Medicines Regulatory Authority websites: Review of progress made since 2001

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Abstract. Background: Medicines Regulatory Authorities (MRAs), among other core regulatory functions, play a vital role in stimulating the rational use of medicines by providing regulatory information of good quality to all stakeholders. Little research has attempted to report on existence and maintenance of MRA websites at global level, as well as the types of information made publicly available.

Objectives: To identify functioning MRA websites on a global level, to update a study carried out in 2001 on the development of the quality and types of information of 51 websites, and to identify model components within existing websites.

Methods: The Internet was searched and WHO Medicines Regional Advisers and WHO medicines country advisers (National Professional Officers) were contacted in order to identify MRA websites. The 51 websites assessed in 2001 were assessed again, using the same criteria for the quality and types of information as in 2001.

Results: The number of MRA websites identified has risen from 53 to 116. Most criteria, such as frequency of updates, pharmacovigilance information and regulatory guidance for applicants for medicines marketing authorization (registration) have improved substantially. However, navigability of websites has weakened.

Conclusion: Quantitative growth of the number of MRA websites is impressive. The quality of information provided on the 51 assessed websites has improved. Exemplary website components are proposed to help MRAs to improve transparency by developing and maintaining high-quality websites.

Keywords: Medicines Regulatory Authorities, websites, information, transparency

1. Introduction

In the twenty-first century, the Internet is probably one of the most important and extensively used tool for patients, health professionals and pharmaceutical companies to obtain information on pharmaceutical products. Through the Internet, Medicines Regulatory Authorities (MRAs) can provide access to regulatory requirements for ensuring quality, safety and efficacy of medicines, provide regulatory guidance,
provide information on approved products and ensure transparency of their procedures and activities to all stakeholders. The objective of every MRA is to ensure that all medicines marketed in the respective country are of assured quality, safety and efficacy, and are accompanied by appropriate information to promote their rational use. Therefore, the existence of reliable and accessible MRA websites is very important to all stakeholders.

This review is an update of a study that was undertaken in 2001, identifying 53 MRA websites and assessing the quality of information that was available on 51 of those MRA websites\(^1\) \([2, 8]\). Since then, there has been a major increase in the number of countries that maintain a MRA website. This paper analyses the developments achieved during 2001–2009 and provides a detailed comparison of the quality of MRAs’ websites of the same 51 countries, both in 2001 and 2009. Sections of the websites that still need improvement are identified and useful examples of model sections of specific MRA sites are provided. This paper is primarily of interest for officials responsible for information management and website administrators of MRAs.

2. Background

The study undertaken in 2001 identified websites only in 53 WHO Member States MRAs (including China, Hong Kong Special Administrative Region and European Medicines Agency) out of 196 potential websites\(^2\) \([2, 8]\). It also demonstrated that many of these websites provided limited information that was often not easy to access. Almost 60% of the websites did not have an adequate search engine. Over 80% of the websites had inadequate sections on medicines safety alerts and reporting of adverse drug reactions and more than 50% of the websites did not give access to information on registered medicines. The 2001 paper stressed the need for current medicines information in order to stimulate rational use of medicines and facilitate efficient medicines supply.

The information gap about legitimately marketed medicines and restricted/cancelled marketing authorizations is of concern to many health-care professionals and researchers. A number of publications have expressed the need for transparency and the provision of good-quality health information by Medicines Regulatory Authorities \([3, 4, 6, 11]\). In 2008, Vitry et al. \([14]\) studied MRA websites of USA, Canada, UK, France, Australia, New Zealand and European Medicines Agency (EMEA) in order to assess the availability of information. They concluded that the type and amount of information varied widely, with several MRAs not making basic information, such as summary of products’ characteristics (SPCs) and patient information leaflets (PILs) publicly available. Only EMEA published complete information on cancelled marketing authorizations. The website of Canada’s MRA was the only site to offer full access to pharmacovigilance data, and none of the websites released the periodic safety update reports that companies have to provide to the MRAs \([14]\). Vitry et al. criticized the lack of openness and called for increased transparency and independence of regulatory authorities’ activities related to products evaluation, surveillance and information.

Apart from industries and other medicines oriented business, researchers and health care professionals, the public is also a stakeholder in the debate on the relative lack of certain types of information related to medicines. Nahiri reported in 2007 that 20% of Finnish medicine users \((n = 714)\) name the Internet as

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\(^1\) Greece and Austria had MRA websites in 2001 but these websites were not reviewed, thus only 51 out of 53 identified websites were reviewed.

\(^2\) Potential websites include 193 WHO Member States’ websites, plus EMEA, China, Hong Kong Special Administrative Region and China, Province of Taiwan.
a source of medicine information, with up to 30% in the age group of 15–34-years old [12]. Medical
doctors, pharmacists and PILs were reported as the most reliable sources of medicines information,
followed by MRAs, nurses, medicines information leaflets and medicine guides and textbooks. Only
24%–43% of medicine users evaluated the Internet as reliable, with the older respondents having less
trust in the medium than the younger ones. In Singapore in 2009, 15% of consumers reported having used
the Internet as a medicines information source; with 34% of these consumers having problems finding
reliable and accurate information [7]. Among physicians in Thailand, 29% of faculty and 25% of residents
used the Internet as the first medium through which they learned about new medicines [10]. Provided
consumers and health care professionals trust the national MRA as much as was reported in Finland, a
MRA website could be very successful in addressing their need of reliable medicines information.

As a consequence of increased demand, the amount and quality of information available on the Internet
has increased enormously over the past eight years. However, it is not clear which countries are leading
and which subject areas still need strengthening on their websites.

This study aims to give an update on the status of MRA websites. It will give insight into the number
of MRAs that have websites, and the association to the World Bank income group classification of the
country. It makes an attempt to review the accessibility, completeness and quality of information on MRA
websites and identify model website components.

3. Objectives

The objectives of this review were:

1. To identify MRA websites that are available on a global level.
2. To update the WHO study that was carried out by Jambert in 2001 on the number of MRA websites
   that are available online and on the development of the quality of 51 websites identified at that time
   over the years from 2001 to 2009, according to the same scoring system [2, 8].
3. To identify model components of websites within existing websites that can serve as examples to
   MRAs that are creating or revising their websites.

4. Methods

4.1. Global identification of available websites

The MRA websites that were online were identified through:

– the list of 53 websites from the study of 2001 [8]
– available lists of MRAs in Europe (http://www.emea.europa.eu/Inspections/Links.html), Africa
  portaleami.org/directAutorid/home.htm)
– a Google search on (country name) plus DRA/drug authority/autoridad de medicamentos/autorité
des médicaments, ministry of health/ministère de santé/ministerio de salud/saude
– contacting the WHO medicines country advisers (NPOs) and WHO Regional Advisers of the Essential
  Medicines and Pharmaceutical Policies department (EMP)

Links that were not working and websites that only mentioned the name of a MRA were not listed as
MRA websites. The existence or nonexistence of websites could not be confirmed for some countries.
When confirmation was received that a website did not exist, this was reported \(^3\). The relative numbers of countries were classified into WHO regions and World Bank income categories \(^{13}\).

4.2. Comparison of the quality of 51 websites in 2001 with 2009

In order to measure the progress made in the quality of websites, 51 Member States MRA websites which were reviewed in 2001, were studied again \(^8\). The comparison included the same pool of countries, but countries could not be matched as the original country scoring data was not available.

The criteria and the scoring system that were used to evaluate the quality, were adapted with some modifications from the 2001 study \(^4\). These are:

General criteria
1. User-friendliness
2. Site map
3. Navigability
4. Speed
5. Search
6. Update

Specific criteria
7. Mission statement
8. Contact information
9. Organizational structure
10. Services
11. News, events, and meetings
12. Safety alerts and adverse drug reactions (pharmacovigilance)
13. Feedback form for informing the DRA
14. Regulatory guidance on legislation and regulations
15. Instructions for applicants
16. Medicinal products (human/veterinary medicines)
17. Approved manufacturers
18. Import and export
19. Approved wholesalers, distributors, pharmacies
20. Basic statistics on drug consumption
21. Basic statistics on country profile
22. Basic statistics on DRA activities
23. Links
24. Publications
25. Languages

\(^3\) The list of Globally identified Websites of Medicines Regulatory Authorities is published at: http://www.who.int/entity/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf

However, some adjustments were made as described below. One change to the criteria is the addition of a separate language criterion. In the 2001 criteria, language was evaluated in the ‘user-friendliness’ criterion. In the present study, a separate criterion was added to emphasize on the importance of the availability of information in both English and the national language.

Minor changes to the list of criteria applied were as follows:

- Speed: using Web Page Analyzer 0.98 from Website Optimization the speed of websites was assessed [15]. Download times at a connection rate of 56K per second were reported.
- Mission statement: activities and programmes are no longer a prerequisite within this criterion, since this information is assessed in ‘organizational structure’ or ‘services’.
- Feedback form: this form does not necessarily have to be downloadable; most websites have an electronic field that can be filled in and submitted online.
- Medicinal products: information on orphan drugs and products under special post-marketing surveillance monitoring is no longer assessed in this criterion. Also the language condition has been taken out since it is already assessed separately in criterion 25.
- Approved manufacturers: charts and graphics and last inspection date are no longer a prerequisite.
- Import and export: statistics are no longer a prerequisite.
- Approved wholesalers, distributors, pharmacies: information on activities and volume of business is not a prerequisite anymore.

The assignment of scoring was done by one researcher. In order to harmonize the scoring used by the original author and the current one, thorough consultations were held with the author of the previous study.

Scores were assigned as follows:

0 = inadequate, information is not available, or very outdated
1 = intermediate, for example when information is difficult to find or not complete
2 = good, the information provided is up-to-date, complete and easy to find and explore

5. Results

5.1. Global identification of available websites

In 2009, 116 websites could be identified, out of 196 potential websites. In addition to 193 Member States that have joined World Health Organization (WHO) websites, the European Medicines Agency (EMA) website, China, Province of Taiwan (Taiwan, China) and China, Hong Kong Special Administrative Region (Hong Kong SAR) websites were included. EMA was included because of its major importance to the European Union regulatory environment and having its own regulatory functions; Hong Kong SAR was included because of its autonomy and the autonomous nature of its MRA. Taiwan, China was included due to the independence of their regulatory functions.

The percentage of countries with websites more than doubled from 27% in 2001 to 59% in 2009. Table 1 shows the increase in numbers and percentage of countries with identified MRA websites per WHO region.

The percentage of countries with websites was categorized according to World Bank income categories⁵, as shown in Table 2.

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⁵ http://siteresources.worldbank.org/DATASTATISTICS/Resources/CLASS.XLS.
Table 1
The numbers and percentages of countries with identified Medicines Regulatory Authorities websites per World Health Organization region

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of MRA websites 2001*</th>
<th>%</th>
<th>Number of MRA websites 2009</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>4 of 46</td>
<td>9</td>
<td>16 of 46</td>
<td>35</td>
</tr>
<tr>
<td>AMRO/PAHO</td>
<td>7 of 35</td>
<td>20</td>
<td>20 of 35</td>
<td>57</td>
</tr>
<tr>
<td>EMRO</td>
<td>1 of 21</td>
<td>5</td>
<td>11 of 21</td>
<td>52</td>
</tr>
<tr>
<td>EURO**</td>
<td>29 of 54</td>
<td>54</td>
<td>47 of 54</td>
<td>87</td>
</tr>
<tr>
<td>SEARO</td>
<td>3 of 11</td>
<td>27</td>
<td>8 of 11</td>
<td>73</td>
</tr>
<tr>
<td>WPRO**</td>
<td>9 of 29</td>
<td>31</td>
<td>14 of 29</td>
<td>48</td>
</tr>
<tr>
<td>Totals</td>
<td>53 of 196 potential websites</td>
<td>27</td>
<td>116 of 196 potential websites</td>
<td>59</td>
</tr>
</tbody>
</table>

*The list of countries for 2001 has been adjusted to be the same as the 2009 list.
**Potential websites include 193 World Health Organization countries plus in EURO: European Medicines Agency and in WPRO: China, Hong Kong Special Administrative Region and China, Province of Taiwan.

Table 2
The number and percentage of countries per World Bank income category with MRA websites

<table>
<thead>
<tr>
<th>Income Category</th>
<th>Number of countries*</th>
<th>Number of countries with MRA websites*</th>
<th>Percentage of countries with MRA websites (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low income</td>
<td>43</td>
<td>15</td>
<td>35</td>
</tr>
<tr>
<td>Lower middle income</td>
<td>53</td>
<td>25</td>
<td>47</td>
</tr>
<tr>
<td>Upper middle income</td>
<td>44</td>
<td>32</td>
<td>73</td>
</tr>
<tr>
<td>High income</td>
<td>50</td>
<td>42</td>
<td>84</td>
</tr>
<tr>
<td>Total</td>
<td>190</td>
<td>114</td>
<td>60</td>
</tr>
</tbody>
</table>

*Cook Islands, Nauru, Niue and Tuvalu were not included in the analysis because these countries were not included in the World Bank list. EMEA and China, Province of Taiwan were not included, while China, Hong Kong Special Administrative Region was included.

5.2. Comparison of the quality of 51 websites in 2001 with 2009

Table 3 shows the scores for the 51 countries assessed in 2001, together with the results from 2009 for the same 51 countries.

The detailed results of the individual websites are available, so that a paired comparison can be undertaken in the future. Some examples of model websites per criterion and examples of additional components were identified during the study. Although, they were not assessed in our set of criteria but may serve as models to MRA websites. These additional website components include a glossary, separate web pages for medicine users, providing, for example, tools to assess health information on the Internet or general information on medicines, blacklisted companies and Frequently Asked Questions (FAQ).

6. Discussion

Many researchers have argued that the provision of information by MRAs is inadequate [3, 4, 6, 11, 14]. We have shown that especially on potentially confidential and controversial subjects, such as clinical
Table 3
The results of the scoring per criterion for 51 countries assessed in 2001 and in 2009

<table>
<thead>
<tr>
<th>Criteria</th>
<th>2001 Percentage of scores</th>
<th>2009 Percentage of scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inadequate</td>
<td>Intermediate</td>
</tr>
<tr>
<td>User-friendliness</td>
<td>22</td>
<td>49</td>
</tr>
<tr>
<td>Site map</td>
<td>61</td>
<td>12</td>
</tr>
<tr>
<td>Navigability</td>
<td>10</td>
<td>31</td>
</tr>
<tr>
<td>Speed*</td>
<td>18</td>
<td>26</td>
</tr>
<tr>
<td>Search</td>
<td>57</td>
<td>18</td>
</tr>
<tr>
<td>Update</td>
<td>55</td>
<td>8</td>
</tr>
<tr>
<td>Mission statement</td>
<td>18</td>
<td>51</td>
</tr>
<tr>
<td>Contact information</td>
<td>29</td>
<td>33</td>
</tr>
<tr>
<td>Organizational structure</td>
<td>31</td>
<td>28</td>
</tr>
<tr>
<td>Services</td>
<td>71</td>
<td>10</td>
</tr>
<tr>
<td>News, events and meetings</td>
<td>53</td>
<td>20</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>80</td>
<td>8</td>
</tr>
<tr>
<td>Feedback form</td>
<td>57</td>
<td>14</td>
</tr>
<tr>
<td>Regulatory guidance on legislation and regulation</td>
<td>33</td>
<td>39</td>
</tr>
<tr>
<td>Instructions for marketing applicants</td>
<td>28</td>
<td>26</td>
</tr>
<tr>
<td>Medicinal products</td>
<td>53</td>
<td>33</td>
</tr>
<tr>
<td>Licensed manufacturers</td>
<td>84</td>
<td>10</td>
</tr>
<tr>
<td>Import and export</td>
<td>80</td>
<td>12</td>
</tr>
<tr>
<td>Approved wholesalers, distributors, pharmacies</td>
<td>75</td>
<td>20</td>
</tr>
<tr>
<td>Basic statistics on medicines consumption</td>
<td>88</td>
<td>4</td>
</tr>
<tr>
<td>Basic statistics on country profile</td>
<td>88</td>
<td>0</td>
</tr>
<tr>
<td>Basic statistics on medicines regulatory authority activities</td>
<td>75</td>
<td>4</td>
</tr>
<tr>
<td>Links</td>
<td>51</td>
<td>18</td>
</tr>
<tr>
<td>Publications</td>
<td>59</td>
<td>20</td>
</tr>
<tr>
<td>Languages</td>
<td>33</td>
<td>28</td>
</tr>
</tbody>
</table>

*The speed of the MRA websites of Thailand and Morocco could not be assessed using the website optimization tool.

The potential strength of this review is that the criteria and scoring system that were used remained the same, or nearly the same, thus enabling potentially comparison and measuring changes. The development of quality and the types of information provided by the 51 countries regulatory websites could have been measured in principle/what exactly does it mean: can be deduced in a legitimate way legitimate in this context is not a correct term, because the same websites were reviewed. However, this study is based...
on aggregate scoring; it is not a paired comparison as the original scoring data is no longer available. Therefore it is not possible to demonstrate the improvement that individual websites have made since 2001.

An important limitation of this study is the high level of subjectivity in the information gathering and processing. However, efforts were made to coordinate the scoring between the researchers of 2001 and 2009 in order to achieve consistent scoring. On the other hand, issues such as the accessibility and user-friendliness as experienced by users will always remain subjective; therefore it is important that MRAs seek feedback from the stakeholders to make their websites as clear and easily accessible as possible.

Although efforts were made to identify as many websites as possible, the methods might have failed to identify some websites. We did not contact all WHO country representatives to enquire about the existence of MRA websites. The fact that many countries did not have a traceable MRA website reflects an opportunity for improvement.

The list of criteria from 2001 has been incorporated in the present study. Some might argue that not all criteria are as relevant as others and that the scoring system is too rigid to evaluate the websites as a whole. Nevertheless, the authors believe that the list of criteria provides a simple practical tool to assess what type of information is available. These criteria also match to a great extent with the specific criteria that *Prescrire*, a non-profit continuing education organization, uses to evaluate MRA websites [1] and the more general criteria that Kim et al. identified to evaluate health related websites [9]. The objective of this review is to give general insight into the type and quality of information available on websites and what changes have occurred. The authors recognized that the scoring system used has certain limitations. Therefore, the results should not be interpreted in absolute terms, but merely as an indication of trends in strengths and weaknesses. For example, the 2001 study demonstrated that only 27% of the countries eligible had a MRA website. The increase in the percentage of countries with websites to 59% in 2009 is impressive.

It is clear that national income category has a strong positive association with the existence of MRA websites, but a number of low income countries, particularly in Africa now have MRA websites. Also the improvement of content of the websites under study is obvious. Whereas many websites provided no more than contact information and an organigram in 2001, most of the websites include comprehensive pages on legislation and regulatory guidance, information on medicinal products and pharmacovigilance in 2009.

Also the user-friendliness of the regulatory websites has improved. The percentage of user-friendly sites increased from 29% in 2001 to 43% in 2009. Still, the presentation of more than half of sites could be done in a more user-friendly, logical and attractive way.

The presence of good sitemaps has increased from 28% in 2001 to 71% in 2009. Navigability of sites is one of the criteria that appear to have deteriorated. This may be because of the increased quantity of information, which is accompanied with more complex and problematic logical organization of the site. Almost 60% of websites were easy to navigate in 2001, while only 35% was assessed to be easily navigable in 2009.

Efficient search engines and subject indexes are often missing, even though the percentage of countries with intermediate search engines increased from 18% to 73%. It is still only 14% of the countries that really allow thorough searching on the website. Australia’s MRA website is an excellent example of a website that enables users to search it thoroughly through an advanced search engine and comprehensive “a–z” index.

Good examples of websites that were user-friendly and easy to navigate include the United Kingdom’s and Denmark’s MRAs. The average time spent on these websites was respectively 2.3 and 2.8 min a day [5]. For Ireland’s and India’s MRA websites, which scored intermediate on navigability, the average time
spent was 5.0 and 5.5 min a day. This could reflect the difficulties that users have when searching the websites for more specific information. Thus, the website owners cannot be assured that users will have the persistence needed to locate the sought information.

Many MRAs provide enormous amounts of information and documents on their websites but navigability is often poor. The importance of a good infrastructure, the availability of a sitemap and efficient search engines cannot be underestimated.

Updating of websites has improved significantly. Fifty five percent of websites reviewed in 2001 were not updated during the previous year. This percentage declined to 16% in 2009. Currently, 71% of websites studied are being updated monthly.

In 2009, many websites were found to have sections with general information on the MRA. The percentage of websites with clear mission statements rose from 31% to 63%. The percentage of websites without adequate contact information declined from 29% to 10%. However, many websites could improve their contact information by making names of contact people available (when possible, as certain restrictions may be justified) and show information for each activity, in addition to a central contact point, like the Australian and Canadian MRA websites do.

In 2009, 27% of websites provided good information on organizational structure, including an organizational chart and an overview of the responsibilities or activities per department. This percentage is lower than the 41% reported in 2001. Fifty three percent of websites assessed in 2001 had inadequate sections on news, events and meetings. This percentage decreased to 29% in 2009. There has been little change in the number of MRAs that propose a feedback form on their website: 57% of websites were without feedback forms in 2001, this figure decreased to 51% in 2009. These changes may reflect the relative increase of the new websites from the small MRAs from resource constrained settings with less sophistication and transparency on Government structures.

The greatest improvement in MRA websites has been made in the section on pharmacovigilance. Over 80% of the websites assessed in 2001 did not provide adequate information on how to report adverse drug reactions, or did not publish safety alerts. Today, only 18% of websites scored ‘inadequate’ on this item and 41% of the websites had good sections on pharmacovigilance. For example, the United States FDA website gives very detailed pharmacovigilance data.

Regulatory guidance was considered good in 28% of websites assessed in 2001. This percentage rose to 45% in 2009, still leaving more than half of the surveyed websites with intermediate or inadequate information on relevant legislations, regulations and guidelines applicable to medicines in these countries.

Clear instructions for marketing authorization (registration) applicants were given in 47% of websites in 2001, and in 49% of websites in 2009. Although the number of websites with good information on import and export of medicines has doubled to 18% in 2009, this percentage is still low. The lack of progress in making publicly available through websites items such as instructions for marketing authorization applicants, including regulatory requirements for proving quality, safety and efficacy of medicines, regulations for import and export, is of concern as it affects businesses and can cause delays in timely access to medicines.

A database of registered medicinal products was available on 14% of websites in 2001. This percentage rose to 37% in 2009, a promising, but not sufficient, development. Scarcely any websites provided information on orphan drugs, cancelled marketing authorizations, and products under special post-marketing surveillance monitoring. A positive exception was the United States’ FDA website which gives comprehensive information about these topics.

Websites with listings of licensed manufacturers rose from 6% in 2001 to 37% in 2009, lists of licensed wholesalers, distributors and pharmacies remained more rare, 6% in 2001 rose to 18% in 2009.
Basic statistics on medicines consumption, country profile and medicines regulatory authority activities’ were regarded as good in 2001, respectively present in 8%, 12% and 22% of websites. These percentages remained low in 2009, being respectively 14%, 4% and 31%. In Costa Rica, the regulatory authority is part of the Ministry of Health and its website provides basic statistics on the country profile. More MRA websites should make these statistics available. As the reports are often published by Ministries of Health accessibility can easily be accomplished by means of links to Portable Document Format (PDF) files.

Fifty one percent of websites did not provide adequate “Links” pages in 2001, this percentage declined to 25% in 2009. Overlooked by many, a “Links” page is actually one of the more important components of a MRA website. By identifying and listing reliable sources of health and medical information for consumers, health professionals and industries, “Links” pages can improve access to independent health information.

Publications were not published on 59% of websites assessed in 2001, and on 37% of websites in 2009. The assessment of the language criterion in 2009 study has illustrated that more than half of websites are not completely available in their official national language(s) or in English language. Thirty three percent of websites were only available in either the national language or in English, while 28% of websites were partly available in English, often leaving out key functions such as the medicinal products database and search engines. Of note, there were five countries that were only available in English, not in their national language6.

Speed of navigation might not have worsened as much as the results seem to imply. In 2001, speed was subjectively assessed. In 2009 the website optimization programme was used to measure speed quantitatively [5, 8]. The authors have updated this criterion because they believe that Internet users have higher demands with regards to speed than they did eight years ago. Thus, the decline in the percentage of websites with good speed from 57% in 2001 to 33% in 2009 might reflect the demand of Internet users more than it reflects the actual development of the speed of websites.

Since the review only considered those websites that were already available in 2001, the results of the review cannot simply be extrapolated to get insight into the overall quality of the websites that are available in 2009. Websites that have been online for eight years are more likely to have improved both in terms quality and content. In addition, the countries that had websites in 2001 were mainly high income countries and seem to score better in general. Taking this into account, the outcome of this study might be more optimistic than the outcome of a study on all existing websites in 2009 would be. On the other hand, a number of new websites have been identified that truly exceed some of the older websites. Particularly good examples of new MRA websites are those of Sudan and Argentina.

The difficulties the researchers encountered in identifying websites and in reviewing them indicate the need for more user-friendly and accessible websites. In countries where The Ministry of Health (MOH) has regulatory functions, specific web pages to the regulatory part of their activities with relevant information should be launched. Websites should endeavour to improve their accessibility by establishing links from other sites, such as the relevant Governmental authorities and institutions (MOH, Ministries of Commerce and Trade, Customs authorities, etc.), general health information sites and regional (if present) medicines regulatory authorities’ sites.

Some MRA website components that the authors believe are necessary are missing, even though these are often existing on paper and easy to publish online, such as mission statements, SPCs, PILs and lists of licensed manufacturers. Substantial progress has been made since the study of 2001 was carried out, but many opportunities for improvement still exist.

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6 Morocco’s MRA website was not available in Arabic. Philippines not in Filipino, India not in Hindi, Malaysia not in Malay, Singapore not in Malay, Mandarin Chinese or Tamil.
In conclusion, the development of new MRA websites over the past eight years is impressive. The number of websites has more than doubled. It is remarkable how countries from all income categories have made efforts to launch and maintain websites that provide the general public, health professionals and industries with good-quality regulatory information.

The selection of the 51 countries that have maintained websites over the past eight years shows considerable improvement in the content and comprehensiveness of the information provided. Such subjects as sitemaps, updates and mission statements that were missing in 2001 are now fully covered in most of these websites. On the other hand, there is still room for improvement on all topics, including key subjects like regulatory guidance, pharmacovigilance and registries of medicinal products.

This review identified the achievements over the past and the information gaps that need to be addressed in the future. Useful examples to help MRAs and their website administrators to improve the websites are provided. It is hoped that this article will contribute to the process of improving and maintaining good-quality MRA websites.

Acknowledgements

The following people provided information or contacts on national websites and their contribution is gratefully acknowledged. Mr Mohamed Abdelkahim, Dr Badr Abdulhamid, Dr Raffaella Giovanna Balocco, Mr Donatien Bigirimana, Dr Khalid Bukhari, Dr Edelisa Carandang, Ms Mhiyin Chang, Ms Munkhdelger Chimedtseren, Dr Moses Chisale, Mr Kees de Joncheere, Dr Ivone Dourado, Dr Socorro Escalante, Dr James Fitzgerald, Mr Semere Gebregiorgis, Msh Neha Maria Gomes, Dr Sallik Govind, Dr Baohin Huang, Dr Bounlonh Ketsouvannasane, Dr Michel Klopfenstein, Mr James Komeh, Ms Anita Korinek Porta, Ms Lisbeth Sjaelborg Lindhardt, Mr William Mfuko, Dr Zafar Mirza, Dr Anastasie Mulumba, Dr Mamadou Ngom, Dr Ahmad Shah Pardis, Dr Valerio Reggi, Dr Andre Reiffer, Dr Daniel Robndoh, Dr Juanita Rodriguez, Dr Budiono Santoso, Ms Nina Sautenkova, Dr Isabel Seaman, Ms Giulia Tognana, Dr Jean-Marie Trapsida, Dr Krisantha Weerasuriya.

Ms Elodie Jambert provided invaluable information about the scoring in the 2001 study. Mr Jean Cornips and Ms Iris Buysse assisted with measuring the speed of websites. Mr Jörg Uwe Hetzke and Mr Thiago Moura Miranda provided information on software to assess website information. Professor Bert Leufkens and Dr Aukje Mantel were responsible for organizing the internship of Ms Claire Cornips.

Abbreviations

AFRO Regional Office for Africa
AMRO/PAHO Regional Office for the Americas/Pan American Health Organization
EMRO Regional Office for the Eastern Mediterranean
EURO Regional Office for Europe
EMEA European Medicines Agency
SEARO Regional Office for South East Asia
WPRO Regional Office for the Western Pacific
References