Healthcare

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Key figures				
			Change	
€ million	2020	2019	€ million	%
Net sales	6,639	6,714	-75	-1.1%
Operating result (EBIT) ¹	1,804	1,149	654	56.9%
Margin (% of net sales) ¹	27.2%	17.1%		
EBITDA ¹	2,184	1,896	288	15.2%
Margin (% of net sales) ¹	32.9%	28.2%		
EBITDA pre ¹	2,267	1,922	346	18.0%
Margin (% of net sales) ¹	34.1%	28.6%		
Business free cash flow ¹	1,895	1,252	643	51.4%

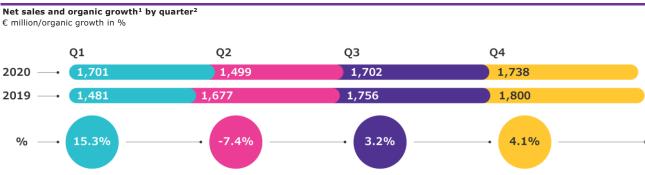
 $^{^{\}rm 1}\,{\rm Not}$ defined by International Financial Reporting Standards (IFRS).

Development of sales and results of operations

In fiscal 2020, the Healthcare business sector recorded net sales of € 6,639 million (2019: € 6,714 million). Organic sales growth amounted to 3.4%. All in all, net sales decreased by -1.1% due to unfavorable exchange rate developments (-3.6%) and the disposal of the Allergopharma allergy business in the first quarter of 2020 (-0.9%). The exchange rate effect reflects the unfavorable development of various currencies against the euro, particularly the U.S. dollar, individual Latin American currencies, and the Russian ruble.

The net sales in the individual quarters as well as the respective organic growth rates in 2020 are presented in the following graph:

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 $^{^{\}rm 1}$ Not defined by International Financial Reporting Standards (IFRS). $^{\rm 2}$ Quarterly breakdown unaudited.

Net sales of the key product lines and products developed as follows in 2020:

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€ million	2020	Share	Organic growth ¹	Exchange rate effects	Total change	2019	Share
Oncology	1,116	17%	12.0%	-3.6%	8.4%	1,030	15%
thereof: Erbitux®	891	13%	6.0%	-3.7%	2.3%	871	13%
thereof: Bavencio®	156	2%	57.4%	-4.9%	52.5%	103	2%
Neurology & Immunology	1,662	25%	6.7%	-2.4%	4.3%	1,594	24%
thereof: Rebif®	1,131	17%	-9.4%	-1.7%	-11.1%	1,273	19%
thereof: Mavenclad®	531	8%	70.5%	-5.2%	65.4%	321	5%
Fertility	1,079	16%	-10.7%	-2.7%	-13.4%	1,247	19%
thereof: Gonal-f®	630	9%	-12.7%	-2.5%	-15.2%	743	11%
General Medicine & Endocrinology	2,585	39%	5.9%	-4.8%	1.1%	2,557	38%
thereof: Glucophage®	903	14%	8.1%	-5.0%	3.1%	877	13%
thereof: Concor®	529	8%	4.4%	-4.7%	-0.2%	530	8%
thereof: Euthyrox®	455	7%	18.6%	-5.5%	13.1%	402	6%
thereof: Saizen®	234	4%	4.0%	-5.8%	-1.8%	238	4%
Other	197	3%				287	4%
Healthcare	6,639	100%	3.4%	-3.6%	-1.1%	6,714	100%

¹ Not defined by International Financial Reporting Standards (IFRS).

The oncology drug Erbitux® (cetuximab) posted organic sales growth of 6.0% in fiscal 2020. Taking into account negative exchange rate effects of -3.7%, global net sales of Erbitux® increased by 2.3% to € 891 million (2019: € 871 million). While China continued to see encouraging development following the addition of Erbitux® to the National Reimbursement Drug List (NRDL) in 2018, growth in the Asia-Pacific region as a whole stagnated as a result of the difficult competitive situation in Japan due to the launch of new drugs. The situation in the core European markets was also characterized by a difficult competitive environment, but positive effects from successful tenders resulted in moderate organic growth of 1.9%. All in all, Erbitux® sales in Europe amounted to € 404 million (2019: € 405 million). A partnership with Eli Lilly and Company, United States, also had a positive impact. Services performed for the production of cetuximab as part of this cooperation resulted in net sales in the United States in 2020.

In the area of immuno-oncology, sales of the oncology drug Bavencio® (avelumab) posted organic growth of 57.4%. Taking into account negative exchange rate effects of -4.9%, net sales of € 156 million were generated in 2020 (2019: € 103 million). This highly encouraging growth was due in particular to the approval granted for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) in the United States in June 2020. Bavencio® is the first immunotherapy to demonstrate an improvement in overall survival in a Phase III study compared with the standard treatment in the first-line setting for patients with locally advanced or metastatic urothelial carcinoma. Sales growth was also driven by the approval of Bavencio® in combination with axitinib for the treatment of patients with advanced renal cell carcinoma (RCC) in Europe and Japan in 2019.

Mavenclad®, for the oral short-course treatment of highly active relapsing multiple sclerosis, also made a substantial contribution to the encouraging organic growth in the Healthcare business sector. Mavenclad® posted net sales of € 531 million in fiscal 2020, almost double the figure recorded in the previous year (2019: € 321 million). In a market environment impacted by Covid-19, prescription rates for Mavenclad® declined temporarily. However, the second half of 2020 in particular saw strong signs of a recovery, supported by new safety data indicating that patients treated using Mavenclad® who acquire Covid-19 are not at an increased risk of severe outcomes. With the additional approvals obtained in 2020, Mavenclad® is now approved in more than 80 countries around the world.

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Product sales and organic growth ¹ of Rebif	, Glucophage [®] and Erbitux [®] by region – 2020
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	_	Total	Europe	North America	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
	€ million	1,131	331	705	11	34	50
Rebif [®]	Organic growth ¹	-9.4%	-2.3%	-11.2%	-3.2%	-2.4%	-28.1%
	Share	100%	29%	62%	1%	3%	5%
	€ million	903	123		543	128	110
Glucophage®	Organic growth ¹	8.1%	1.9%		8.4%	18.0%	2.1%
	Share	100%	14%		60%	14%	12%
	€ million	891	404	32.2	342	64	48
Erbitux®	Organic growth ¹	6.0%	1.9%	>100.0%	0.6%	15.9%	-2.0%
	Share	100%	45%	4%	39%	7%	5%
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 $^{^{\}mathrm{1}}$ Not defined by International Financial Reporting Standards (IFRS).

Sales of the drug Rebif®, which is used to treat relapsing forms of multiple sclerosis, saw an organic decline in net sales of -9.4% in fiscal 2020. This meant the long-term downward trend slowed temporarily in the year under review. Taking into account negative exchange rate effects of -1.7%, global net sales decreased to 1,131 million (2019: 1,273 million). The drop in sales was attributable to the persistently difficult competitive situation on the interferon market and the competition from alternative therapies, including oral dosage forms and high-efficacy therapies.

Fertility was the product line in the Healthcare business sector that was hardest hit by the Covid-19 pandemic. Gonal- f^{\otimes} , the leading recombinant hormone used in the treatment of infertility, saw an organic decline in net sales of -12.7% in 2020 that was exacerbated by negative exchange rate effects of -2.5%. As a result, global sales fell to \in 630 million (2019: \in 743 million). Despite signs of a recovery and isolated catch-up effects in the second half of 2020, only the North America region reported moderate organic growth of 2.7% in 2020, whereas full-year sales in the other regions were down compared to the previous year.

The General Medicine & Endocrinology franchise (including CardioMetabolic Care) recorded organic growth of 5.9% in fiscal 2020. The franchise includes medicines to treat cardiovascular diseases, thyroid disorders, diabetes, and growth disorders. Taking into account negative exchange rate effects of -4.8%, net sales in the General Medicine & Endocrinology franchise amounted to € 2,585 million (2019: € 2,557 million).

The diabetes drug Glucophage[®] from the General Medicine franchise became the second-strongest drug in the Healthcare product portfolio in terms of net sales, which increased to € 903 million (2019: € 877 million). This corresponds to organic growth of 8.1%, which was offset by negative exchange rate effects of -5.0%. The main driver of this development was positive performance in China and Latin America.

The beta-blocker Concor[®] also generated positive organic sales growth of 4.4%. However, negative exchange rate effects of -4.7% meant that total sales stagnated at € 529 million (2019: € 530 million).

Euthyrox®, a medicine to treat thyroid disorders, developed very favorably with organic sales growth of 18.6%. Taking into account negative exchange rate effects of -5.5%, net sales increased to € 455 million (2019: € 402 million).

Sales of the growth hormone Saizen® declined slightly to € 234 million in fiscal 2020 (2019: € 238 million). Organic growth of 4.0% was not enough to offset negative exchange rate effects of -5.8%.

Net sales of the Healthcare business sector by region in 2020 developed as follows:

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Net sales by region								
€ million	2020	Share	Organic growth ¹	Exchange rate effects	Acquisitions/ divestments	Total change	2019	Share
Europe	2,158	32%	1.1%	-2.0%	-2.8%	-3.7%	2,241	33%
North America	1,554	23%	7.8%	-2.3%		5.5%	1,474	22%
Asia-Pacific (APAC)	1,831	28%	2.4%	-1.5%		0.9%	1,816	27%
Latin America	641	10%	9.3%	-18.0%		-8.8%	702	11%
Middle East and Africa (MEA)	455	7%	-3.5%	-2.0%		-5.5%	482	7%
Healthcare	6,639	100%	3.4%	-3.6%	-0.9%	-1.1%	6,714	100%
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 $^{^{\}rm 1}\,{\rm Not}$ defined by International Financial Reporting Standards (IFRS).

The following table presents the composition of EBITDA pre in fiscal 2020 in comparison with 2019. The IFRS figures have been modified to reflect the elimination of adjustments included in the functional costs.

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Reconciliation EBITDA pre ¹							
_		2020			Change		
€ million	IFRS	Elimination of adjustments	Pre ¹	IFRS	Elimination of adjustments	Pre ¹	Pre ¹
Net sales	6,639		6,639	6,714		6,714	-1.1%
Cost of sales	-1,613	7	-1,606	-1,605		-1,605	0.1%
Gross profit	5,026	7	5,033	5,109		5,109	-1.5%
Marketing and selling expenses	-1,664	47	-1,617	-2,305	3	-2,303	-29.8%
Administration expenses	-320	7	-313	-344	15	-329	-4.8%
Research and development costs	-1,640	24	-1,616	-1,666	2	-1,663	-2.9%
Impairment losses and reversals of impairment losses on financial assets (net)	-4	_	-4	-1	_	-1	>100.0%
Other operating income and expenses	406	-1	405	357	6	363	11.5%
Operating result (EBIT) ¹	1,804			1,149			
Depreciation/amortization/ impairment losses/reversals of impairment losses	381	-2	379	747	-1	746	-49.2%
EBITDA ¹	2,184			1,896			
Restructuring expenses	95	-95		17	-17	_	
Integration expenses/IT expenses	4	-4		13	-13	_	
Gains (-)/losses (+) on the divestment of businesses	-16	16	_	-5	5	_	
Acquisition-related adjustments	-			_			
Other adjustments	-			-			
EBITDA pre ¹	2,267		2,267	1,922		1,922	18.0%
of which: organic growth ¹							26.6%
of which: exchange rate effects						-	-8.5%
of which: acquisitions/ divestments						-	-0.1%

 $^{^{\}rm 1}$ Not defined by International Financial Reporting Standards (IFRS).

The gross profit of the Healthcare business sector after adjustments declined slightly to € 5,033 million (2019: € 5,109 million). This was largely due to the sales development. At 75.8%, the resulting gross margin was down slightly on the 2019 reporting period (76.1%).

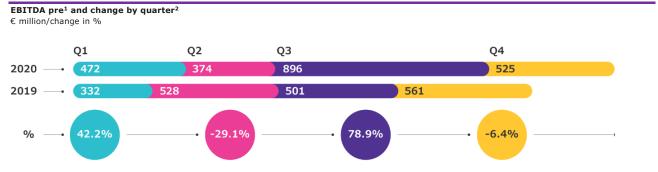
Marketing and selling expenses after adjustments declined by -29.8% year-on-year to € 1,617 million (2019: € 2,303 million). The main reasons were lower costs due to the Covid-19 pandemic and the end of scheduled amortization in connection with purchase price allocation for the Serono acquisition in 2006. With investment requirements for our development portfolio being slightly lower at present, research and development costs declined by -2.9% to € 1,616 million in the year under review (2019: € 1,663 million). The change in other operating expenses and income was due to several factors. Earnings were positively affected in the amount of € 365 million as a result of the reversal of a provision for potential compensation payments for damages in connection with the patent dispute with Biogen Inc., United States (Biogen). This was offset by the end of the recognition of the upfront cash payment by Pfizer Inc., United States, from 2014. The 2019 reporting period was also positively influenced by the recognition of milestone payments of € 75 million from BioMarin Pharmaceutical Inc., United States, in connection with the sale of Palynziq[™] rights in 2016 and € 90 million from the partnership with Pfizer following the extension of approval of Bavencio[®] for the treatment of advanced renal cell carcinoma in combination with axitinib.

EBITDA pre developed very favorably in 2020, rising by 18.0% to € 2,267 million (2019: € 1,922 million). Organic earnings growth amounted to 26.6%. Overall, the EBITDA pre margin also saw growth of more than 5 percentage points to 34.1% (2019: 28.6%).

The restructuring expenses eliminated in calculating EBITDA pre are primarily attributable to transformation and growth programs initiated in fiscal 2020 (see Note (27) "Other provisions" in the Notes to the Consolidated Financial Statements).

The development of EBITDA pre in the individual quarters in comparison with 2019 is presented in the following overview:

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- $^{\mbox{\scriptsize 1}}$ Not defined by International Financial Reporting Standards (IFRS).
- ² Quarterly breakdown unaudited.

Development of business free cash flow

In 2020, business free cash flow increased by 51.4% year-on-year to \in 1,895 million (2019: \in 1,252 million). This was primarily due to the higher EBITDA pre and the positive development of receivables compared with the previous year.

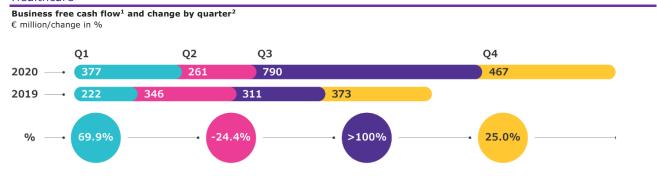
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		Change		
2020	2019	€ million	%	
2,267	1,922	346	18.0%	
-448	-427	-22	5.1%	
-20	-94	73	-78.2%	
170	-100	270	>100.0%	
-47	-50	3	-5.5%	
-26				
1,895	1,252	643	51.4%	
	2,267 -448 -20 170 -47 -26	2,267 1,922 -448 -427 -20 -94 170 -100 -47 -50 -26 -26	2020 2019 € million 2,267 1,922 346 -448 -427 -22 -20 -94 73 170 -100 270 -47 -50 3 -26 -26	

 $^{^{1}}$ Not defined by International Financial Reporting Standards (IFRS).

The development of business free cash flow items in the individual quarters in comparison with 2019 is presented in the following overview:

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 $^{^{\}rm 1}$ Not defined by International Financial Reporting Standards (IFRS). $^{\rm 2}$ Quarterly breakdown unaudited.

 $^{^{\}rm 2}$ Excluding payments for low-value leases and interest components included in lease payments.