

AESTIMO Briefing

Addiction to legal products: market, needs and innovation opportunities

(Alcohol Usage Disorders and Smoking Cessation)

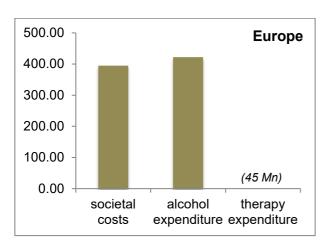
Excessive usage of health damaging products, that leads to addiction, results in mental and physical health consequences that requires a comprehensive and caring approach that includes support, rehabilitation and care systems and pharmacological intervention.

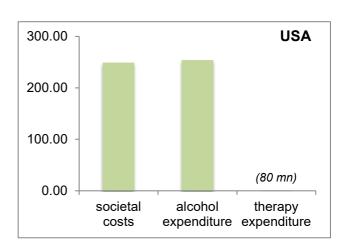
In todays global demographic of healthcare needs and unsustainable healthcare costs, many of the costs associated with these needs are avoidable. But, because these are lifestyle choices, often considered harmless by the user, and despite health warnings, usage remains high, globally.

There is clearly a need for a prevention solution that decreases unnecessary and very expensive long-term healthcare costs.

Tobacco and Alcohol usage and addiction costs (values indicated in Billions of US dollars)

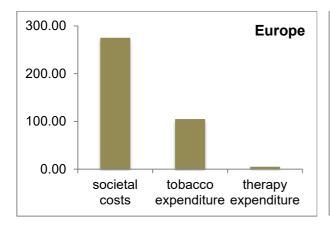
Alcohol

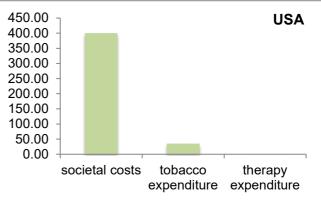




Note: Alcohol Rehab market values only available for USA, equalling \$35Bn/year

Tobacco





NB: none of the above values include productivity loss costs

Additionally, given that the healthcare resource use and costs as well as long-term impacts of addiction are well documented, any solution that reduces usage immediately is very likely going to have a long-term beneficial impact. Innovation in this field is further supported by clinical testing dynamics: the clinical trial durations are short and therefore lower cost. But because intervention uptake is generally low, investment in new innovative approaches, which will solve this significant problem, remains low.

There is clearly a significant differential between socioeconomic cost reduction possibilities and actual sales and potential sales of products. Market penetrance, patient benefit and indeed identification and prescription of the problem, thereby enabling correction, is clearly an issue. No one wants to think they have an addiction or abuse disorder.

Analysis

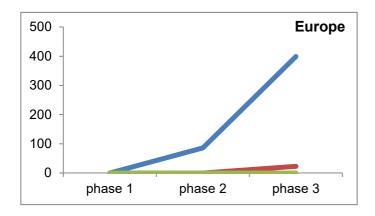
For both alcohol and tobacco cessation approaches, we performed valuations comparing the published analysts best market predictions, the true market value based on actual total sales and the best selling intervention on the market. These were used as the Terminal Market Values in the rNPV calculation for Europe and the USA.

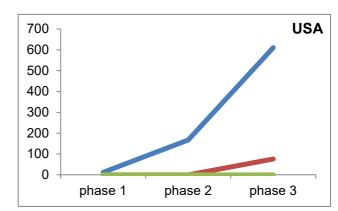
From a pure intervention research and development this represents a conundrum: despite the market need and opportunity, inputting the **global best selling drugs lifetime global cumulative sales value** as a terminal market value in rNPV calculations reveals that positive rNPVs are never obtained at any point throughout the development life cycle. Basically, treating one of the worlds largest causer of healthcare costs is very high risk: for a company, initiating a programme dedicated to this need will literally mean 'betting the house'.

rNPV value calculations

Values are indicated in millions of USD: Blue line represents published Market value from market analysts assessments; Red line represents Market Value based on indication specific total product sales; Green Line represents Market Value of present best selling product.

Tobacco





Alcohol:

For Alcohol Usage Disorders, despite using either the most optimistic published market reports, the true intervention expenditure or the best selling therapy sales as Terminal Market Values, a positive rNPV could not be obtained for phase 1, 2 or 3.

Fundamentally, when modelling, accounting for indication specific clinical testing characteristics, positive valuations are only obtained from phase 2 onwards, when a minimum of \$4Bn in global sales can be obtained, but, importantly, such an achievement does result in very positive ROI's, liberating capital for further value adding innovation.

The market potential for both issues is high: clearly existing preventative and control measures are not having the necessary impact, but only large incumbents seem marginally interested in developing potential solutions.

Market opportunity:

From our perspective, due to low clinical trial costs for interventions for addiction:

- Specialist Pharma or generic developers able to repurpose innovations validated from phase 2 onwards for tobacco, or approved market released solutions for alcohol, can achieve global penetration and will be able to produce a high value healthcare beneficial and profitable solution.
- Innovation from scratch and only limited geographic market penetrance offers zero to very limited returns.
- For Alcohol Usage Disorders, alternative solutions, if correctly designed and validated, may
 provide high impact approaches to enable personal reduction in alcohol consumption.
 Alternatively, interventions based on repositioning, but designed for global impact from their
 initial testing are going to generate high value.
- There also needs to be further policy changes: given associated healthcare costs, the prices
 of regulated addictive products needs to be increased further to reduce consumption. This is
 now blindingly obvious: tax and VAT revenue on health damaging products obtained by
 governments has literally no impact on the longer term healthcare costs that the same
 governments have to pay for.

About Aestimo Briefings.

Using indication specific clinical trial success rates, trial design, and full value chain costs, we routinely assess global market needs in healthcare for our clients and partners. Aestimo Briefings are limited summaries of these analyses, for which we only choose to report publicly on specific interventions for European and US markets.

More complete analyses for all indications are available upon request which, where relevant, also include:

- Medical devices, diagnostics, tissue engineered products, alternatives and nutriceuticals assessments
- Global market regions (APAC, MEA, LATAM), and specific country breakdowns including local regulations and reimbursement policies
- Comparisons of all selling/reimbursed interventions, mechanism of actions, types/classes of interventions and details of interventions in development by country
- Morbidity and comorbidity impact in indications and interventions
- pd-DRR valuations that incorporate total value chain and market approval related risks

are available upon request

For more information on complete value chain analyses, global feasibility studies, portfolio and pipeline design, investment support and high value implementable global strategy designs based on early stage to reimbursement approval, please contact us.

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