

Healthcare

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Key figures

€ million	2021	2020	Change	
			€ million	%
Net sales	7,089	6,639	450	6.8%
Operating result (EBIT) ¹	1,823	1,804	19	1.0%
Margin (% of net sales) ¹	25.7%	27.2%		
EBITDA ²	2,146	2,184	-39	-1.8%
Margin (% of net sales) ¹	30.3%	32.9%		
EBITDA pre ¹	2,153	2,267	-114	-5.0%
Margin (% of net sales) ¹	30.4%	34.1%		

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

² Not defined by International Financial Reporting Standards (IFRS); EBITDA corresponds to operating result (EBIT) adjusted by depreciation, amortization, impairment losses, and reversals of impairment losses.

Development of sales and results of operations

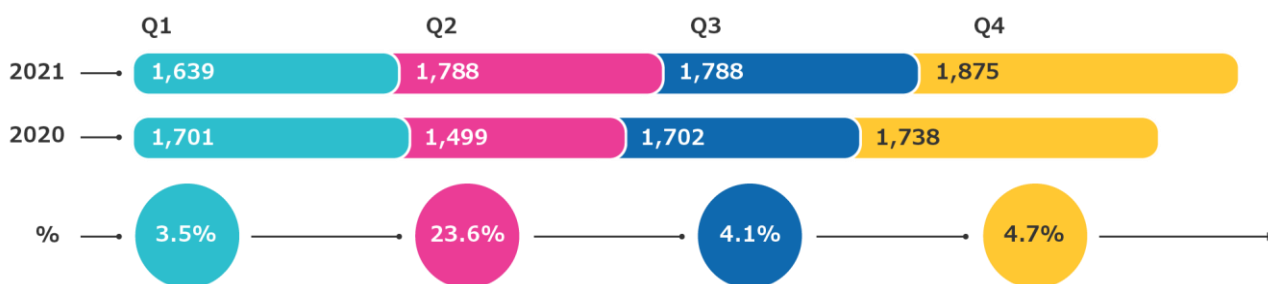
The Healthcare business sector reported organic sales growth of 8.5% in fiscal 2021. Including negative foreign exchange effects of -1.4%, which were largely attributable to the development of the U.S. dollar, and the impact of the divestment of the Allergopharma allergy business in the first quarter of 2020 (-0.3%), net sales amounted to € 7,089 million (2020: € 6,639 million).

The net sales in the individual quarters as well as the respective organic growth rates in 2021 are presented in the following graph:

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Net sales and organic growth¹ by quarter²

€ million/organic growth in%



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

² Quarterly breakdown unaudited.

Net sales of the key product lines and products developed as follows in 2021:

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Net sales by major product lines/products

€ million	2021	Share	Organic growth ¹	Exchange rate effects	Total change	2020	Share
Oncology	1,411	20%	28.5%	-1.9%	26.6%	1,116	17%
thereof: Erbitux®	987	14%	12.2%	-1.3%	10.8%	891	13%
thereof: Bavencio®	373	5%	> 100.0%	-5.4%	> 100.0%	156	2%
Neurology & Immunology	1,645	23%	1.2%	-2.2%	-1.1%	1,662	25%
thereof: Rebif®	952	13%	-13.6%	-2.3%	-15.9%	1,131	17%
thereof: Mavenclad®	693	10%	32.6%	-2.1%	30.5%	531	8%
Fertility	1,337	19%	25.6%	-1.7%	23.9%	1,079	16%
thereof: Gonal-f®	767	11%	23.8%	-1.9%	21.9%	630	9%
Cardiovascular, Metabolism and Endocrinology	2,540	36%	-1.1%	-0.7%	-1.8%	2,585	39%
thereof: Glucophage®	864	12%	-4.4%	-	-4.4%	903	14%
thereof: Concor®	523	7%	0.1%	-1.2%	-1.1%	529	8%
thereof: Euthyrox®	470	7%	3.8%	-0.6%	3.2%	455	7%
thereof: Saizen®	248	3%	7.3%	-1.3%	6.0%	234	4%
Other	157	2%				197	3%
Healthcare	7,089	100%	8.5%	-1.4%	6.8%	6,639	100%

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

In fiscal 2021, the oncology drug Erbitux® (cetuximab) surpassed Rebif® to become the top-selling medicine in the Healthcare product portfolio, generating a year-on-year increase of 10.8% to € 987 million (2020: € 891 million). Organic growth amounted to 12.2%, with negative foreign exchange effects having an impact of -1.3%. In addition to the lower prior-year figures due to the pandemic and the related catch-up effects, high demand in China and Japan was the main contributor to the strong organic growth. Accordingly, net sales in the Asia-Pacific region saw organic growth of 14.2% to € 391 million (2020: € 342 million). Higher demand was also recorded in Europe, with net sales in the region increasing organically by 5.0% to € 417 million (2020: € 404 million). In North America, a temporary partnership with Eli Lilly and Company, United States, had a positive impact on growth in Erbitux® sales. The product was contract manufactured for Eli Lilly and the resulting sales were allocated to the United States. As a result of this special effect, net sales for North America increased to € 59 million (2020: € 32 million).

In the field of immuno-oncology, sales of the oncology drug Bavencio® more than doubled to € 373 million (2020: € 156 million) in spite of negative foreign exchange effects of -5.4%. All regions contributed to this very positive development. The main growth drivers were the approvals granted for the first-line maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) in the United States in June 2020 and Europe and Japan in the first quarter of 2021.

Mavenclad®, for the oral short-course treatment of highly active relapsing multiple sclerosis, saw organic sales growth of 32.6% in fiscal 2021. Taking into account negative exchange rate effects of -2.1%, net sales of € 693 million were generated in 2021 (2020: € 531 million). The main drivers for the positive development of Mavenclad® were the partial recovery of the high-efficacy MS therapy segment, which was negatively impacted by the pandemic in the previous year, and increased demand in the United States and Europe in particular. Moreover, independent data were published showing that Mavenclad®-treated patients who received an mRNA Covid-19 vaccine have a similar antibody response to the general population. Mavenclad® was also approved in additional countries in fiscal 2021, meaning that it is now approved in more than 80 countries.

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Product sales and organic growth¹ of Rebif®, Glucophage® and Erbitux® by region - 2021

		Total	Europe	North America	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
	€ million	987	417	59	391	71	49
Erbitux®	Organic growth ¹	12.2%	5.0%	83.7%	14.2%	15.9%	4.8%
	Share	100%	42%	6%	40%	7%	5%
	€ million	952	286	571	10	32	52
Rebif®	Organic growth ¹	-13.6%	-12.2%	-16.1%	-11.0%	-1.9%	4.4%
	Share	100%	30%	60%	1%	3%	6%
	€ million	864	127	-	491	139	107
Glucophage®	Organic growth ¹	-4.4%	5.5%	-	-11.5%	15.0%	-2.3%
	Share	100%	15%	-	57%	16%	12%

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

Sales of the drug Rebif®, which is used to treat relapsing forms of multiple sclerosis, amounted to € 952 million in fiscal 2021 (2020: € 1,131 million). Although the long-term downward trend slowed temporarily in the previous year due to the pandemic, an organic decline in net sales of -13.6% was recorded in 2021 as a result of the persistently difficult competitive situation on the interferon market and the competition from oral dosage forms and high-efficacy MS therapies. Sales in North America, the biggest sales market for Rebif®, fell by -16.1% organically to € 571 million (2020: € 705 million), while sales in Europe saw an organic decline of -12.1% to € 286 million (2020: € 331 million).

Sales in the cardiovascular diseases, metabolic disorders and endocrinology segment were down slightly on the previous year. With an organic decline of -1.1% and negative foreign exchange effects of -0.7%, net sales amounted to € 2,540 million (2020: € 2,585 million). Sales of the diabetes drug Glucophage® amounted to € 864 million in fiscal 2021 (2020: € 903 million). The organic downturn of -4.4% was primarily due to the price volume regulation (volume-based procurement) that has been in effect in China since 2020. Sales of the beta-blocker Concor®, which has also been subject to this regulation in China, stagnated at the prior-year level. The products Euthyrox® and Saizen® enjoyed positive organic sales growth in fiscal 2021, thereby largely offsetting the decline in Glucophage® sales.

The Fertility product line reported very good organic sales growth of 25.6%. Taking into account negative exchange rate effects of -1.7%, global net sales increased to € 1,337 million (2020: € 1,079 million). The sales growth was largely due to Covid-19-related catch-up effects in the North America and Asia-Pacific regions and overall strong demand for our fertility products. Gonal-f®, the leading recombinant hormone used in the treatment of infertility, recorded organic growth of 23.8% and increased its net sales to € 767 million (2020: € 630 million).

Net sales of the Healthcare business sector by region in 2021 developed as follows:

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Net sales by region

€ million	2021	Share	Organic growth ¹	Exchange rate effects	Acquisitions/divestments	Total change	2020	Share
Europe	2,268	32%	7.4%	-1.5%	-0.8%	5.1%	2,158	32%
North America	1,673	23%	11.0%	-3.3%	-	7.7%	1,554	23%
Asia-Pacific (APAC)	1,997	28%	8.1%	1.1%	-0.2%	9.0%	1,831	28%
Latin America	682	10%	10.2%	-3.7%	-	6.5%	641	10%
Middle East and Africa (MEA)	468	7%	4.5%	-1.6%	-	2.9%	455	7%
Healthcare	7,089	100%	8.5%	-1.4%	-0.3%	6.8%	6,639	100%

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

The following table presents the composition of EBITDA pre in fiscal 2021 in comparison with 2020. The IFRS figures have been modified to reflect the elimination of adjustments included in the functional costs.

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Reconciliation EBITDA pre¹

€ million	2021			2020			Change
	IFRS	Elimination of adjustments	Pre ¹	IFRS	Elimination of adjustments	Pre ¹	Pre ¹
Net sales	7,089	–	7,089	6,639	–	6,639	6.8%
Cost of sales	-1,713	-3	-1,715	-1,613	7	-1,606	6.8%
Gross profit	5,376	-3	5,374	5,026	7	5,033	6.8%
Marketing and selling expenses	-1,600	7	-1,593	-1,664	47	-1,617	-1.5%
Administration expenses	-313	12	-302	-320	7	-313	-3.6%
Research and development costs	-1,712	5	-1,707	-1,640	24	-1,616	5.6%
Impairment losses and reversals of impairment losses on financial assets (net)	5	–	5	-4	–	-4	>100.0%
Other operating income and expenses	67	-8	59	406	-1	405	-85.4%
Operating result (EBIT)¹	1,823			1,804			
Depreciation/amortization/impairment losses/reversals of impairment losses	323	-6	317	381	-2	379	-16.3%
EBITDA²	2,146			2,184			
Restructuring expenses	11	-11	–	95	-95	–	
Integration expenses/IT expenses	9	-9	–	4	-4	–	
Gains (-)/losses (+) on the divestment of businesses	-13	13	–	-16	16	–	
Acquisition-related adjustments	–	–	–	–	–	–	
Other adjustments	–	–	–	–	–	–	
EBITDA pre¹	2,153	–	2,153	2,267	–	2,267	-5.0%
of which: organic growth ¹							-1.7%
of which: exchange rate effects							-3.2%
of which: acquisitions/divestments							-0.1%

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² Not defined by International Financial Reporting Standards (IFRS); EBITDA corresponds to operating result (EBIT) adjusted by depreciation, amortization, impairment losses, and reversals of impairment losses.

The adjusted gross profit of the Healthcare business sector rose to € 5,374 million in fiscal 2021 (2020: € 5,033 million). At 75.8%, the resulting gross margin was at the same level as in the 2020 reporting period (75.8%).

Marketing and selling expenses after adjustments declined by -1.5% year-on-year to € 1,593 million (2020: € 1,617 million). This was primarily due to positive effects from the transformation and growth program initiated in fiscal 2020 as well as the end of scheduled amortization in connection with the co-marketing agreement with Pfizer Inc., United States, for Xalkori®. The increase in research and development costs to € 1,707 million (2020: € 1,616 million) was especially attributable to two effects: the lower level of costs in the previous year, which reflected the lower spending requirements at the time, and the provisions recognized in the year under review for subsequent costs from the near-complete discontinuation of the bintrafusp alfa program due to the termination of the partnership with GlaxoSmithKline plc (GSK) by mutual consent. The reduction in the income balance of other operating expenses and income to € 59 million (2020: € 405 million) was primarily due to the income from the release of a provision of € 365 million for potential damages relating to patent litigation with Biogen Inc., United States, in the previous year. Earnings were positively affected in the amount of € 50 million as a result of the milestone payments recognized in the year under review for the approval of Bavencio® as a first-line maintenance treatment for locally advanced or metastatic urothelial carcinoma (UC) in Europe and Japan.

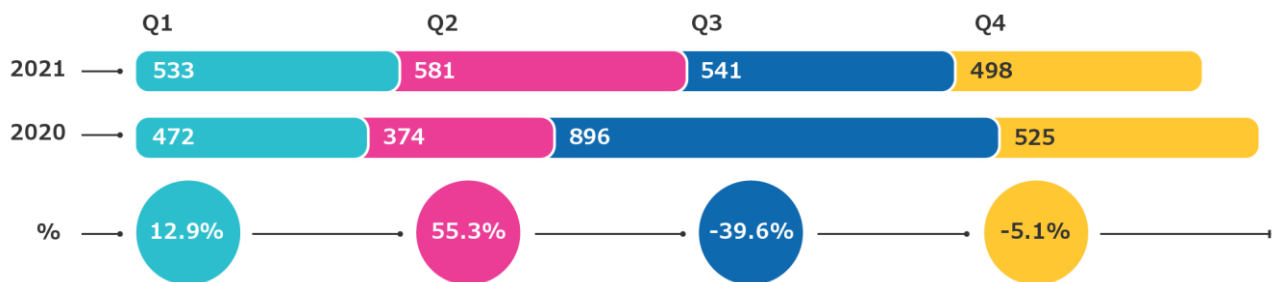
After eliminating adjustments, amortization, and depreciation, EBITDA pre fell by -5.0% to € 2,153 million in fiscal 2021 (2020: € 2,267 million). This was mainly due to the aforementioned income from the release of a provision for potential damages in the previous year. The organic decline amounted to -1.7%, with negative foreign exchange effects having an impact of -3.2%. This resulted in an EBITDA pre margin of 30.4% (2020: 34.1%).

The development of EBITDA pre in the individual quarters in comparison with 2020 is presented in the following overview:

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EBITDA pre¹ and change by quarter²

€ million/change in%



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

² Quarterly breakdown unaudited.