

PRODUCT STEWARDSHIP PROGRAMME FOR LIQUID LAUNDRY DETERGENT CAPSULES Status Update - June 2017¹

16/6/2017

Executive Summary

Relative to their market presence, the number of accidental exposures with Liquid Laundry Detergent Capsules, as reported to Poison Control Centers of five EU countries, has decreased substantially. This trend is observed to be still ongoing in all monitored countries for the period April 2016 - March 2017.

The A.I.S.E. Product Stewardship Programme (PSP) for Liquid Laundry Detergent Capsules (LLDC), a voluntary industry initiative, aims at significantly reducing the incidence of accidental exposures - in particular involving small children - to these products. This is achieved through product safety requirements and the promotion of safe use and storage. The PSP was launched end 2012, with implementation of measures by mid 2013. Communication efforts have been significantly reinforced as of April 2014, with child-safety messaging included on all LLDC brand communication and advertising. A further extension of the PSP with additional voluntary measures is open for signature as of 12 June 2017.

For five countries (the Czech Republic, Ireland, the Netherlands, Italy, and Spain)², the relative incident frequency (reported exposures per unit sold) over the past 12-month period (April 2016 until March 2017) were compared to the immediately preceding 12-month period, and where possible also to the 12-month period prior to the introduction of the PSP measures ('baseline'):

- A decreasing trend is observed in all monitored countries (ranging from 11.7% to 31% comparing the past 12-months to the preceding 12-month period).
- Compared to the baseline, there was a substantial reduction in the number of reported exposures per capsule sold in all countries where this information was available. The decrease ranged from 43% up to 75% depending on the country.

Country	Past 12M vs. baseline	Past 12M vs. preceding 12M
Czech Republic	-75.1 %	- 31.2 %
Ireland	-43.4 %	-11.7 %
Italy	-65.6 %	- 19.1 %
The Netherlands	-50.5 %	- 19.7%
Spain	N.A.	- 17.2 %

¹ This progress report focuses on developments since October 2015. For more information on the A.I.S.E. Product Stewardship Programmes for Liquid Laundry 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".

² Information about the UK incident statistics can currently not be disclosed by the PCC, until the data have been formally published in the scientific literature, to avoid issues related to 'dual publication'. However, Spain is now included as an additional country where incident statistics are monitored.



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, and was extended 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 market is covered by six companies that have signed up to the 2012 PSP. Today, essentially all products on the shelf comply with its requirements. This is also thanks 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 liquid laundry unit dose products placed on the market as of June 2015 (with official phase-out of non-compliant products by end 2015).

Since 12th June 2017, the formal agreement for additional safety measures in form of a new PSP has been opened for signature. This PSP-2017 introduces superior child impeding properties of the packaging, and an advertising code of conduct.

Communication efforts have been significantly reinforced as of April 2014, with child-safety messaging included on all LLDC brand communication and advertising. In 2014, the "Keeps Caps From Kids" (KCFK) educational campaign was also launched. The KCFK web site will be revamped mid 2017, and additional education campaigns are being explored.

Incident Statistics - Reported Exposures to PCCs

Methodology

Exposure statistics.

The numbers of exposures reported to PCCs, on a monthly basis, are available until March 2017 for Ireland (IE), 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 these 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 individual 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.

For public health, the absolute number of exposures - as reported by the PCCs - is highly relevant. However, to assess the trend and the effectiveness of risk reduction measures, a normalisation 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)³ basis.

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.

³ 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 to be divided by the number of capsules sold over that year.



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: -75.1% versus Baseline

Exposures:

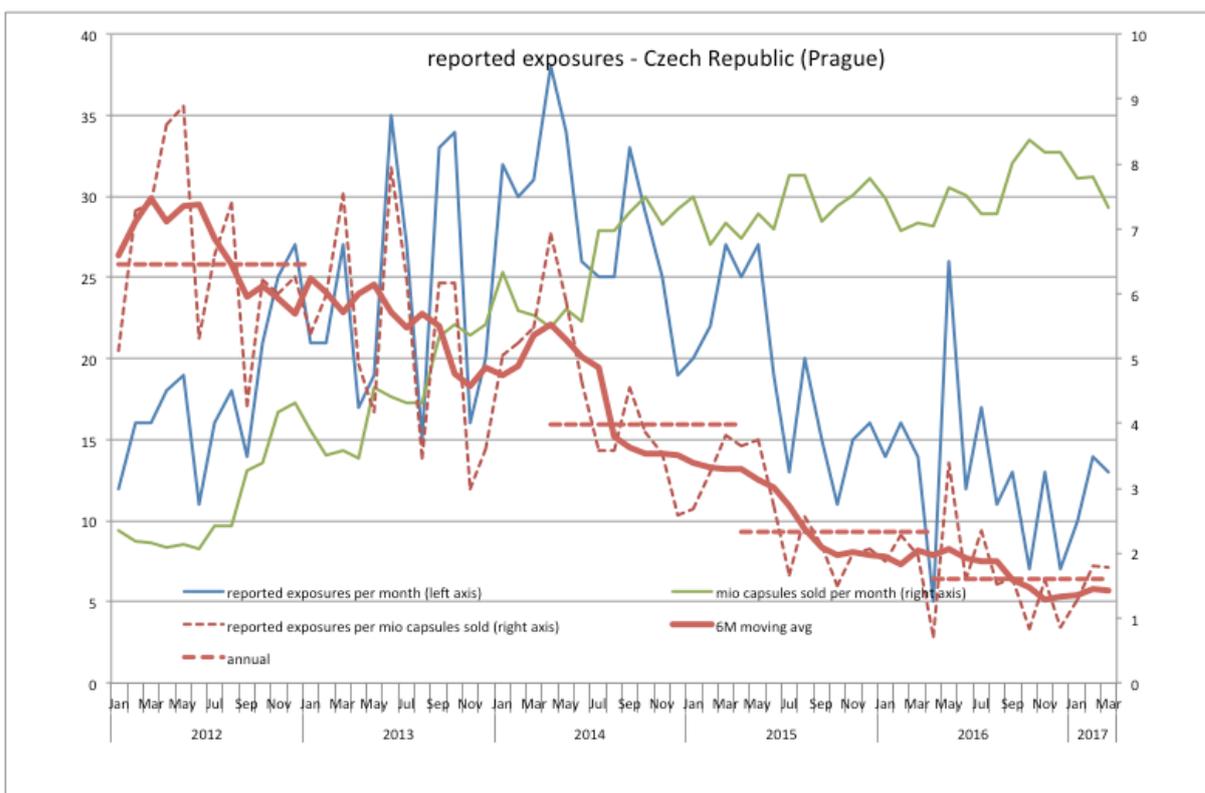
After having reached a maximum in April 2014, with 38 cases per month, the number of reported exposures has decreased to 12.3 per month on average over the past 12 months. This is substantially below the numbers the two preceding 12-month periods (with respectively 17.1 and 26.9 exposures per month). It is also 30% below the average of 17.8 exposures per month that were reported during the baseline year 2012.

Market:

During 2012, 2013 and 2014, the market has grown substantially from less than 2.5 million units per month in early 2012, to reach an average of 7.3 million per month in 2015, still gently growing to 7.7 million per month on average over the past 12 months.

Assessment:

There were 1.60 reported exposures per million capsules over the past 12 months. This is a decrease by 75.1% (significant, $p < 0.001$) compared to the baseline year 2012, with 6.45 cases per million. Compared to the preceding 12-month periods (until respectively March 2016 and March 2015), with respectively 2.3 and 4.0 exposures per million capsules, this is respectively a 31.2% reduction (significant, $p < 0.001$) and a 59.6% (significant, $p < 0.001$) reduction. This shows that since the start of the data tracking in 2012, the decrease has been consistent over time.



Ireland: -43.4% versus Baseline

Exposures:

On average, the number of reported exposures over the past 12-month period (April 2016 until March 2017) was 19.6 per month. This is 7% higher than in the baseline year 2012, in which on average 18.3 cases had been reported per month. It is actually 23% higher than in the preceding 12-month period (until March 2016), which saw 16 exposures per month. Very noticeable, and driving the average across the past 12-months, are the peaking exposure counts in July '16 (34 cases) and September '16 (33 cases). Since then (over the 4th quarter of 2016 and the 1st quarter of 2017) the average has dropped to 15 exposures per month. Nevertheless, this is still 15% above the average of 13 cases during the same period one year before.

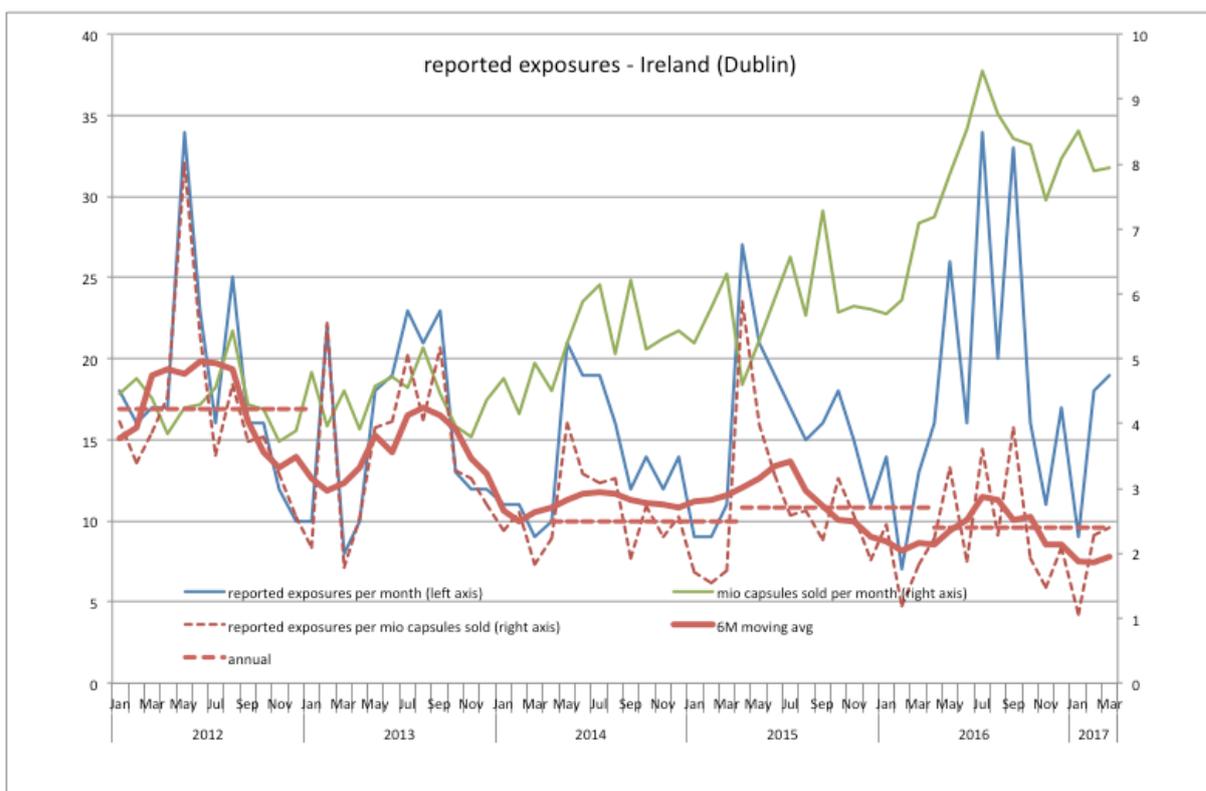
Market:

The capsules market in Ireland has been dynamic over the past 1.5 years, with significant growth (around 50%) between end 2015 and mid 2016, reaching over 9 million capsules sold in July 2016. Since then the market has dropped back to an average of 8 million capsules per month over the past 2 quarters. Across the past 12-month period, the average sales were of 8.2 million units per month.

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 2.4 accidental exposures per million capsules on the market. Despite the higher absolute incident count compared to the baseline year 2012, this does represent a notable decrease of 43.4% (significant, $p < 0.001$) relative to market presence - as the 2012 incident frequency was 4.2 cases per million capsules. It is a reduction by 11.7% (not significant, $p = 0.200$) from the preceding 12-month period (until March 2016, with 2.7 cases per million), but only by 4.5% (not significant, $p = 0.647$) relative to the 12-month period until March 2015 - in which 2.5 exposures had been reported per million capsules. Hence, over the past year the decreasing trend which had been very pronounced in 2014, but which had disappeared in 2015, was re-established - albeit not yet as prominently as in 2014, or as in the other monitored countries.



Italy: -65.6% 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:

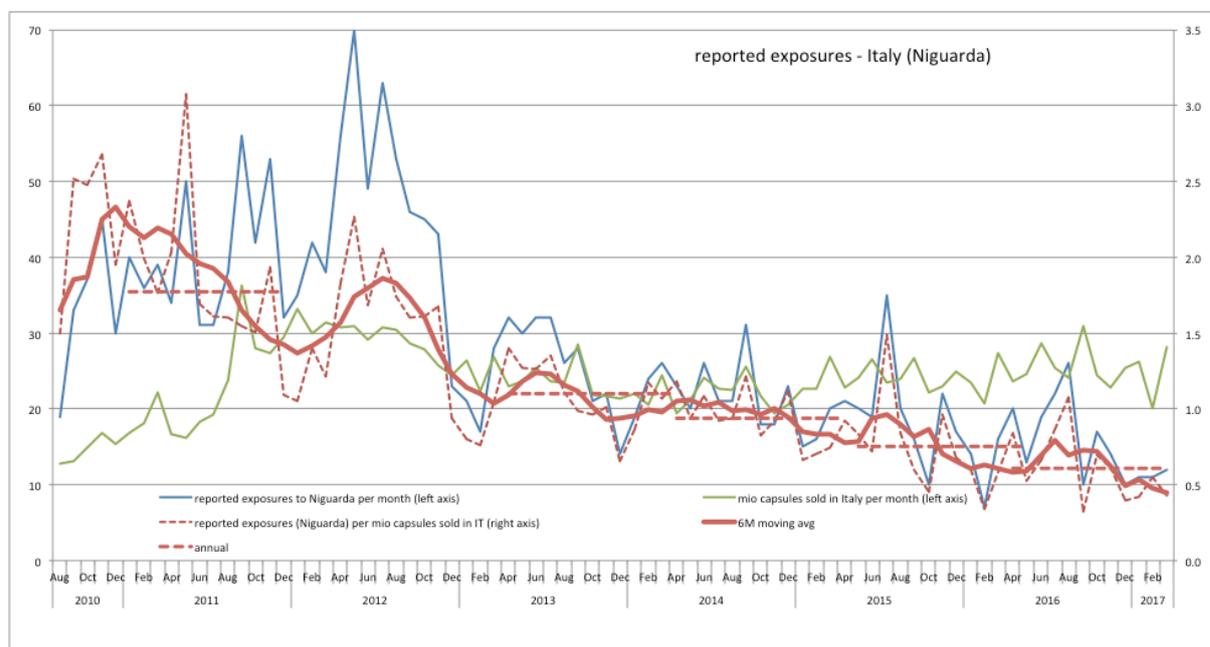
Overall, a steady decrease of the number of reported exposures can be seen since the mid-2012 peak of 70 cases per month. In 2013 the average number of cases per month had decreased to 25.2, and further down to 22.5 in 2014, and 19.3 in 2015. Over the past 12 months (until March 2017) the average was at 14.5 reported exposures per month.

Market:

Over 2015 and 2016, the liquid laundry detergent capsules sales volume in Italy has shown a modest growth, with an average volume during the past 12 months of 25.4 million units per month. This is about 15% higher than the market size in 2014, and 5% higher than the 2015 volume. Before this, a higher market volume plateau (30 million units per month) had been reached from mid-2011 to mid-2012, followed by a decrease until the end of 2013.

Assessment:

During the past 12-month period, 0.61 accidental exposures have been reported to the Niguarda PCC per million liquid laundry detergent capsules on the Italian market. This is 65.6% 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 2016), with 0.75 exposures per million capsules, the reduction was by 19.1% (significant, $p = 0.035$). Relative to the 12-month periods further back in time (until respectively March 2015, and March 2014 - with respectively 0.94 and 1.10 exposures per million capsules), the reduction was by respectively 35.0% (significant, $p < 0.001$) and 44.6% (significant, $p < 0.001$). These data show that the decreasing trend has been ongoing steadily and consistently over the past several years following the initial introduction of risk mitigation measures.



The Netherlands: -50.5% 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:

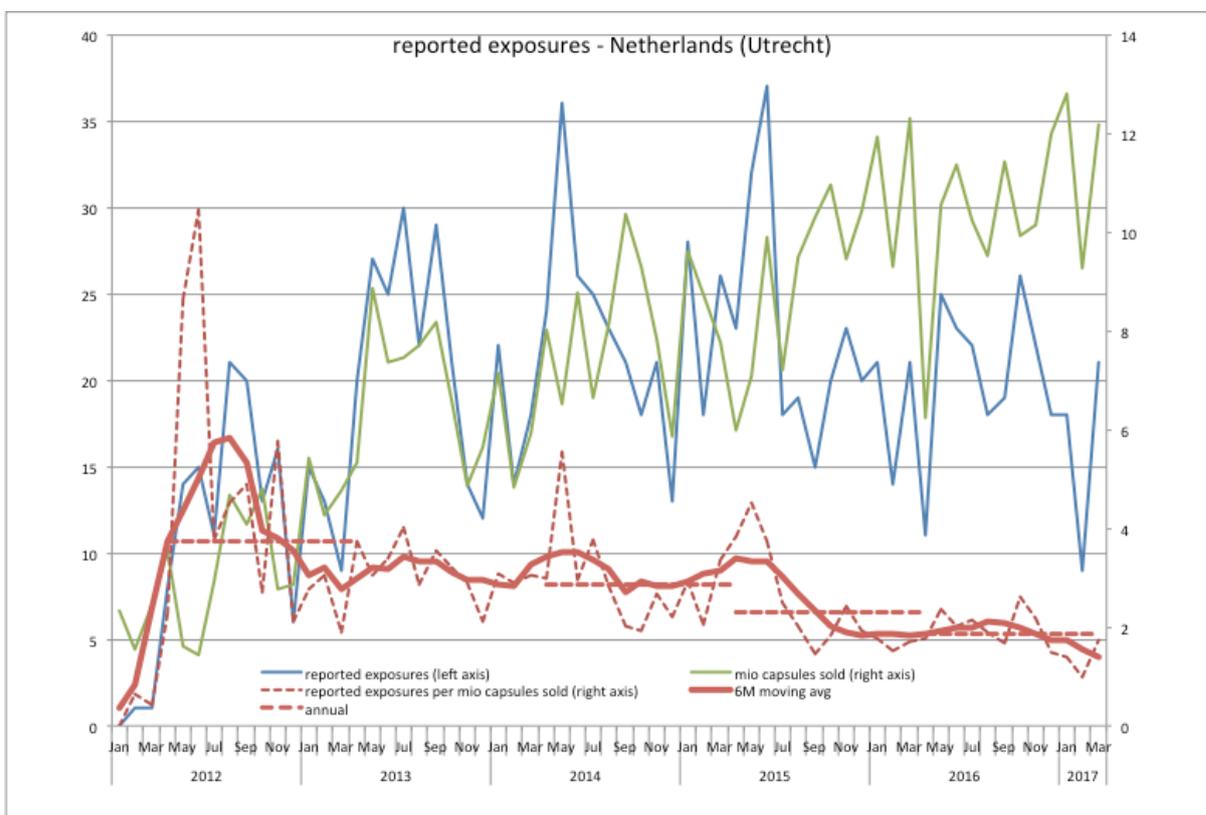
Between 2012 and 2015 there was a large fluctuation of the number of reported exposures per month. Variations between different months sometimes exceeded a factor 3. Since mid 2015 the fluctuation has decreased, and the absolute numbers have also steadily dropped. Over the past 12 months, on average 19.3 exposures were reported. In the preceding 12-month periods this was respectively 21.9 and 23.3 per month. Prior to the PSP introduction the absolute number of reported exposures was lower (on average 13.4 cases per month) - due to the much lower market presence.

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 was on average 10.5 million capsules per month.

Assessment:

Over the past 12 months, 1.85 exposures were reported per million capsules on the market, a reduction by 50.5% (significant, $p < 0.001$) versus the 3.73 cases per million capsules for the baseline period (April 2012-March 2013). This also represents a 19.7% decrease (significant, $p = 0.015$) versus the preceding 12-month period (until March 2016), in which 2.30 exposures had been reported per million capsules on the market. It is a 35.4% decrease (significant, $p < 0.001$) compared to the 12-month period until March 2015. Hence, since 2014, the decrease has been consistent over time.



Spain: Ongoing decrease (-17.2% over 1 year, -40.2% over 2 years)

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:

Between 2012 and then end of 2014, the number of accidental exposures to LLDCs has increased from essentially zero (due to minimal market presence) up to a peak of 60 per month in September 2014. Fluctuations from month to month were very large. Since early 2015 the fluctuation has decreased, and the absolute numbers have started to drop. Over the past 12 months, on average 27.8 exposures were reported. In the preceding 12-month periods (until respectively March 2016 and March 2015) this was respectively 29.9 and 33.7 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 due to 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 30.1 million capsules per month over the past 12 months. Since 2014 (with on average 21.1 million capsules per month) this has been a steady growth.

Assessment:

Over the past 12 months, 0.93 LLDC exposures were reported per million units on the market. This is 17.2% less (significant, $p=0.013$) than in the preceding 12-month period (until March 2016), with 1.1 reported exposures per million capsules. It is a 40.2% decrease (significant, $p<0.001$) compared to the 12-month period until March 2015. Hence, since 2014, the decrease has been consistent over time.

