



**MENARINI**  
*group*



# COMPANY PROFILE

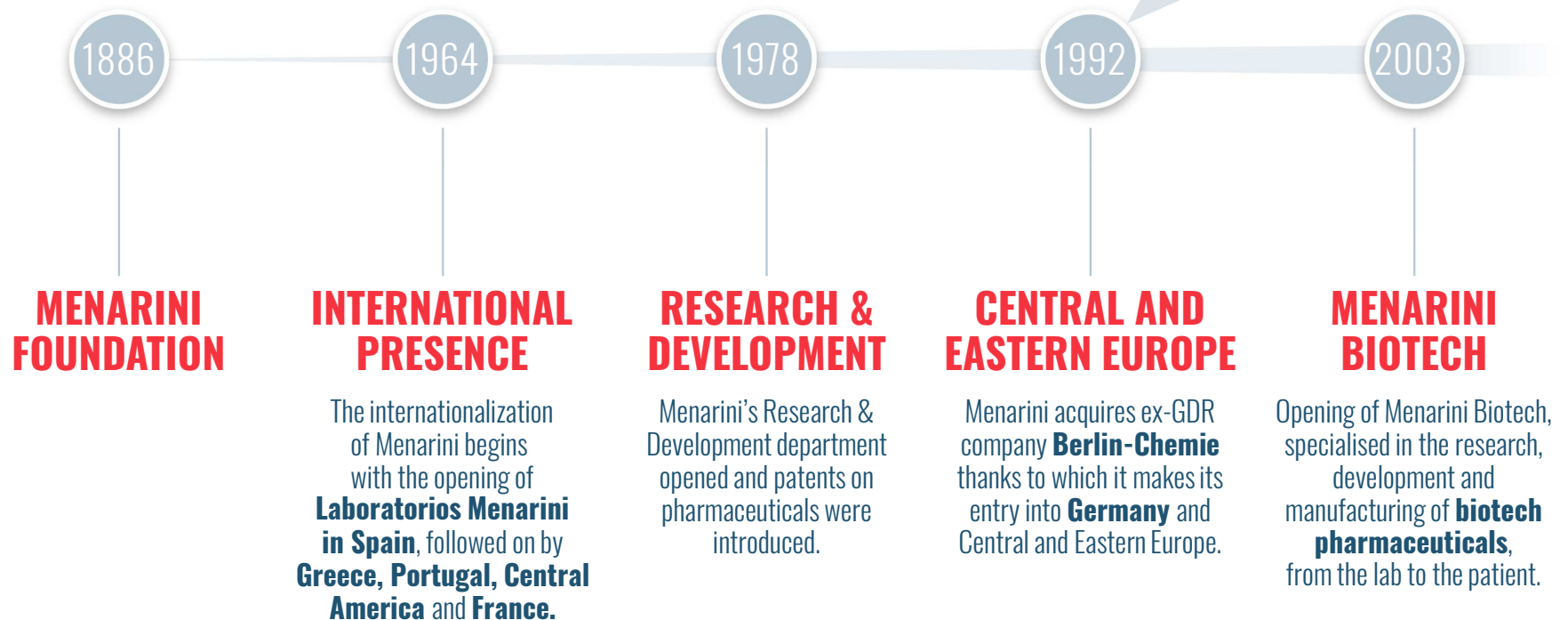
6<sup>th</sup> March 2024



Menarini was  
**founded in 1886.**

In 1915 its  
headquarters were  
established  
in **Florence.**

# Milestones





# Milestones

2011

## ASIA PACIFIC

Menarini makes its entry into Asia Pacific thanks to the acquisition of a company based in **Singapore** and present in **13 countries** throughout the region, from China to Australia.

2013  
2016

## SILICON BIOSYSTEMS

Acquisition of Silicon Biosystems, a start-up of innovative technologies for liquid biopsies.

## CELLSEARCH

Acquisition of Cell Search, an FDA approved technology in the field of **circulating tumor cells**.

2020

## U.S.A.

Menarini makes its entrance into the USA through to the acquisition of **Stemline Therapeutics**, biopharmaceutical company publicly listed on NASDAQ, and their product **Tagraxofusp**, the only FDA approved therapy available for BPDCN, thus strengthening Menarini's presence in oncology.

2023

## FDA&EMA

U.S. FDA and EU (EMA) approve **Elacestrant** as the first oral treatment for patients with ER+/HER2-, ESR1-mutated advanced or metastatic breast cancer.

# Consolidated turnover

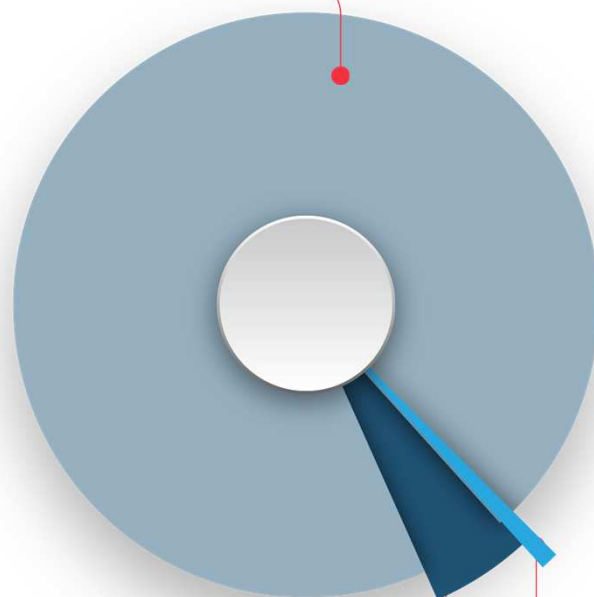
Million euro



Source: internal data.

# Consolidated turnover

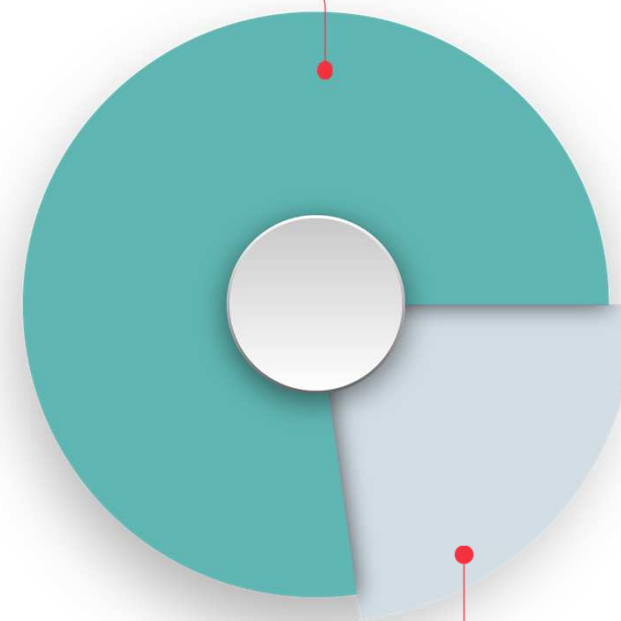
Pharmaceutical **96%**



Diagnostic **3%**

Other **1%**

Abroad **79%**



Italy **21%**

Source: internal data.

# Menarini in the **WORLD**

Present in **140 countries** worldwide (with its affiliates, distributors and franchises).



# U.S.A.

## Stemline

acquisition June 2020

### Tagraxofusp

- For the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), commercially available in the US. In Europe, in January 2021, Tagraxofusp was approved by the EMA, as monotherapy for the first-line treatment of adult patients with BPDCN and commercialization started in Europe with the first launch in Germany in July 2021.
- Tagraxofusp is also in clinical trials in other CD123+ indications, including acute myeloid leukemia (AML), myelofibrosis (MF) and chronic myelomonocytic leukemia (CMML).

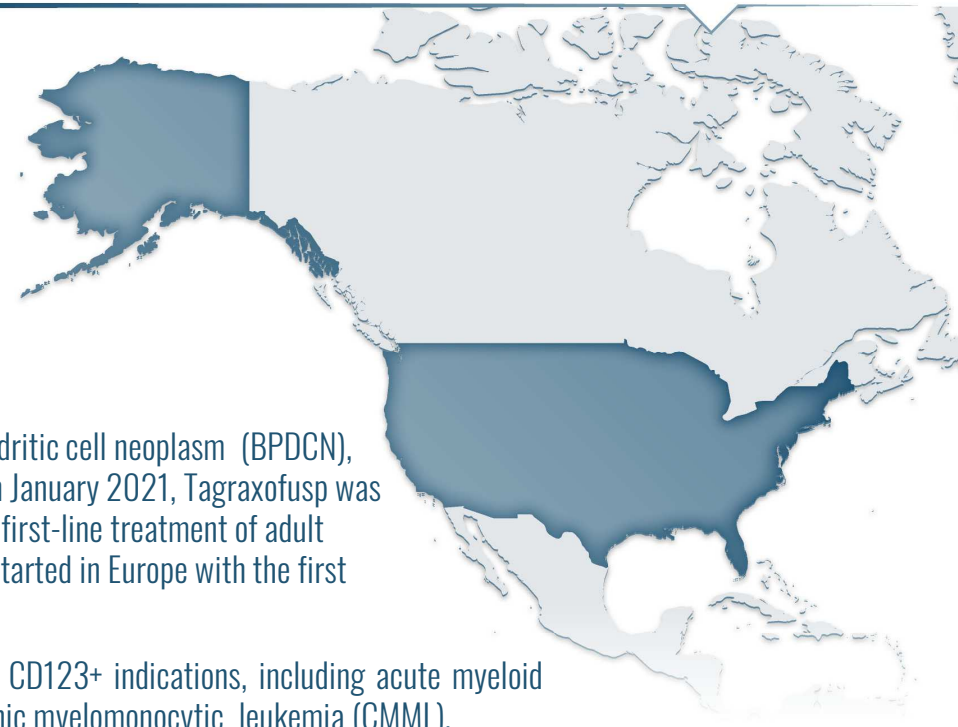
### Elacestrant

For the treatment of postmenopausal women or adult men with ER+/ HER2-, ESR1-mutated advanced or metastatic breast cancer. Elacestrant, in 2023, was approved: by the US FDA in January 2023; by the EMA (Europe) in September, followed by the Norwegian Medicine Agency in Norway and the Icelandic Medicines Agency (IMA) in Iceland; by the Ministry of Health (MOH) in the United Arab Emirates (UAE) and by SFDA (Saudi Food & Drug Authority) in Kuwait; by the MHRA in the United Kingdom in December.

Additional studies of elacestrant in combination with other drugs and monotherapy have been initiated to provide further treatment options to patients with breast cancer.

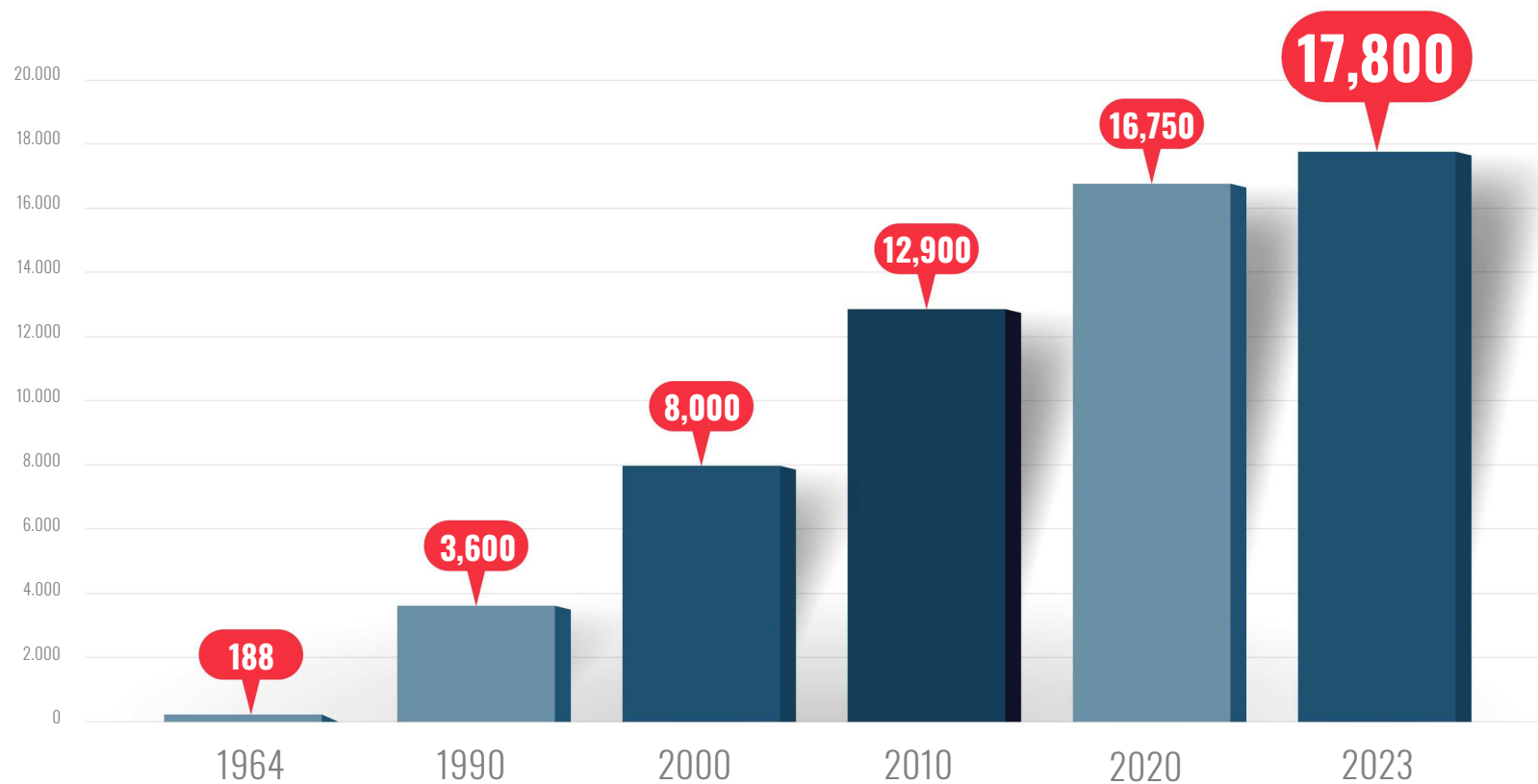


Location: New York, U.S.A.



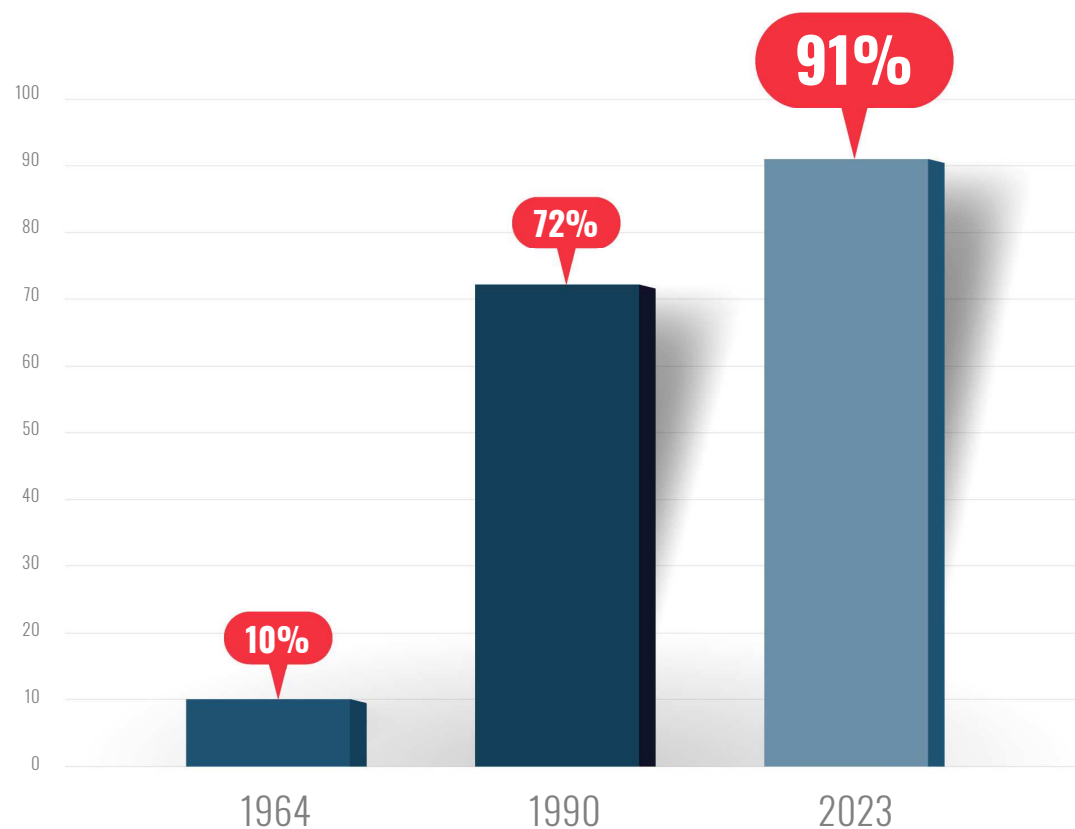


# Number of employees



Source: internal data.

# Employees % of graduates and technicians



# 18 manufacturing plants

## EUROPE is the Group's heart of production

In 2023 **609 million packs** were produced at these sites

### Italy

Pisa (2 plants), Florence (2 plants)  
Pomezia\*, L'Aquila, Lomagna (Lecco),  
Casaletto Lodigiano (Lodi)

### Spain

Barcelona

### Germany

Berlin (2 plants), Dresden

Plants dedicated to the **production for local markets** are located in Central America (Guatemala City), Ireland (Shannon), Turkey (Istanbul), Russia (Kaluga) and Indonesia (Jakarta).

U.S.A. (Philadelphia - Huntingdon Valley): **diagnostic production**



\*Biotech manufacturing with development and production processes also for third parties.

# 9 Research & Development centers



\*Pomezia.



# Research & Development Projects **ONCOLOGY**

COMPOUND	DRUG CLASS (TARGET)	INDICATION	DEVELOPMENT STAGE
<b>Elacestrant<sup>o</sup></b>	SERD (ER)	Monotherapy: ER+/HER2- Metastatic Breast Cancer	<b>EMA and FDA: approved</b>
<b>Elacestrant</b>	SERD (ER)	Monotherapy: CDK4/6 Inhibitor-naïve ER+/HER2- Metastatic Breast Cancer (ELCIN trial)	<b>Phase II</b>
<b>Elacestrant</b>	SERD (ER)	Combination therapy: ER+/HER2- Metastatic Breast Cancer (ELEVATE trial)	<b>Phase II</b>
<b>Elacestrant</b>	SERD (ER)	Combination therapy: ER+/HER2- Breast Cancer with brain metastasis (ELECTRA trial)	<b>Phase II</b>
<b>Tagraxofusp</b>	TB (CD123)	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	<b>EMA and FDA: approved</b>
<b>Tagraxofusp</b>	TB (CD123)	Chronic myelomonocytic leukemia (CMML)	<b>Phase II</b>
<b>Tagraxofusp</b>	TB (CD123)	Myelofibrosis (MF)	<b>Phase II</b>
<b>Tagraxofusp</b>	TB (CD123)	Acute Myeloid Leukemia (AML)	<b>Phase II</b>
<b>SL-701</b>	IT (IL-13R $\alpha$ 2, EphA2, Survivin)	Recurrent Glioblastoma	<b>Phase II</b>
<b>MEN1703</b>	SME (PIM/FLT3i)	Relapsed/refractory Diffuse Large B-cell Lymphoma (DLBCL)	<b>Phase II</b>
<b>MEN1611</b>	SME (PI3Ki)	Colorectal Cancer	<b>Phase II</b>
<b>MEN1611</b>	SME (PI3Ki)	Breast Cancer	<b>Phase II</b>
<b>MEN1309</b>	ADC (Anti-CD205)	Solid Tumors	<b>Phase Ib</b>
<b>Felezonexor</b>	SME (XP01i)	Solid Tumors	<b>Phase Ib</b>
<b>MEN2312</b>	SME (KAT6i)	Breast Cancer/Solid and Heme Tumors	<b>Phase I</b>
<b>Selinexor<sup>oo</sup></b>	SME (XP01i)	Multiple Myeloma	<b>EMA and FDA: approved</b>

<sup>o</sup><https://www.menarini.com/en-us/news/news-detail/european-commission-approves-menarini-groups-orserdu174-elacestrant-for-the-treatment-of-patients-with-er-her2-locally-advanced-or-metastatic-breast-cancer-with-an-activating-esr1-mutation>

<sup>oo</sup><https://www.menarini.com/it-it/news/dettaglio-news/karyopharm-and-menarini-group-receive-full-marketing-authorisation-from-the-european-commission-for-nexpovio174-selinexor-for-the-treatment-of-patients-with-multiple-myeloma-after-at-least-one-prior-t>

TB, Targeted Biologic; SERD, Selective Estrogen Receptor Degrador; IT, Immunotherapy; SME, Small Molecule Entity; ADC, Antibody Drug Conjugate.

# Research & Development Projects **CARDIO-METABOLIC**

COMPOUND	DRUG CLASS	INDICATION	DEVELOPMENT STAGE
<b>Obicetrapib</b>	Cholesteryl ester transfer protein (CETP) inhibitor	Lipid Lowering agent administered to patients previously treated with statins Prevention of Major Adverse CardioVascular events	<b>Phase III</b>
<b>Obicetrapib+Ezetimibe</b>	Cholesteryl ester transfer protein (CETP) inhibitor + Niemann-Pick C1-like 1 (NPC1L1) protein inhibitor	Lipid Lowering agent administered to patients previously treated with statins	<b>Phase III</b>

<https://www.menarini.com/en-us/news/news-detail/newamsterdam-pharma-and-the-menarini-group-sign-licensing-deal-to-commercialize-obicetrapib-in-europe>

# Research & Development Projects **ANTI-INFECTIVES**

COMPOUND	DRUG CLASS	INDICATION	DEVELOPMENT STAGE
<b>Meropenem + Vaborbactam</b>	Carbapenem + $\beta$ -lactamase inhibitor	Complicated urinary tract infections, Complicated Intra abdominal infections, Hospital acquired pneumonia, Ventilator associated pneumonia and Bacteremia	<b>EMA, FDA and Thailand: approved</b>
<b>Delafloxacin</b>	Anionic fluoroquinolone	Acute Bacterial Skin and Skin Structure – ABSSSI Community Acquired Bacterial Pneumonia - CABP	<b>EMA and FDA: approved</b>
<b>Oritavancin</b>	Semisynthetic glycopeptide	Acute Bacterial Skin and Skin Structure - ABSSSI	<b>EMA and FDA: approved</b>
<b>Oritavancin (new formulation)</b>	Semisynthetic glycopeptide	Acute Bacterial Skin and Skin Structure - ABSSSI	<b>EMA and FDA: approved</b>
<b>Cefepime + Taniborbactam</b>	beta-lactam + $\beta$ -lactamase inhibitor	Complicated urinary tract and intra abdominal infections, Hospital-acquired bacterial pneumonia and Ventilator-associated bacterial pneumonia	<b>Phase III</b>

# Menarini For People: our social responsibility projects



## Wheelchair basketball

Volpi Rosse Menarini and Menarini Joventut  
*When sport can help break down barriers and foster inclusion and independence*



## A pediatricians' network

Help up 15.000  
"sentinel doctors"  
recognise child abuse



## Together with Red Cross

Contributions to support  
populations  
in emergency



## Menarini Forest

15.000 trees planted  
in several countries  
all over the world



## Standing by children in difficulty

Healthcare, nutrition  
and education for  
children from  
economically  
disadvantaged  
families



## Donations of medicines

To support those in  
need and promote  
better health for all





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