Heterogeneity of the pharmacologic treatment of allergic rhinitis in Europe based on MIDAS and OTCims platforms

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The Authors. Clinical & Experimental Allergy published by John Wiley & Sons Ltd.
1 | INTRODUCTION

Allergic rhinitis (AR) is one of the most common chronic conditions. Available treatments include allergen avoidance, pharmacotherapy with H₁-antihistamines or intranasal corticosteroids (INCS) and allergen-specific immunotherapy (AIT). Many patients are dissatisfied with their treatment for various reasons. Management does not consider the patients’ needs, no cure is available, adherence to long-term therapy is poor, and/or the patients do not fully understand their condition. Real-world data obtained via mobile technology have suggested that there are differences in medication use between countries.

MASK-air® is a Good Practice of DG Santé concerning the digital transformation of health. The practice of allergology varies widely between countries, and the costs and sales for the treatment of rhinitis differ depending on practices and health systems. To understand these differences and their implications, the rhinitis market was studied in some of the EU countries.

2 | METHODS

2.1 | Study design

This ARIA study evaluated the market for allergic rhinitis (AR) treatment (prescribed and over-the-counter (OTC) medications) in five EU countries in the years 2016–18. We conducted a pharmaco-epidemiological database analysis to assess the medications that were being prescribed for allergic rhinitis in the years 2016, 2017 and 2018. We used the IQVIA platforms for prescribed medicines (MIDAS®—Meaningful Integration of Data, Analytics and Services) and for OTC medicines (OTC International Market Tracking—OTCims). We selected the five most important markets in the EU (France, Germany, Italy, Poland and Spain).

Results: Intranasal decongestants were excluded from the analyses because they are rarely prescribed for allergic rhinitis. For both Standard Units (SU) and costs, France is leading the other countries. In terms of SU, the four other countries are similar. For costs, Poland is lower than the three others. However, medication use differs largely. For 2018, in SU, intranasal corticosteroid is the first treatment in Poland (70.0%), France (51.3%), Spain (51.1%) and Germany (50.3%), whereas the Italian market is dominated by systemic antihistamines (41.4%) followed by intranasal corticosteroids (30.1%). Results of other years were similar.

Discussion: There are major differences between countries in terms of rhinoconjunctivitis medication usage.

Keywords: allergic rhinitis, costs, medications, MIDAS, units
dose prescribed and treatment duration. We used manufacturing costs rather than costs for the healthcare system as, in some countries, there are rebates that are not publicly available.

### 2.2 Medications

#### 2.2.1 Definitions used

We used SU (Standard Units) and LEU/MNF (Local Currency Euro/Manufacturer Price Level) to compare data between countries.

An SU is a unit defined by IQVIA to represent the smallest daily unit of consumption, for example one tablet, one vial/ampoule or 5 ml of liquid. As an example, a pack of 100 tablets with a dosage recommendation of two tablets a day will lead to Unit = 1, Counting Units = 100 and SU = 50.

LEU/MNF per year represents the total sales in Local Currency Euro at Ex-Manufacturer Price Level per Calendar Year.

We chose Manufacturing Cost of the drugs, and it was not possible to mention healthcare system costs due to rebates that are not publicly available.

#### 2.2.2 Selection of medications

We selected medications registered for AR, as well as nasal or ocular decongestants which may also be administered for AR.

The World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classifies drugs by their active ingredients and their defined daily dose (DDD), a fixed attribute that allows the conduct of national or international drug use studies. This ATC system is based on the earlier Anatomical Classification System, which was intended as a tool for the pharmaceutical industry to classify pharmaceutical products (as opposed to their active ingredients). This system was initiated in 1971 by the European Pharmaceutical Market Research Association (EphMRA). In the present study, we used the EphMRA system and gave the ATC correspondence.

For prescribed medications, the study was performed by IQVIA Ltd., London, England, using de-identified prescription data from MIDAS® for 2016, 2017 and 2018 (in € for sales) as well as numbers of treatments. MIDAS® provides connectivity and international standardization of national-level pharmaceutical audits to allow the cross-country analysis of company and product performance, as well as additional insights and attributes not available at a local level. MIDAS® captures and harmonizes the data from 92 countries worldwide, mainly for registered medicines (prescription and non-prescription) in pharmacy and hospital channels. MIDAS® integrates and extends IMS National Audits that accurately detail estimated product volumes, trends and market share by product and therapy class, through retail and non-retail channels. MIDAS® tracks the direct sales (i.e., sales invoices) of pharmaceuticals from the manufacturer to pharmacies or hospitals. MIDAS® also tracks indirect sales (sales going through a middleman, i.e., the wholesaler) to pharmacies and hospitals. MIDAS® tracks inflow or what these different channels are purchasing (i.e., the sales made into those outlets). It represents the full European market through representative panel projections for both retail and hospital channels.

The following subgroups include symptomatic AR drugs and ophthalmic drugs (since rhinitis is often associated with conjunctivitis). Montelukast was not used as it is an asthma and a rhinitis treatment and is only indicated in patients with both rhinitis and asthma. The following medications were considered (Table 1).

For OTC medications, the QuintilesIMS OTCims (OTC International Market Tracking) database was used. OTCims is a Customized Global Information Offering that provides granular data for the effective tracking of company and competitor performance in the Consumer Health marketplace. It uses IQVIA Consumer Health Classification based on Market Positioning. Data are available across four main market segments: OTC, Personal Care, Patient Care, and Nutrition. Data are included for 36 countries from Europe, Asia Pacific, and North and Latin America. Clients are supported in both own as well as competitor product/pack performance tracking against key performance indicators.

The MIDAS® database does not identify the disease for which the medication has been used. This is the case for systemic anti-histamines (R06A0) which include treatments for the nose, skin and other organs. They cannot be distinguished. INCS (R01A1) can also be administered for AR, non-allergic rhinitis and rhinosinusitis.

The list of OTC medications is given in Table 2. The four OTC therapy classes include ‘oral H1-antihistamines’ and ‘INCS’. The list is too far from ATC to propose any correspondence.

### 2.3 Allergen-specific immunotherapy

The only country where AIT is mostly delivered in pharmacies is Germany. We only provided data for AIT in Germany (allergens, V1A0).

#### 2.3.1 Selection of countries

The market for prescribed medications (in costs for patients) for 2018 in all EU countries was ranked in order to choose the markets with the highest sales (Table S1). OTC medications were not considered in the country selection because a single database cannot be used in all countries. AIT was not considered in the country selection since large variations exist between countries in terms of supply (pharmacies, hospitals, Named-Patient Products, etc.).

The first six countries with the highest sales for AR medications and nasal decongestants were France, Germany, Italy, Spain, Poland and the UK. There was a big gap between UK N°6 and Sweden N°7. Thus, we considered only the first six countries. In the UK, a significant proportion of sales took place in supermarkets and these were not considered by IQVIA. Thus, the country had to be excluded.
The ‘Sell-Out’ (Medication dispensed in pharmacies) data and, if not available, the ‘Sell-In’ (Medication delivered in pharmacies) data were obtained from IQVIA. For the countries selected, the databases were from different origins, and the data type differed taking into account the country specificities on drug dispensing (Table 3).

2.4 | Collection of information

There are different methods of collecting the information, and we needed to make assumptions.

It is possible to compare ‘Sell-in’ (from wholesaler to retail pharmacy, effects like stocking are included) and ‘Sell-out’ (from retail pharmacy to patient) data, bearing in mind some biases. Therefore, for one quarter, the ‘Sell-in’ data might be higher when compared to ‘Sell-out’ due to stock, but these effects are minimized for yearly data. In the countries tested, ‘hospital’ means hospital consumption from hospital to patient.

For the OTCims Panel, all panels are ‘Sell-out’.

2.5 | Analyses

We conducted a descriptive analysis to evaluate the medications used in different countries. To derive figures for anti-rhinitis consumption per person over the three years, we linked consumption by SU to population estimates.

**Stratification:** The analyses were performed separately for prescription data and OTC data. In some countries, the same products could be prescribed and were also available OTC. Thus, in order to prevent multiple counts, a complex merger process between prescriptions and OTC was necessary.

**Data periods:** The analyses covered the periods 2016, 2017 and 2018. Results were processed on a yearly basis.

**Analyses were performed once at the same time.**

**Projection:** The results were projected yearly per country.

3 | RESULTS

3.1 | Intranasal decongestants (R1A7 and 01B2)

Intranasal decongestant sales (R1A7 and 01B2) are extremely variable, with low sales in France (from 612,073 to 751,739 kSU per year, 12.6%–14.8% of total sales) and high sales in Germany (from 6,586,460 to 6,890,822 kSU per year, 71.6%–79.6%) (Table 4). We checked the monthly variation of R1A7 in Germany in 2018 and found that they were purchased less often during the pollen season than outside (Figure S4). In Germany, although the majority of products were available in pharmacies, they were non-prescribed. We therefore excluded R1A7 and 01B2 from further analyses as they are unlikely to represent patients with allergic rhinitis.

3.2 | Overall results without intranasal decongestants (R1A7 and 01B2)

The results are presented in Table S2, Table 5 and Figure 1. For both SU and costs, France is leading the other countries. In terms of SU,
the four other countries are similar. For costs, Poland is lower than the three others. However, medication use differs largely. For 2018, in SU, INCS is the first treatment in Poland (70.0%), France (51.3%), Spain (51.1%) and Germany (50.3%), whereas the Italian market is dominated by systemic antihistamines (41.4%) followed by INCS (30.1%). Results of other years are similar. MPAze-Flu (DYMISTA) is represented from less than 1% in Spain to 1.5% in Poland and Germany and to around 2.6% in France of SU in 2018.

In costs for 2018, INCS represent 20.7% of the market in Poland, around 26–28% in Germany, Italy and Spain, and up to 38.6% in France. Systemic antihistamines represent from 45.8% (Italy) to 49.3% (France), 57% to 59% (Germany, Spain) and 67% (Poland).

3.3 | Rhinocconjunctivitis medication consumption per person in Europe

There are very large differences in medication consumption (SU) per person in Europe depending on the country (Table 6). In France, there are 4.3 times more INCS sold per inhabitant than in Germany. On the other hand, in Germany, there are 9.25 times more nasal decongestants sold per inhabitant than in France.

Although the proportion of reimbursement/out of pocket differs between countries, and even in the same country, for different classes of drugs, reimbursement and OTC availability of medications differ in EU countries (Table S3).

3.4 | Allergen immunotherapy

In Germany, AIT represents between 33.2% and 37.3% of LEU/MNF (Table 4).

4 | DISCUSSION

The present paper shows that there is a great heterogeneity in AR medications across Europe. Some explanations may be proposed including reimbursement strategies.
TABLE 4 Overall units and costs obtained by MIDAS and OTCims

|                  | Annual SU (thousands) |                      |                        | Annual LEU/MNF (million €) |
|------------------|------------------------|----------------------|------------------------|-----------------------------|
|                  | 2016 | 2017 | 2018 | 2016 | 2017 | 2018 |
| **France**       |      |      |      |      |      |      |
| All without      | 4,345,542 (85.2%)      | 4,232,505 (85.8%)    | 4,262,629 (87.4%)     | 297,502 (91.1%)             |
| R1A7 + 01B2      | 751,739                   | 697,063              | 612,073              | 29,107                      |
| Total            | 5,097,281                 | 4,929,568            | 4,874,702            | 326,609                     |
| **Germany**      |      |      |      |      |      |      |
| All without      | 1,873,427 (28.4%)        | 1,813,819 (20.4%)    | 1,988,758 (22.4%)    | 148,607 (50.2%)             |
| R1A7 + 01B2      | 6,586,460                 | 6,763,831            | 6,964,445            | 147,137                     |
| Total            | 8,459,887                 | 8,577,650            | 8,955,203            | 295,744                     |
| **Allergens**    |      |      |      |      |      |      |
| (V1A0)           | 896,439                   | 841,312              | 964,073              | 107,746                     |
| **Italy**        |      |      |      |      |      |      |
| All without      | 1,584,524 (63.5%)        | 1,560,315 (63.5%)    | 1,560,179 (62.3%)    | 163,988 (75.6%)             |
| R1A7 + 01B2      | 908,777                   | 897,072              | 945,276              | 52,739                      |
| Total            | 2,493,301                 | 2,457,387            | 2,505,455            | 216,727                     |
| **Poland**       |      |      |      |      |      |      |
| All without      | 1,725,720 (62.4%)        | 1,804,554 (63.5%)    | 1,806,021 (63.7%)    | 98,413 (69.1%)              |
| R1A7 + 01B2      | 1,039,763                 | 1,037,053            | 1,029,205            | 44,063                      |
| Total            | 2,765,483                 | 2,841,607            | 2,835,226            | 142,476                     |
| **Spain**        |      |      |      |      |      |      |
| All without      | 1,659,893 (71.1%)        | 1,696,172 (72.4%)    | 1,746,283 (73.4%)    | 158,275 (83.5%)             |
| R1A7 + 01B2      | 675,098                   | 645,544              | 631,286              | 31,317                      |
| Total            | 2,334,991                 | 2,341,716            | 2,377,569            | 189,592                     |

4.1 Limitations

Although the IQVIA platform appears to be a good source of data for estimating drug consumption in different countries, there are several limitations.

First, we can only use the classification of medications proposed by IQVIA and some classes assess medications for multiple diseases such as ‘Systemic antihistamines’. It is likely that their use differs between countries and that the results reported in this paper may not be totally comparable.

Second, in the IQVIA database, medications are not classified by disease and there are overlaps between skin and respiratory diseases. Furthermore, in respiratory diseases, there are different indications such as allergic and non-allergic rhinitis or rhinosinusitis.

Third, we had to make assumptions that were discussed in the methods. It does not seem that these estimations may have led to significant problems.

Fourth, another limitation is non-adherence to prescribed drugs in patients that cannot be estimated. Thus, the results of the study do not consider lack of adherence to medication which was reported to be quite high.

Finally, the exclusion of nasal decongestants was proposed because they are not indicated in AR and are largely used for common cold and cough in some countries. The BSCAI guidelines (the only European guidelines) and ARIA (global guidelines) - used in most European countries - do not recommend the regular use of intranasal decongestants. In ARIA, the last recommendation was made in 2010; there have not been any other important papers on the subject since. In adults with AR and severe nasal obstruction, we suggest a very short course (no longer than 5 days, and preferably shorter) of intranasal decongestants while co-administering other drugs (conditional recommendation, very low-quality evidence). We suggest that clinicians should not administer and that parents should not use intranasal decongestants in preschool children.
| Country     | Standard units 2016 (Absolute) | Standard units 2017 (Absolute) | Standard units 2018 (Absolute) | LEU/MNF 2016 (Absolute) | LEU/MNF 2017 (Absolute) | LEU/MNF 2018 (Absolute) |
|------------|-------------------------------|-------------------------------|-------------------------------|------------------------|------------------------|------------------------|
| France     | 5,097,280,885                 | 4,929,568,274                 | 4,874,702,206                 | 326,609,288            | 315,187,283            | 313,398,985            |
| Hospital   | 24,443,211                    | 22,347,969                    | 19,213,960                    | 3,994,101              | 3,930,879              | 3,901,789              |
| R1A1       | 4,430,987                     | 3,142,635                     | 3,008,948                     | 323,730                | 307,361                | 336,467                |
| R1A7       | 4,165,245                     | 3,735,215                     | 3,600,270                     | 61,833                 | 52,174                 | 48,840                 |
| R6A0       | 12,383,393                    | 12,163,848                    | 12,668,770                    | 3,124,229              | 3,209,892              | 3,284,036              |
| *Dymista   | 0                             | 720                           | 144,840                       |                        |                        |                        |
| S1G1       | 14,980                        | 13,119                        | 20,349                        |                        |                        |                        |
| S1G2       | 3,376,938                     | 3,251,404                     | 4,251,647                     |                        |                        |                        |
| S1G3       | 63,456                        | 35,431                        | 170,362                       |                        |                        |                        |
| Germany    | 8,474,999,252                 | 8,595,106,633                 | 8,898,547,120                 | 691,220,202            | 686,781,024            | 707,408,598            |
| Hospital   | 249,496,527                   | 255,184,305                   | 250,282,157                   | 8,711,628              | 7,863,795              | 8,272,906              |
| R1A1       | 5,474,147                     | 5,439,325                     | 5,575,688                     | 324,277                | 282,455                | 299,298                |
| R1A7       | 228,397,070                   | 234,976,448                   | 229,199,632                   | 2,923,767              | 2,942,361              | 2,909,478              |
| R6A0       | 13,346,015                    | 12,761,105                    | 13,384,968                    | 2,066,290              | 1,923,863              | 2,484,365              |
| V1A0       | 17,442                        | 12,954                        | 13,269                        |                       |                       |                       |
| *Dymista   | 64,240                        | 44,400                        | 72,120                        | 13                     | 0                      |                        |
| S1G1       | 291,274                       | 303,232                       | 410,628                       | 10,349                 | 11,407                 | 11,025                 |
| S1G2       | 1,387,085                     | 1,278,129                     | 1,156,591                     | 16,949                 | 13,627                 | 14,754                 |
| S1G3       | 583,494                       | 413,112                       | 541,381                       | 34,953                 | 21,948                 | 29,107                 |
| Phmscope   | 7,867,016,585                 | 7,966,630,528                 | 8,257,235,986                 | 674,286,284            | 669,888,195            | 689,539,848            |
| R1A1       | 775,921,033                   | 755,819,069                   | 829,008,199                   | 37,308,422             | 37,331,516             | 42,471,934             |
| R1A7       | 6,231,082,998                 | 6,396,953,648                 | 6,486,356,795                 | 139,382,223            | 148,708,228            | 155,314,296            |
| R6A0       | 564,852,155                   | 543,717,940                   | 608,321,693                   | 92,324,525             | 80,342,707             | 88,917,806             |
| V1A0       | 15,095,779                    | 17,444,001                    | 18,953,549                    | 392,140,744            | 391,651,448            | 387,486,192            |
| *Dymista   | 36,562,768                    | 34,240,092                    | 36,755,760                    | 6,093,972              | 5,706,703              | 6,165,471              |
| S1G1       | 39,119,160                    | 33,719,080                    | 44,437,320                    | 2,479,823              | 2,128,481              | 2,849,695              |

(Continues)
|            | Standard units 2016 (Absolute) | Standard units 2017 (Absolute) | Standard units 2018 (Absolute) | LEU/MNF 2016 (Absolute) | LEU/MNF 2017 (Absolute) | LEU/MNF 2018 (Absolute) |
|------------|-------------------------------|-------------------------------|-------------------------------|------------------------|------------------------|------------------------|
| S1G2       | 106,793,840                   | 94,276,360                    | 104,978,800                   | 2,957,406              | 2,544,410              | 2,862,850              |
| S1G3       | 134,151,620                   | 124,700,430                   | 165,179,630                   | 7,693,141              | 7,181,405              | 9,637,075              |
|            |                               |                               |                               |                        |                        |                        |
| Pharmacy   | 193,137,402                   | 210,177,201                   | 216,417,121                   | 5,093,515              | 5,681,215              | 5,846,784              |
| 01B2       | 83,858,450                    | 98,444,811                    | 103,622,407                   | 2,281,585              | 3,043,918              | 3,246,814              |
| 07A5       | 100,576,690                   | 104,101,960                   | 105,335,380                   | 2,088,516              | 2,002,415              | 2,000,027              |
| O1E1       | 5,926,522                     | 4,475,960                     | 4,168,654                     | 578,025                | 481,892                | 452,820                |
| 07A2       | 2,775,740                     | 3,154,470                     | 3,290,680                     | 145,389                | 152,990                | 147,123                |
| Discount              | 8,832,814                     | 8,533,946                     | 8,590,854                     | 257,229                | 197,507                | 193,400                |
| 01B2       | 113,170,473                   | 114,023,434                   | 124,054,013                   | 1,999,975              | 2,237,524              | 2,572,119              |
| Drugstore  | 38,898,835                    | 36,600,671                    | 37,537,948                    | 778,642                | 823,753                | 893,062                |
| O1E1       | 26,857,170                    | 19,024,460                    | 15,197,810                    | 272,864                | 184,562                | 174,842                |
| 07A2       | 0                            | 4,272,160                     | 4,959,840                     | 0                      | 71,889                 | 80,231                 |
| 07A5       | 0                            | 1,261,375                     | 3,312,875                     | 0                      | 200,545                | 521,960                |
| S/Market   | 8,832,814                     | 8,353,946                     | 8,590,854                     | 257,229                | 197,507                | 193,400                |
| 01B2       | 8,832,814                     | 30,506,765                    | 32,530,143                    | 733,210                | 724,048                | 766,362                |
| Drugstore  | 38,898,835                    | 36,600,671                    | 37,537,948                    | 778,642                | 823,753                | 893,062                |
| O1E1       | 26,857,170                    | 19,024,460                    | 15,197,810                    | 272,864                | 184,562                | 174,842                |
| 07A2       | 0                            | 4,272,160                     | 4,959,840                     | 0                      | 71,889                 | 80,231                 |
| 07A5       | 0                            | 1,261,375                     | 3,312,875                     | 0                      | 200,545                | 521,960                |
| Small SMKT | 4,446,616                     | 4,136,548                     | 4,212,660                     | 45,432                 | 51,778                 | 51,792                 |
| 01B2       | 3,781,336                     | 3,682,438                     | 3,629,200                     | 45,432                 | 51,778                 | 51,792                 |
| 07A2       | 0                            | 2,176,640                     | 1,022,880                     | 0                      | 34,308                 | 18,346                 |
| 07A5       | 0                            | 85,250                        | 355,725                       | 0                      | 13,619                 | 56,562                 |

**Italy**  

2,493,701,426  

Hospital  

19,268,623  

30,506,765  

3,781,336  

665,280  

0  

4,446,616  

0  

Small SMKT  

9,292  

80,231  

18,346  

56,562  

13,619  

521,960  

18,346  

51,792  

20,468  

172  

3166  

*Dymista  

12,628  

30,759,112  

230,409,525  

230,409,525  

214,051,423  

183,808,168  

20,468  

172  

3166  

230,409,525  

230,409,525  

214,051,423  

183,808,168  

(Continues)
|                        | Standard units 2016 (Absolute) | Standard units 2017 (Absolute) | Standard units 2018 (Absolute) | LEU/MNF 2016 (Absolute) | LEU/MNF 2017 (Absolute) | LEU/MNF 2018 (Absolute) |
|------------------------|-------------------------------|-------------------------------|-------------------------------|------------------------|------------------------|------------------------|
| **O1E1**               | 18,147,917                   | 15,335,022                    | 13,921,881                    | 1,525,029              | 1,454,974              | 1,373,791              |
| **07A2**               | 23,223,460                   | 24,866,070                    | 25,146,300                    | 1,345,096              | 1,761,222              | 2,005,317              |
| **07A5**               | 195,211,214                  | 202,401,346                   | 224,849,740                   | 17,808,502             | 18,049,321             | 18,549,494             |
| **Para pharm**         |                               |                               |                               |                        |                        |                        |
| **01B2**               | 62,842,213                   | 61,141,481                    | 57,418,452                    | 760,555                | 722,685                | 2,043,213              |
| **O1E1**               | 3,130,451                    | 2,712,157                     | 2,786,754                     | 289,792                | 304,747                |                        |
| **07A2**               | 811,270                      | 1,139,910                     | 856,970                       | 72,531                 | 72,711                 |                        |
| **07A5**               | 22,258,465                   | 23,602,930                    | 25,236,525                    | 1,157,789              | 1,151,717              |                        |
| **Mass market**        |                               |                               |                               |                        |                        |                        |
| **01B2**               | 113,035,642                  | 110,123,888                   | 104,286,137                   | 4,382,715              | 4,382,715              | 4,382,715              |
| **O1E1**               | 3,130,451                    | 2,712,157                     | 2,786,754                     | 289,792                | 304,747                |                        |
| **07A2**               | 811,270                      | 1,139,910                     | 856,970                       | 72,531                 | 72,711                 |                        |
| **07A5**               | 22,258,465                   | 23,602,930                    | 25,236,525                    | 1,157,789              | 1,151,717              |                        |
| **Poland**             |                               |                               |                               |                        |                        |                        |
| **Hospital**           | 2,765,988,564                | 2,842,199,367                 | 2,835,908,301                 | 160,226,726            | 164,378,170            |                        |
| **R1A1**               | 15,137,626                   | 16,445,222                    | 15,776,895                    | 1,157,789              | 1,151,717              |                        |
| **R1A7**               | 7,500,858                    | 8,190,886                     | 7,891,661                     | 67,923                 | 70,286                 |                        |
| **R6A0**               | 4,753,783                    | 4,890,510                     | 5,023,220                     | 699,454                | 700,018                |                        |
| **V1A0**               | 18,573                       | 17,682                        | 17,331                        | 762,527                | 658,504                |                        |
| *Dymista*              |                               |                               |                               |                        |                        |                        |
| **S1G1**               | 376,200                      | 407,800                       | 388,700                       | 5658                   | 5468                   |                        |
| **S1G2**               | 160,400                      | 154,620                       | 162,200                       | 1783                   |                        |                        |
| **S1G3**               | 28,860                       | 34,620                        | 32,180                        | 1987                   |                        |                        |
| **Retail**             | 2,366,366,557                | 2,417,153,496                 | 2,431,208,428                 | 150,426,738            | 153,779,672            |                        |
| **R1A1**               | 653,132,400                  | 703,686,012                   | 713,149,704                   | 20,705,341             | 20,673,273             |                        |
| **R1A7**               | 1,004,863,014                | 1,011,149,604                 | 992,832,758                   | 45,819,743             | 46,349,359             |                        |
| **R6A0**               | 486,694,708                  | 493,734,398                   | 503,733,894                   | 66,049,824             | 67,962,276             |                        |
| **V1A0**               | 668,615                      | 573,662                       | 665,272                       | 13,306,862             | 13,759,838             |                        |
| *Dymista*              | 6,561,360                    | 8,876,280                     | 21,715,680                    | 2,772,401              |                        |                        |
| **S1G1**               | 32,080,900                   | 28,343,000                    | 26,681,800                    | 519,091                | 490,397                |                        |
| **S1G2**               | 142,996,760                  | 131,793,440                   | 139,948,300                   | 1,259,054              | 1,311,795              |                        |
| **S1G3**               | 46,130,160                   | 47,873,380                    | 54,196,700                    | 3,498,734              |                        |                        |
| **Offtake**            | 384,484,381                  | 408,600,649                   | 388,670,885                   | 8,943,692              |                        |                        |
| **01B2**               | 27,399,224                   | 27,711,821                    | 27,497,770                    | 1,596,898              | 1,479,956              |                        |
| **O1E1**               | 70,555,480                   | 59,164,147                    | 59,314,467                    | 3,395,491              |                        |                        |
| **07A2**               | 19,943,700                   | 40,539,400                    | 52,760,100                    | 1,368,100              |                        |                        |
| **07A5**               | 266,585,977                  | 281,185,281                   | 249,296,548                   | 2,700,145              |                        |                        |
| **Spain**              | 2,335,455,930                | 2,342,195,399                 | 2,378,256,266                 | 2,027,34,932           |                        |                        |
| **Hospital**           | 9,112,183                    | 11,052,976                    | 10,225,055                    | 1,560,387              |                        |                        |
| **R1A1**               | 2,172,526                    | 3,357,987                     | 2,535,450                     | 75,791                 |                        |                        |

(Continues)
(conditional recommendation, very low-quality evidence). A report by Statistica (https://www.statista.com/statistics/417727/cough-and-cold-self-medication-market-sales-in-europe/) showed the same ranking order for cold and cough drugs as the IQVIA data for nasal decongestants. Germany ranked first (1,557 million € for 2017), followed by Italy (718), Poland (609), Spain (552) and France (490). In Germany, in 2018, the months with the highest pollen counts were those with the lowest use of nasal decongestants.

4.2 | Interpretation

Although many papers dealt with AR costs, we were not able to find any that analyzed the units sold. Moreover, costs are difficult to compare between papers as OTC and prescribed drugs vary between countries, and direct AR costs reduced considerably when OTC medications became available. In the present paper, we found large differences between EU countries and particularly between France (low nasal decongestants, high INCS consumption) and Germany (the opposite).

In a Swedish study, it was found that 71.6% of patients with AR were using OAH, 44% INCS and 41% nasal decongestants.21

In France, most medications are reimbursed if prescribed. A long wait to consult French medical specialists encourages the quick purchase of OTC drugs, during pollen seasons, for example. French pharmacists are often well trained for offering OTC drugs: easy-to-use, inexpensive oral OAH, nasal sprays and eye drops. ENT physicians and allergists traditionally prescribe these molecules and train general practitioners to also do so. These molecules were prescribed very early by pediatricians, also to children of atopic families who present nasal signs. These children are used to these methods from the age of 3.

In Germany, the situation is more complex than in other countries. The general reimbursement strategy is outlined in Table 4. 8.7% of the population are privately insured; this is only possible for people who are self-employed or for employees who earn an above-average salary. For privately insured patients, all allergic rhinitis medications are usually reimbursed but this depends very much on the individual contracts. Some privately insured patients, for instance, have a contract where they are only reimbursed for medications and other healthcare costs above a chosen limit, for example 1,000€ per year. This is a contract which young people very often choose, with the monthly costs being lower and the speculation of not having to use this fixed rate in the year. These patients often tend

| TABLE 5 (Continued) |
|----------------------|
|                      |
| R1A7                |
| R6A0                |
| *Dymista            |
| S1G1                |
| S1G2                |
| S1G3                |
| Sell-out            |
| R1A1                |
| R1A7                |
| R6A0                |
| V1A0                |
| *Dymista            |
| S1G1                |
| S1G2                |
| S1G3                |
| Off-Take            |
| O1B2                |
| O1E1                |
| O7A2                |
| O7A5                |
| Parapharm           |
| O1B2                |
| O1E1                |
| O7A5                |
|                      |
| Standard units 2016 (Absolute) | Standard units 2017 (Absolute) | Standard units 2018 (Absolute) | LEU/MNF 2016 (Absolute) | LEU/MNF 2017 (Absolute) | LEU/MNF 2018 (Absolute) |
|----------------------|
| R1A7                | 2,005,927 | 2,283,341 | 2,158,777 | 88,131 | 93,613 | 92,522 |
| R6A0                | 4,027,829 | 4,395,427 | 4,440,996 | 1,309,209 | 1,392,995 | 1,316,609 |
| *Dymista            | 0        | 0        | 0        | 0     | 0     | 0     |
| S1G1                | 119,460  | 150,960  | 183,220  | 6728  | 8488  | 10,080 |
| S1G2                | 9300     | 5300     | 11,700   | 378   | 208   | 459   |
| S1G3                | 777,141  | 859,961  | 894,912  | 58,871 | 63,533 | 64,926 |
| Sell-out            | 2,194,730,398 | 2,195,372,883 | 2,242,126,707 | 180,353,377 | 182,800,026 | 191,487,364 |
| R1A1                | 855,946,916 | 889,440,180 | 919,688,976 | 42,155,216 | 45,579,352 | 47,849,302 |
| R1A7                | 627,535,576 | 601,079,486 | 590,371,990 | 28,513,887 | 29,012,900 | 29,795,483 |
| R6A0                | 457,352,438 | 465,876,773 | 487,974,761 | 91,904,533 | 91,040,256 | 96,059,459 |
| V1A0                | 465,028  | 479,164  | 686,600  | 1,074,098 | 1,110,096 | 1,584,551 |
| *Dymista            | 9,252,292 | 11,344,080 | 12,349,804 | 1,233,993 | 1,596,132 | 1,852,831 |
| S1G1                | 111,263,360 | 102,285,020 | 107,474,200 | 5,855,324 | 5,514,404 | 5,680,404 |
| S1G2                | 33,539,100 | 29,905,100 | 29,050,300 | 772,194 | 681,761 | 669,877 |
| S1G3                | 108,627,980 | 106,307,160 | 106,879,880 | 10,078,125 | 9,861,257 | 9,848,288 |
| Off-Take            | 129,508,699 | 131,988,535 | 122,727,936 | 8,702,319 | 8,969,019 | 9,517,896 |
| O1B2                | 46,051,527 | 42,168,335 | 38,740,393 | 2,714,808 | 2,595,648 | 2,513,212 |
| O1E1                | 4,814,504  | 4,447,039  | 5,056,991  | 1,025,215 | 760,457  | 834,638  |
| O7A2                | 184,714    | 434,790    | 2,210,500  | 57,610   | 131,428  | 218,062  |
| O7A5                | 78,457,954 | 84,938,371 | 76,720,052 | 4,904,686 | 5,481,486 | 5,951,984 |
| Parapharm           | 2,104,650  | 3,781,005  | 3,176,568  | 96,536   | 194,883  | 168,676  |
| O1B2                | 4050      | 13,875     | 14,850     | 256     | 817     | 1038     |
| O1E1                | 1640      | 4660       | 11,710     | 308     | 1505    | 3941     |
| O7A5                | 2,098,960  | 3,762,470  | 3,150,008  | 95,972   | 192,561  | 163,697  |
not to buy medications recommended by the physician. The rest of the population is under the statutory health insurance (Gesetzliche Krankenversicherung) but can choose between policies of different companies. Also, the official healthcare insurance companies have different reimbursement strategies, and details vary. The general reimbursement strategy is outlined in Table 4 but another variable comes into play. Physicians treating patients under the statutory health insurance scheme in Germany have a fixed budget for medication costs and can be made liable if they do not adhere to the very strict economic prescription pathways. Although OAH can be reimbursed for severe allergic rhinitis, even if over-the-counter products are available, physicians often choose not to prescribe these medications on a panel prescription allowing reimbursement. They choose rather to give a private prescription to the patient which means that he/she has to cover the full costs. Last but not least, another limiting factor in Germany is the fact that all patients above 12 years of age also have to pay a cost share fee for every drug at the pharmacy (10% of the price of the product), with a minimum of 5 € and maximum of 10 €.

In Italy, most medications for rhinoconjunctivitis are provided through medical prescription. OAH are reimbursed by the NHS (National Healthcare System), whereas INCS (including INCS + INAH) are not, except in the region of Tuscany.

In Poland, the situation is similar to France. The medications for Allergic Rhinoconjunctivitis are reimbursed if prescribed by the physician. Everyone is covered by the National Health Fund (NHF), but the private sector is also very active. Patients can visit specialists working under the NHF for free, but they have to wait for a few months to consult. Otherwise, they can choose to visit a private doctor and pay out of pocket for the service without having to wait. Physicians in private and public sectors can prescribe reimbursed medications. Many medications which are reimbursed if prescribed also have an OTC version, including INCS and OAH. Similar to France, these molecules were prescribed very early by pediatricians, also to children of atopic families who present nasal symptoms. These children are used to these methods from the age of 2. In Poland, nasal washing with isotonic saline is also very common.

In Spain, most medications for rhinoconjunctivitis are provided through medical prescription. Nevertheless, there are a few formulations which may be acquired as OTC, including some OAH, such as cetirizine, and INCS, such as fluticasone propionate. A recent study has calculated the direct and indirect costs of AR in patients attending specialized clinics in Spain. Data showed that the mean drug treatment per year was significantly higher in persistent AR (77.88 ± 134.22€) compared to intermittent AR (45.62 ± 78.93€). On the other hand, no significant differences were found when comparing mild, moderate and severe AR (41.77 ± 86.02€, 70.36 ± 127.07€ and 72.16 ± 114.60€, respectively). Direct costs accounted for 24% of total costs, and drug therapy was only 10%-13% of the direct costs.

Cultural and reimbursement differences between countries may explain trends in treatment.

Many studies reported that OAH are more often used than INCS and this accords with the results of the present study. However, this is the first multi-national study to compare medication delivery.

The large differences between countries in INCS use are surprising since the guidelines of ARIA, the British Society of Allergy and Clinical Immunology and the US Practice parameters all recommend INCS as the first-line treatment for moderate to severe AR and

| Country | Population 2015 (in thousands) | All without nasal decongestants | Nasal decongestants | INCS |
|---------|--------------------------------|---------------------------------|---------------------|------|
| France  | 66,352                         | 64.2                            | 9.2                 | 33   |
| Germany | 81,175                         | 24.5                            | 85.1                | 7.6  |
| Italy   | 60,795                         | 25.7                            | 15.6                | 8.3  |
| Poland  | 38,005                         | 47.5                            | 27.0                | 18.8 |
| Spain   | 46,440                         | 36.5                            | 13.7                | 20.0 |
it is likely that AR severity is similar between countries. However, the reimbursement strategies of some countries may impair the implementation of guidelines. Moreover, although most AR patients consulting a physician have moderate to severe rhinitis, the low level of ICNS prescribed is surprising. These data may at least partly explain the poor satisfaction of AR patients.

There are also very large differences between countries in intranasal decongestants. Although the indications cannot be assessed using the IQVIA database, it is likely that many patients in Germany use intranasal decongestants for AR. This does not accord with guidelines. In ARIA, ‘in adults with AR and severe nasal obstruction, we suggest a very short course (no longer than 5 days, and preferably shorter) of intranasal decongestants while co-administering other drugs (conditional recommendation, very low-quality evidence).’

5 CONCLUSIONS

With the limitations discussed, this study is of great interest for assessing the heterogeneity of pharmacotherapy in some European countries and can be used as a baseline for future studies to show treatment trends.

CONFLICT OF INTEREST

CB reports personal fees from Meda. JB reports personal fees from Chiesi, Cipla, Hikma, Menarini, Mundipharma, Mylan, Novartis, Purina, Sanofi-Aventis, Takeda, Teva, Uriach, other from KYomed-Innov, outside the submitted work. VC reports personal fees from ALK, Allergopharma, Allergy Therapeutics, Diater LETI, Thermofisher, Stallergenes, outside the submitted work. PD reports personal fees and non-financial support from Astra Zeneca, Chiesi, personal fees from Mylan, personal fees from Sanofi, GlaxoSmithKline, Menarini, outside the submitted work. LK reports grants and personal fees from Allergopharma, LETI Pharma, MEDA/Mylan, Sanofi, personal fees from HAL Allergie, Allergy Therapeut, grants from ALK Abelló, Stallergenes, Quintiles, ASIT biotech, Lofarma, AstraZeneca, GSK, ImmuNoTOK outside the submitted work; and Membership: AeDA, DGHN, Deutsche Akademie für Allergologie und klinische Immunologie, HNO-BV GPA, EAACI. OP reports personal fees and non-financial support from ALK-Abelló, Allergopharma, Anergis S.A., Stallergenes Greer, HAL Allergy Holding B.V./HAL Allergie GmbH, Bencard Allergie GmbH/Allergy Therapeutics, Lofarma, ASIT Biotech Tools S.A., Laboratorios LETI/LETI Pharma, grants from Biomay, Circassia, Glaxo Smith Kline, personal fees from MEDA Pharma/MYLAN, Mobile Chamber Experts (a GA2LEN Partner), Indoor Biotechnologies, Astellas Pharma Global, EUFOREA, ROXALL, NOVARTIS, SANOFI AVENTIS, Med Update Europe GmbH, streamedup! GmbH, outside the submitted work. BS reports grants from AstraZeneca, personal fees from Mylan, Polpharma, outside the submitted work. GS reports personal fees from ALK-Abelló, Mylan, GSK, Bayer outside the submitted work. EVG reports personal fees from PELyon, outside the submitted work. TZ reports: Organizational affiliations:Committee member: WHO-Initiative ‘Allergic Rhinitis and Its Impact on Asthma’ (ARIA). Member of the Board: German Society for Allergy and Clinical Immunology (DGAKI); Head: European Centre for Allergy Research Foundation (ECARF); President: Global Allergy and Asthma European Network (GA2LEN). Member: Committee on Allergy Diagnosis and Molecular Allergology, World Allergy Organization (WAO).

AUTHOR CONTRIBUTIONS

Jean Bousquet designed and interpreted the study data and wrote the paper. Detlef Schröder-Bernhard co-designed the study and participated in the analysis interpretation. Claus Bachert, G. Walter Canonica, Victoria Cardona, Elisio M Costa, Wienczyslaw Czarlewski, Philippe Devillier, Joao A. Fonseca, Ludger Klimek, Piotr Kuna, Olga Lourenco, Joaquim Mullol, Oliver Pfaar, Nhan Pham-Thi, Boleslaw Samolinski, Glenis Scadding, Sophie Scheire, Eric Van Ganse, Torsten Zuberbier interpreted the data and reviewed the paper. They all gave their agreement for the publication. Julia Saueressig, Ann-Kathrin Stroh analyzed the data.

DATA AVAILABILITY STATEMENT

The data is the property of IQVIA.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Bousquet J, Schröder-Bernhardi D, Bachert C, et al. Heterogeneity of the pharmacologic treatment of allergic rhinitis in Europe based on MIDAS and OTCims platforms. *Clin Exp Allergy*. 2021:00:1-13. https://doi.org/10.1111/cea.13884