monthly and on an annual (i.e., 12 month period)¹ basis.

¹ This is a time-independent measure, i.e. irrespective of whether it is calculated on a monthly, quarterly, or annual basis. This is because the time parameter is removed when [the number of incidents per month] is divided by [the number of capsules sold per month] (as 'per month' appears both in the numerator and the denominator). 'Monthly basis' only means that each calculation refers to one specific month. To derive the annual value, the number of reported exposures across one year is divided by the number of capsules sold over that year.



These data allow comparing the most recent 12-month period with the pre-PSP baseline. This baseline is the 12-month period preceding the on-shelf introduction of the PSP measures across the EU in mid-2013 (or mid-2012 in Italy). In addition, the most recent period can also be compared to the immediately preceding 12-month period to assess the extent to which the trend is ongoing.

Assessment.

1) Versus pre-PSP baseline:

- In principle, the year 2012 is used as the baseline - because PSP measures were first introduced across the EU market mid 2013.
- For Italy, the baseline is calendar year 2011 - because in Italy very similar measures were already introduced as of mid 2012
- For the Netherlands, the baseline was taken as April 2012 - March 2013 - because early 2012 the product category had only recently been launched and a meaningful number of incidents was only reported as of April 2012.
- For Spain, no assessment versus the pre-PSP situation was possible, due to lack of market size estimates for this period.
- In all cases, exactly one full year is reflected in both the pre-PSP baseline and the assessed periods. This is to rule out any potential bias due to seasonality effects, should those be occurring.

2) Ongoing trend post-PSP introduction:

The past 12-month period is compared to the immediately preceding 12-month period (i.e. versus 12 to 24 months ago). This approach allows assessing whether an ongoing reduction trend can be observed.

Graphical Representation.

Time series charts are plotted for each of the five countries. The number of reported exposures and the market size estimate are presented on a quarterly basis to illustrate the dynamics over time while not emphasising short term variability (month to month). The calculated exposure frequencies per million capsules are presented on an annual basis, i.e. per calendar year and also for the most recent 12-month period. As such, seasonality effects are excluded from the exposure frequency.

Statistical significance.

The statistical significance of the observed differences was assessed by means of the Generalized Linear Model (Poisson distribution) approach, using aggregated data across the 12-month periods. A threshold $\alpha = 0.05$ was used to determine significance. This method was found to provide the most robust statistical assessment for this type of data. The calculations were conducted by means of the software "R" version 3.2.2.

Aggregation across countries.

Care must be taken when interpreting aggregated PCC data across countries. As mentioned above, data are often not comparable between different countries: e.g. due to different access to the PCC, cultural aspects, and geographical coverage. Consequently, no aggregation across countries is included in this report.



Czech Republic: -76.2 % versus Baseline

Exposures:

After having reached a maximum in April 2014, with 38 cases per month, the number of reported exposures has decreased to under 15 per month on average over the past 12 months until March 2019. During the baseline year 2012, there was a monthly average of 17.8 reported exposures.

Market:

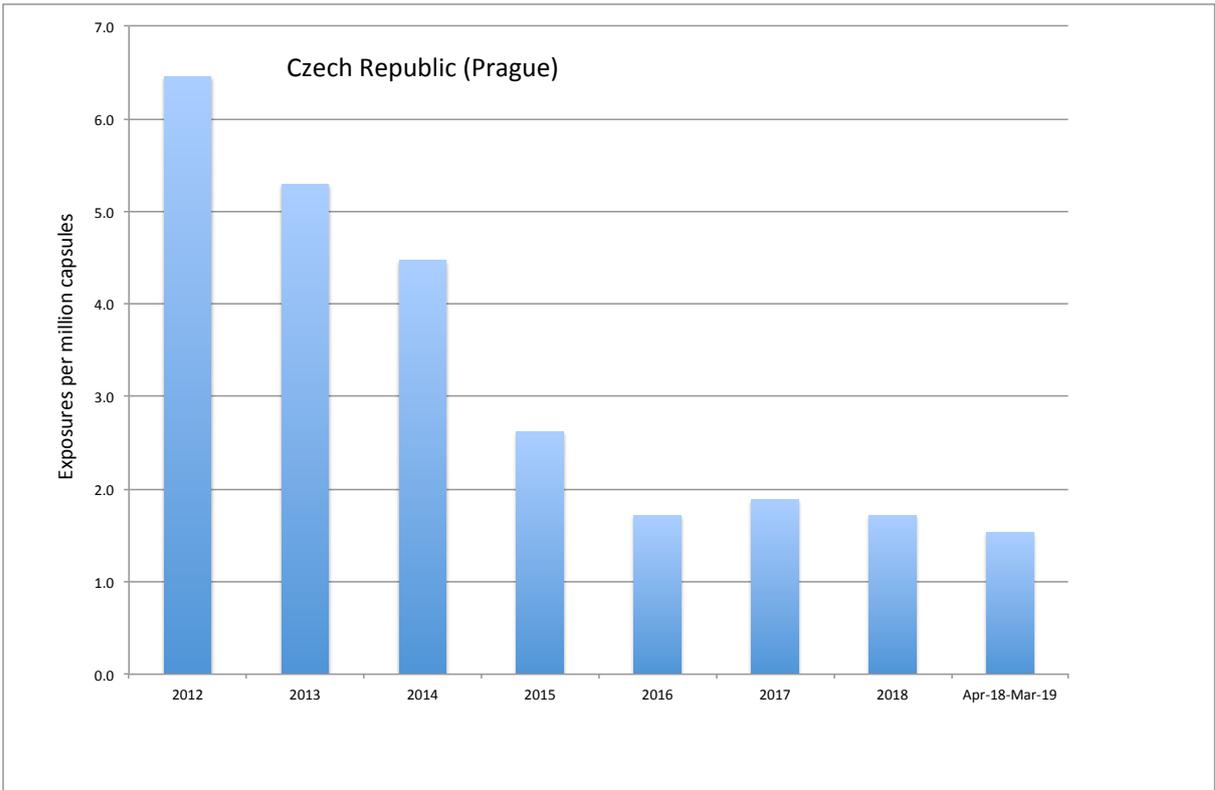
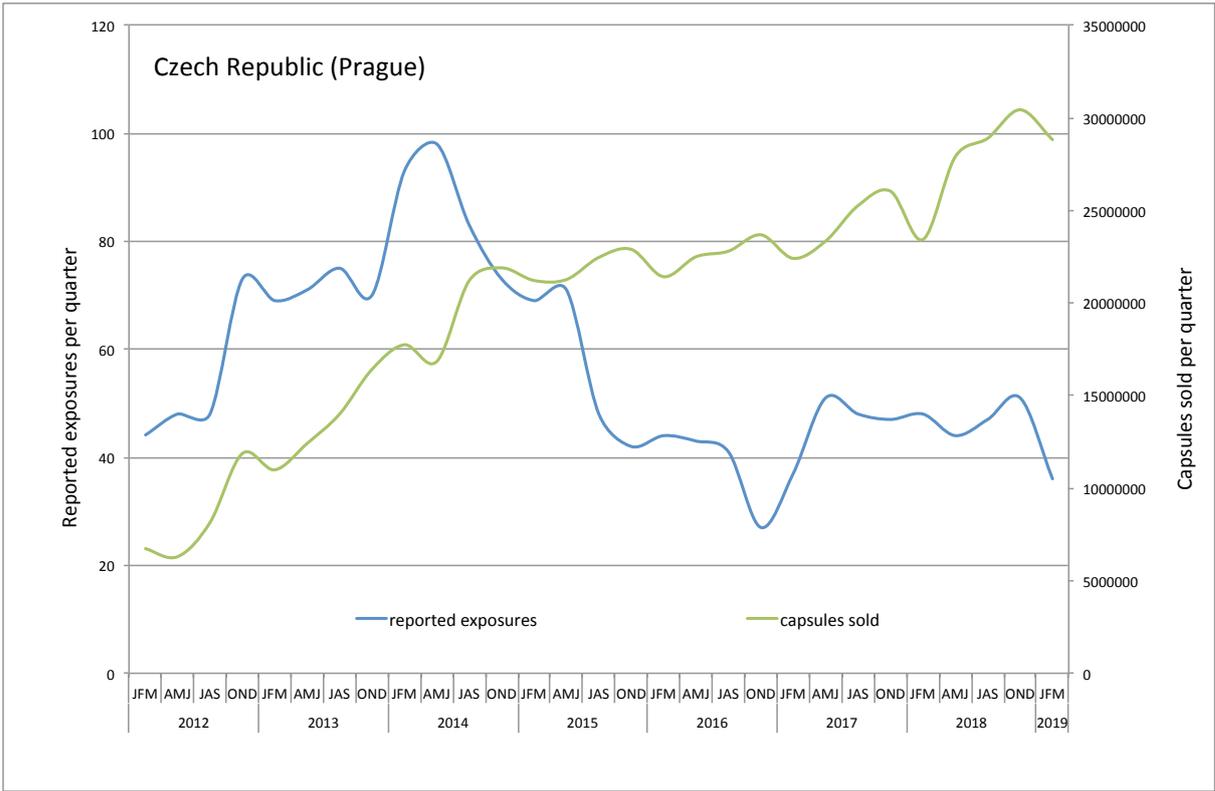
From 2012 to 2014, the market has grown substantially from less than 2.5 million units per month in early 2012, reaching an average of 7.3 million per month by 2015. Since then, growth has continued more gently, reaching 9.7 million per month on average over the past 12 months. The overall maximum was nearly 11 million capsules sold in October 2018.

Assessment:

There were **1.53 reported exposures per million capsules** over the past 12 months. This is a very relevant decrease by 76.2% (significant, $p < 0.001$) compared to the baseline year 2012, which had 6.45 cases per million capsules. Most of the reduction happened between 2012 and 2016. Since then, the incident frequency has fluctuated - but most recently, compared to the preceding 12-month period (until March 2018) there was again a decrease by 22.5% (significant, $p = 0.0142$).

These observations show that since the start of the data tracking in 2012, the decrease has been consistently strong until the end of 2016. However, as of 2017, the observed reduction has not been consistent.





Ireland: -42.9% versus Baseline

Exposures:

On average, the number of reported exposures over the past 12-month period (until March 2019) was 24.5 per month - 33% higher than the baseline year 2012, in which on average 18.3 cases had been reported per month. It is also 33% more than the average of 18.4 reported exposures per month observed for the preceding 12-month period (until September 2017). This seems to be driven by an unusually high exposure count in the second quarter of 2018, with an average of 33 per month - in the subsequent quarters, the situation went back to a lower average, with 21.6 cases per month from Q3 2018 through Q1 2019.

Market:

The capsules market in Ireland has continued to grow over the past several years, with an average of nearly 10.2 million capsules per month across the past 12-month period.

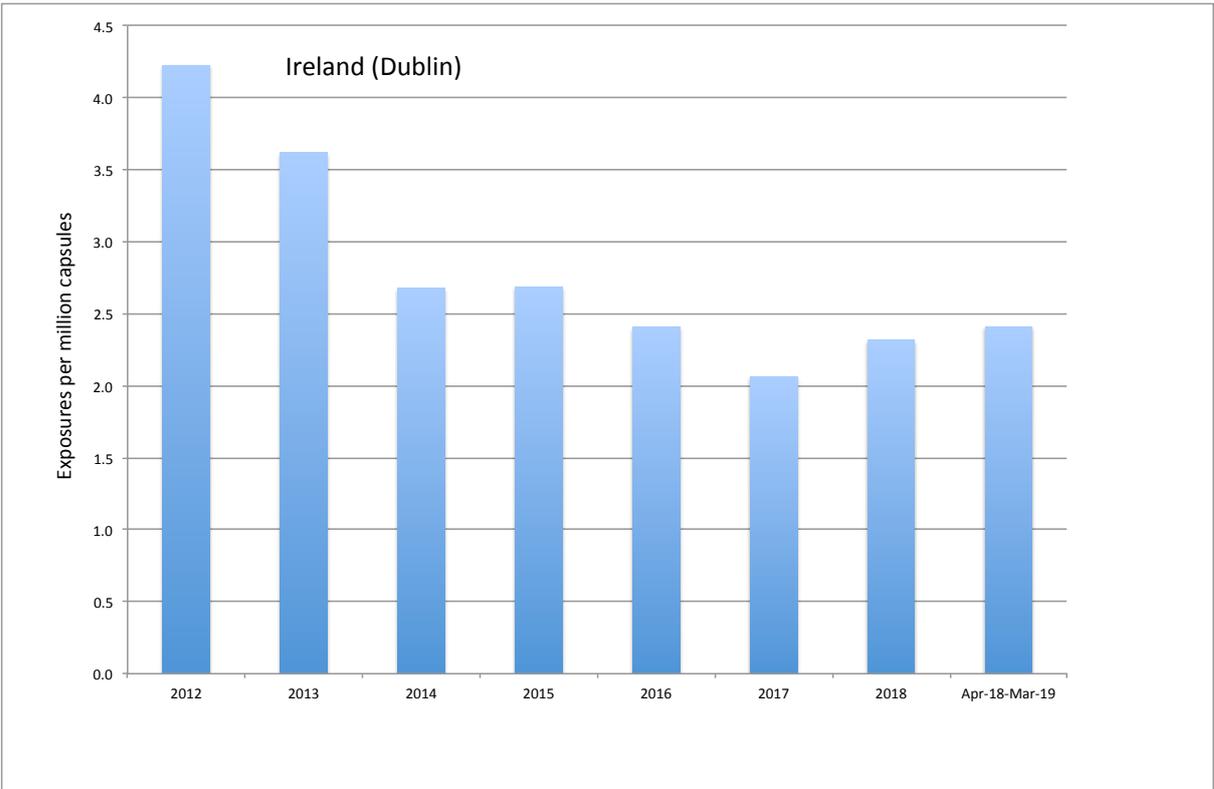
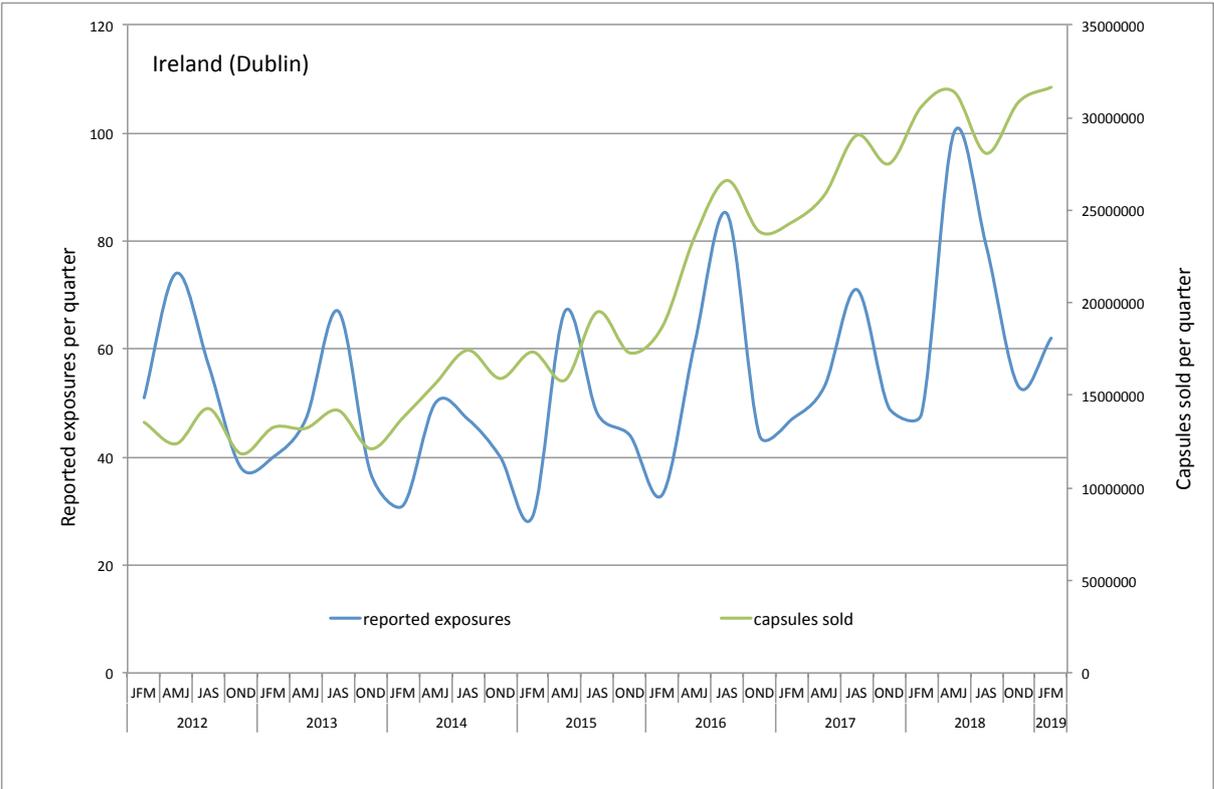
Earlier, the market size had remained largely stable over 2012 and 2013 (on average 4.4 million units per month). The upward trend started in 2014, towards 5.8 million capsules per month by the end of 2015, and then became very prominent in 2016 as outlined above. During 2018, however, the growth rate appears to have declined.

Assessment:

Over the past 12 months, there were on average **2.41 accidental exposures per million capsules** on the market. Despite the higher absolute incident count compared to the baseline year 2012, relative to market presence this does represent a notable decrease of 42.9% (significant, $p < 0.001$) - as the 2012 incident frequency was 4.2 cases per million capsules. On the other hand, compared to the preceding 12-month period (until March 2018) an increase was observed (+23.2%, significant $p = 0.019$). This seems to be driven by an unusually high number of incidents in Q2 2018 - rather than being due to an upward trend.

These observations show that since the start of the data tracking in 2012, there has been a decrease until 2016/17. However, since then, no further reduction has been observed.





Italy: -62.9% versus Baseline

To note: In Italy, initial risk reduction measures were already implemented as of mid-2012, one year prior to the PSP. Because of this, a longer data series (starting mid-2010) is shown than for the other countries. Furthermore, as a pre-PSP baseline, the year 2011 is used.

Background: The Milan PCC started reporting an increasing number of LLDC-related poisonings shortly after their launch on the open market, in August 2010. The PCC immediately alerted the industry about the increasing number of symptomatic cases that originated directly from the hospital's Emergency Room. Since September 2010, a series of working meetings with industry representatives was initiated with the purpose of finding ways to reduce this emerging risk. During these sessions, among the various considered response strategies, the use of opaque packaging was one of the first, and most widely supported. This was first implemented mid-2012, and made mandatory as of early 2013.

Exposures:

Overall, a steady decrease of the number of reported exposures can be seen from the mid-2012 peak (of 70 cases per month) until the end of 2016. In 2013 the average number of cases per month had decreased to 25.2, further to 22.5 in 2014, then 19.3 in 2015, and finally down to 15.7 in 2016. However, since Spring 2016 no further decrease was observed. The average over the past 12-month period, 24.3 reported exposures per month, was actually one-third higher than in the same period one year before.

Market:

Since mid-2017, the liquid laundry detergent capsules sales volume in Italy has shown a prominent growth. Across April 2018 until March 2019, the average volume was 37 million unit doses per month, with sales exceeding 45 million capsules in September 2018.

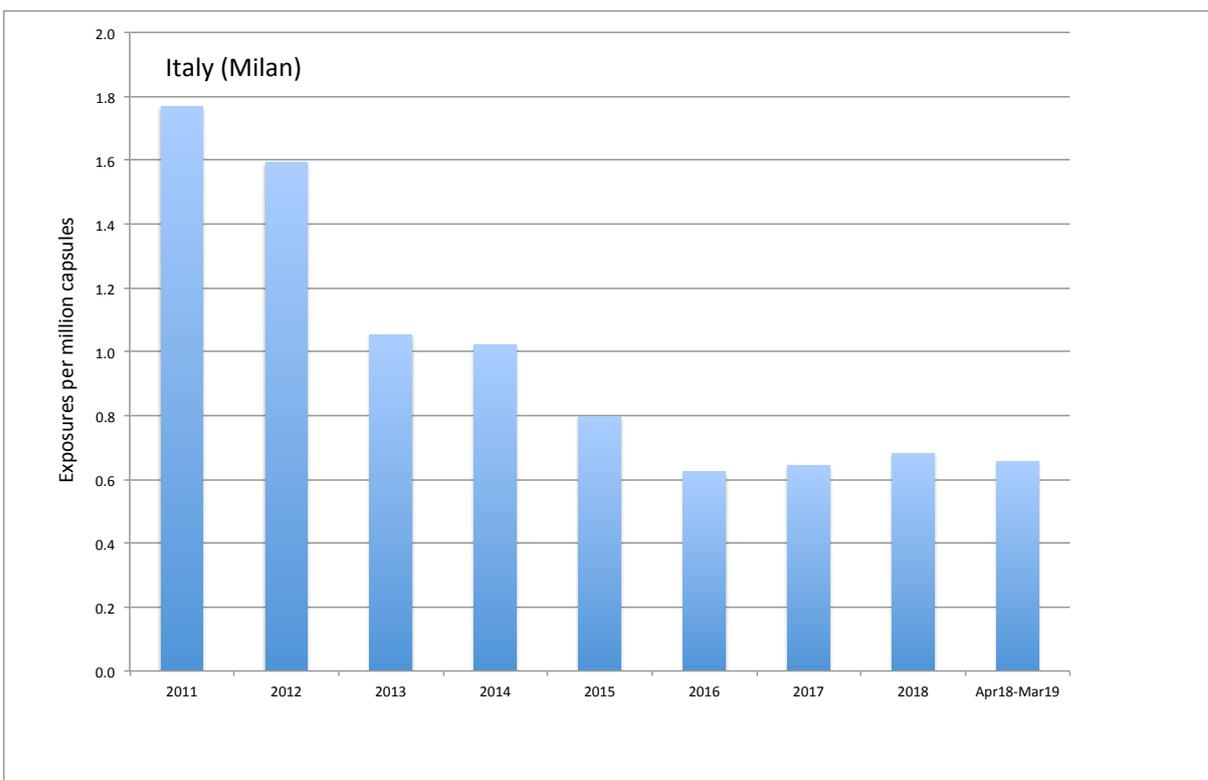
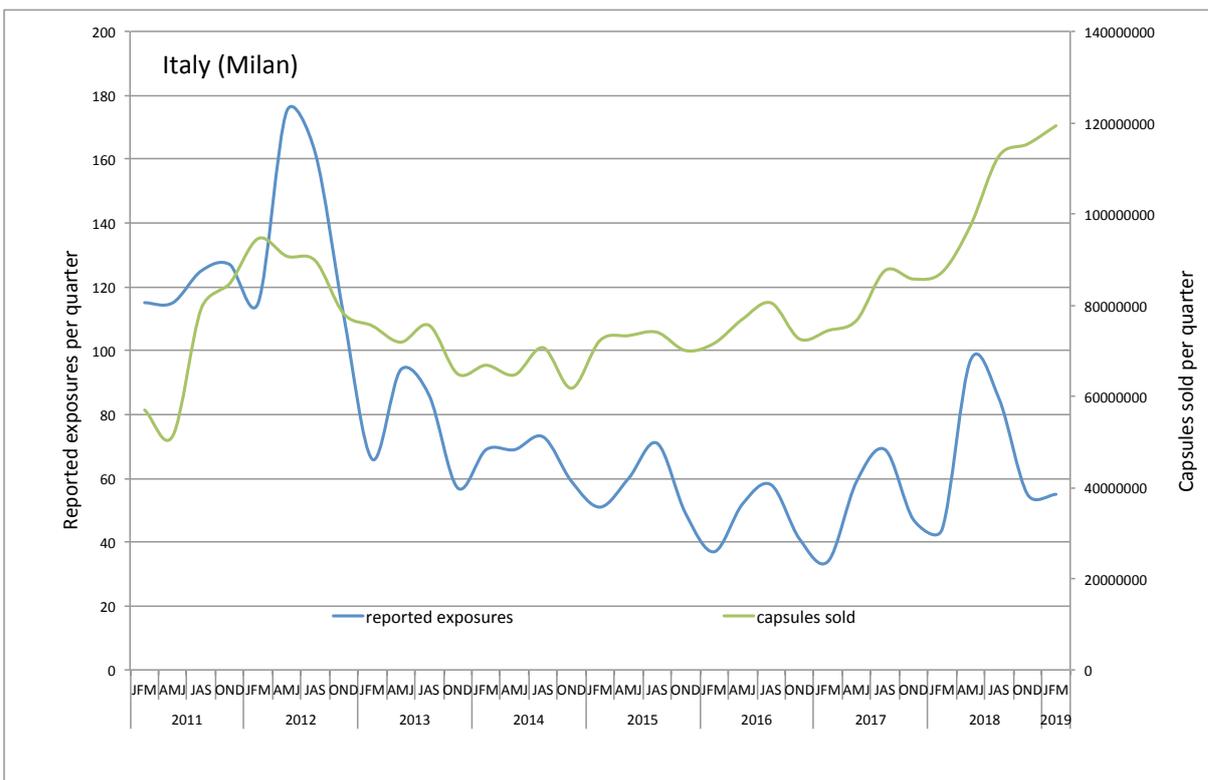
Earlier, from mid-2011 to mid-2012, a market volume plateau (of about 30 million units per month) had been reached, which was followed by a decrease until the end of 2013 and modest growth over 2015 and 2016.

Assessment:

During the past 12-month period, **0.66 accidental exposures** have been reported to the Niguarda PCC per million liquid laundry detergent capsules on the Italian market. This is 62.9% less (significant, $p < 0.001$) than for the baseline year 2011, before the introduction of the first measures (with 1.77 exposures per million capsules). Compared to the preceding 12-month period (until March 2018), there was no meaningful change (+1.1%, statistically significant, $p = 0.906$).

These data show that the decreasing trend has been ongoing steadily and consistently since the initial introduction of risk mitigation measures, until 2016. But since then, no further decrease has been observed.





The Netherlands: -58.0% versus Baseline

To note: in The Netherlands, LLDCs were not significantly present on the market until early 2012. Meaningful numbers of exposures were only reported as of April 2012. To take this into account, as a baseline period, April 2012-March 2013 was taken instead of January 2012-December 2012.

Exposures:

Over the past 12 months, on average 29.1 exposures were reported per month in the Netherlands. This is higher than what was observed for the preceding 12-month period (22.5 per month). Prior to the PSP introduction the absolute number of reported exposures was lower (on average 13.4 cases per month) - in line with the much lower market presence at that time.

Market:

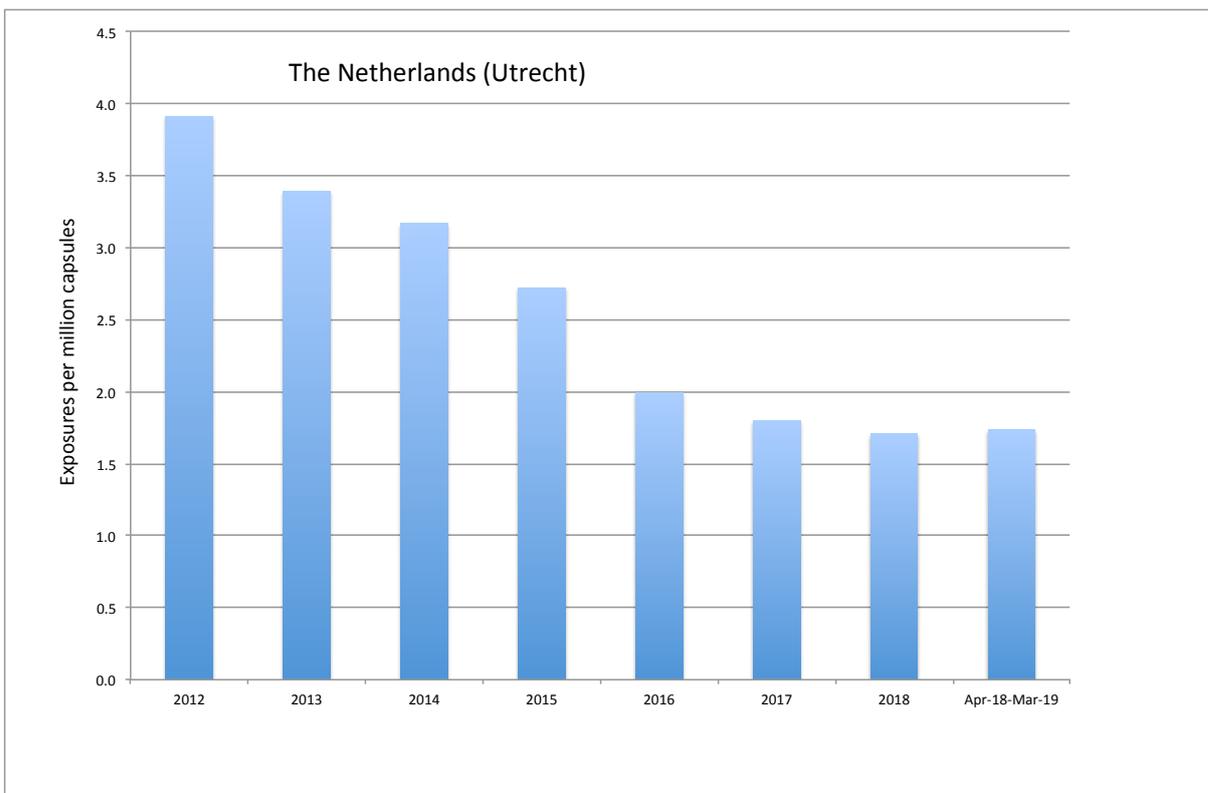
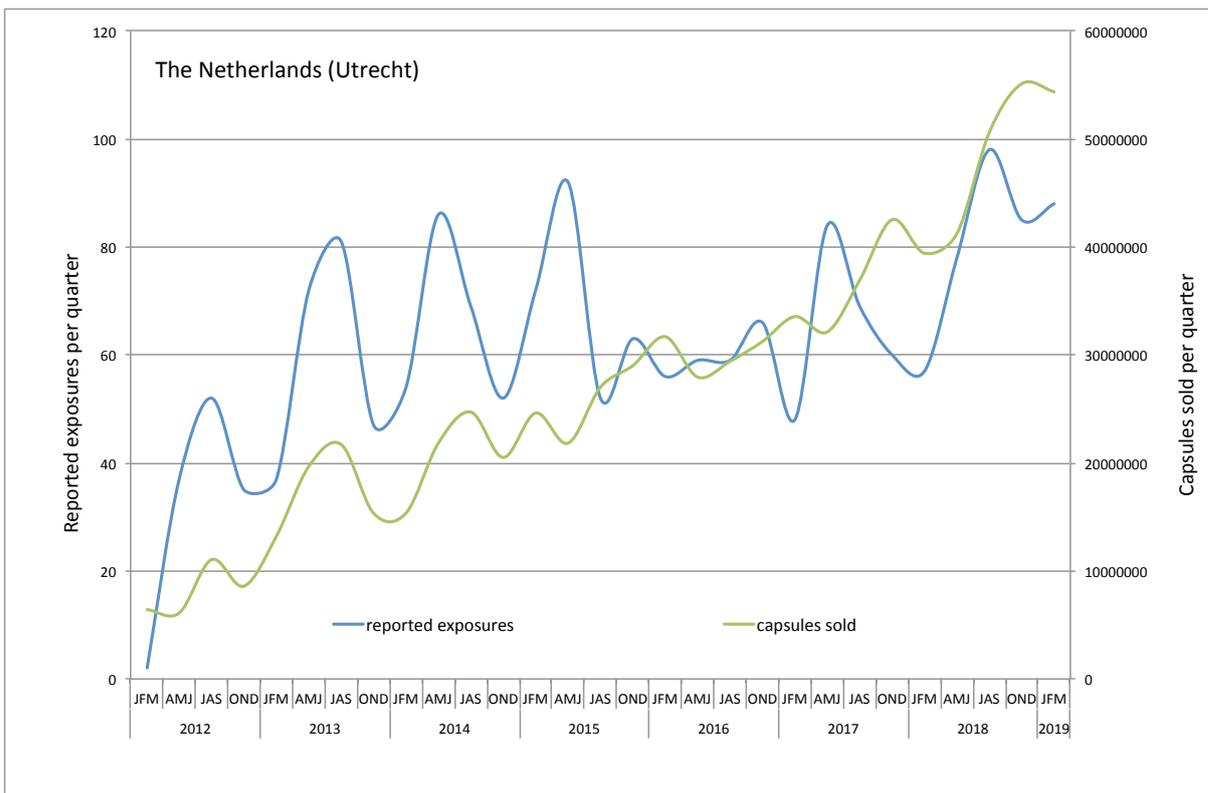
Since the market introduction, the LLDC market in the Netherlands has continued to grow steadily and substantially, from an average of under 3 million units sold per month in 2012 to more than 10 million per month on average in 2016. Over the past 12 months, the volume increased further to an average of nearly 17 million capsules per month.

Assessment:

Over the past 12 months, **1.73 exposures were reported per million capsules** on the market, a reduction by 58.0% (significant, $p < 0.001$) versus the 4.13 cases per million capsules for the baseline period (April 2012-March 2013). Compared to the preceding 12-month period (until March 2018), there was no significant decrease (-3.1%, $p = 0.702$).

These observations show that since the start of the data tracking in 2012, there has been a decrease until 2017. However, since then, no further meaningful reduction has been observed.





Spain: -28.1% since 2014

To note: for Spain, LLDC market data could not be obtained for the period before 2014. Hence, no market-normalised assessment versus the pre-PSP baseline was possible.

Exposures:

Early 2012 there were very few exposures, in line with the minimal market presence. As of mid-2012, the number of accidental exposures to LLDCs increased, with large fluctuations, to an average of 32.8 reported exposures per month in 2014 (peaking at 60 cases in September 2014). Over the past 12 months, on average 40.5 exposures were reported. This is 7% higher than in the preceding 12-month period (until March 2018) with 37.7 reported exposures per month. Prior to the PSP introduction the absolute number of reported exposures was lower (on average 7.9 cases per month in 2012), but this was in line with the low market presence, just following the product launch.

Market:

The Spanish LLDC market has grown, since its introduction around early 2012, to an average of 36.2 million capsules per month over the past 12 months. Market data are available as of 2014. Since then, (with an average of 21.1 million capsules per month) the growth has been steady.

Assessment:

Over the past 12 months, **1.1 exposures were reported per million units** on the market. This is 28.1% less (significant, $p < 0.001$) than for the year 2014, when there were 1.55 cases per million capsules. Compared to the preceding 12-month period, however, the incident frequency was not significantly different (-2.2%, $p = 0.732$).

These observations show a decrease until 2016, but no further reduction since then.



