

PRODUCT STEWARDSHIP PROGRAMME FOR LIQUID LAUNDRY DETERGENT CAPSULES

Status Update - June 2018

28/06/2018

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 the past five years. In Ireland this trend is observed to be still ongoing, whereas in the other four monitored countries this is unclear. Additional voluntary measures (i.e. improved closures and an advertising code of conduct) are reaching the market place in the course of 2018. Also, the “Keep caps from kids” education campaign has been revamped in Fall 2017.

The A.I.S.E. Product Stewardship Programme (PSP) for Liquid Laundry Detergent Capsules (LLDC), a voluntary industry initiative, was initially 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 are to reach the market in the course of 2018. A re-vamp of the “Keep Caps From Kids” website was launched in September 2017, including a new video.

For the Czech Republic, Ireland, the Netherlands and Italy, the relative incident frequency (reported exposures per million unit doses sold) over the past 12-month period was compared to the period before the introduction of PSP measures. The reduction has been substantial, ranging from 53% up to 70% depending on the country.

For these countries, and in addition for Spain, the incident frequency over the past 12 months was also compared to the preceding 12-month period. Only in Ireland this was significantly lower (a 17% reduction). In other countries there was no significant difference, except for Spain where an increase was observed that deserves further attention. Ongoing monitoring will allow to assess the effect of the implementation of the enhanced PSP (e.g. improved child impeding closures).

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 shall be implemented for every new advertising / promotion contract established as of January 2018.

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 campaigns at the national level are currently being executed in some EU countries.



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, 12-24 months ago, etcetera), 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 (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(s) 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 periods (i.e. versus 12 to 24 months ago, 24 to 36 months ago, etc.). 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. For every month, the number of reported exposures, the market size estimate, and the calculated exposure frequency per million capsules, are shown. For the latter, a 6-monthly moving average is also provided. This is plotted more prominently, as it provides a clearer view of the longer-term trend, not influenced by short-term variability. In addition, the annual frequencies for the different 12-month periods being assessed are shown by means of horizontal dashed lines.

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: -69.5% versus Baseline

Exposures:

After having reached a maximum in April 2014, with 38 cases per month, the number of reported exposures has decreased to 16.2 per month on average over the past 12 months until March 2018. This is higher than during the preceding 12-month period (with an average of 12.3 per month) and slightly below the 12 months before that (with 17.1 monthly exposures). Note that during the baseline year 2012, here was a monthly average of 17.8 reported exposures.

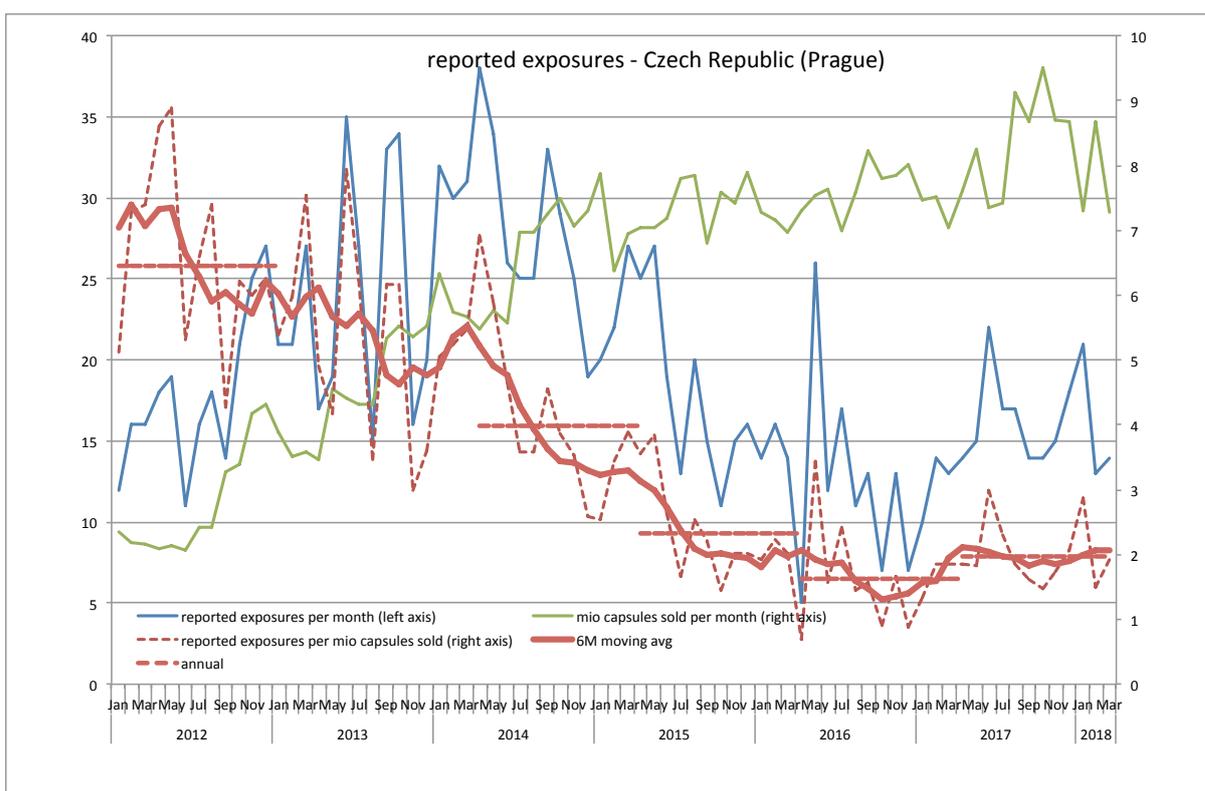
Market:

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 8.2 million per month on average over the past 12 months. The overall maximum was 9.5 million capsules, sold in October 2017.

Assessment:

There were **1.97 reported exposures per million capsules** over the past 12 months. This is a very relevant decrease by 69.5% (significant, $p < 0.001$) compared to the baseline year 2012, which had 6.45 cases per million capsules. Compared to the preceding 12-month period (until March 2017), with 1.63 exposures per million capsules, there was an increase by 21.0% (not significant, $p = 0.079$). On the other hand, relative to the 12-month period before that (until March 2016), with 2.33 exposures per million unit doses, there was a reduction by 15.5% (not significant, $p = 0.093$).

These observations show that since the start of the data tracking in 2012, the decrease has been consistently strong until the end of 2016. As of 2017, no further reduction was observed.



Ireland: -53.2% versus Baseline

Exposures:

On average, the number of reported exposures over the past 12-month period (April 2017 until March 2018) was 18.6 per month - very similar to the baseline year 2012, in which on average 18.3 cases had been reported per month. It is 5% less than the average of 19.6 reported exposures per month observed for the preceding 12-month period (until March 2017).

Market:

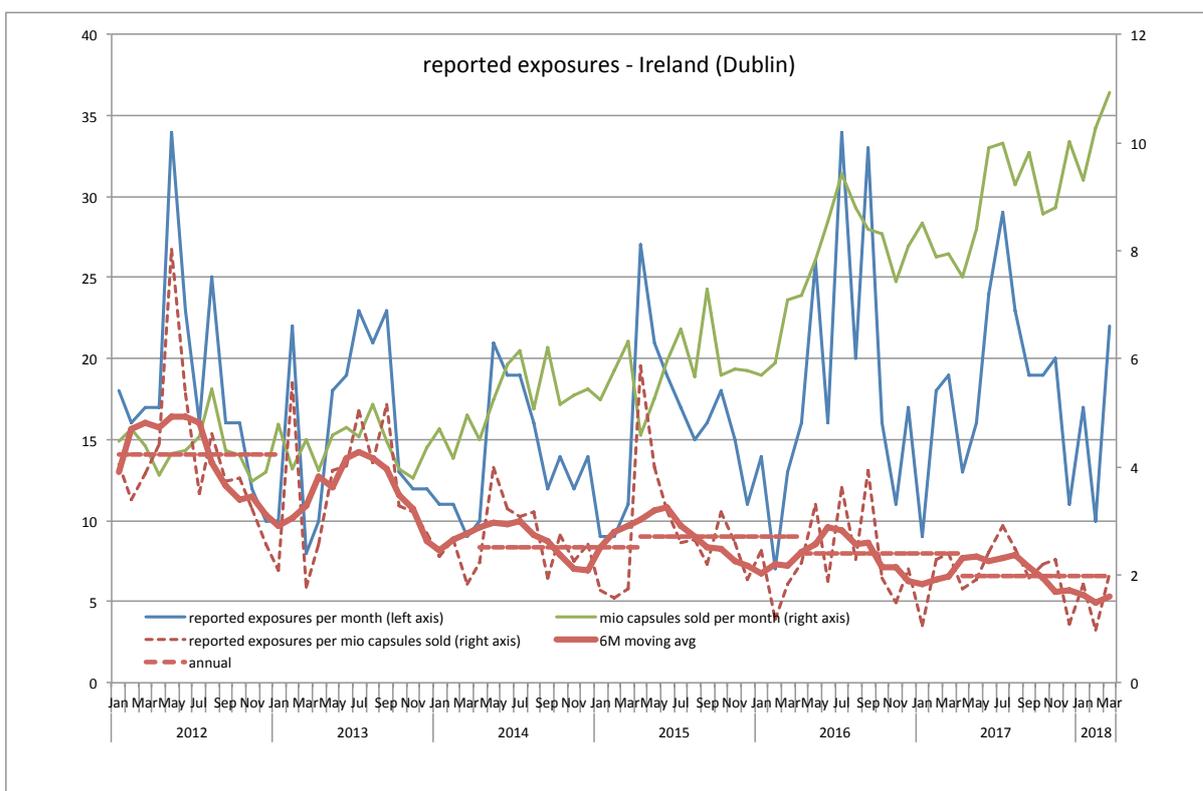
The capsules market in Ireland has continued to grow steadily over the past several years, exceeding an average of 10 million capsules per month in the first quarter of 2018. Across the past 12-month period, the average sales were 9.4 million units per month. *To note that at the time of writing, the market data for March 2018 were not yet definitive.*

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.

Assessment:

Over the past 12 months, there were on average **1.98 accidental exposures per million capsules** on the market. Despite the similar absolute incident count compared to the baseline year 2012, relative to market presence this does represent a notable decrease of 53.2% (significant, $p < 0.001$) - as the 2012 incident frequency was 4.2 cases per million capsules. It is a reduction by 17.3% (significant, $p = 0.042$) compared to the preceding 12-month period (until March 2017, with 2.39 cases per million), and by 27.0% (significant, $p = 0.0014$) relative to the 12-month period until March 2016 - in which 2.71 exposures had been reported per million capsules.

Despite the absence of a decreasing trend over 2015 and 2016, this has now been clearly re-established. As such, the overall incident reduction in Ireland is comparable to the other monitored countries.



Italy: -63.1% 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:

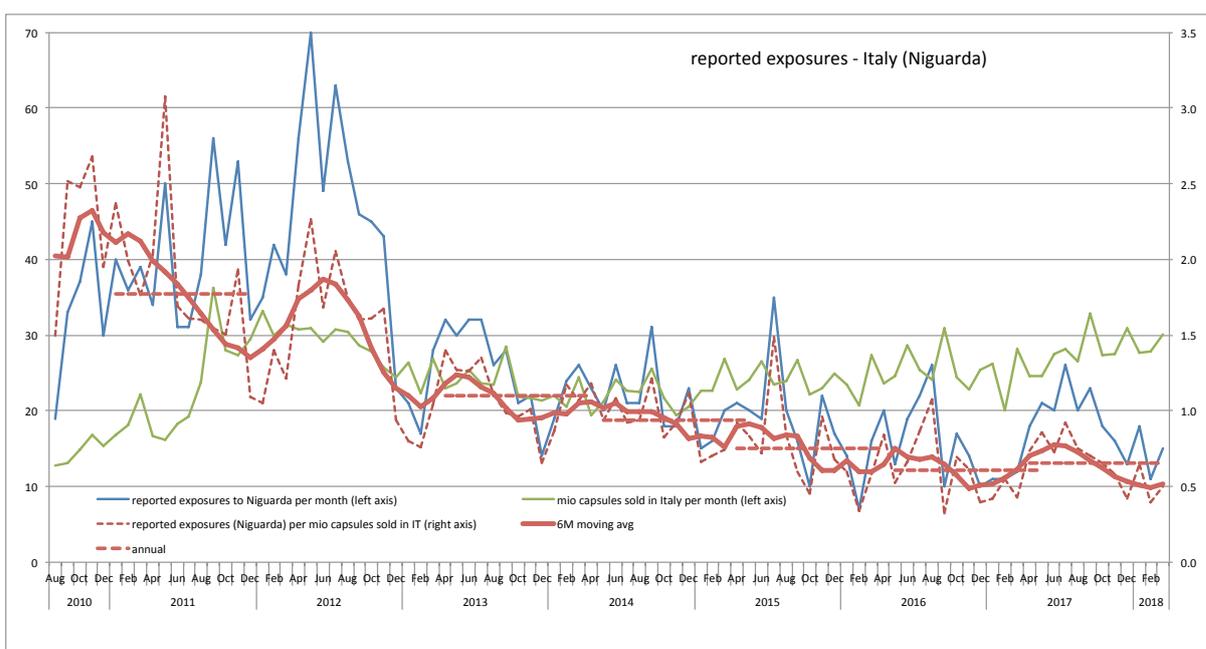
Overall, a steady decrease of the number of reported exposures can be seen from the mid-2012 peak (of 70 cases per month) until the end of 2016. In 2013 the average number of cases per month had decreased to 25.2, further to 22.5 in 2014, then 19.3 in 2015, and finally down to 15.7 in 2016. However, over the past 12 months (until March 2017) no further decrease was observed. The average, 18.3 reported exposures per month, was 16% higher than in 2016.

Market:

Over the past three years (2015 until Q1 2018), the liquid laundry detergent capsules sales volume in Italy has shown a modest growth, with an average volume during the past 12 months of 27.9 million unit doses per month. Earlier, from mid-2011 to mid-2012, a higher market volume plateau (of about 30 million units per month) had been reached, which was followed by a decrease until the end of 2013. This market size of 30 million units per month was again reached in March 2018.

Assessment:

During the past 12-month period, **0.65 accidental exposures** have been reported to the Niguarda PCC per million liquid laundry detergent capsules on the Italian market. This is 63.1% 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 2017), with 0.61 exposures per million capsules, there was an increase (+7.4%) (not significant, $p = 0.47$). Relative to the 12-month periods further back in time (until respectively March 2015, and March 2014 - with respectively 0.75 and 0.94 exposures per million capsules), the reduction was by respectively 13.1% (not significant, $p = 0.14$) and 30.2% (significant, $p < 0.001$). These data show that the decreasing trend has been ongoing steadily and consistently since the initial introduction of risk mitigation measures, until 2016. But during 2017 no further decrease has been observed.



The Netherlands: -55.8% 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.

To note: due to market data no longer being available from one of the sources, the market size estimate was recalculated across the entire monitoring period based on the data from the currently still available sources. This has an implication for the volume during the baseline period, and consequently, also for the baseline incident frequency which is now higher than in the previous reports.

Exposures:

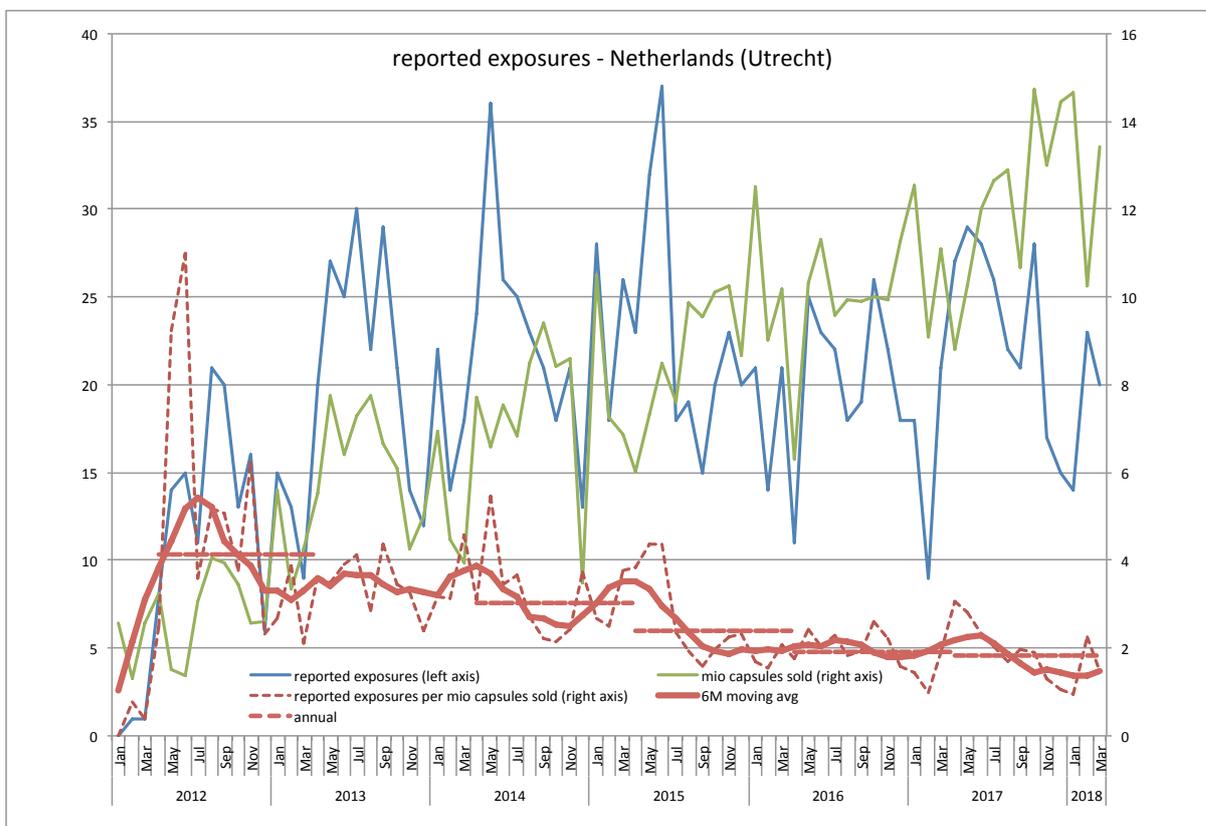
Over the past 12 months, on average 22.5 exposures were reported in the Netherlands. This is higher than what was observed for the preceding 12-month period (19.3 per month) and similar to the 12-month period before that (with 21.9 reported exposures per month). Prior to the PSP introduction the absolute 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 12.3 million capsules per month.

Assessment:

Over the past 12 months, **1.83 exposures were reported per million capsules** on the market, a reduction by 55.8% (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 2017), this is a decrease by 4.5% (not significant, $p = 0.61$). It is a 23.9% decrease (significant, $p = 0.0016$) compared to the 12-month period until March 2016. Hence, from 2014 to 2016, the decrease has been consistent - but over 2017 the reduction has been less pronounced.



Spain: -26.5% 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 37.7 exposures were reported. In the preceding 12-month periods (until respectively March 2017 and March 2016) this was respectively 27.8 and 29.9 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 just below 33 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, although more recently the growth appears to have been reduced.

Assessment:

Over the past 12 months, **1.14 exposures were reported per million units** on the market. This is 36.5% 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 higher (+23.5%, significant, $p = 0.0034$). Consequently, the strong decrease between 2014 and 2016 does not appear to be continued over 2017.

