
***The Pharmaceutical BFS
International Operators
Association***
Annual Report for 2018

The Annual Report
was presented and
adopted at the Annual
General Meeting of
the Association
on 19 / 6 2019

Chairman



Indholdsfortegnelse

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Management's Statements

The Board of Directors has today considered and adopted the Annual Report of The Pharmaceutical BFS International Operators Association for the financial year 1 January - 31 December 2018.

The Annual Report is prepared in accordance with the Danish Financial Statements Act.

In our opinion, the Financial Statements give a true and fair view of the financial position at 31 December 2018 of the Association and the results of the Association operations for 2018.

We recommend that the Annual report be adopted at the Annual General Meeting.

Nørre Alslev, 17 June 2019

Board of Directors

Peter Åkermann
Chairman

Martin Haerer
Regulatory officer

Jesper Laursen
Officer of Operation
(Communication & Treasurer)

Kevin Downey
Technical officer

Independent Auditor's Report

To the Members of The Pharmaceutical BFS International Operators Association

Opinion

In our opinion, the Financial Statements give a true and fair view of the financial position of The Pharmaceutical BFS International Operators Association at 31 December 2018, and of the results of The Pharmaceutical BFS International Operators Association's operations for the financial year 1 January - 31 December 2018 in accordance with the Danish Financial Statements Act.

We have audited the Financial Statements of The Pharmaceutical BFS International Operators Association for the financial year 1 January - 31 December 2018, which comprise income statement, balance sheet and notes, including a summary of significant accounting policies ("financial statements").

Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and the additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the *Auditor's Responsibilities for the Audit of the Financial Statements* section of our report. We are independent of the Company in accordance with the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the additional requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Management's Responsibilities for the Financial Statements

Management is responsible for the preparation of Financial Statements that give a true and fair view in accordance with the Danish Financial Statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Independent Auditor's Report

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting in preparing the financial statements and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and contents of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.

Independent Auditor's Report

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Ringsted, 17 June 2019

PricewaterhouseCoopers

Statsautoriseret Revisionspartnerselskab



Brian Petersen

State Authorised Public Accountant

mne28701

Association Information

Association

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CVR No: 20 49 21 39

Financial year: 1 January - 31 December

Board of Directors

Peter Åkerman, Chairman
Martin Haerer, Regulatory officer
Jesper Laursen, Officer of Operation
Kevin Downey, Technical officer

Auditors

PricewaterhouseCoopers
Eventyrvej 16
DK-4100 Ringsted

Bankers

Danske Bank
Finanscenter Sjælland Syd
Torvet 6, 3
4100 Ringsted

Accounting Policies

Basis of preparation

General

The accounting policies applied are consistent with those applied last year.

The annual report for The Pharmaceutical BFS International Operators Association for 2018 is prepared in accordance with the Danish Financial Statements Act provisions for companies, class A.

Translation policies

Transactions in foreign currencies are translated at the exchange rates at the dates of transaction. Gains and losses arising due to differences between the transaction date rates and the rates at the dates of payment are recognised in financial income and expenses in the income statement.

Receivables, payables and other monetary items in foreign currencies that have not been settled at the balance sheet date are translated at the exchange rates at the balance sheet date. Any differences between the exchange rates at the balance sheet date and the transaction date rates are recognised in financial income and expenses in the income statement.

Income

Income comprises the invoiced subscriptions and sponsorships for the year.

Expenses

Expenses comprise cot for meeting activities as well as administration expenses, etc.

Financial income and expenses

Financial income and expenses are recognised in the income statement at the amounts relating to the financial year.

Receivables

Receivables are valued less provision for bad debts calculated on the basis of an individual assessment of the receivables.

Financial debt

Debt is measured at amortised cost which in all materiality corresponds to nominal value.

Income Statement 1 January - 31 December

	Note	2018 EUR	2017 EUR
Subscriptions and sponsorships	2	203,019	219,195
Income		203,109	219,195
Administration	3	-37,494	-41,674
Meeting activities	4	-200,275	-158,928
Expenses		237,769	-200,602
Interest		-508	-502
Exchange rate adjustments		9,565	-19,035
Financial income		9,057	-19,537
Profit/loss for the year		-25,693	-944

Balance Sheet at 31 December

Assets

	Note	2018 EUR	2017 EUR
Receivable		1,732	0
VAT receivable		4,431	3,716
Cash at bank and in hand		<u>240,837</u>	<u>260,009</u>
Assets		<u>247,000</u>	<u>263,725</u>

Liabilities

Retained earnings		<u>217,027</u>	<u>243,492</u>
Equity	5	<u>217,027</u>	<u>243,492</u>
Other payables		<u>29,973</u>	<u>20,233</u>
Short-term debt		<u>29,973</u>	<u>20,233</u>
Debt		<u>29,973</u>	<u>20,233</u>
Liabilities and equity		<u>247,000</u>	<u>263,725</u>
Key activities	1		

Notes to the Annual Report

1 Key activities

The objects of the Association are:

- To promote appropriate standards in the production and quality assurance of pharmaceutical products produced by Blow-Fill-Seal (BFS) technology.
- To establish and agree with the relevant bodies standards appropriate to the pharmaceutical application of the BFS technology.
- To provide a vehicle for conducting both the coordinated views of the members of the Association and their requirements to the manufactures of BFS machines, filters, plastic resin and other components forming an integrated part of the BFS process.
- To provide a forum for the exchange of technical information between members using BFS technology to produce pharmaceutical products.
- To provide a means of informing members of the Association of regulatory requirements and developments.
- To facilitate co-operation between of the Association.
- To take any lawful action incidental to or conducive to the attainment of the above objects.

	2018 EUR	2017 EUR
2 Subscriptions and links		
Subscriptions	154,351	179,918
Sale of books	83	
Sponsorship	48,585	39,277
	203,019	219,195

3 Administration

Administration fee	25,949	25,984
Audit and accounting assistance, etc	1,676	1,612
Marketing/Brochure	1,218	3,113
Website (incl. license, hosting, consultant)	5,998	8,282
Bank commission and fees	2,653	2,683
	37,494	41,674

Notes to the Annual Report

	2018 EUR	2017 EUR
4 Meeting activities		
Meetings USA	112,847	73,119
Meetings Asia	40,146	33,227
Meetings Europe	34,497	52,582
Training Seminar	10,012	0
PTC Workshop	2,773	0
	<u>200,275</u>	<u>158,928</u>
5 Equity		
Equity at 1 January	243,492	244,706
Exchange rate adjustment	-772	-270
Net profit/loss for the year	<u>-25,693</u>	<u>-944</u>
Equity at 31 December	<u>217,027</u>	<u>243,492</u>